Inspection report on compliance with HTA licensing standards
Inspection date: **19 October 2023**

The Public Mortuary at Flax Bourton
HTA licensing number 12536

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 **The Public Mortuary at Flax Bourton**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*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 The Public Mortuary at Flax Bourton ('the establishment') had met the majority of the HTA's standards, three major and one minor shortfall 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.

Major shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
c) Procedures on body storage prevent practices that disregard the dignity of the deceased	Whilst documented condition checks are undertaken, these are limited to: on admission; at post mortem examination; prior to a viewing by the family; and on release into the care of Funeral Directors. There is a risk that deterioration to a body may occur should the deceased be stored for a prolonged period of time after a viewing or post mortem examination and before being released to funeral directors.	**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).	There is a procedure in place to provide confirmation of receipt of samples sent off site for analysis. However, the standard operating procedure (SOP) lacks detail for the escalation process for following up on forms not received from the contracted establishment. The inspection team found that the establishment had a number of samples where confirmation of receipt had not been received. This poses a risk of loss of tissue traceability. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**Major**
PFE1 The premises are secure and well maintained and safeguard the dignity of the deceased and the integrity of human tissue.		
a) The premises are clean and well maintained	There is significant damage to the fabric of the building which has led to large areas of exposed plaster and some areas of exposed wood in the post mortem suite, body store and viewing room. There was a breach in the seal between the base of one post mortem table and the floor. Additionally, a metal cupboard in an ante chamber in the forensic post mortem room had significant areas of corrosion. This poses the risk of ineffective cleaning and decontamination.	**Major**

Minor Shortfalls

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	Whilst fridge and freezer units are subject to regular maintenance, during the inspection staff had difficulty opening a freezer door due to the seal being frozen. This poses the risk of a reportable incident occurring involving equipment failure. *The establishment submitted sufficient evidence to address this shortfall before the report was finalised.*	**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(a)	Whilst regular body audits are carried out and documented condition checks are undertaken on admission, the audits are not clear if bodies identified as unviewable were admitted to the mortuary in a poor condition. The DI should consider the addition of information describing the condition of bodies on admission into the audit.
2.	GQ3(g)	Whilst there is a system in place for pathologists to acknowledge the reading of SOPs, this is paper based. To provide additional oversight and assurance visiting pathologists have read and acknowledged the most up to date versions of SOPs, the DI should consider introducing an electronic

		system to capture this information.
3.	GQ5(b)(c)	The DI is advised to consider the introduction of an electronic system for recording incidents and near misses. This will support trend analysis and evidence the investigation process and corrective and preventative actions taken.
4.	PFE1(d)	To provide additional assurance security systems in place remain effective, the DI should consider changing the mortuary alarm access code on a regular basis.
5.	PFE3(a)	The DI is advised to expedite existing plans in place to replace the rusted castors on the trolleys used in the post mortem suite, and the repair to the painted surface of the hydraulic trolleys, which are showing areas of rust.

Background

The Public Mortuary of Flax Bourton has been licensed by the HTA since 2009. This was the fifth inspection of the establishment; the most recent previous inspection took place in May 2021.

Since the previous inspection, there have been no significant changes to the licence arrangements, or the activities carried out under the licence. However, during the inspection major building work was being carried out to provide additional capacity, including long term and bariatric 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
54 of the 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017), standards C1(a-g), C2 (a-d) are not applicable as the establishment does not seek consent for post mortem examinations. Standard GQ2(c) could not be assessed as the mortuary register is not paper based. Standards T1(f), T2 (a-d) were not assessed as the establishment does not store or dispose of tissue taken during post mortem examinations, and standard PFE2(h) does not apply as the care of paediatric or perinatal deceased is not undertaken.

Review of governance documentation
The inspection included a review of the establishment's governance documentation relating to licensed activities. This included policies and procedural documents relating to licensed activities, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents and training records for mortuary staff.

Visual inspection
The inspection included a visual assessment of the establishment including body storage areas and viewing rooms. The inspection team observed the processes for admission, release and viewing of bodies within the mortuary.

Audit of records
Audits were conducted onsite of bodies from four bodies in refrigerated storage and one body in long term frozen storage. Identification details on bodies were crosschecked against the information recorded in the register and associated paperwork in addition to information held electronically. No discrepancies were identified.
Audits of traceability were conducted for tissue removed at PM. These were limited to audits of the documentation relating to transfer of tissue offsite for analysis and confirmation of receipt from the receiving establishment. The inspection team identified 21 cases with outstanding tissue receipt confirmation (see shortfall against T1 (g) for further detail).

Meetings with establishment staff
Staff carrying out processes under the license were interviewed including the DI, Deputy mortuary manager, APT and Pathologist.

Report sent to DI for factual accuracy: 06/11/2023

Report returned from DI: 20/11/2023

Final report issued: 20/11/2023

Completion of corrective and preventative actions (CAPA) plan

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

Date: 4 July 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.