Focused Virtual Regulatory Assessment (VRA) on compliance with HTA licensing standards
Inspection date: **23 November 2023**

Antrim Area Hospital
HTA licensing number 12018

Licensed under the Human Tissue Act 2004

Licensed activities

The table below shows the activities this establishment is licensed for and the activities currently undertaken at the establishment.

Area	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	Storage of the body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose
Hub site **Antrim Area Hospital**	Not Licensed	Not Licensed	Licensed
Mortuary	-	-	*Not carried out* *(See background section below)*

Summary of inspection findings

On the basis of the limited inspection of Standards undertaken through the VRA, the HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation. However, the HTA was concerned

that there had been a significant period of some months when there was no DI in post and that this had not been communicated to the HTA.

Although the HTA found that Antrim Area Hospital ("the establishment) had met the majority of HTA's standards, one major shortfall was found against the standard for Governance and quality systems in relation to audits.

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.

The HTA carried out a focused virtual regulatory assessment of the establishment (see description of inspection activities below).

A follow-up site visit inspection is planned to complete the assessment of the establishment against all applicable standards and to review the assessment of the suitability of the DI and Licence Holder.

Compliance with HTA standards

Major Shortfall

GQ2 There is a documented system of audit		
a) There is a documented schedule of audits.	Although the establishment have a schedule of audits, audits of swipe card access against CCTV have not yet taken place as this has been recently identified by the establishment to be included in the audit schedule.	**Major**

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

Number	Standard	Advice
1.	C1 (f)	The DI is advised to review all consent documentation and patient information leaflets, to ensure consent givers have relevant contact numbers and withdrawal time frames in a documented format.
2.	GQ1 (a)	Staff are advised to review all Standard Operating Procedures (SOPs) to ensure they contain sufficient detail of procedures to reflect current practice for identification of bodies.
3.	GQ2 (a)	Staff are advised to include regular audits of the process and documentation for sending bodies for PM examination to other establishments in the audit schedule. Staff are also advised to continue with their plans to regularly audit swipe card access to the mortuary.
4.	GQ6 (b)	Staff are advised to review risk assessments to ensure they include all mitigating actions such as the same/similar name procedure and the processes for checking the minimum three points of identification of bodies.

Background

Antrim Area Hospital has been licensed by the HTA since July 2007. This was the fourth inspection of the establishment. The most recent previous inspection took place in April 2019.

Since the previous inspection, there has been a recent change of DI. The establishment are considering revoking the licence as they have informed the HTA that they do not conduct any licensable activities. The establishment has informed the HTA that bodies are stored in the mortuary for a short period prior to sending them to other licensed establishments for PM examination. Section 16 of the Human Tissue Act 2004 exempts the activity of storage from licensing where it is ‘incidental to transportation’.

Description of inspection activities undertaken
The HTA's regulatory requirements are set out in Appendix 1. The inspection team covered the following areas during the inspection:

Standards assessed against during inspection
The HTA conducted a focused virtual regulatory assessment as the establishment have informed the HTA that they are not conducting any licensable activities and are considering revoking the licence. 42 out of the HTA's 72 standards were covered during the assessment. Standards covered at this inspection are listed in Appendix 3.

Review of governance documentation
The assessment team reviewed the establishment's self-assessment document provided by the establishment in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Audits, risk assessments and incidents were also reviewed.

Visual inspection
There was no site visit inspection as part of this assessment.

Meetings with establishment staff
The inspection team had discussions with staff carrying out activities under the licence. This included the DI, Head of Pathology, Clinical Services Manager for the Mortuary and the Mortuary Lead.

Report sent to DI for factual accuracy: 09 January 2024

Report returned from DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 26 January 2024

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: 4 June 2024

Appendix 1: The HTA's regulatory requirements

Prior to the grant of a licence, the HTA must assure itself that the DI is a suitable person to supervise the activity authorised by the licence and that the premises are suitable for the activity.

The statutory duties of the DI are set down in Section 18 of the Human Tissue Act 2004. 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 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.

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 Human Tissue Act 2004 (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 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:

   - A notice of proposal being issued to revoke the licence
   - 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.
   - A notice of suspension of licensable activities
   - Additional conditions being proposed
   - 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 Codes of Practice, 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 review or at the time of the next 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. Establishments 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 inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.

Appendix 3: Standards assessed during inspection

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.
c) There is written information for those giving consent, which reflects the requirements of the HT Act and the HTA's codes of practice.
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.
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.
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.
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.
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits.
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.
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.
b) There are clear reporting lines and accountability.

c) Staff are assessed as competent for the tasks they perform.
d) Staff have annual appraisals and personal development plans.
e) Staff are given opportunities to attend training courses, either internally or externally.
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.
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.
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 (whistleblowing).
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.
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.

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.
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.
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.
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).
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.
d) There is a 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.
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
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.