Inspection report on compliance with HTA licensing standards
Inspection date: **16 May 2024**

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

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

Although the HTA found that Antrim Area Hospital ('the establishment') had met the majority of the HTA's standards, one major and two minor shortfalls were found against standards for Premises, facilities and equipment.

The HTA has assessed the establishment as suitable to be licensed for the activities specified, subject to corrective and

preventative actions.

Compliance with HTA standards

Major Shortfalls

PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue		
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).	Although the chiller unit for the bariatric fridge is in an area where the public do not access, the unit could be accidently switched off from outside the unit. At the time of the inspection, there were no bodies in storage, however there is a potential risk to damage to bodies should the unit be inadvertently switched off when the fridges are in use. Furthermore, whilst the key to the mortuary office is a security key there was no key holder list available for review by the inspection team. *See advice, item 1*	**Major**

Minor Shortfalls

PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
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	All fridge and freezer units are temperature montoried and alarmed with the low temperature alarm set at 0°C. Although the establishment does not store bodies for more than a few days, this poses a risk of bodies being frozen.	**Minor**

PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
a) Items of equipment in the mortuary are in good condition and appropriate for use	The fridges and freezers have minor areas of rust and are showing signs of corrosion at the bottom of some fridges. This makes it difficult to clean and decontaminate.	**Minor**

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.

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

Number	Standard	Advice
1.	PFE1 (d)	Mortuary staff are advised to keep a list of staff who have keys to the mortuary office.
2.	General advice	Occasionally police identifications of bodies take place in the decommissioned post mortem room in the mortuary as there is no viewing room. This area has been highlighted to the Trust for refurbishment and the DI is advised to continue with these plans.

Background

Antrim Area Hospital has been licensed by the HTA since July 2007. This was the fifth inspection of the establishment. The most recent previous inspection, which was conducted as a focused virtual regulatory assessment (VRA), took place in November 2023.

This inspection was conducted as a focused inspection on standards not covered during the VRA (see description of inspection activities undertaken below).

The establishment is not currently undertaking any licensable activities but have informed the HTA that they wish to keep the licence in the event that another establishment will use their facilities as contingency storage.

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 carried out a focused inspection on the following standards: GQ1(c), T1(a), T1(b), T1(c), T1(d), T1(e) T1(f), PFE1(a), PFE1(c), PFE1(d), PFE1(e), PFE2(a), PFE2(b), PFE2(c), PFE2(d), PFE2(e), PFE2(f), PFE2(g), PFE3(a), PFE3(b), PFE3(d) and PFE3(f).

Review of governance documentation

The assessment team reviewed the establishments security audits, security procedures, maintenance records, cleaning records and temperature monitoring records.

Visual inspection

The inspection included a visual inspection of the mortuary body store and decommissioned post mortem room.

Audit of records

No bodies were in storage at the time of the inspection. Records for sending bodies to another licenced establishment for PM examination were reviewed. No discrepancies were found.

Meetings with establishment staff
The inspection team had discussions with staff carrying out activities under the licence. This included the DI, Persons Designated, Quality Manager, Clinical Services Manager, Mortuary Manager and a Portering Supervisor.

Report sent to DI for factual accuracy: 13 June 2024

Report returned from DI: 19 June 2024

Final report issued: 28 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.