Site visit inspection report on compliance with HTA licensing standards

University Hospital of Wales

HTA licensing number 12163

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**

9 - 10 August 2017

Summary of inspection findings

The HTA licensing arrangements cover the University Hospital of Wales (the establishment). This was the first inspection of this establishment against the HTA's revised licensing standards, which came into force on 3 April 2017. The previous inspection took place in September 2012, since when there has been a significant decline in compliance, with shortfalls identified across all four groups of standards. Three critical shortfalls were found in relation to traceability of PM samples and failures in the management of PM samples that have resulted in the establishment having built up a significant store of whole organs and tissue samples from PM examination for which they do not have up-to-date records to ensure timely disposal. In addition, fourteen major shortfalls and nine minor shortfalls were found across the range of standards.

The HTA found the Designated Individual (DI) not suitable in accordance with the requirements of the legislation. An application from the establishment to change the DI was approved by the HTA following the inspection.

There is significant work to be done to bring the establishment back up to an acceptable level of compliance.

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI 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 DI are set down in Section 18 of the Human Tissue Act 2004 (the HT Act). 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

University Hospital of Wales is part of Cardiff and Vale University Health Board. It has been licensed by the HTA since July 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

The mortuary and Cellular Pathology Laboratory, where the licensed activities take place, are managed as part of the Cellular Pathology Services for Cardiff and Vale University Health Board. Mortuary services are provided by the mortuary at University Hospital of Wales (the establishment) and an unlicensed body store at a different site where no HTA-licensed activities take place. Mortuary procedures are aligned across the two sites and Anatomical Pathology Technologists (APTs) work across both facilities. The mortuary is staffed by seven APTs, one of whom will occasionally be based at the unlicensed body store. The Mortuary Manager is based at University Hospital of Wales.

The establishment undertakes between 800 and 850 PM examinations each year comprising adult, paediatric and perinatal cases, including Home Office and high-risk cases (up to hazard group 3 biological agents). The majority are adult PM examinations; in 2016, the establishment received 655 adult cases under coronial authority and six hospital consented adult cases. It is a referral centre for perinatal and paediatric PM examinations and received 31 perinatal/paediatric cases under coronial authority and 72 hospital consented cases. In addition, 57 Home Office PM examinations were undertaken in 2016.

Consent for hospital PM examinations is sought using consent forms and information booklets which are part of the 'All Wales' collaboration of NHS Health Boards in Wales. In adult cases, consent is sought by clinical staff, who are required to complete a triennial PM examination consent training session or electronic course (see Advice, item 3). Staff are required to confirm that they have up-to-date training in seeking consent on a consent process checklist. In perinatal and paediatric cases, consent is sought by clinical staff who are required to complete a biennial training course, and there is a central register of staff trained to seek consent for these. This includes staff at referring centres seeking consent for PM examinations to be undertaken at the establishment. The establishment's procedures require the pathologist to check the consent process checklist (for adult cases) or the central register of trained staff (for perinatal/paediatric cases) to confirm that the person who sought consent for the PM examination has up-to-date training (see minor shortfall against standard C2(b)).

The mortuary has 116 fridge spaces for adult bodies, including four spaces for bariatric bodies. Sixty-eight of these spaces are in a walk-in cold room, which provides flexibility in the layout and provision of spaces, meaning that additional bariatric storage space can be

provided if required. One refrigerated storage unit with six spaces can be used for frozen storage where bodies require long-term storage. The mortuary also has a separate fridge with ten spaces for perinatal and paediatric bodies. Perinatal and paediatric cases are transferred directly to the mortuary and are not stored elsewhere in the hospital. There is a storage temperature monitoring and alarm system for the mortuary fridges and freezers; however, this system is not tested regularly (see minor shortfall against standard PFE2(e)).

The unlicensed body store provides contingency arrangements for storage of bodies when necessary. The establishment has not experienced difficulties with storage capacity for bodies and has not had to invoke any other contingency storage arrangements. However, its contingency plan in the event of insufficient storage capacity includes expediting release of bodies to funeral services and delaying transfer of bodies to the establishment from referral centres where possible (see Advice, item 25).

The mortuary is secured by swipe card and key code access and there is an intercom system for staff to allow entry to visitors. There is closed-circuit television (CCTV) monitoring of the mortuary entrances. Despite these measures, the mortuary does not have adequate access control arrangements (see major shortfall against standard PFE1(d)).

On receipt of a body into the mortuary, a mortuary unique reference number is assigned and recorded, with details of the deceased, in the paper mortuary register and logbook; this number is used as part of the establishment's traceability procedures for bodies and PM samples. The establishment's procedures for traceability of bodies are not sufficiently robust and present significant risks of misidentification of bodies (see major shortfalls against standards T1(b), T1(c) and T1(d)).

The main PM suite has five PM tables and benches for the preparation of tissue samples. There is a separate forensic PM suite, which has one PM table and a bench for the preparation of tissue samples. Known or suspected high-risk PM examinations are undertaken in the forensic PM suite, if it is available, or in the main PM suite when no other cases are being undertaken. The mortuary premises and facilities, including the PM suites, are not cleaned or maintained to a sufficient standard (see major shortfall against standard PFE1(a) and minor shortfall against standard PFE3(c)), and a number of items of mortuary equipment are in a poor condition (see minor shortfall against standard PFE3(a)).

Removal of relevant material from the deceased does not take place other than in the mortuary. All cases where this activity is required, for example in cases of sudden unexpected death in infancy (SUDI), are transferred to the mortuary.

Material taken at PM examination may be transferred to the establishment's Cellular Pathology Laboratory for histological analysis, or to other establishments for toxicology or specialist tests.

There are dedicated storage rooms for tissue blocks and slides, which are secured by either swipe card or key code access. Frozen tissues are stored in the laboratory, which is secured by swipe card access. Whole organs and PM samples awaiting return to the family are stored in a separate area of the mortuary. PM samples are traced using the mortuary unique reference number. The establishment uses an electronic database to record sample details, including consent for hospital consented PM examinations, the family's wishes for the fate of the samples, details of transfer of samples to other organisations for analysis and disposal of samples. The establishment's traceability procedures for PM samples are poor (see critical shortfall against standard T1(g) and major shortfall against standard T2(d)). In addition, procedures for ensuring that samples are disposed of in a timely manner following the end of coroner's or police authority are inadequate (see critical shortfalls against standards GQ2(c) and T2(a) and major shortfall against standard T2(b)).

The establishment plans to introduce an electronic laboratory information management system to record details of bodies and PM samples (refer to Advice, item 18).

The establishment is also storing existing holdings; i.e. tissue that was being stored for use for scheduled purposes at the time of the commencement of the HT Act. The HTA was shown a collection of four skeletons and a number of brain slices which are being kept for use for the scheduled purpose of 'education or training related to human health'. Although these specimens are stored on licensed premises and the DI agreed for them to be stored under this licence, they are not subject to the governance arrangements for the licence (see major shortfall against standard GQ1(g)).

Tissue samples and organs retained for police purposes are also being stored. Under section 39 of the HT Act, relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. However, the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority contained a recommendation that police exhibits held on HTA-licensed premises should be included within the regular HTA inspection process. Therefore, procedures for Home Office PM examinations and management of tissues and organs taken for criminal justice purposes were reviewed by HTA at this site visit inspection. Any findings solely in relation to Home Office PM examinations and/or police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Description of inspection activities undertaken

This report describes a routine site visit inspection of the establishment in August 2017. The inspection team interviewed a number of staff involved with licensable activities, reviewed documentation and conducted visual inspections of the mortuary, Cellular Pathology Laboratory and the two storage rooms where PM tissue blocks and slides are stored.

A traceability audit was conducted on four adult bodies and three paediatric bodies in the mortuary, including bodies in freezer storage. The identifiers on the body identification tags were checked against the mortuary register and log book, including the storage locations. There were discrepancies in the traceability of one body, where the deceased's name was different in the mortuary register and on the body identification tag, and the body identification tag did not include the mortuary unique reference number (see major shortfall against standard T1(b)). This audit also found one case where the same/similar name alert card was on the wrong body tray and the notice on the fridge door had not been completed with the same/similar name warning (see major shortfall against standard T1(d)).

Audits were conducted of the mortuary processes for admission and release of bodies. The HTA observed mortuary staff check the identification of a body prior to release based only on a verbal check of two identifiers (see major shortfall against standard T1(c)). The HTA halted the procedure to ensure that the identification check was performed in accordance with the required standards.

Audits of traceability were conducted for samples from three PM examinations under coroner's authority and two hospital consented PM examinations, including consent documentation for the retention of samples, consent forms for the hospital PM examinations and disposal records. A number of discrepancies were identified:

- Although there were no discrepancies in the completion of the hospital PM examination consent forms, the establishment could not evidence that the consent seeker for one of these cases had received up-to-date training (see minor shortfall against standard C2(b)).

- There was a discrepancy in the traceability of PM samples from one case where the deceased's name was spelled differently on the body identification tag, label on the whole organ and electronic sample database (see critical shortfall against standard T1(g)).

- There were discrepancies in the number of slides stored for both PM cases audited by the HTA. Although the establishment later provided an additional record for traceability of slides for one of these cases, the establishment's procedures for traceability of

slides are not robust (see critical shortfall against standard T1(g)).

- The establishment's procedure for recording disposal does not require details of the number of organs, block and slides disposed of to be recorded, meaning that the establishment cannot demonstrate a complete audit trail of samples (see critical shortfall against standard T1(g)).

The establishment is storing whole organs and tissue samples from a number of PM cases for which it is not known whether coroner's or police authority for retention has ended. Procedures for auditing these samples, to enable timely disposal where consent has not been given for continued retention, are inadequate.

This presents a significant risk that the establishment is storing PM material without coroner's or police authority or consent from the family (see critical shortfalls against standards GQ2(c) and T2(a) and major shortfall against standard T2(b)). Immediately following the inspection, the HTA required the establishment to undertake an audit of PM samples. This audit identified a number of samples had been stored beyond the end of authority without consent from the family. The establishment has a plan to deal with these samples and they have been quarantined to ensure that they are not used for a scheduled purpose without consent.

Inspection findings

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

The number and severity of shortfalls in meeting the HTA standards demonstrates that the DI has failed to discharge their duty under section 18 of the HT Act to supervise the licensed activity; specifically that they have failed "to secure that suitable practices are used in the course of carrying on that activity".

Therefore, the HTA found that the DI was not fulfilling their statutory responsibilities under the HT Act and is not suitable to act in this capacity. The HTA required the Health Board to identify an alternative person to take on the role of DI as a matter of priority. An application from the establishment to change the DI was approved by the HTA following the inspection.

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		
b) There is a documented standard operating procedure (SOP) detailing the consent process	Although there are documented SOPs for seeking consent for adult and paediatric/perinatal PM examinations, not all staff at the establishment undertaking this activity are aware of these SOPs. *Refer to shortfall for standard GQ1(e).*	**Minor**

C2 Staff involved in seeking consent receive training and support in the essential requirements of taking consent		
b) Records demonstrate up-to-date staff training	The establishment could not provide evidence that the member of staff who sought consent for a perinatal PM examination had received up-to-date training in seeking consent.	**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.	Many of the SOPs covering key mortuary procedures do not contain sufficient detail of the procedures that staff must follow. For example: • SOPs describing the process for identifying bodies do not state the minimum number of identifiers to be used and how the identification check should be performed; • the SOP for viewing of bodies does not describe what information is required from the family before staff perform the identification check or that cosmetic adjustments should only be undertaken with the permission of the family; and • SOPs governing the long-term storage of bodies do not explain the process for switching the refrigeration unit from fridge to freezer mode, including changing the temperature alarm trigger points, the check of the identification of the body and the requirements to record the details of the transfer in the mortuary register.	**Major**

	This lack of detail means there is a risk that procedures are not undertaken in a consistent manner. The HTA audit found discrepancies in traceability of bodies, which were the result of deviations in procedures. In addition, there are no documented policies or procedures relating to the existing holdings of skeletons and brain slices, which are being stored and used for the scheduled purpose of 'education or training relating to human health'. Therefore, the establishment cannot provide assurance that these are used in accordance with the requirements of the HT Act and the HTA standards and Codes of Practice. *Refer to shortfalls against standards GQ1(g) and T1(c), and Advice, item 4.*	
e) There is a system for recording that staff have read and understood the latest versions of these documents	The establishment's system for recording that staff have read and understood the latest versions of documents is poor and does not provide assurance that staff are aware of and conforming to SOPs that govern their work. • Some staff included on the distribution lists for key SOPs have not acknowledged that they have read and understood them. For example, one member of mortuary staff had 20 documents to read and acknowledge, some of which have been outstanding for almost twelve months. • Some staff are not included on the distribution lists for key SOPs so are not required to acknowledge that they have read and understood all SOPs relevant to the procedures they perform. For example, not all Pathologists are included on the distribution list for the SOP for conducting a PM examination. • Not all staff have access to the electronic document control system or are aware of where to find hard copies of controlled documents. This means that some staff undertaking key activities are not aware of the SOPs relevant to their work. For example, some staff who seek consent for hospital PM examinations were not aware of the SOPs governing the consent process.	**Major**

	• Where staff do not have access to the electronic document control system, there is no system to record that they have read and understood hard copies of documents or ensure that they are notified of changes to documents.	
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity	The establishment's procedures require that deviations from documented SOPs are recorded and monitored; however, examples of discrepancies in the completion of records and procedures were found that had not been recorded or investigated appropriately. For example, the HTA's traceability audits identified a case where the deceased's name was different in the mortuary register and on the body identification tag, and was also spelled differently on the whole organ label and the electronic sample database. In addition, the body identification tag did not include the mortuary unique reference number. Although staff at the establishment were aware of the discrepancy in the name recorded in the mortuary register and on the body identification tag, this deviation from the procedure for body traceability had not been documented, nor investigated. Consequently, no actions were taken to ensure the records were correct. *Refer to shortfall for standard T1(b).*	**Minor**
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	The establishment could not provide assurance that all collections of relevant material on the premises are subject to oversight by the DI as part of the overall governance framework. For example, the establishment is storing a collection of existing holdings for use for the scheduled purpose of 'education or training related to human health'. Although these are stored on licensed premises and the DI agreed for them to be stored under this licence, they are not subject to the governance arrangements for the licence. As there are no documented policies or procedures relating to the storage and use of these samples, the DI does not have oversight of all HTA-licensed activities and there is a risk that samples are not stored or used in accordance with the requirements of the HT Act and the HTA standards and Codes of Practice.	**Major**

h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff	Although some governance meetings are held by departments engaged with licensed activities, these meetings do not cover all matters relating to the HTA licence and the DI does not attend regularly or receive minutes. Given that the DI does not have regular contact with mortuary staff and attends the mortuary very infrequently, he does not have appropriate oversight of licensed activities taking place in the mortuary. *Refer to Advice, item 11.*	**Major**

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits	Although the establishment had undertaken an audit of mortuary compliance with HTA standards immediately prior to the inspection, there is no evidence of regular audits of mortuary activities. For example, there is no evidence of the establishment undertaking process audits of compliance with procedures, horizontal audits of body checks or traceability of bodies. *Refer to shortfall against standard GQ2(b) and Advice, item 12.*	**Major**
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these	Significant findings from the establishment's audit of mortuary compliance with the HTA standards, which was undertaken prior to the inspection, have not been addressed and an action plan has not been agreed due to disagreements between the departments about the findings of the audit. Many of the audits of licensed activities in the Cellular Pathology Laboratory are poor: • Reports focus on corrective actions only and do not consider whether preventative actions are also required. • In some cases, records of corrective actions are not sufficiently detailed and so it is not clear whether the actions taken are appropriate. For example, an audit of traceability of PM slides revealed a discrepancy in the number of slides found in storage and the number recorded on the electronic database. The audit report details only that the slide number was amended on the electronic database and does not detail whether an investigation was undertaken to determine if slides were missing.	**Major**

	This is particularly important given the weaknesses in the establishment's procedures for traceability of PM samples. *(Refer to shortfall against standard T1(g).)* • Not all actions identified have been completed within the acceptable timeframes. For example, at the time of the inspection, there were 416 outstanding actions relating to the Cellular Pathology Department on the establishment's quality control system.	
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	The establishment does not follow its procedure for auditing and following up with third parties to determine when authority for storage of PM samples has ended and whether they should be disposed of. As a result, the establishment has built up a significant store of whole organs and tissue samples from PM examinations dating back to 2009. The lack of up-to-date records does not enable staff to identify those samples that should have been disposed of. This is particularly important as the establishment's procedure for disposal of PM tissue blocks slides allows the DI to retain samples at their discretion in cases where coroner's or police authority has ended and the family have stated their wish for disposal of the samples. Examples are where the DI decides to allow time for the family to reconsider their decision. However, the SOP does not provide details of timescales or how this process should be managed to ensure timely disposal of samples where consent is not given for their continued retention. Immediately following the inspection, the HTA required the establishment to undertake an audit of PM samples. This audit identified a number of samples had been stored beyond the end of authority without consent from the family. The establishment has a plan to deal with these samples and they have been quarantined to ensure that they are not used for a scheduled purpose without consent. Due to the lack of up-to-date records and the establishment's failure to follow its procedure for auditing and following up when samples should be disposed of, there remains a significant risk that the establishment is storing PM material for use for scheduled purposes without coroner's or police authority or consent	**Critical**

	from the family for its continued retention, in breach of the HT Act. *Refer to shortfall against standard T2(a).*	

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	Although mortuary staff receive some training in mortuary procedures when they begin working at the establishment, the system for refresher training for APTs is poor. A number of mortuary procedures have changed and not all APTs have been trained in the revised procedures, for example the procedure for management of bodies with same or similar names. *Refer to shortfall against standard GQ3(c) and Advice, item 13.*	**Minor**
c) Staff are assessed as competent for the tasks they perform	Mortuary staff undergo competency assessments when they begin working at the establishment; however, there is no formal system for refresher training or ongoing competency assessments. A number of mortuary procedures have changed and many staff have not been assessed as competent to undertake the revised procedures. *Refer to shortfall against standard GQ3(a).*	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	The establishment's SOP for incident reporting does not include a complete list of the categories of HTA Reportable Incidents (HTARIs) which must be reported to the HTA, and does not provide details of the required timeframe for reporting HTARIs and the procedure for submitting HTARI notifications to the HTA. *Refer to Advice, item 16.*	**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	The establishment's documented risk assessments do not cover all mortuary activities and the risks of incidents associated with these activities. For example, the following risks have not been assessed: • accidental damage to a body; • viewing of the wrong body; and • PM examination on the wrong body. Where risk assessments have been documented, many of the assessments of risks and current control measures have not been incorporated into mortuary procedures and practices. *Refer to Advice, item 17.*	**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	The establishment's procedures for traceability of bodies are not sufficiently robust. The HTA's traceability audits identified a case where the deceased's name was different in the mortuary register and on the body identification tag, and the body identification tag did not include the mortuary unique reference number. For this case, the name was also spelled differently on the label on the whole organ and the electronic sample database. Although staff at the establishment were aware of the discrepancy in the name recorded in the mortuary register and on the body identification tag, this had not been documented, investigated or corrected. *Refer to shortfall for standard GQ1(f).*	**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	The establishment's procedures for identification of bodies do not always use three identifiers. The SOPs for viewings, release of bodies from the mortuary, and PM examination do not contain the minimum number of identifiers that should be used and how the identification checks should be performed. The HTA observed mortuary staff check the identification of a body for release from the mortuary based only on a verbal check of two identifiers. This presents a significant risk of misidentification of the deceased. *Refer to Advice, item 19.*	**Major**

d) There is system for flagging up same or similar names of the deceased	The establishment's procedure for managing bodies with same or similar names is weak and poses a significant risk of misidentification of bodies with same or similar names: • The establishment revised the management of bodies SOP, which includes the same/similar name procedure, immediately prior to the inspection; however, not all mortuary staff had been trained in the revised SOP and the procedure is not followed consistently. • The SOP does not provide sufficient details of how and when bodies should be checked for same/similar names, which means that the establishment cannot be assured that mortuary staff are consistently flagging bodies with same/similar names. • The same/similar name alert card, which is the primary system to flag bodies of deceased with same/similar names, is not secured to the mortuary register or the fridge tray, which means there is a risk the card could become unattached. The HTA audit found one case where the same/similar name alert card was on the wrong tray in the fridge and the notice on the correct fridge door had not been completed with the same/similar name warning. *Refer to Advice, item 20.*	**Major**
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	The establishment's procedures do not provide for full traceability of PM slides: • Records of slides are not completed in a consistent manner. For example, the establishment does not always record when additional slides are made. • The establishment does not record when slides are returned from Pathologists to the laboratory. • The establishment does not record disposal of slides that are broken. This means that when slides are not stored in the laboratory, the establishment does not know whether the slides are being stored by the Pathologist, are lost or have been disposed of because they were broken. Even in cases where the number of slides in storage is the same as the number of slides recorded on the database, the establishment cannot be assured that all the slides are accounted for, since it is possible that additional	**Critical**

	slides were made that were not recorded on the system. The establishment could not demonstrate full traceability of slides for the two cases where slides were audited by the HTA. Although the establishment later provided records to demonstrate traceability of slides for one of these cases, the weaknesses in the establishment's procedures for traceability of slides mean that full traceability cannot be assured. In addition, the HTA's traceability audits found one case where the deceased's name was spelled differently on the body identification tag, label on the whole organ and electronic sample database, compromising traceability. The failure to meet this standard means that the establishment cannot demonstrate that PM tissue samples are not being stored and used without consent. *Refer to Advice, item 21.*	

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	The establishment cannot provide assurance that tissue is disposed of as soon as reasonably possible. Although there is a procedure for following up with third parties to determine when coroner's or police authority has ended, this has not been followed and the establishment is storing whole organs and tissue samples from a number of PM cases where it is not known whether coroner's or police authority for retention has ended. Although in some cases, the family's consent for continued storage of samples may have been obtained, the establishment has not undertaken periodic audits of these samples to establish which samples should be disposed of. In addition, the establishment's procedure for disposal of PM tissue blocks and slides allows the DI to retain samples at their discretion in cases where coroner's or police authority has ended and the family have stated their wish for disposal of the samples. The procedure, if followed, has the potential to result in a statutory breach of the HT Act.	**Critical**

	Immediately following the inspection, the HTA required the establishment to undertake an audit of PM samples. This audit identified a number of samples had been stored beyond the end of authority without consent from the family. The establishment has a plan to deal with these samples and they have been quarantined to ensure that they are not used for a scheduled purpose without consent. Due to the lack of up-to-date records and the establishment's failure to follow its procedure for following up when samples should be disposed of, there remains a significant risk that the establishment is storing PM material for use for scheduled purposes without coroner's or police authority or consent from the family for its continued retention, in breach of the HT Act. *Refer to shortfall against standard GQ2(c).*	
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	Although the establishment has a procedure for following up with third parties to determine when coroner's or police authority ends, this procedure has not been followed. This means that the establishment cannot ensure that tissue is not kept for longer than necessary. *Refer to shortfall against standard GQ2(c).*	**Major**
d) The method and date of disposal are recorded	The establishment's records of disposal record only that whole organs, tissue blocks and slides have been disposed of and do not include details of which organ(s) or the number of tissue blocks and slides disposed of. This means that the establishment cannot provide evidence that all organs, tissue blocks and slides have been disposed of in accordance with the family's wishes. This is particularly important given the weaknesses in the establishment's procedures for traceability of PM samples. *Refer to shortfall against standard T1(g).*	**Major**

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	The mortuary premises are not cleaned or maintained to a sufficient standard: • Some of the tiles on the floors of the body store and the forensic and main PM suites are cracked and there is evidence of failure of the grouting, meaning that the floors are difficult to clean; • There are areas of exposed porous concrete on the floor of the body store and main PM suite where the cold-room doors have been installed; these areas are contaminated and cannot be cleaned effectively; • The floor in the main PM suite underneath and behind the washing machine is not clean, including discarded consumables; • There are areas of peeling paint and exposed plaster in the forensic and main PM suites as a result of damp; • The frames of the PM tables in the main PM suite are contaminated and require deep-cleaning; • There is a split in the base of the PM table in the forensic PM suite and the base of this table is not sealed with the floor properly, meaning that this area is contaminated and cannot be cleaned effectively; and • At the time of the inspection, the sharps bin in the forensic PM suite was found to be overflowing.	**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 mortuary does not have adequate security arrangements: • There is no access control on the door from the mortuary corridor to the room used as an observation gallery for the forensic PM suite and short-term storage of samples from forensic PM examinations. • The establishment has taken steps recently to review electronic access rights to the mortuary. However, a large number of staff have electronic swipe card access and there remains a risk that staff have access who do not legitimately require it because the premises allow for	**Major**

	convenient access to other areas of the hospital. • The lock on the viewing room doors to restrict access from the viewing room to the rest of the mortuary does not provide adequate security since it does not prevent the door from being opened. Although mortuary staff stay in this area of the mortuary whilst viewings take place, there remains a risk of visitors gaining unauthorised access to the mortuary from the viewing room.	

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	Although the storage units are connected to a temperature monitoring alarm, the alarm system is not tested regularly.	**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	In addition to the issues of cleanliness and maintenance described against standard PFE1(a), a number of items of mortuary equipment are in a poor condition. Several key items of equipment are rusting, including: • hydraulic trolleys; • clinical waste bin frames; • the frame of the ionising radiation protection board in the PM suite; and • the stepladder in the forensic PM suite. A whiteboard in the main PM suite has an area of exposed wood where the edging of the board has been damaged.	**Minor**

c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	Although the mortuary ventilation system has been tested, the establishment could not provide evidence that the system has been checked and maintained at least annually. The most recent ventilation system validation report available was from April 2016. The ventilation system validation reports from October 2015 and April 2016 show the necessary ten air changes per hour were achieved at that time; however, the reports state that parts of the system are original and a programme of replacement should be implemented.	**Minor**

Advice

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

No.	Standard	Advice
1.	C1(a)	The DI is advised to review the policies and SOPs for seeking consent for hospital consented PM examinations to ensure that the details of who can give consent under the HT Act are clear in all relevant sections of these documents.
2.	C1(g)	When the consent forms for hospital PM examinations are next reviewed, the DI is advised to: • include a section on the form for an interpreter to sign in cases where interpreting services have been accessed during the consent process; and • make sure that contact details for the HTA are up to date where these are included on the form.
3.	C2(b)	The DI is advised to review the frequency of refresher training for staff seeking consent for PM examinations. Some staff may undertake this activity infrequently, in which case more frequent refresher training will help to ensure that they are familiar with the establishment's procedures for seeking consent and the requirements of the HT Act and the HTA standards and Codes of Practice. The DI is also advised to remind staff of the importance of signing and dating the training record for seeking consent for PM examination. The training record provides evidence that staff have up-to-date training in undertaking this procedure, and the date of completion on this form provides part of the audit trail to evidence this.
4.	GQ1(a)	As part of the corrective and preventative actions required to address the shortfall against standard GQ1(a), all policies and procedures relating to licensed activities should be reviewed to ensure that: • they accurately reflect practices and contain sufficient details of the procedures to be followed; • they reflect the requirements of the HT Act and guidance contained in the HTA's Codes of Practice and Standards and Guidance document, as well

		as guidance from the Health and Safety Executive and Royal College of Pathologists; and • references to the 'next of kin' in relation to consent under the HT Act are removed. The DI is also advised to review the quality manual for the Cellular Pathology Department (which includes the mortuary) to ensure that the mortuary is covered in all relevant sections, including audits and staff competency assessments. *See also Advice, items 7 and 19.*
5.	GQ1(a)	The DI is advised to review signage in the mortuary and to include signage indicating: • when the storage unit is in freezer mode so that staff are aware of where bodies can be placed; and • the requirements and procedures for reporting incidents, including HTARIs. This will help to raise awareness of, and ensure compliance with, the establishment procedures for mortuary activities.
6.	GQ1(a)	The DI is advised to keep under review the establishment's arrangements for lone working in the mortuary to ensure that they are appropriate and protect the safety of staff. Whilst there are wall-mounted panic alarms in the mortuary, use of individual lone working alarms in addition may help to manage further the risks of lone working in the mortuary. This is particularly important where staff undertake viewings out-of-hours.
7.	GQ1(b)	The establishment's procedure for PM examination is for the Pathologist to confirm consent or authorisation for the PM examination, check the identification of the body and complete the external examination of the body prior to instructing the APTs to undertake evisceration of the body. The DI should ensure that the SOP for PM examination includes sufficient details of this procedure, including how the identification check is performed and that evisceration must not commence until the appropriate checks and the external examination have been completed by the Pathologist.
8.	GQ1(d)	The DI is advised to ensure that all relevant staff are consulted when controlled documents are reviewed. This will help to identify changes required to policies, procedures and forms, including where additional clarification or details of procedures are required.
9.	GQ1(d)	The DI is advised to include the date of review on controlled documents. Although this information is available when viewing documents on the establishment's electronic document control system, only the date of issue of the first version is included on the document itself. This will help staff to ensure that they are referring to the most recent versions of documents. This is particularly important given that some staff do not have access to the electronic document control system and so rely on controlled hard copies of documents. The DI is also advised to ensure that all documents and records relating to licensed activities, including the incident log in the mortuary, are subject to the establishment's document control procedures.

10.	GQ1(g)	As part of the corrective and preventative actions required to address the shortfall against standard GQ1(g), the DI should nominate the key staff who oversee consent for hospital PM examinations as Persons Designated on the licence. This will help the DI to ensure appropriate oversight of consent and staff awareness of the policies and procedures for seeking consent for hospital PM examinations. This will also ensure that staff have access to and meet regularly with the DI. The DI is also advised that copies of the HTA licence certificate should be displayed in all areas where licensed activities are carried out, including in the Cellular Pathology Laboratory, in order that it can easily be read by persons who are involved in the carrying out of those activities. This is a standard licence condition and will help raise awareness of staff and provide clarity as to where licensed activities are taking place.
11.	GQ1(h)	In addition to the corrective and preventative actions required to address the shortfall against standard GQ1(h), the DI is advised to ensure that minutes of meetings relating to licensed activities provide sufficient details of the matters discussed and the outcomes and actions agreed. The DI is also advised to include incidents and non-conformances as a standing item on the agendas for departmental meetings covering licensed activities. This will help to ensure that staff are aware of the types of incidents that must be reported to the HTA and encourage learning from incidents and non-conformances.
12.	GQ2(a)	To address the shortfall against standard GQ2(a), the DI should ensure that, as a minimum, the audit schedule includes a range of: • process audits of staff undertaking procedures; • vertical and horizontal audits checking compliance with documented procedures, the completion of records and traceability; and • audits of traceability of bodies, including in freezer storage (and where there are cases that cannot be audited by mortuary staff, for example forensic cases, this should be documented as part of the audit report). The DI is advised that audits should be undertaken on a regular basis and following incidents or material changes to procedures. Audits can help to ensure that procedures are performed in accordance with SOPs and identify where a process needs to be amended. It may be beneficial for audits to be undertaken by staff who do not perform the procedures regularly so that they can take a ‘fresh eyes’ approach to the audit.
13.	GQ3(a)	The DI is advised that process audits of staff undertaking procedures may also help to identify areas where additional training is required. Process audits may form part of the establishment’s process for staff annual review and personal development plans.
14.	GQ3(e)	The DI is advised to review the training available for mortuary staff to ensure that they are all provided with opportunities for training and development. The Mortuary Manager has extensive experience and training, and the DI is advised to consider ways in which learning can be shared with all mortuary staff. For example, this may include internal training sessions for staff to share information from external courses they have attended and experience from working at other HTA-licensed establishments. APTs should also be encouraged to work towards achievement of the Royal Society for Public Health Level 3 Diploma in Anatomical Pathology Technology.

15.	GQ4(b)	The DI is advised to remind staff of the requirements for written amendments of records. The HTA found examples of minor written amendments of records for traceability of bodies and PM samples, which had not been completed in accordance with the establishment's procedure.
16.	GQ5(a)	To address the shortfall against standard GQ5(a), the DI should ensure that the establishment's SOP for reporting incidents includes: • that it is a requirement to notify that HTA of any reportable incidents, including near misses, within five working days of the incident occurring or being discovered; • the complete list of HTARIs categories; and • details of the establishment's procedure for reporting HTARIs, including that notifications are submitted to the HTA using the HTA's secure web Portal. Information on HTARIs, including the incident categories and timeframes for reporting, can be found on the HTA website: www.hta.gov.uk/policies/post-mortem-hta-reportable-incidents. The DI is also advised to ensure that sections of the establishment's business continuity plan that describe the actions to be taken in the event of serious incidents also include reference to the requirements and SOP for notifying the HTA of any HTARIs.
17.	GQ6(a)	To address the shortfall against standard GQ6(a), the DI should ensure that all procedures related to licensed activities are risk assessed on a regular basis. The HTARI categories may provide a useful reference for staff when considering what the risks of undertaking licensed activities could be. The HTA's guidance document 'Regulation of the PM sector 2014-16; What we have learned' provides further advice on risk assessments in this sector: www.hta.gov.uk/news/regulation-post-mortem-sector-2014-16-what-we-have-learned.
18.	T1(b)	The establishment plans to introduce an electronic laboratory information management system (LIMS) to record details of bodies and PM samples. The DI is advised to ensure that thorough testing of this system and comprehensive training for all relevant staff is undertaken prior to implementing the LIMS. The DI is also advised to ensure that regular audits of the LIMS records are undertaken to identify discrepancies in records and any additional training requirements. This is particularly important given the significant weaknesses in the establishment's procedures for traceability of bodies and PM samples identified by the HTA.
19.	T1(c)	As part of the corrective and preventative actions to address the shortfall against standard T1(c), the DI should ensure that all three identifiers are used to identify bodies and tissue, including at least one unique identifier. SOPs describing the procedure for checking the identification of bodies should describe, as a minimum,: • the minimum number of identifiers that must be used and what these identifiers are expected to be; • what records or information are required for the identification check; • how the identification check should be performed, including against what records the body identification tag should be checked against; and

		• the actions to take in the event of any discrepancies in the identifiers. The DI should ensure that the procedure for viewings includes details of what information the family are required to provide to mortuary staff so that the identification check of the deceased is conducted in line with the required standards. The DI may wish to consider introducing a form to gather this information from the family in a way that is sensitive and ensures that the required standard is met for the identification check of the deceased. The DI is also advised to consider recording the police log number in the mortuary register as an additional identifier, where this is available. This may be particularly important for cases where the identity of the deceased is not known at the time of admission to the mortuary.
20.	T1(d)	As part of the corrective and preventative actions to address the shortfall against standard T1(d), the DI should strengthen the procedure for management of bodies with same or similar names, and ensure that it is followed consistently. This may be through the use of: • coloured identification tags to be placed on the body; • coloured stickers to be affixed to the relevant entries in the mortuary register and log book; and • magnetic warning notices to be placed on the whiteboard next to the details of the deceased.
21.	T1(g)	As part of the corrective and preventative actions to address the shortfall against standard T1(g), the DI should ensure that the traceability system for PM samples ensures that the following details are recorded: • material sent for analysis on or off-site, including confirmation of arrival; • receipt upon return to the laboratory or mortuary; • the number of blocks and slides made; • repatriation with the body; • return for burial or cremation; and • disposal or retention for future use.
22.	PFE1(a)	As part of the corrective and preventative actions to address the shortfall against standard PFE1(a), the DI should review the arrangements for the siting of the washing machine in the main PM suite. The current arrangements mean that it is difficult to clean this area of the PM suite floor properly.
23.	PFE1(d)	The DI is advised to review the CCTV coverage of the mortuary premises to ensure that the key areas are covered and to consider whether additional CCTV cameras may be required. This should be considered as part of the ongoing risk assessment of mortuary security.
24.	PFE2(f)	The DI is advised to introduce a regular formal review of the temperatures of mortuary fridges and freezer. This may help to identify issues with the functioning of storage units, including potential additional maintenance or servicing that may be required. The DI is advised that refrigeration of bodies should be at a temperature of approximately 4°C and the optimal temperature for freezer storage is around minus 20°C (plus or minus 4°C).

25.	PFE2(i)	The DI is advised to review the establishment's contingency plan for storage capacity to consider whether this plan could be strengthened by additional contingency arrangements. Further advice on contingency storage arrangements can be found in the HTA's guidance document 'Storage capacity and contingency arrangements in mortuaries: Guidance for DIs in HTA-licensed establishments': www.hta.gov.uk/sites/default/files/Capacity%20and%20Contingency%20Report%20Nov%2015.pdf.
26.	PFE3(a)	As part of the corrective and preventative actions to address the shortfall against standard PFE1(a), the DI should keep the suitability of the mortuary facilities under regular review, including the PM facilities and ventilation system, to ensure that they are fit for purpose, clean and well maintained.
27.	PFE3(f)	Servicing of mortuary equipment is managed by the hospital's Estates Department. Servicing of the ventilated cabinet for storage of formalin in the main PM suite expired on June 2017. The DI is advised to ensure that the mortuary is notified of all servicing of mortuary equipment and provided with copies of service records. This will allow mortuary staff to ensure timely servicing of all mortuary equipment.

Concluding comments

Despite the significant shortfalls against HTA standards, the HTA observed some areas of strength. The mortuary and Bereavement Services staff demonstrated a sensitive approach to the services they provide, including provision of memory boxes with keepsakes for bereaved parents and guidance on support services available to bereaved families. Clinical staff seeking consent for hospital PM examination also demonstrated a sensitive approach to their work and a good knowledge of the requirements of the HT Act and the HTA's Codes of Practice.

The Mortuary Manager has worked hard to implement changes to mortuary procedures in an effort to improve practices and compliance with the regulatory standards. Staff demonstrated that there is good communication between several departments, including between the mortuary, Bereavement Services and hospital nursing staff teams. The Mortuary Manager hosts monthly learning sessions with groups of hospital nursing staff to raise awareness of end of life care and procedures at the establishment.

The Cellular Pathology Department, including the mortuary, is accredited to ISO 15189 (2012) Medical Laboratories standards. The Cellular Pathology Department quality management team, including the Service Manager, also demonstrated a commitment to continual improvement.

There is evidence that where the mortuary and Cellular Pathology Laboratory teams have worked together to undertake investigations and root cause analyses of incidents and

deviations from procedures, this had led to implementation of corrective and preventative actions that have improved practices and compliance with the HTA standards.

Staff at the establishment had been aware of some of the issues raised during the inspection and had been trying to rectify these. A number of staff, including the Mortuary Manager, Cellular Pathology Department Service Manager and members of the Clinical Board present during the inspection, demonstrated a commitment to improvement and compliance with the regulatory requirements and were open to the advice given by the HTA.

Although the HTA found that the establishment had met some of the HTA's standards, significant shortfalls were found against the governance and quality systems, traceability and premises, facilities and equipment standards, with three shortfalls assessed as critical and fourteen shortfalls assessed as major (see Appendix 2 for information about the HTA's classifications of shortfalls). The number and severity of shortfalls in meeting the HTA standards is of significant concern and demonstrates that the DI has failed to discharge their duty under section 18 of the HT Act to supervise the licensed activity; specifically that they have failed 'to secure that suitable practices are used in the course of carrying on that activity.

Therefore, the HTA found that the DI was not fulfilling their statutory responsibilities under the HT Act and is not suitable to act in this capacity. The HTA required the Health Board to identify an alternative person to take on the role of DI as a matter of priority. An application from the establishment to change the DI was approved by the HTA following the inspection.

The HTA has written to the Health Board's Medical Director, who is the corporate licence holder contact for the purposes of HTA licensing, the Chief Executive and the DI outlining the actions that must be taken as a matter of urgency to address the critical and major shortfalls identified.

All shortfalls will be managed through the HTA's process for agreeing and overseeing corrective and preventative actions plans (CAPAs). The HTA requires the DI to submit a completed CAPA plan 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 will be maintaining oversight of the actions taken to address the shortfalls to ensure that they are rectified promptly and appropriately.

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

Report sent to DI for factual accuracy: 6 September 2017

Report returned from DI: 18 September 2017

Final report issued: 12 October 2017

Appendix 1: HTA licensing standards

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

Consent

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

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.