Virtual regulatory assessment (VRA) inspection report on compliance with HTA licensing standards
Inspection date: **26-27 May 2021**

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
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.

The Public Mortuary at Flax Bourton (the establishment) had one minor shortfall which 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 shortfall identified. .

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored		
c) The ventilation system provides the necessary ten air changes per hour and is checked and maintained at least annually	The air changes for the ventilation system was last checked in December 2018 and is overdue for servicing.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1 (a)	The DI is advised to amend the standard operating procedure (SOP) for routine autopsy to include procedures for seeking consent for removal and testing of samples in the event of a needlestick injury during a post-mortem examination.
2.	GQ2 (a)	The establishment has a well-constructed audit schedule which includes a variety of vertical and horizontal audits. To further develop the audits, the DI is advised to include audits against all applicable HTA standards.
3.	GQ5 (a)	The DI is advised to include a list of HTARI categories in the HTARI SOP to remind staff of incidents that need to be reported to the HTA. In addition, the DI is advised to place signage in the mortuary detailing the HTARI categories and incident reporting procedure for funeral directors admitting bodies out of hours.
4.	PFE2 (b)	The establishment has reviewed contingency arrangements and there is a business case to improve the exterior of the building and increase storage capacity. The HTA advises the establishment to continue with these plans for improvement of the premises.

5.	PFE 2 (f)	The establishment regularly reviews the fridge temperature records for trends. The DI is advised to formalise the process by recording when these are checked. This may help identify any variations in temperatures that may assist in preventing equipment failures before they occur.

The HTA requires the DI to submit a completed corrective and preventative action (CAPA) plan setting out how the shortfall 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.

Background

The Public Mortuary at Flax Bourton has been licensed by the HTA since 2009. This was the fourth inspection of the establishment; the last inspection took place in January 2016.

Since the previous inspection, there have been no significant changes to the licence arrangements or the activities carried out under the licence.

Description of inspection activities undertaken

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

Standards assessed against during inspection

58 out of the total 72, were covered during the assessment (standards published 3 April 2017). The standards in relation to consent procedures (C1 a-g) and standards relating to consent training (C2 a-d) were not applicable as the establishment does not seek consent for PM examination. Standards T2 (a, c and d) were not applicable because the establishment does not retain or dispose of tissues outside the authority of the Coroner.

Review of governance documentation

Policies and procedural documents relating to licensed activities for the mortuary and post-mortem room, records of servicing, ventilation reports, audits, risk assessments, meeting minutes, temperature monitoring for the storage units, incidents, and staff training records were also reviewed.

Visual inspection

There was no site visit inspection as part of this assessment.

Meetings with establishment staff

The inspection team met with staff carrying out processes under the licence, including mortuary staff, a pathologist who conducts PM examinations and the DI.

Material held for the police

Under section 39 of the Human Tissue Act 2004 (HT Act), relevant material held for criminal justice purposes is outside the scope of HTA regulation and is not subject to the licensing requirements for storage. Any information provided by the establishment in relation to police holdings have been shared with the Home Office, but do not appear in this report as they are outside the scope of the HT Act.

Report sent to DI for factual accuracy: 22 June 2021

Report returned from DI: 20 July 2021

Final report issued: 21 July 2021

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]/[Virtual Regulatory Assessment] Report.

Date: 21 July 2021

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.

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 site visit.

   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 site visit inspection
- a request for information that shows completion of actions
- monitoring of the action plan completion
- follow up at next routine site visit inspection.

After an assessment of the proposed action plan establishments will be notified of the follow-up approach the HTA will take.