Inspection report on compliance with HTA licensing standards
Inspection dates: **7 April (remote) and 15 April (site visit) 2026**

Cardiff School of Biosciences
HTA licensing number 12065
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
Cardiff School of Biosciences, CF10 3AX	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.

Cardiff School of Biosciences (‘the establishment’) was found to have met all HTA standards.

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.	GQ4(a)	The establishment maintains separate registers for different categories of relevant material. The DI is advised to consider implementing a centralised register to support a consistent and comprehensive record of all material held under the licence.
2.	GQ2(b)	The establishment's audit reports identify responsible individuals and timeframes for addressing non-compliance findings. The DI is advised to consider incorporating this information into the CAPA plan to support oversight and tracking of actions.
3.	GQ6(a)	The establishment has two body transfer trolleys in the mortuary, one of which is due for servicing. The DI is advised to ensure this is reflected within the risk assessment, including appropriate mitigation measures, to ensure contingency arrangements are clearly documented in the event of equipment failure.

Background
Cardiff School of Biosciences provides anatomy teaching to undergraduate medical and dental students, as well as training for healthcare professionals. Activities include the receipt, embalming, storage, use and disposal of donated bodies and body parts for anatomical examination, education and training. The establishment manages formalin-embalmed and fresh-frozen donated material, alongside specimens that include skeletal, foetal and plastinated material, to support teaching.
Cardiff School of Biosciences has been licensed by the HTA since February 2008. This was the third inspection of the establishment; the

most recent previous inspection took place in February 2022.

Since the previous inspection, one Corporate Licence Holder contact (CLHc) and one Designated Individual (DI) have been appointed

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

Standards assessed against during inspection
All 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017).

Review of governance documentation
Policies and procedural documents relating to all licensed activities, including standard operating procedures and traceability systems were assessed. Documents detailing adverse events, incidents, risk assessment, governance meetings, agreements with the establishments providing donated material and audits were also reviewed

Visual inspection
The inspection included a visual inspection of the anatomy suite including the areas where staff receive and store embalmed bodies, prosections and relevant material, and the areas where relevant material and specimens are used for surgical skills training and anatomical examination

Audit of records
An audit was undertaken of records, consent and labelling for eight embalmed bodies, two frozen bodies, two prosections, four plastinated specimens, and nine potted museum samples and five bone collections. Full traceability was demonstrated for all items audited.

Meetings with establishment staff
The inspection included discussions with the DI and three Persons Designated.

Report sent to DI for factual accuracy: 01 May 2026
Report returned from DI: 05 May 2026
Final report issued: 06 May 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.