Site visit inspection report on performance against HTA quality standards
State Pathologist's Department, Belfast
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**

14 December 2011

Executive Summary

A site visit inspection of the State Pathologist's Department (the establishment) was carried out by the HTA on 14 December 2011.

The establishment was found to meet the majority of the HTA standards across the four areas of: consent; governance and quality; premises, facilities and equipment; and disposal. Minor shortfalls were found in relation to governance and quality and these are detailed on page 4 of this report. Examples of strengths or good practice are included in the concluding comments section of the report.

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

All 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 is a public mortuary and is also the Northern Ireland Regional Forensic Mortuary. It therefore carries out only coronial, including forensic, post mortem ("pm") examinations. High risk pm examinations, up to category three, are also carried out at the establishment within a specially constructed high risk suite. The establishment carries out approximately 1200 – 1500 pm examinations annually.

There is storage for 60 bodies on site, with 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 to trace metallic foreign objects. Radiographs are photographed for record purposes.

Each body received into the mortuary, and relevant details are entered into the paper mortuary register and the electronic case management system ("CMS"). Each body is given a sequential mortuary 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. The establishment 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 examination.

The establishment receives authorisation to carry out pm examination direct from the coroner, by the receipt of a faxed form of authority. In each case an investigating police officer is assigned and attends at the PM 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 pro forma, which the examining pathologist also uses to detail preliminary findings.

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

The Coroner's Liaison Officer then 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 his inquest has closed and authority ended, the establishment produces a report from the CMS database, which allows staff to retrieve tissues, blocks and slides where relatives have instructed disposal. Disposal is recorded on the laboratory paper register and in CMS.

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.

A periodic audit of organs retained is carried out, and the coroner is contacted to check whether his authority has ended.

The inspection was routine and comprised a visual inspection, review of documentation, including the quality manual, mortuary and laboratory registers in paper and electronic form, interviews with key staff, including mortuary staff, pathologists, laboratory staff and a coroner's liaison officer.

As part of the inspection, an audit of traceability was carried out:

- Two bodies were located in the body store and their identity and location compared with entries in the mortuary register.
- A PM case was selected and, using the unique identifying number the number of blocks and slides produced was checked in the paper laboratory register and in CMS and then located in store.
- Blocks and slides related to another PM were located in store and then traced back, through the laboratory register and CMS to ensure consistency of recording.
- Two organs retained in store pending confirmation of the release from the authority of the coroner were selected and details checked in the laboratory register and CMS.
- Records of one organ which had been sent for specialist examination and then returned for cremation were examined. Details of sending and receipt were checked in the laboratory register and CMS, and the form confirming release for cremation was located.

No discrepancies were found.

Meeting the HTA's licensing standards

The HTA developed its licensing standards with input from its stakeholders, in order to ensure the safe and ethical use of human tissue and the dignified and respectful treatment of the deceased. The HTA expects licensed establishments to meet these standards.

This is an exception-based report: only those standards that have been assessed as not met are included. Where the HTA determines that a licensing standard is not met, the level of the shortfall will be classified as 'Critical', 'Major' or 'Minor' (see Appendix 3: Classification of the level of shortfall).

Unless otherwise advised, the establishment is required to inform the HTA within 14 days of the receipt of the final report of the corrective and preventative actions that will be taken to ensure that the improvements are addressed. A template for this purpose is provided as a separate Word document.

HTA standards not met

Governance and Quality

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of quality management and audit.	Some limited audits have been carried out, of organs in store, documents received from the coroner and samples sent for specialist examination. However, no vertical audits of traceability, from pm examination to storage or disposal of tissues, have been carried out. Similarly, there has been no audit of record accuracy in relation to the transfer of information held in paper and electronic registers or of how staff carry out activities against standard operating procedures. By scheduling regular audits of records, traceability and procedures, the DI will be able to identify any areas where processes are not being followed or where errors are arising, allowing him to adapt processes or address training needs. This will inform continued improvement at the establishment and also minimise the risk of tissues being retained for longer than necessary after the ending of the coroner's authority in cases where relatives' wishes are for disposal or return.	**Minor**
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, COSHH, and of processes within the laboratory. However, no risk assessments have been carried out in relation to licensed activities, which would identify potential risk of regulatory non compliance. By risk assessing the processes carried out within the mortuary, the DI will be able to inform the review of documented procedures and alter processes to minimise any identified risk. Advice has also been provided in relation to this shortfall (see below).	**Minor**

Advice

Below are matters which the HTA advises the DI to consider.

No.	Standard	Advice
1.	GQ7	The DI is advised to ensure that, at any future revision of the establishment's Adverse Incident procedure, the requirement to advise the DI of any incident is detailed so that any staff unfamiliar with the process have appropriate guidance.
2.	GQ8	The DI is advised, when addressing the shortfall relating to this standard, to consider risk assessing the likelihood of the occurrence of Serious Untoward Incidents using the HTA's classification of Serious Untoward Incidents. Doing so will identify and allow him to address risks which could have reputational consequences and cause distress to relatives as well as risks relating to regulatory compliance.
3.	PFE3	The DI is advised to document the current informal contingency arrangements with Royal Victoria Hospital for body storage in the event of a failure of refrigeration plant at the establishment.
4.	PFE5	The DI is advised to revise the SOP detailing the procedure to be followed when noting storage temperatures, and / or the form used to record these temperatures, to clarify the acceptable limits and the actions to be taken in the event temperatures fall outside permitted levels. This will enable any less experienced or locum staff to understand the requirements for safe storage and also guide them in the event of equipment failure.
5.	D2	The DI is advised to document the current procedure of contacting the coroner for instructions relating to organs and tissues retained on his authority in order to arrange for timely disposal and to ensure that a regular audit of material retained under the authority forms part of any audit schedule This will help to ensure that the risk of retention of tissues outside the coroner's authority without relatives consent to do so is minimised.
6.	N/A	The DI is advised to discuss with the coroner the possibility of clarifying the wording on the form authorising retention of tissues as part of the medical record to clarify the scheduled purpose for which such material is being retained, to reflect the information provided to relatives by the coroners liaison officers when obtaining their instructions.

Concluding comments

The HTA noted that the establishment is staffed by well motivated individuals who take a great deal of pride in their work. The systems have been set up to meet the local requirement for rapid burial of the deceased and there is excellent communication between establishment staff, the coroner and the Police Service of Northern Ireland.

The HTA noted various examples of good practice. Care had been taking in the design of the establishment to provide an environment which helps to minimise distress to grieving families. This is also assisted by establishment staff using processes designed 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 involved in identification of the deceased , and as the officer identifies the deceased at PM, this, coupled with the minimising of time bodies are in storage reduces the risk of misidentification.

The recent assignment of a member of staff to a defined role in quality management has meant that the quality manual has been recently reviewed and the documentation relating to

it is clear and in a format readily accessible to staff. Much work has been done on reviewing and updating procedures and policies but the HTA noted that as a result of continuing staff pressures at the establishment, the process of review of the quality systems has not progressed as quickly as hoped for.

The HTA noted throughout the day, the importance placed on minimising distress to the families of the deceased, and the extent to which their feelings had been taken into account in devising the procedures carried out by the establishment staff.

Report sent to DI for factual accuracy: 20 December 2011

Report returned from DI: No comments on factual accuracy received

Final report issued: 16 January 2012

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: 8 July 2014

Appendix 1: HTA inspection process

The Human Tissue Authority regulates the removal, storage, and use of human bodies, body parts, organs and tissue for activities such as research, transplantation, and education and training. The legal requirements for establishments which carry out such activities are set out in the Human Tissue Act 2004 and The Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006.

We license establishments in England, Wales and Northern Ireland that carry out these activities, and inspect them to make sure legal requirements are met.

Inspections

We use the term 'inspection' to describe when we:

- visit an establishment to meet with staff, view premises and facilities, and review policies and procedures (a site-visit inspection); or
- assess written information we have requested from an establishment (a desk-based assessment / inspection).

We carry out inspections to assess if the Designated Individual (DI) is suitable to supervise the activity covered by the licence, as it is their responsibility to ensure that:

- other staff working under the licence are suitable;
- suitable practices are used when carrying out the activity; and
- the conditions of the licence are met.

We also need to be satisfied that the licence applicant or holder, the establishment's premises, and the practices relating to licensed activities, are suitable.

To help us reach our decisions, we have developed standards under four headings: Consent; Governance and Quality; Premises, Facilities and Equipment; and Disposal.

After every site visit inspection, we write a report documenting our findings. Where we find a particular standard is not fully met, we will describe the level of the shortfall as 'Critical', 'Major' or 'Minor'. In most cases, it will be the responsibility of the DI to seek the HTA's agreement on how they will address the identified shortfalls. More information about the classification of shortfalls can be found in Appendix 3.

The majority of our site-visit inspections are announced. If we have concerns about an establishment, we can also undertake an unannounced site visit inspection.

You can find reports for site visit inspections which took place after 1 November 2010 on our website.

Appendix 2: HTA standards

Standards which are not applicable to this establishment have been highlighted.

Consent standards
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the code of practice
• There is a documented policy which governs consent for post-mortem examination and the retention of tissue and reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent. • There is a documented SOP detailing the consent process (including who is able to take consent, what training they must receive, and what information must be provided to those giving consent for post-mortem examination). • There is written information about the consent process (provided to those giving consent), which reflects the requirements of the HT Act and the latest version of the HTA Code of Practice on consent.
C2 Information about the consent process is provided and in a variety of formats
• Relatives are given an opportunity to ask questions. • Relatives are given an opportunity to change their minds and is it made clear who should be contacted in this event. • Information contains clear guidance on options for how tissue may be handled after the post-mortem examination (repatriated with the body, returned to the family for burial/cremation, disposed of or stored for future use). • Where consent is sought for tissue to be retained for future use, information is provided about the potential uses in order to ensure that informed consent is obtained. • Information on the consent process is available in different languages and formats, or there is access to interpreters/translators.
C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent
• There is a training programme for taking consent for post-mortem examination and tissue retention which addresses the requirements of the HT Act and HTA code of practice on consent. • Refresher training is available (e.g. annually). • Attendance at consent training is documented. • If untrained staff are involved in consent taking, they are always accompanied by a trained individual.

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.

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria.

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 or tissue taken during post mortem examination are fully traceable, including blocks and slides. The traceability system ensures that the following details are recorded:
    - material sent for analysis on or off-site, including confirmation of arrival
    - receipt upon return to the laboratory or mortuary
    - number of blocks and slides made
    - repatriation with a body
    - return for burial or cremation
    - disposal or retention for future use.
- 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 outline 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.
- There are documented procedures for disposal of human tissue, including blocks and slides.

D2 The reason for disposal and the methods used are carefully documented

- There are systems in place that ensure tissue is disposed of in accordance with the documented wishes of the deceased person's family.
- Disposal records include the date, method and reason for disposal.
- Tissue is disposed of in a timely fashion.

  (Note: this means that tissue is disposed of as soon as reasonably possible once it is no longer needed, e.g. when the coroner's or police authority ends or consented post-mortem examination is complete.)

Appendix 3: 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.

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.

Follow up actions

A template corrective and preventative action plan is available as a separate Word document. 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.