Inspection report on compliance with HTA licensing standards
Inspection date: **10 June 2025**

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 Trust - Royal Victoria Hospital	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	-	*Carried out*
Satellite site Oasis Group	Not licensed	Not licensed	Licensed
	-	-	*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, three major and two minor shortfalls were found against standards for Governance and quality systems, Traceability and 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

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ2 There is a documented system of audit		
c) Regular audits are carried out of tissue being stored so that staff are fully aware of what is held and why and to enable timely disposal of tissue where consent has not been given for continued retention	Whilst the establishment undertake audits of stored tissue, they lack sufficient frequency and breadth to give assurance that this standard has been fully met. *(See Shortfall against standard T2(a) and T2(c))* *(See advice item 1)*	**Major**

T1 A coding and records system facilitates traceability of bodies and human tissue, ensuring a robust audit trail		
g) Organs or tissue taken during post-mortem examination are fully traceable, including blocks and slides (including police holdings).	Systems for tracking samples do not provide full traceability. The inspection team discovered that the system used to archive material did not specify individual cases. Furthermore, a limited amount of tissue had inadvertently been sent from the satellite site to a linked site which was not licenced. *The establishment took immediate action to transfer tissue to a licenced site.*	**Major**
T2 Disposal of tissue is carried out in an appropriate manner and in line with the HTA's codes of practice.		
a) Tissue is disposed of as soon as reasonably possible once it is no longer needed, such as when the coroner's or police authority over its retention ends or the consented post-mortem examination process is complete	The inspection team identified several cases where tissue held in archives had not been disposed of following completion of the post mortem examination process.	**Major cumulative**
c) Disposal is in line with the wishes of the deceased's family	The inspection team identified several cases where tissue held in archives had not been disposed of in line with relatives wishes.	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks		
c) Staff are assessed as competent for the tasks they perform	Maternity staff do not have competency assessments for the release and viewing processes on the maternity unit.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue.		
a) Storage arrangements ensure the dignity of the deceased	A freezer in the Mortuary has been utilised by the establishment to store anatomical waste awaiting disposal. The storage arrangements impact the dignity of the deceased and increase the risk of reputational damage to the establishment.	**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.	GQ2(c)	The DI may wish to consider increasing the frequency of audits. Furthermore, the DI is advised to consider relocating all archived tissue blocks and slides to the Mortuary. This will assist with the process of audit and managing disposal.
2.	T1(b)	The DI may wish to consider the use of an electronic system to aid traceability and reduce the use of paper records which will mitigate risks associated with transcription errors.

Background
Royal Victoria Hospital is licensed for the making of a PM examination, removal of relevant material from the deceased and storage of bodies of the deceased and relevant material for use for scheduled purposes.

Royal Victoria Hospital has been licensed by the HTA since May 2007. This was the fifth inspection of the establishment; the most recent previous inspection took place in September 2022.

Since the previous inspection, the SUDI process in the Emergency Department and Paediatric wards have ceased due to a change in Northern Ireland policy.

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 inspection team reviewed documentation on site and submitted after the inspection. Standard operating procedures, risk assessments and policies were reviewed. Audit schedules, competency records, cleaning record forms and meeting minutes were inspected as part of the review process.

Visual inspection
The inspection included a visual assessment of the body storage areas in the mortuary, PM room, viewing room and tissue storage areas. The storage area on the Maternity unit was also visually assessed. No visual inspection of the satellite site was undertaken as part of this inspection.

Audit of records
A traceability audit of three bodies in storage was undertaken. This included bodies from hospital including one in long term storage. Details were cross checked against identity bands, information recorded in the mortuary register and relevant documentation. No discrepancies were found.

Audits of traceability were conducted for tissue blocks and slides from 10 hospital consented PM cases, including audits of the consent documentation for the retention and disposal of these tissues at the hub site. Discrepancies were noted in five of the cases which related to loss of traceability and tissue not being disposed of in line with consent.

Meetings with establishment staff
The inspection team conducted interviews with staff carrying out processes under the licence. This included the Designated Individual, Quality Manager, Bereavement Midwife and Managing Director of the contracted Funeral Service. The Mortuary Manager and other Mortuary staff provided evidence of compliance during the site visit.

Report sent to DI for factual accuracy: 30 June 2025

Report returned from DI: 30 June 2025

Final report issued: 30 June 2025

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.