Inspection report on compliance with HTA licensing standards
Inspection date: **2 December (remote) and 4 December (site visit) 2025**

Queen's University Belfast
HTA licensing number 12113

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Carrying out of an anatomical 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 a body of a deceased person or relevant material which has come from a human body for use for a scheduled purpose	Storage of an anatomical specimen
Queen's University Belfast	Licensed	Licensed	Licensed	Licensed

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.

Queen's University Belfast ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

Compliance with HTA standards

All applicable HTA standards have been assessed as fully met.

Advice

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

Number	Standard	Advice
1.	N/A (operational)	At the time of the inspection, there was no Bequeathal Officer in post, affecting the body donation programme again. To minimise the impact/s to service delivery, the establishment is encouraged to pursue active recruitment to the vacant position.
2.	GQ1(a)	The establishment has implemented a new form to record the condition of donated bodies from arrival and throughout the embalming and storage procedures. The DI is advised to include reference to this form within the embalming SOP (QUB-HTA-ANATPROC-001) as staff are expected to complete the form during this procedure.
3.	GQ6(a)	The establishment has a suite of risk assessments covering licensed activities, with mitigating actions included. The risk assessment on the manual handling of donated bodies covers risks to technical staff only. The DI is advised to extend the category of 'persons at risk' to also include the deceased donors. Furthermore, to strengthen linkages between risks and mitigations, the DI is advised to consider including references to staff training and the pertinent SOPs.
4.	PFE1(b)	The Anatomy Mortuary was found to be secure, with two locks on the Funeral Directors' entrance - one key lock and one coded lock, with only relevant Anatomy staff having access. Due to safety considerations, there are plans to change this configuration. The DI is advised to review the new plans

		to ensure that the changes continue to strictly control access to only those who have authorisation.
5.	PFE2(c)	There are a number of potted specimens that have been identified as needing general maintenance (such as the replenishment of preservative fluid). Due to staffing issues this has been delayed. The DI is advised to organise the work as soon as possible in order to conserve the integrity of the specimens.

Background

Queen's University Belfast has been licensed by the HTA since June 2007. This was the third inspection of the establishment; the most recent inspection took place in July 2019.

Since the previous inspection, there have been some changes.

- The body donation programme has been paused on a number of occasions since 2021, and the programme was fully suspended from May 2023 to September 2025 due to staffing issues.
- The Corporate Licence Holder contact was changed in August 2023.

Description of inspection activities undertaken

The HTA's regulatory requirements are set out in Appendix 1. Regulation Manager covered the following areas during the inspection:

Standards assessed against during inspection

All 47 of the HTA licensing standards were covered during the assessment (standards published 3 April 2017).

Review of governance documentation

The Regulation Manager reviewed the establishment's self-assessment document provided by the DI. Policies and procedural documents relating to licensed activities were reviewed. These included standard operating procedures (SOPs), policies, the Quality manual, internal audits, incidents, meeting minutes and risk assessments. During the site visit, the establishment's electronic specimen traceability system was also assessed.

Visual inspection

The Regulation Manager undertook a site visit inspection of the premises which included the entrances and exits, the anatomy suites, the preparation room, storage facilities, office area and potted specimen museum.

Audit of records

The Regulation Manager undertook traceability audits for eight cadavers and specimens stored within the department. These included three embalmed bodies stored for anatomical examination, and five prosected body parts. Traceability details were crosschecked between the identification tags and information on the electronic register through to consent documentation. No discrepancies were identified.

A review of the bone collection, potted specimen collection and historical holdings cabinet was also reviewed.

Meetings with establishment staff

The Regulation Manager met with staff carrying out activities under the licence. These included Anatomy Technicians, one of whom also undertakes prosecting duties, Technical Manager, Anatomy Laboratory Manager, Research Governance Manager, Centre Manager, Centre Director, Bequeathal Secretary, Senior Lecturer for Education and the Designated Individual.

Report sent to DI for factual accuracy: 30 December 2025

Report returned from DI: 9 January 2026

Final report issued: 12 January 2026

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 the 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.