Site visit inspection report on compliance with HTA licensing standards

Calderdale Royal Hospital

HTA licensing number 12108

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**

23 & 24 January 2019

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.

Although the HTA found that Calderdale Royal Hospital had met the majority of the HTA's standards, eight major and fifteen minor shortfalls were found against standards for Consent, Governance and Quality, Traceability and Premises, Facilities and Equipment.

The shortfalls relate to post-mortem (PM) examination consent training and consent seeking procedures; standard operating procedures (SOPs); records management; storage of bodies; audits; traceability; maintenance of premises and equipment; security and body store alarms.

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

The establishment consists of a hub (Calderdale Royal Hospital (CRH)) and a satellite site (Huddersfield Royal Infirmary (HRI)). The establishment has been licensed by the HTA since June 2007 and this report describes the fourth routine site visit inspection, with the previous inspection occurring in August 2015.

The establishment ceased performing post mortem (PM) examinations in 2012. Both adult and perinatal PM examinations are conducted at other HTA licenced establishments. All tissue taken at PM examination was sent to other HTA licensed establishments for analysis. A relatively small archive of tissue blocks and slides are held by the establishment for cases between 2015 and 2017, when histological analysis of samples from both Coronial and hospital consented PM examinations was being undertaken at CRH (see shortfalls against T2(b) and T2(c)).

There are two full-time mortuary staff (a Senior Mortuary Assistant and Mortuary Assistant). The Senior Mortuary Assistant has recently resigned and the establishment is currently training five Medical Laboratory Assistants (MLAs) to undertake mortuary duties on a rotational basis. Currently, only one MLA has nearly completed their training.

The establishment receives bodies from A&E, hospital wards and from the community if they have recently been an in-patient at the hospital or have been discharged into local care homes/hospices. No general community bodies are admitted to the mortuary. Bodies received into the mortuary from the hospital have an identity wrist band attached detailing name (or unknown male/unknown female, plus a city), date of birth (DOB), NHS number and hospital number. A carbon copy of the notification of death (NOD) form is also attached to the shroud on the body which has name, DOB, date of death (DOD), address, hospital number and place of death. Those from the community or local hospices have a wrist band attached with name DOB, DOD and address.

Release of bodies occurs in both normal working hours and occasionally out-of-hours. During normal working hours, release of bodies is undertaken by a single mortuary staff member with the funeral director (FD). FDs arrive with various forms of paperwork detailing the name, DOB and address of the deceased. This paperwork is cross checked against the details on the identity wrist band and the mortuary register (see shortfall against T1(c)). Out-of hours, release is conducted by the Clinical Site Team with the FD's. The same procedure is followed.

Viewings are conducted by mortuary staff in-hours and by the Clinical Site Team out-of-hours . Verbal confirmation of who relatives have come to view is obtained prior to the viewing (see shortfall against T1(c)). Viewings of adult bodies occur at both sites; CRH also has facilities to also view paediatric and perinatal bodies (see shortfall against PFE1(e)).

No long-term storage facilities are available at this establishment, however a service level agreement (SLA) exists with another HTA licenced establishment as part of their contingency arrangements (see shortfalls against GQ1(a) and PFE2(c)).

Removal of tissue for Sudden Unexplained Death in Infants/Children (SUDIC) occurs in the A&E department, but also on the paediatric wards and neonatal wards when required (see shortfall against GQ1(g)).

Although adult, perinatal and paediatric PM cases are transferred to other HTA-licensed establishments, consent is sought for these PM examinations on-site by clinicians and midwives, respectively (see shortfall against C2(a)). Consent for perinatal and paediatric PM examinations is recorded using the Stillbirth and Neonatal Death (SANDs) documentation. Stillbirths and perinatal deaths are transferred to the mortuary within a few hours by porters in a dedicated transfer bag (see shortfall against T1(h)).

The mortuary is accessed from a service corridor in the pathology unit or via a rear entrance from the car park. The service corridor is used by porters to bring bodies from the hospital wards and A&E department, as well as relatives who are accompanied by mortuary staff for viewings. The rear entrance is used by funeral directors to collect bodies from the mortuary. Both doors are secured with key locks (keys for which are held by mortuary staff and porters) and a bell for attention. CCTV, visual or voice intercom is not in place at either entrance (see shortfall against PFE1(d)).

The body store consists of 45 refrigerated body spaces, four of which are suitable for semi-bariatric bodies. Paediatric/perinatal cases are stored in one bank of fridges, if capacity allows (see shortfall against PFE2(h)) or stored on the uppermost spaces in adult fridges at times of peak activity. A temporary unit is also available which can be used to store one bariatric body, or provide an additional twelve standard sized refrigerated body spaces.

The mortuary has a single PM suite with three PM tables. PM examinations are no longer conducted at this site, however, tissue retrieval and pace maker removal is undertaken in these facilities (see shortfall against PFE1(a)).

Huddersfield Royal Hospital

The mortuary at HRI is accessed from a main public corridor or via a rear entrance with a loading bay and platform lift to allow collection of bodies by FDs (see shortfall against PFE3(f)). The corridor entrance is used by porters to bring bodies from the hospital wards and A&E departments, a separate door is used by relatives accompanied by mortuary staff for viewings. The entrance used by porters with hospital bodies is secured by a key lock and key code entry system in-hours, but only by key lock out-of-hours. CCTV, visual or voice intercom is not in place at either entrance (see shortfall against PFE1(d)).

The body store consists of 54 refrigerated body spaces, four of which are suitable for bariatric cases.

Description of inspection activities undertaken

An audit was undertaken at each of the sites cross referencing details in the paper based mortuary register with those both on the fridge door plates (CRH) or door cards (HRI) and NOD form on the shroud. The name, DOB and hospital number were checked against those on the identity tags found on the body:

- CRH - four bodies (three adults and one baby) were audited; discrepancies in identifiers were found between the details on the NOD form, the mortuary register and the wrist bands

- HRI – four adult bodies were audited; no discrepancies were identified;

In addition, four cases from between 2015 and 2017 of tissue removed during PM examination at another HTA establishment and prepared by the histology department at CRH were audited for traceability. No consent wishes forms could be provided at the time of inspection for three of the Coronial cases and the form for the hospital PM examination had been completed incorrectly. The establishment is required to complete this audit and provide evidence to the HTA. (see shortfalls against T2(b) and T2(c)).

Interviews were conducted with: Consultant Histopathologist (the DI); Mortuary/Cellular Pathology Manager; clinician who obtains consent for adult PM examinations; Bereavement Midwife who oversees consent seeking for perinatal PM examinations; Consultant Paediatrician who is lead for SUDIC protocol; Consultant Paediatrician who removes relevant material in SUDIC cases; Charge Hand Porter, Facilities Manager and Assistant Facilities Manager for porter activities and Quality Manager.

Inspection findings

Although the HTA found the Licence Holder and the Designated Individual to be suitable in accordance with the requirements of the legislation, the number and severity of shortfalls identified is of concern. Advice and guidance was given to the DI to further improve practices following the last inspection in 2015. During the current inspection similar areas for improvement were identified, and are captured in the shortfalls below.
Although the DI has been deemed to be a suitable person to hold the role, the shortfalls identified indicate that he has not ensured that there are suitable practices in place for the conduct of the licensed activities.

The HTA will monitor progress of these shortfalls through the Corrective and Preventative Action (CAPA) plan to be completed by the establishment and will keep the suitability of the DI under review.

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	While a policy exists for the 'Consent to Examination or Treatment' (C-8-2011, version 3), there is no reference to seeking consent for hospital PM examination. The policy review date is both 30 September 2018 and May 2017 for different sections. The front index page numbers do not correlate with the actual pages in the document.	**Minor**
b) There is a documented standard operating procedure (SOP) detailing the consent process	While an SOP for seeking consent for an adult PM examination (SOP M20-045) is available, it lacks sufficient details of the process for a user to ensure all aspects of the consent seeking process are addressed. Reference is made to out of date HTA codes of practice and the training package link provided does not work as the training package was unavailable for review at the time of inspection.This issue was identified by the establishment prior to the inspection but is still yet to be resolved. SOP M20-014 describes the process for seeking consent for disposal of pregnancy loss remains. The SOP lacks any reference to options for disposal that should be relayed to the mother to ensure that all available options have been discussed.	**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	Those involved in seeking consent for PM examinations do not always have adequate and up-to-date training. Records of those who have received training which addresses the requirements of the HT Act and the HTA codes of practice, are not held by the relevant departments. Consent training records reviewed showed some individuals seeking consent were last trained in 2008. Therefore it is not possible for the DI to assure himself that appropriately trained staff are seeking consent for either adult or paediatric PM examinations. *Standards C2(b), C2(c) and C2(d) could not therefore be assessed.*	**Major**

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 a number of the required SOPs in place, they lack sufficient detail or attention to wording, these include but are not limited to: • SOP M20-053 – refers to SOP M20-035 for the long-term storage of bodies procedure, however, this SOP does not provide details of the procedure for movement of bodies for long-term storage to another HTA licenced facility for which an SLA is in place. • Bodies were identified as being held in refrigerated storage for longer than the recommended 30 day period (see shortfall against PFE2(c)). Staff were not aware of procedures for initiating transfer of bodies into long-term storage at another HTA licenced establishment. • SOP M20-035 – refers to the transfer of bodies from the establishment to other HTA licenced premises. This SOP does not detail the requirement of cross referencing three identifiers found on the body with those on the paperwork provided by the person collecting the body for transfer. The SOP also fails to stipulate what paperwork should be provided by those collecting the body to ensure three identifiers for the body can be checked.	**Major**

	• SOP M20-027 and SOP M20-113 both identify forename and surname as two separate identifiers. However, forename and surname combined is classed as one identifier. • SOP M20-032 – lacks sufficient detail of the procedure. It does not state that three identifiers should be obtained from those wishing to view the body and this information cross referenced with the information on the identity tag of the body prior to viewing. All SOPs require review to ensure they contain sufficient detail and correct up-to-date references to external documents, for example, the HTA's codes of practice. This is especially important with the introduction of new staff in to the mortuary. Issues with SOPs was identified as a shortfall in the previous site visit inspection, it appears only the SOPs that were submitted for review to the HTA have been reviewed and updated, despite the DI providing assurances that all SOPs would undergo this process.	
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework	It was reported to the inspection team that removal of relevant material from SUDIC cases does not occur only in designated areas such as A&E. Removal of relevant material is not under pre-emptive authority of the Coroner and therefore is removed with the consent of the family. Staff responsible for removal of tissue from the deceased were not aware of the requirements of the HT Act or the need to obtain consent from the family if consent from the Coroner is not obtained.	**Minor**

GQ2 There is a documented system of audit		
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	While a schedule of audits is conducted, there are no audits of tissue retained from PM examinations that have been analysed by the establishment.	**Minor**

GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	Staff were unaware of HTA Reportable Incidents (HTARIs), how they should be reported or who at the establishment can report these incidents to the HTA via the HTA website portal. The internal incident reports were reviewed by the inspection team which identified a number of incidents since the previous inspection that may be either near misses or HTARIs, but which had not been reported to the HTA.	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
c) Three identifiers are used to identify bodies and tissue, (for example post mortem number, name, date of birth/death), including at least one unique identifier	At present, a variety of documentation is obtained from funeral directors which is used to identity a body before it is released. The wrist band on a body routinely states, name, DOB and hospital number. Paperwork provided for release at most will state: name, DOB, DOD and address, therefore only two identifiers can be cross referenced from the body to the paperwork provided by those collecting the body. In addition, bodies are viewed after staff are provided with only verbal communication of the identity of the deceased from those visiting the mortuary. No further identification check of the body is performed prior to the viewing. These practices pose a risk of releasing or viewing a wrong body.	**Major**
d) There is system for flagging up same or similar names of the deceased	While there is a system for highlighting bodies with a same/similar name while they are stored at CRH, there was no evidence of this system being adhered to when records were reviewed by the inspection team. This presents a risk of releasing the wrong body.	**Minor**
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	Records are not kept by the maternity departments at either site for pregnancy loss remains relevant material that have been collected and transferred to the mortuary. This poses a risk that traceability may be lost between these departments and the mortuary.	**Minor**

T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
b) There are effective systems for communicating with the Coroner's Office, which ensure tissue is not kept for longer than necessary	During the inspection, a number of PM cases where tissue had been retained were reviewed. On average, two years had elapsed between the time of the PM examination and the establishment obtaining the wishes of the family from the Coroner. There is no effective system for communication in place between the establishment and the Coroner. This presents a risk that the establishment are storing tissue without authority or consent. In addition to the three cases identified during the tissue audit, the DI is required to establish the family's wishes for all retained tissues being stored at the establishment.	**Major**
c) Disposal is in line with the wishes of the deceased's family	One of the four PM cases audited during the inspection was a hospital consented case where tissue has been retained for scheduled purposes. The tissue is being used for teaching and training purposes by the DI. However, the consent form has been completed incorrectly; the option for disposal and teaching/training has been completed, making the consent for retention and use of the tissue ambiguous. The tissue must not be used again until consent is reobtained, or the retained tissue must be disposed of.	**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	PM examinations are not conducted at the establishment however, tissue retrieval and pace maker removal is undertaken by staff in the PM suites at both sites. At CRH, clinical waste bins are also being cleaned in the PM suite. Both PM suites have become storage areas for excess equipment and other non-clinical items. For example, wooden pallets and cardboard boxes, making these areas unsuitable for undertaking the PM activities that they are utilised for. In addition, there were issues identified with the cleanliness and maintenance of the PM suite, including but not limited to: • Hair in drains and rubbish on the PM tables at CRH; • Contaminated dissection board and PM room floor at HRI; • Damaged wooden door frames and wooden instruments at HRI.	**Minor**

	Damaged fixtures and storage of (porous) items in the PM suites mean they cannot be adequately cleaned or decontaminated, when these areas have been used, posing a potential health and safety risk to mortuary staff.	
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)	No CCTV is present to monitor the access to the body store areas at either site. In addition, there is no visual/voice intercom at the external or internal entrances to the body store areas, only a bell. This increases the risk of the doors being opened to unauthorised people, potentially causing a security and/or safety issue for staff.	**Major**
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The toilet facilities adjoining the viewing room at CRH are currently and frequently used by patients of a clinical department; visitors viewing the deceased at the mortuary are not permitted to use them. CRH performs a number of viewings including some perinatal cases and therefore access to toilet facilities are often required by visitors. In addition, the increased numbers of clinical patients in this area increases the risk of unauthorised access to the body store and viewing room, especially when this area is not monitored by CCTV or has a video intercom system.	**Minor**

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Staff access the viewing room, when required, through the door directly into the body store. The use of this door may allow unintentional viewing of mortuary activities within the body store. There is a large gap between the body store doors into the viewing room. Relatives may be able to see through this gap and it does not prevent noise from the body store infiltrating the viewing room.	**Minor**

c) Storage for long-term storage of bodies and bariatric bodies is sufficient to meet needs	Bariatric storage facilities at CRH are limited to one space in a temporary storage unit which currently is erected when required. The establishment rely upon their ability to transfer bariatric patients to HRI, however the size of the patient can render this option obsolete. An incident has occurred where the body could not be transferred using hospital transfer facilities and no acceptable storage conditions were available. HRI also has limited bariatric storage facilities with only three spaces available in practicality, based on refrigerated bariatric body store design. There are no on-site freezer storage facilities, however an SLA for contingency and long term storage of bodies is in place with another HTA licenced establishment. Despite the SLA, bodies were identified as being held in refrigerated storage for periods far in excess of the HTA's recommended 30-day time scale.	**Minor**
e) Fridge and freezer units are alarmed and the alarms are tested regularly to ensure that they trigger when temperatures go out of upper or lower set range	The temporary fridge at CRH is not connected to the alarm system and the alarm system of the permanent refrigerated body storage units fail to activate if there is a power failure. Mortuary staff would not be alerted if this was to happen outside the limited working hours for which staff attend this site. The current upper trigger point for the refrigerated body store is 12^{o}C. The DI is advised to reduce this trigger point nearer to the set running temperature of 4-6^{o}C, with an appropriate time delay before the alarm triggers. This will facilitate the correct storage temperature of bodies and ensure staff are made aware of insufficient refrigerator function at a more appropriate temperature.	**Major**
h) There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies	Perinatal/paediatric cases while shrouded are placed directly onto the trays in refrigerated storage. The inspection team witnessed the removal of a baby from a fridge tray located at an above waist-height position without removal of the tray using appropriate equipment. This lack of use of appropriate equipment could result in accidental damage to the body when removing the body from refrigerated storage.	**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 is an SLA in place with another HTA licenced establishment for storage of bodies when required, there is no SOP for activation of the contingency plan. Mortuary staff are not aware of how or at what capacity levels they should alert the DI or appropriate individuals to activate the contingency arrangements.	**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	The establishment has a ceiling hoist system at CRH, however, this is not suitable for use for bodies in the mortuary. At HRI, the ceiling hoist system is only partially installed and not yet operational. As there are limited numbers of staff at either site, the lack of appropriate manual handling equipment to handle bodies, poses an increased risk of accidental damage to a body.	**Minor**
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	No ventilation records for either PM suites were available for review at the time of inspection. The systems at both sites are not routinely tested to provide assurance the ventilation systems are providing the necessary ten air changes per hour. As the PM suites are still used for some PM activities, for example, tissue retrievals, this poses a potential health and safety risk to all staff.	**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	At HRI the trolley lift used by FDs/hospital transport for the transfer of bodies from the vehicle to the mortuary entrance is an essential piece of equipment, however, does not appear to be regularly serviced or maintained by estates.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1(a)	The DI is advised to archive any SOPs which are no longer of use due to changes in local procedures.
2.	GQ1(h)	While meetings to discuss HTA matters currently form part of other cellular pathology departmental meetings, a number of staff members involved in mortuary activities do not attend these meetings and are not aware of the requirements of the HT Act or HTA licensable activities. The DI is therefore advised to set up a quarterly meeting to discuss HTA matters and invite all appropriate members of staff, who are involved in the HTA licensable activities both in the mortuary and areas remote to the mortuary.
3.	GQ6(b)	While risks assessments are in place for licensable activities, the DI is advised to perform separate risk assessments for each activity at both CRH and HRI due to the slightly different procedures at each site.
4.	GQ6(b)	In light of revisions made to SOPs the DI is advised to ensure risks assessments are reviewed to incorporate changes to the SOPs and procedures at both CRH and HRI.
5.	T1(c)	A smart code sticker Is currently added to the mortuary register at both CRH and HRI. The DI is advised to review the use of this unique identifier and related

		computer system to determine if it could be used to assist with the traceability of bodies.
6.	T1(c)	At CRH the chalk board plates are difficult to read and are easily smudged. At HRI door cards are placed in holders in the door. However, the door cards are ill fitting and could easily fall out. The DI is advised to replace these boards and card holders with a more appropriate method of labelling the outer fridge doors.
7.	T1(c)	The NOD forms can be very difficult to read as they are a carbon copy of the original. The DI is advised to consider reviewing the format of the NOD form to improve its legibility.
8.	T1(c)	The DI is advised to ensure all clinicians are reminded that the identity wrist band on the body should be used to verify the identity of the deceased when performing checks to complete cremation paperwork not solely rely on the name on fridge door plate to ensure they are completing paperwork for the correct person.
9.	PFE1(d)	The body store and PM room areas at both sites are accessible by key locks only. Therefore, the Di may wish to consider additional security, for example implementing the use of the key code access system at HRI at all times and putting a similar system in place at CRH.
10.	PFE2(b)	Staff expressed concerns over failure by FDs to collect bodies and Pregnancy Loss Remains (PLRs) in a timely manner despite them being notified they are ready for collection. The DI is advised to review the current situation and look at means to encourage FD's to collect bodies which are ready for release to remove pressures on capacity of the mortuaries at both CRH and HRI.
11.	PFE2(c)	The DI is advised to ensure porters place all bodies including bariatric bodies onto designated trays in the refrigerated bariatric storage units rather than placing the bed into the refrigerated body store. This will reduce the need for difficult and further unnecessary handling of the body once the bariatric bed has deflated, which could also increase the risk of accidental damage, and increase available storage capacity for bariatric bodies.
12.	PFE2(h)	While perinatal and paediatric cases are stored on separate shelves, the DI is advised a designated set of trays are clearly identified within the adult refrigerated body storage units and labelled clearly to assist identification of the trays in use for these bodies.
13.	PFE2(h)	Due to use of the top trays in the refrigerated body store for the storage of perinatal/paediatric cases in times of peak activity, the DI is advised perinatal and paediatric cases are placed into appropriate containers while in storage. This will facilitate the identification of the tray being in use, helping to mitigate against the risk of accidental damage to the body when trays are being removed from storage.
14.	PFE3(a)	At CRH the uppermost storage positions in the refrigerated body store units are difficult to access due to only manual retraction trolleys being available for use. The DI is advised to review and risk assess the current equipment available to staff accessing these spaces.
15.	PFE3(d)	The DI is advised to ensure PPE is located in appropriate areas within the PM suites, so it is accessible in the correct area, when required. For example, placing over-shoes near the PM suite access doors.

Concluding comments

Despite the number of shortfalls identified, areas of good practice were observed during the inspection. Staff in the mortuary demonstrated a commitment to the continual improvement of practices and compliance with the HT Act. Areas of good practice include:

- communication between mortuary staff members and team work to ensure cover at both sites;
- all staff interviewed were open to suggestions for how improvements could be made to current practices.

All staff demonstrated a clear dedication to the role they undertake, a conscientious approach to the handling and traceability of relevant material and a compassionate approach to arranging viewings of the deceased at both mortuary sites, with evidence of gratitude expressed by visitors to the mortuary.

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

The HTA requires the Designated Individual to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfalls will be addressed, within 14 days of receipt of the final report (refer to Appendix 2 for recommended timeframes within which to complete actions). The HTA will then inform the establishment of the evidence required to demonstrate that the actions agreed in the plan have been completed.

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

Report sent to DI for factual accuracy: 11 February 2019

Report returned from DI: 26 February 2019

Final report issued: 26 February 2019

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: 30 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.