Site visit inspection report on compliance with HTA minimum standards

State Pathologist's Department

HTA licensing number 12493

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**

09 December 2015

Summary of inspection findings

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

State Pathologist's Department (the establishment) was found to have met the majority of applicable HTA standards. HTA consent standards do not apply to this establishment, as all post mortem (PM) examinations are performed under the authority of HM Coroner. One minor shortfall was found in relation to risk assessments. The HTA has given advice to the DI with respect to document control, audits, staff meeting attendance and alarm testing.

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

The HTA's regulatory requirements

The HTA must assure itself that the Designated Individual, Licence Holder, premises and practices are suitable.

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.

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. The HTA inspects the establishments it licences against four groups of standards:

- consent
- governance and quality systems
- premises facilities and equipment
- disposal

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a standard is not met, 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 given to the DI.

Reports of HTA inspections carried out from 1 November 2010 are published on the HTA's website.

Background to the establishment and description of inspection activities undertaken

The establishment has been licensed by the HTA since July 2007 for the making of a post mortem (PM) examination, removal of relevant material from the deceased and storage of the deceased and relevant material for use for scheduled purposes.

The establishment is a public mortuary and carries out only coronial, including forensic, PM examinations. High-risk PM examinations are also carried out at the establishment within a specially constructed high-risk suite. The establishment carries out approximately 1,200 post mortem (PM) examinations a year, including around 150 suspicious/homicide PM examinations. A small number of suspicious/homicide/traumatic paediatric examinations are performed at the NIRFM.

There is storage for 56 bodies on site, including four freezer spaces and four bariatric fridge spaces. Within the post mortem suite, there are four height-adjustable tables with dedicated tissue preparation areas. There is an additional downdraught table within the high risk suite, which also has appropriate camera equipment necessary for forensic cases. The establishment also has a radiography room, allowing for radiological examination of bodies primarily to trace metallic foreign objects.
For each body received into the mortuary, relevant details are entered into the paper mortuary register and the electronic case management system (CMS). Each body is given a sequential mortuary register number. The procedure used for receipt of bodies differs slightly depending on whether the body is received within or outside working hours and whether the

death is considered suspicious. Mortuary staff, pathologists and laboratory staff provide cover every day, including public holidays, as it is customary in Northern Ireland for bodies to be buried within three days of death. The establishment, in conjunction with the coroner and the Police Service of Northern Ireland, has put in place systems for bodies to be received, examined and released for burial within that timescale in the majority of cases.

Where a PM examination is to be carried out, the body is assigned a further unique number, entered onto CMS, which is then used to trace the body through the PM examination process to release, and is also used as an identifier for tissues taken at PM examination for further analysis. Authorisation for the PM examination is received from the Coroner by an electronically transferred form of authority. In each case, an investigating police officer is assigned and attends to confirm the identity of the deceased, where known, and also to provide the pathologist with social and medical background details which may be relevant to the examination. Information is entered onto a proforma, which the examining pathologist also uses to detail preliminary findings. Prior to commencement of the PM examination, the Anatomical Pathology Technologists remove the body from storage, checking identification details, which are re-checked by the pathologist.

Tissues are retained for examination during virtually every PM examination. Details of what tissues and organs have been retained are entered onto a form and this is electronically transferred to the Coroner, with details also being entered into a paper laboratory register and in the CMS. This is subsequently updated to record the numbers of blocks and slides produced.

The Coroner's Liaison Officer speaks to the family of the deceased to seek instructions on how the retained tissues or organs are to be dealt with when the Coroner's authority ends. Options given are: tissues/organs to be retained as part of the medical record, where information may be relevant to another family member; retained for education or research; returned to the family; or respectful disposal by the establishment.

When the Coroner provides confirmation that their inquest has closed and authority ended, the establishment produces a report from the CMS, which allows staff to retrieve tissues, blocks and slides where relatives have instructed disposal. Disposal is recorded on the laboratory paper register and in the case management system. The establishment records details of tissues or organs it sends to other establishments for specialist examination, and also the receipt of those tissues or organs when returned.

This was the third routine inspection of the establishment, the previous inspection having been carried out in 2011. The inspection comprised a visual inspection of the premises, document review and interviews with key staff, including mortuary staff, pathologists, laboratory staff and a Coroner's Liaison Officer.

A traceability audit was conducted for three bodies in storage and their identity and location compared with entries in the mortuary register and case management system. No discrepancies were found. Blocks from two PM cases were located in storage and traced back through the laboratory register and CMS to ensure consistency of recording. No discrepancies were found. Details of blocks retained from two further PM cases were located on the CMS and traced back to storage. One discrepancy was found as one extra block was recorded but not found in storage.
Under s39 of the Human Tissue Act 2004 (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, police holdings were reviewed by HTA at its 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 Act.

Inspection findings

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

Compliance with HTA standards

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately.	The establishment has carried out various risk assessments in relation to health and safety and manual handling within the mortuary and of processes within the laboratory. However, no risk assessments have been carried out in relation to licensed activities. By identifying the risks associated with these activities, particularly those where a failure in the system could result in a HTA reportable incident (HTARI), the establishment can take action to mitigate these risks and help to prevent any adverse incidents.	**Minor**

Advice

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

No.	Standard	Advice
1.	GQ1	Although the Quality Manual accurately reflects current practices, some of the content refers to work that was due to be carried out in 2010-2011 and therefore needs to be updated to reflect this.
2.	GQ1	The DI is advised to organise meetings between mortuary and laboratory staff, as there are currently no meetings attended by both groups. This would give members of staff the opportunity to discuss practices governed by the HTA licence and would facilitate shared learning.
3.	GQ2	The DI is advised to make sure that results of audit findings are communicated to all members of staff to ensure continuous learning and to ensure that a dedicated person is appointed to action any findings where a discrepancy is identified.
4.	GQ2	Although the current audit schedule covers current practices adequately, it does not include an audit of documentation covering operating procedures. The DI is advised to incorporate this type of audit to the audit schedule, to ensure that all

		procedures are updated to reflect current practices.
5.	GQ6	The current identification system used at the establishment involves the use of wrist and toe tags that include the name, surname, address and date of birth of the deceased. The DI is advised to consider the addition of the unique register number, in accordance with this standard.
6.	GQ7	The DI is advised to update the current SOP on incident reporting to include a list of what is considered to be a HTA reportable incident (HTARI), as an aid to staff.
7.	PFE3 & PFE5	The establishment has installed a new alarm system to ensure that fridge temperatures remain within the accepted temperature range. The DI is advised to test the alarm system periodically between maintenance visits, to ensure that it still works according to specifications.

Concluding comments

This report describes the third HTA site visit inspection of the State Pathologist's Department. During the inspection, several areas of strength were observed.

The mortuary staff have developed robust mortuary procedures, which ensure consistency of practice and compliance with HTA standards. The team is dedicated to ensuring that the dignity of the deceased is maintained and staff members work together to ensure that body release for burial or cremation is expedited as quickly as possible.

As a dedicated investigating police officer is allocated to each case and responsible for identifying the deceased prior to PM examination, the risk of misidentification of bodies is reduced.

The DI has a good understanding of the HT Act and works to ensure improvements are implemented as required. The DI is well supported in his role by the Persons Designated, having good oversight of licensable activities at the establishment.

The HTA has given advice to the DI with respect to document control, audits, staff meeting attendance and alarm testing.

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 shortfall identified during the inspection.

Report sent to DI for factual accuracy: 8 January 2016

Report returned from DI: 21 January 2016

Final report issued: 2 February 2016

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: 2 May 2016

Appendix 1: HTA standards

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

Governance and quality system standards

GQ1 All aspects of the establishments work are supported by ratified documented policies and procedures as part of the overall governance process

- Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity. These may include:
    - post-mortem examination, including the responsibilities of the APTs and Pathologists (e.g. evisceration) and management of high risk cases
    - record keeping
    - receipt and release of bodies, which reflect out of hours arrangements
    - lone working in the mortuary
    - transfer of bodies and tissue (including blocks and slides) to other establishments or off site
    - ensuring that tissue is handled in line with documented wishes of the relatives
    - disposal of tissue (including blocks and slides)

  (Note that individual SOPs for each activity are not required. Some SOPs will cover more than one activity.)
- Policies and procedures are regularly reviewed (for example, every 1-3 years).
- There is a system for recording that staff have read and understood the latest versions of these documents.
- Deviations from documented SOPs are recorded and monitored.

GQ2 There is a documented system of quality management and audit

- There is a quality manual which includes mortuary activities.
- Policies and SOPs are version controlled (and only the latest versions available for use).
- There is a schedule for audits to be carried out (which may include vertical and/or horizontal audits).
- Audits include compliance with documented procedures, records (for completeness) and traceability.
- Audit findings document who is responsible for follow up actions and the timeframe for completing those actions.
- Regular audits of tissue being stored at the establishment ensure that staff are fully aware what material is held and why.
- There is a complaints system in place.

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

- Staff are appropriately trained/qualified or supervised.
- Staff have annual appraisals.
- Staff are given opportunities to attend training courses, either internally or externally.
- Attendance by staff at training events is recorded.
- There is a documented training programme for new mortuary staff (e.g. competency checklist).

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

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

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

- Bodies are tagged/labelled upon arrival at the mortuary.
- There is a system to track each body from admission to the mortuary to release for burial or cremation (e.g. mortuary register, patient file, transport records).
- Organs and tissue samples taken during PM examination are fully traceable.
- Details of organs retained and the number of wax blocks and tissue slides made are recorded.
- The traceability system includes the movement of tissue samples between establishments.
- Details are recorded of tissue that is repatriated or released with the body for burial or cremation.
- Regular audits of tissue storage and traceability are undertaken to ensure compliance with operational procedures; tissue samples found which are not being stored with consent are disposed of with reference to the family's wishes.
- Multiple identifiers used, including at least one unique identifier (e.g. post mortem number, name, dates of birth/death, etc) to identify bodies and tissue.

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

- Staff are trained in how to use the incident reporting system.
- Staff know how to identify incidents and near-misses which must be reported, including those that must be reported to the HTA
- The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
- The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.
- Information about incidents is shared with all staff (including the reporter) to avoid repeat errors.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

- All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed.
- Risk assessments include risks associated with non-compliance with HTA standards as well as health and safety risks.
- Risk assessments are reviewed regularly (along with SOPs), for example every 1-3 years.
- 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.

Premises, facilities and equipment standards

PFE1 The premises are fit for purpose

- There is sufficient space for the activities to be carried out.
- Refrigerated storage units are in good working condition and well maintained.
- Surfaces are made of non-porous materials.
- The premises are in reasonable condition (structure and cleanliness of floors, walls, entranceways).
- The premises are secure (e.g. there is controlled access to bodies, tissue, equipment and records).

PFE 2 Environmental controls are in place to avoid potential contamination

- There is clear separation of clean, transitional and dirty zones (e.g. doors, floor markings, signs).
- There is appropriate PPE available and routinely worn by staff.
- There is adequate critical equipment and/or PPE available for high risk post mortems.
- There are documented cleaning and decontamination procedures.
- There are documented cleaning schedule and records of cleaning and decontamination.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records.

- There is sufficient capacity for storage of bodies, organs and tissues.
- Temperatures of fridges and freezers are monitored on a regular basis.
- There are documented contingency plans in place should there be a power failure, or overflow.
- Bodies are shrouded whilst in storage.
- There is separate storage for infants and babies. If not, special measures are taken for the bodies of infants and babies.

PFE 4 Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination

- There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary (e.g. lab, other establishment), including record-keeping requirements.
- There are written agreements in place with any external parties (e.g. undertaker, or courier) who transport bodies and/or tissue behalf of the establishment (laboratory or mortuary).

  (Note that coroners usually have their own agreements with external parties for transportation bodies and tissue; however, documentation for traceability purposes must still be maintained by the establishment for these cases.)

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

- Items of equipment in the mortuary are in a good condition and appropriate for use:
  - fridges / Freezers
  - hydraulic trolleys
  - post mortem tables
  - hoists
  - saws (manual and/or oscillating)
  - PPE for high risk cases (e.g. respirators)
- The use of porous materials is kept to a minimum and has been risk assessed
- Maintenance/service records are kept for equipment, including fridges/freezers, trolleys, post mortem tables (if downdraught) and post mortem suite ventilation.

(Note: These records may be held by the mortuary or centrally by the Trust, e.g. Estates Department.)

Disposal Standards

D1 There is a clear and sensitive policy for disposing of human organs and tissue

- There is a documented Trust or mortuary/laboratory policy for the disposal of human tissue, which reflects the requirements of the HTA code of practice on disposal.
- The policy states the position with regard to the retention and use of microscope slides, and in particular that tissue slides must be disposed of or returned to the family in accordance with their wishes if consent is not obtained for their continued storage and future use once the PM has concluded.

D2 PM tissue is disposed of if consent is not given for its storage and use for scheduled purposes

- There are documented procedures for disposal of human tissue, which include methods of disposal for whole organs, wet tissue, wax blocks and microscope slides.
- Tissue is disposed of in accordance with the documented wishes of the deceased person's

family.

- Disposal details of organs and tissue blocks are recorded, including the date and method of disposal.
- There is a rolling programme of tissue disposal that ensures that tissue, including microscope slides, is disposed of in a timely fashion when it is no longer needed for the purposes of the Coroner or to determine the cause of death.

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.