Site visit inspection report on compliance with HTA licensing standards

John Radcliffe Hospital

HTA licensing number 12052

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**

4-5 July 2017

Summary of inspection findings

The HTA found the Designated Individual (DI), the Licence Holder (LH) and the premises to be suitable in accordance with the requirements of the legislation.

Although the HTA found that John Radcliffe Hospital had met the majority of the HTA's standards, three major shortfalls were found in relation to: (i) porter training; (ii) the security arrangements of the external refrigerated storage units; and (iii) the appropriateness of the external refrigerated storage units in ensuring the dignity of the deceased. In addition, three minor shortfalls were found in relation to: (i) version control of policies and procedures; (ii) the cleaning of the external refrigerated storage units; and (iii) ventilation levels in the paediatric post-mortem room.

Advice has been given relating to the Governance and Quality Systems, Traceability and Premises, Facilities and Equipment standards, as well as to licence management.

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

The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the Designated Individual (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. They are to secure that:

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

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

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

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

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

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

Background to the establishment

This report refers to the activities carried out at the John Radcliffe Hospital (the establishment), whose HTA licensing arrangements cover the John Radcliffe Hospital (JRH; the hub site) and the Churchill Hospital (satellite site). A separate body store is situated at the Horton Hospital (part of the same Trust), which is not subject to licensing as bodies there

are held pending release to funeral directors or temporarily, 'incidental to transportation' to JRH for post-mortem (PM) examination.

The establishment was issued an HTA licence in October 2007. This was its fourth HTA site visit inspection (the last one having taken place in March 2015) and was a routine site visit to assess whether the establishment is continuing to meet the HTA's standards.

The hub site is licensed under the Human Tissue Act 2004 (HT Act) for the making of a PM examination, the removal of relevant material from the deceased for use for a scheduled purpose and the storage of a body and relevant material for use for a scheduled purpose. The satellite is licensed under the HT Act for the removal of relevant material from the deceased for use for a scheduled purpose and the storage of a body and relevant material for use for a scheduled purpose.

The DI supervising activities taking place under the licence is Professor of Cellular Pathology and a Consultant Pathologist; the Corporate Licence Holder (CLH) is Oxford University Hospitals NHS Foundation Trust (OUHFT) and the CLH Contact (CLHC) is the Deputy Medical Director. There are currently 15 Persons Designated (PDs) working under the licence (see *Advice*, item 1).

John Radcliffe Hospital (JRH) - the hub site

At the hub site, licensable activities occur within Cellular Pathology, which includes the mortuary and Histopathology Department, the Neuropathology and Emergency Departments, and the Maternity Unit.

Cellular Pathology is accredited by the United Kingdom Accreditation Service (UKAS) to International Organization for Standardization (ISO) standard 15189 (2012). The last UKAS inspection was in March 2015.

Cellular Pathology (Mortuary)

The mortuary at JRH receives approximately 5,000 bodies each year and is a specialist centre for paediatric, perinatal and stillbirth cases. It conducts approximately 1,350 PM examinations each year, including 900 adult and 450 paediatric, perinatal and stillbirth cases.

Most of the adult PM examinations are conducted under Coronial authority, the majority being under HM Coroner, Oxfordshire (with a small proportion under HM Coroner, Buckinghamshire). There were also 73 consented adult PM examinations in 2015, most of these being neuropathology cases. Approximately 30 Home Office PM examinations are conducted each year.

There are six consultant pathologists who conduct routine adult PM examinations, two consultant neuropathologists who carry out neuropathological PM examinations and two consultant paediatric pathologists who conduct paediatric and perinatal PM examinations. They are assisted by a mortuary team consisting of the mortuary manager, two qualified Anatomical Pathology Technologists (APTs) and two trainees. As well as conducting PM examinations, the pathologists and mortuary team remove brains, spinal cords and brain tissue from consenting donors for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body' ('research'). The neurological tissue is stored in the Brain Bank under a separate HTA licence. The mortuary team also assists NHS Blood and Transplant (NHSBT) tissue retrieval teams in procuring multiple tissue types for human application and the JRH 'Heart Valve Bank' staff in procuring heart valves for human application; tissue 'procurement' is under the NHSBT and OUHFT human application licences, respectively.

Consent for paediatric and adult PM cases is sought by staff in the Bereavement Services team using a consent form and information leaflet developed from the HTA template. Consent for stillbirth and perinatal PM cases is sought by staff in the Maternity Unit using the Stillbirth and Neonatal Deaths (Sands) consent form and information leaflet or, where cases are referred to the Unit, by staff at the referring centre. Referring centres are encouraged to use the Sands consent package and JRH provides feedback to the centres on the completion of the consent forms it receives. All staff who seek consent for PM examinations are required to complete the JRH consent training programme.

The mortuary is purpose built and located within the main hospital building. The entrance for funeral directors is screened from public view. Entry and exit points are monitored by closed-circuit television (CCTV) and there are video phones and electronic access control (key code and swipe card). Although suitably staffed, lone working does occur both during and out of hours and there is a procedure to cover this activity.

The body store contains 88 refrigerated spaces, including four which can be used for bariatric storage and six which are reserved for the storage of Hazard Group 3 cases (see *Advice*, item 21). There is a separate bank of six spaces for freezer storage and a separate refrigerator containing space for stillbirths, perinatal deaths and foetuses of more than 13 weeks gestation. There are two additional external refrigerated storage units, each with 16 refrigerated spaces (see *Shortfalls* under PFE1 and PFE2, below). Refrigerators and freezers are subject to regular servicing and planned preventative maintenance.

Refrigerator and freezer temperatures (including those in the external units) are recorded externally via a wired system linked to the hospital switchboard. The system monitors temperatures every 15 minutes and temperature archives are stored on a Trust server. The mortuary manager reviews the temperature data for trends. If temperatures exceed the set limits, a local audible alarm is sounded and an electronic signal is sent to the hospital switchboard for action. There is an on-call rota of mortuary staff available to manage callouts

and the movement of bodies, when required. The system is currently tested every six months (see *Advice*, item 22).

There is a contingency plan for disaster recovery and individual plans for additional body storage demand. Contingency storage is available at the Churchill and Horton hospitals. In addition, a Nutwell unit is available to provide additional space at times of high demand, although this compromises the establishment's ability to conduct viewings on site. The Nutwell unit has been used recently and, following advice from the HTA to develop a standard operating procedure (SOP) and risk assessment if it was required again, these have now been completed.

There are three separate PM rooms within the mortuary. The main room has six PM tables, each with an accompanying dissection bench, and has adequate working space and good lighting. There is a separate room for the management of Hazard Group 3 cases and a PM room for paediatric, perinatal and stillbirth cases (each containing one PM table). The paediatric PM room also contains photography and X-ray equipment. Although ventilation levels in two of the PM rooms were well above the accepted levels, the ventilation system in the PM room dedicated to paediatric, perinatal and stillbirth cases did not provide the necessary air changes (see *Shortfall* under PFE3, below).

Clean, transit and dirty areas are clearly delineated, and there are wall notices and diagrams clarifying when and how personal protective equipment (PPE) should be worn.

There are clear policies and procedures for cleaning and decontamination of the main mortuary (but not the external units) and records of cleaning and decontamination are maintained.

There is a separate storage area within the mortuary for formalin-fixed (wet) tissue specimens retained during the PM examination and held under the Police and Criminal Evidence Act 1984 (PACE) and a separate freezer in the Hazard Group 3 PM room for the storage of frozen tissue specimens pending genetic analysis. This freezer is linked to the wired callout system.

Adjacent to the body store is the viewing facility, which has recently been refurbished. It is well lit, spacious and is discreetly decorated.

Bodies arriving from the community are brought in to JRH by Oxford Council's Fire and Rescue Service under a formal agreement with the Coroner. Those arriving from the Churchill or Horton Hospitals are brought in by a dedicated funeral director under agreement. All bodies from within the hospital are transported by porters (see *Shortfall* under GQ3, below).

Upon arrival, information is entered into the mortuary register and the body is given a

unique, sequential number. Where the deceased requires a PM examination, a separate PM number is also allocated and a record is kept in the PM register. Records from both registers are entered into the Cellular Pathology database, which can be accessed by all Cellular Pathology staff.

If the Fire and Rescue Service or porters bring in a body out-of-hours, they place it in the most appropriate vacant space and leave the paperwork in the mortuary office. The details of the deceased are entered in black pen on the whiteboard and the mortuary team reviews all new cases the next day, changing the details to red pen to indicate that the body has been checked in. Surnames which are the same or similar are highlighted, both on the whiteboard and in the mortuary register.

The details of organs and tissue specimens taken for analysis during PM examination are recorded in the PM register and on the 'Results of Coroner's PM examination' form. These details are then entered into the Cellular Pathology database and on the pathologist's final report. Bodies which require repatriation of tissue samples are highlighted in the PM register and on the whiteboard.

Wet tissue and body fluid specimens removed as part of Home Office PM examinations are transported by a specific courier company to a separate HTA-licensed establishment for analysis. Wet tissue specimens removed as part of Coronial or consented PM examinations are delivered by mortuary staff to the Histopathology or Neuropathology Departments (as appropriate) for histological analysis. Body fluid samples removed as part of Coronial or consented PM examinations are delivered to the Clinical Biochemistry Department for toxicological analysis or are sent externally for toxicological and asbestos fibre analysis. Such samples are transported by a specific courier under agreement.

Cardiac tissue and whole hearts are occasionally sent offsite for specialist examination; they are taken by a specific courier company under agreement to a separate HTA-licensed establishment.

Funeral directors collect bodies throughout the day and bring their own documents (either release forms, signed by families, or the relevant disposal paperwork). These documents do not contain enough fields to add the three unique identifiers and some bodies are released using one identifier alone (see *Advice*, item 8). Bodies under Coronial authority are only released when Coronial release documents have been received directly by the mortuary.

Cellular Pathology (Histopathology)

The Histopathology Department has dedicated storage areas for wet tissue, tissue blocks and tissue slides. The areas are divided into adult and paediatric, perinatal and stillbirth cases. The department uses the same electronic database as the mortuary to record specimen details, including consent for the use of specimens after determining the cause of

death. The specimens may be stored with appropriate consent for use for various scheduled purposes including: (i) obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person); (ii) research (as defined above); and (iii) education or training relating to human health.

Archival blocks and slides are stored offsite at a separate HTA-licensed establishment.

Neuropathology Department

The Neuropathology Department is accredited under Clinical Pathology Accreditation (CPA) and is awaiting UKAS a inspection.

The department operates a specialist analysis laboratory for neurological tissue received from both the mortuary as well as from other establishments (transported by a specific courier under agreement). Specimens, including whole brains, spinal cords and brain tissue samples, are formalin-fixed and stored at room temperature, or fresh-frozen and stored in a -80°C or -20°C freezer. Both freezers are linked to the wired callout system. There is an on-call rota of department staff available to manage callouts and the system is currently tested every six months (see *Advice*, item 22). The freezers are subject to regular servicing and planned preventative maintenance.

Specimens stored in the department are recorded on a dedicated Neuropathology electronic database to ensure sample traceability. Consent for the future use of samples is also recorded on this database.

Emergency Department

The Emergency Department manages approximately ten cases of sudden or unexpected death in infants and children (SUDIC) each year. In such cases, tissue and body fluids are removed by paediatric consultants in a secure area in the department. Samples removed (whole blood and urine for biochemical analysis and skin biopsies for cytogenetic analysis) are sent to the Clinical Biochemistry and Cytopathology Departments. There is no PD overseeing activities in this Department (see *Advice*, item 2).

Maternity Unit

The Maternity Unit is secured by key pad access and contains one refrigerator for the storage of stillbirths and perinatal deaths. The refrigerator temperature is recorded manually on a daily basis by trained staff and is monitored externally via a wired system linked to the Maternity Unit reception. There is an on-call rota of staff available to manage callouts and the system is currently tested every six months (see *Advice*, item 22). The refrigerator is subject to regular servicing and preventative maintenance.

Gynaecology Department

Pregnancy remains of all types are stored in a refrigerator in the Gynaecology Department pending transfer to Cellular Pathology for histological analysis (pregnancy remains up to 13 weeks gestation) or to the mortuary for release to funeral directors (foetuses of more than 13 weeks gestation).

Pregnancy remains are considered to be tissue from the living and the establishment has detailed procedures governing the management and disposal of such remains.

Specimens stored under PACE

Home Office PM examinations take place at this establishment. 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, in response to a recommendation resulting from the 2012 report of the Association of Chief Police Officers' (ACPO) audit of tissue held under police authority, that police exhibits held on HTA licensed premises should be included within the regular HTA inspection process, the management of tissues and organs taken for criminal justice purposes were reviewed by the HTA at this site visit inspection. Any findings in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Churchill Hospital – the satellite site

At the satellite site, licensable activities occur within the body store and in the computerised tomography (CT) scanning unit.

The body store receives approximately 300 bodies each year. It is purpose built and is outside the main hospital building. There is key lock access but there is no monitoring by CCTV (see *Advice*, item 20). It is staffed daily during the working week for for one hour by a member of the JRH mortuary team.

The body store contains 30 refrigerated spaces, including two which can be used for bariatric storage and one which is used for Hazard Group 3 cases. There is a separate bank of four spaces for freezer storage.

The refrigerators and freezers are linked to the wired callout system and the system is currently tested every six months (see *Advice*, item 22). The refrigerators and freezers are subject to regular servicing and planned preventative maintenance.

The satellite body store is currently cleaned on an ad hoc basis (see *Advice*, item 19).

Adjacent to the body store is the viewing facility, which is well lit, spacious and is discreetly decorated.

The satellite site also has a CT scanning facility used to conduct digital PM examinations, enhanced by whole-body perfusion angiography, on behalf of 24 Coroners. Although digital autopsies are not a licensable activity under the HT Act, body fluids (urine, vitreous humour and blood) are frequently removed from the body before the digital scan takes place and are sent for toxicological analysis. Removal of relevant material from the deceased to determine the cause of death is subject to licensing by the HTA. Bodies are brought directly into this facility by funeral directors, accompanied by mortuary staff, and are then transported to funeral director premises or to the JRH for PM examination..

Description of inspection activities undertaken

The timetable for the site visit inspection was developed after consideration of the establishment's previous inspection reports, compliance update information and communications with the HTA. The inspection included a visual inspection of the hub site (Cellular Pathology – Mortuary and Histopathology Department, Neuropathology and Emergency Departments, and Maternity Unit) and satellite site (body store and CT scanning unit), discussions and interviews with key staff, and a review of documentation. Interviews (either face-to-face or by telephone) were held with: the DI, CLHC, three PDs in Cellular Pathology, the PD in Neuropathology, the PD in the Maternity Unit, two PDs in Bereavement Services, two APTs, the HTA lead for Cellular Pathology, the HTA lead for Neuropathology, two other members of the Bereavement Team, a consultant pathologist, the Head of Portering Services and the Training Manager for Portering Services, and the Coroner's Officer Co-ordinator.

A documentation review and horizontal and vertical audits were carried out.

- At the hub, a horizontal traceability audit was conducted on three randomly selected bodies in the refrigerators . Body location and identification details on wrist and toe tags were checked against the labels on the refrigerators doors, whiteboard, mortuary register and Cellular Pathology database. There was one discrepancy where the date of birth on the toe tag had been incorrectly transcribed.

- A vertical audit was conducted on the removal of tissue during PM examination from two cases for Cellular Pathology (one Coronial and one consented case) and two cases for Neuropathology (both consented cases). The samples had been processed into blocks and slides in all cases except one, which was still in the Neuropathology laboratory pending processing. Sample details were checked against the PM register, the histopathology request card, the Cellular Pathology or Neuropathology database and the families' wishes on the completed Coroner's 'Next of kin statement'

or Hospital ‘Consent form for adult PM examination’, as appropriate. There was full traceability, with no discrepancies noted.

- At the satellite, a horizontal traceability audit was conducted on two randomly selected bodies in the refrigerators. Body location and identification details on wrist and toe tags were checked against the labels on the refrigerator doors, whiteboard, mortuary register and Cellular Pathology database. There was full traceability, with no discrepancies noted.

Inspection findings

The HTA found the Licence Holder (LH), the DI and the premises to be suitable in accordance with the requirements of the legislation.

Compliance with HTA standards

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment’s work are governed by documented policies and procedures		
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	During the inspection it was noted that several policies and SOPs were either: (i) written and reviewed by the same individual or (ii) past their review date. Examples included: I. ‘Instructions for porters bringing the deceased into the mortuary (SOP-PM-32) II. ‘Body handling’ (SOP-PM-05) III. ‘Taking and recording tisues removed at autopsy – instructions for pathologists (CP-SOP-01).	**Minor**
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised	Porters are responsible for bringing the bodies to the mortuary both during and out of hours. They have received minimal training in	**Major**

c) Staff are assessed as competent for the tasks they perform	mortuary procedures and do not appear to have detailed knowledge of procedures associated with handling bodies and placing them in storage, or knowledge of the factors that may prevent risk of damage to a body. From review of porter competence training documents at JRH, it was noted that: I. The trainer's signature on each competence sheet was a photocopy and not the original. II. There was no involvement of mortuary staff in providing refresher training for porters and no records of porter refresher training. III. The qualifications and competence of the trainer were not documented. See *Advice*, item 14.	
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	Two refrigerated storage units are situated outside the main mortuary building. There are no policies and procedures for the cleaning and decontamination of these units, no schedule of cleaning and no records of cleaning and decontamination.	**Minor**
c) There are documented cleaning and decontamination procedures and a schedule of cleaning		
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	The two external refrigerated storage units are situated in an area which is not secure and is frequently used by passing members of staff. In addition, it is in close proximity to a parking area used by maintenance staff, to an area regularly used by staff for smoking and to hospital offices.	**Major**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	Although the two external refrigerated storage units are locked, the location of these units (described in PFE1e, above) does not ensure the dignity of the deceased.	**Major**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The ventilation in the paediatric PM room currently delivers four air changes per hour. The low ventilation levels were pointed out in an external review provided to the Trust's Estates Department in 2016 but this was not communicated to the PD for Cellular Pathology, the mortuary manager or the DI. See *Advice*, item 23.	**Minor**

Advice

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

No.	Standard	Advice
1.	N/A	The DI is advised to consider reviewing the role of PDs in relation to the different licensed activities taking place across the Trust to ensure that all areas are covered.
2.	N/A	The DI should appoint a PD in the Emergency Department and notify the HTA of their name and position.
3.	GQ1a	The DI is advised to ensure that mortuary premises and practices are included in the Cellular Pathology Quality Management System (QMS) and the Quality Manual (CPP13).
4.	GQ1a, T1c	The DI is advised to ensure that mortuary staff consistently complete all information fields (including NHS and hospital numbers, when available) in the Cellular Pathology database when admitting bodies to the mortuary.
5.	GQ1a, T1e	The DI is advised to ensure that mortuary staff update the mortuary register when a body is moved to a new refrigerator space and that the SOP is updated.
6.	GQ1a, T1g	The DI is advised to consider using full names when recording specimens in the specimen log book to ensure a more robust identification and traceability system, and to update the relevant SOP.
7.	GQ1a,	The DI is advised to ensure that all bodies in body bags or wrapped in wadding (e.g. paediatric and perinatal cases) have their identity bands

	T1b	checked on release and that this step is incorporated into the SOP.
8.	GQ1a, T1c	The DI is advised to consider implementing a standardised release form for bodies that details the three identifiers required for identification checks on releasing a body, and to update the relevant SOP.
9.	GQ1a	Cellular Pathology and Neuropathology currently use different documents, including separate SOPs. The DI is advised to consider more joint working and information sharing to ensure consistency and uniformity of practices.
10.	GQ1a	The DI is advised to consider modifying the relevant Neuropathology SOPs to include the phrase 'the most appropriate person in the qualifying relationship' hierarchy instead of 'next of kin'.
11.	GQ1a	The DI is advised to consider including guidance on monitoring the Maternity Unit refrigerator as an Appendix to the relevant SOP.
12.	GQ1h	The DI currently meets with staff working under the licence at six-monthly intervals. It is recommended that these meetings are held more frequently (e.g. quarterly). The meetings should be governed by an agenda and minutes should be recorded and circulated. The minutes should include timelines for identified actions and there should be a standing agenda item for discussing progress against actions identified at previous meetings. All PDs involved in licensed activities should attend the meetings. The DI may also wish to consider whether to include representatives from other departments (e.g. Clinical Governance, IT, Estates) to help develop the establishment's working practices.
13.	GQ1h	OUHFT is CLH on three HTA licences. There are currently six-monthly meetings between two of the DIs on the Trust licences to share practices and ensure consistency of good practice. The University of Oxford is CLH on six separate HTA licences. The CLHCs on the Trust and University licences are advised to consider setting up joint governance meetings incorporating all University and Trust licences to ensure consistency of practice. This is especially important as several of the University licences (e.g. the Brain Bank) are on Trust premises. Such joint governance meetings are routinely held in other organisations where there are multiple HTA licences.
14.	GQ3a, c	Porter training at the satellite was not examined during this inspection. Porters at the hub and satellite sites are managed by separate external contractors. Porter training at the hub site formed part of the current

		inspection, although training at the satellite was not examined. The DI is advised to ensure that the there is consistency in porter training across both sites.
15.	GQ5a	The DI is advised to ensure that all relevant staff are trained in capturing untoward incidents in the QMS.
16.	GQ6a	The DI is advised to consider amending the Neuropathology risk management SOP (MRISK 70, version 10) to include reference to the HTA and HTA reportable incidents (HTARIs), and to the process of managing these.
17.	T1c	To further strengthen traceability, the DI is advised to consider using the mortuary register number, assigned to each body when the body arrives, to label the refrigerator door, the whiteboard and the wrist and toe tags.
18.	T2a	The Neuropathology Department currently disposes of tissue on an annual basis. The DI is advised to ensure that such tissue is disposed of in a more timely manner (quarterly) in line with Cellular Pathology policy.
19.	PFE1c	The DI is advised to ensure that there is a schedule of cleaning for the satellite premises and that cleaning records are maintained.
20.	PFE1d	The DI is advised to consider adding CCTV coverage to the satellite body store to improve security and prevent unauthorised entry.
21.	PFE2d	The refrigerator for Hazard Group 3 cases has been out of operation for some time. The DI is advised to ensure that this refrigerator is repaired in a timely manner and that records of maintenance are kept.
22.	PFE2e	The DI is advised to consider testing the refrigerator and freezer alarms on a quarterly rather than six-monthly basis.
23.	PFE3c, f	The DI is advised to ensure that the PM room air handling units are monitored on a regular basis and that records of service visits are held locally within Cellular Pathology.

Concluding comments

During the inspection areas of good practice were noted:

- The enthusiasm and dedication of the teams in all the Departments and Units inspected were noted.

- There are detailed competency training packages for: paediatric and adult consent; trainee APTs; the Fire and Rescue Service.
- There are well lit, spacious and discreetly decorated viewing rooms at both sites.

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

The HTA requires the DI 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: 2 August 2017

Report returned from DI: 16 August 2017

Final report issued: 5 September 2017

Completion of corrective and preventative actions (CAPA) plan

Based on information provided, the HTA is satisfied that the establishment has completed the agreed actions in the CAPA plan and in doing so has taken sufficient action to correct all shortfalls addressed in the Inspection Report.

Date: 6 November 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 that 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 either which will usually be assessed by the HTA by desk based or site visit inspection.

   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.