Inspection report on compliance with HTA licensing standards
Inspection date: **26 June 2024**

John Radcliffe Hospital

HTA licensing number 12052

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 **John Radcliffe Hospital**	Licensed	Licensed	Licensed
Mortuary	*Carried out*	*Carried out*	*Carried out*
Pathology lab	-	-	*Carried out*
Maternity	-	*Carried out*	-
A&E	-	*Carried out*	-
Satellite site **Churchill Hospital**	Not licensed	Licensed	Licensed
Mortuary	-	*Carried out*	*Carried out*

Radiology	-	*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 John Radcliffe Hospital ('the establishment') had met the majority of the HTA's standards, three major and one minor shortfall were found against standards for consent documentation, reporting of incidents, site maintence and security arrangements.

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
GQ5 There are systems to ensure that all untoward incidents are investigated promptly		
a) Staff know how to identify and report incidents, including those that must be reported to the HTA	All staff interviewed were aware of how to identify and report incidents. However, staff carrying out licensed activities, who did not work directly within the mortuary, were unaware of the classifications of incident that are reportable to the HTA. Further, the incident reporting SOP does not include the requirement to report near miss incidents in sufficient detail. The inspection team identified two recent near miss incidents within the classifications of serious security breach and major equipment failure that should have been, but were not, reported to the HTA.	**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	Whilst the interior of the premises were clean at the time of the inspection, the inspection team identified the following areas which require maintenance: <u>Hub Site</u> • Two temporary body storage units remained in the post mortem room, which were expected to have been removed following the last inspection. This poses a risk due to inadequate infection control, as the room is used for high risk post mortems including those with potential airborne pathogens. • Further, the units are placed directly onto the floor, repaired with tape and powered using exposed plug sockets. As this is within a wet area it potentially poses a risk to staff safety and ineffective decontamination. *The establishment took immediate action and removed the temporary body storage units from the post mortem room following the inspectors leaving the site.* <u>Satellite Site</u> • The body store at the satellite site has damage, with potential mould, to the ceiling tiles. The walls also have areas of exposed porous plaster. These pose a risk to ineffective cleaning and decontamination. • The area outside the visitor entrance is not well kept or maintained. The area is littered with debris, has overgrown bushes and weeds, and the external gate is unable to close due to tree roots and cracked concrete. *Concerns regarding the maintence of the satellite site was identified as a major shortfall at the previous inspection, and whilst remedial action has*	**Major**

	taken place in some areas, this has been insufficient to meet the required standard.	
d) The premises are secure (for example there is controlled access to the body storage area(s) and PM room and the use of CCTV to monitor access)	Whilst the mortuary at the satellite site was secure at the time of the inspection, the inspection team identified a number of potential security risks: Hub Site	**Major (cumulative)**

e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access	• Visitors to the mortuary are required to sign in to the department, however they do not routinely sign out. The inspection team noted gaps in the visitors book, and whilst suitable measures are in place to audit access, this poses a risk to lack of oversight of visitors' length of stay within the department. <u>Satellite site</u> • The external doors to the body store do not appear to be fully robust due to age of the doors. The wood in areas is damaged and worn. • The visitor entrance has a number of windows that can be opened fully in the waiting area. Whilst access to the rest of the mortuary is restricted, there is a risk of unauthorised access to the visitor area if the windows are not locked and secured fully before staff leave the building. Furthermore, this entrance is behind a small, gated area, which does not easily close and is not routinely locked. • The external components of the fridge units at the satellite site are accessible outside of the mortuary. This leaves a risk of the external components being tampered with. • The inspection team noted an adjoined building to the mortuary that was no longer in use; the door to this area has been broken and the building can be accessed. As this is within the vicinity of the mortuary grounds it poses a risk to lack of oversight of unauthorised access. *Concerns regarding the satellite's external doors, open windows and accessible fridge units, were identified as a major shortfall at the previous inspection. Whilst requests for remedial action had been made within the establishment, suitable actions had not been taken to meet this standard.*	

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
C1 Consent is obtained in accordance with the requirements of the Human Tissue Act 2004 (HT Act) and as set out in the HTA's codes of practice		
g) The establishment uses an agreed and ratified consent form to document that consent was given and the information provided	The form used for recording adult post mortem consent has not been reviewed since 2017. Whilst the form includes key information and requirements, it is not part of the document management review process. This poses a risk that any national updates to consent guidance will be overlooked. See advice C1(g)	**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.	C1(g)	The Designated Individual is advised to include the adult post mortem consent form to the mortuary document management system.

2.	GQ3(c)	The Mortuary Manager is advised to continue with plans to add the out of hours viewing procedure competency assessments to the site coordinators training package, if this service continues to be offered.
3.	T1(c)	The Designated Individual is advised to liaise with referral centres for neuropathology tissue, to ensure they always arrive with three points of identification on the specimen containers.
4.	PFE1(d)	Exiting the mortuary is currently by a door release switch. The Designated Individual is advised to consider replacing this with the use of the swipe cards. This will improve the efficiency of the mortuary access audits.
5.	PFE1(e)	The Designated Individual is advised to include the mortuary 'internal courtyard' into risk assessments as this is currently a throughfare for non-mortuary staff.
6.	PFE3(a)	The Designated Individual is advised to organise the removal of condemned equipment from the mortuary working areas. This will mitigate against the risk of its accidental use.

Background

John Radcliffe Hospital has been licensed by the HTA since October 2007. This was the sixth inspection of the establishment; the most recent previous inspection took place in September 2022.

Since the previous inspection, there have been an increase in staffing levels, a change of corporate licence holder contact, and a refurbishment of the mortuary fridge room.

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:

Corrective and preventative action plan follow up
This inspection was scheduled in part, as a follow up visit to visually review the actions taken by the establishment, following closure of the Corrective and Preventative Action (CAPA) plan on the shortfalls from their inspection in 2022. Whilst the establishment provided evidence that the actions under that CAPA plan had been undertaken, some similar findings resulted in shortfalls against standards PFE1(a) and PFE1(e). Therefore, an additional focused follow up visit will be arranged to assess the establishment's ability to maintain consistent compliance with HTA standards.

Standards assessed against during inspection
All 72 HTA licensing standards were covered during the inspection (standards published 3 April 2017). 21 of which included assessing CAPA follow up actions from the 2022 inspection.

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, cleaning records for the mortuary, records of servicing of equipment, audits, risk assessments, meeting minutes, reported incidents, and training records for staff.

Visual inspection
The inspection included a visual assessment of the mortuary access points, mortuary fridge rooms, post mortem room, tissue storage areas, maternity storage areas and the viewing facilities. The inspection team observed the processes for admission, release and viewing of bodies within the mortuaries.

Audit of records
Audits were conducted for four bodies at John Radcliffe Hospital and four bodies from the Churchill Hospital. Identification details were crosschecked against the information recorded in the mortuary register and associated paperwork. No discrepancies were identified.

Audits of traceability were conducted for tissue blocks and slides from four coronial cases. These included audits of the consent documentation for the retention or disposal of these tissues. No discrepancies were identified.

Audits were conducted for four neuropathology cases. These included audits of specimen containers and associated paperwork. Whilst no discrepancies were identified, advice was given regarding the admission of specimens from referral centres. *See advice T1(c).*

Meetings with establishment staff
Staff conducting processes under the licence were interviewed including the DI, mortuary manager, APT, Mortuary Support Workers, Pathology lead, Mortuary Porter, Pathologist, Neuropathology Lead, Quality Lead and Bereavement Midwife.

Initial feedback was provided to the Mortuary Manager onsite. Final feedback was provided virtually on 28 June 2024 to the Designated Individual, Corporate Licence Holder Contact, Pathology Manager, Mortuary Manager, Neuropathology Manager, Bereavement Manager, Quality Managers, Portering Manager and Lead Pathologist.

Report sent to DI for factual accuracy: 26 July 2024

Report returned from DI: 08 August 2024

Final report issued: 12 August 2024

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: 15 October 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.