Inspection report on compliance with HTA licensing standards
Inspection date: **31 August and 8 September 2022**

Belfast Health and Social Care Trust - Royal Victoria Hospital

HTA licensing number 12229

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 **Belfast Health and Social Care, Royal Victoria Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
Paediatric Wards		*Carried out*	
A&E	-	*Carried out*	-
Satellite site	Not licensed	Not licensed	Licensed

Oasis group			
	-	-	Carried out

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 Belfast Health and Social Care Trust-Royal Victoria Hospital ('the establishment') had met the majority of the HTA's standards, one minor shortfall was 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 being implemented to meet the shortfalls identified during the inspection.

Compliance with HTA standards

Minor Shortfall

Standard	Inspection findings	Level of shortfall
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
d) Fridge and freezer units are in good working condition and well maintained	Some of the fridge doors in the mortuary are damaged and the seals on the inside of the fridges are coming loose. There is also rust in the fridges which prevents decontamination procedures from being effective.	**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.

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

Number	Standard	Advice
1.	C2 (a)	The DI provides consent training to staff on an individual basis prior to staff seeking consent. This process should be formalised to ensure all staff who seek consent for PM examinations are aware of the requirements of the HT Act and the HTA's codes of practice. In addition, appropriate staff from maternity and the mortuary should consider attending the next consent training so this information can be disseminated to relevant staff who seek consent for paediatric and adult PM examinations. This will ensure that there is resilience in the process of providing training to staff seeking consent.
2.	GQ2 (a)	The DI is advised to add a security audit of access of the mortuary at the hub site and swipe card access at the satellite site. The audit should include a cross check of legitimate rights of access against frequency, duration and patterns of attendance to ensure access is in line with the purpose for which it was granted.
3.	GQ2 (a)	The DI is advised to consider including reverse audits of relevant material transferred to the satellite site from the hub site.
4.	PFE2 (e)	The lower trigger point for the alarm is set at 0 degrees for the maternity fridge. The DI is advised to adjust the temperature within an acceptable range to avoid the risk of bodies freezing should the temperatures deviate.
5.	PFE2 (f)	The DI is advised to do a trend analysis of the fridges in the mortuary and maternity to identify trends and the extent of any variations in storage temperatures. This will help to identify any issues ahead of a fridge failure.

Background

The establishment has been licensed by the HTA since May 2007. This was the fourth inspection of the establishment; the most recent previous inspection took place in August 2017.

Since the previous inspection, Royal Victoria Hospital has a service level agreement in place with another licenced establishment to supply paediatric pathology services.

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

All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the inspection. Policies and procedural documents relating to licensed activities for the mortuary were reviewed. Traceability audits, risk assessments, meeting minutes, incidents, consent seeking procedures and information for relatives giving consent were also reviewed.

Visual inspection
The inspection included a visual inspection of the mortuary body store, viewing room and PM room at the hub site and the security and storage of relevant material at the satellite site.

Audit of records
Audits were conducted for four bodies in refrigerated storage at the hub site. Body location and identification details on bodies were crosschecked against the information recorded in the mortuary register and relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from three hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues at the hub site. No discrepancies were found.

Meetings with establishment staff

Staff carrying out processes under the licence were interviewed including the DI, Anatomical Pathology Technologists, a contracted funeral director, and consent seekers for PM examinations.

Report sent to DI for factual accuracy: 04 October 2022

Report returned from DI: 05 October 2022

Final report issued: 10 October 2022

Completion of corrective and preventative actions (CAPA) plan

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

Date: 7 February 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.