Inspection report on compliance with HTA licensing standards
Inspection date: **30 April 2024**

Restore Plc Document Services Division

HTA licensing number 12450

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 **Restore Plc Document Services Division - Redhill**	Not licensed	Not licensed	Licensed
Satellite site Restore Plc - Spennymoor	Not licensed	Not licensed	Licensed
Satellite site Restore Plc - Goole	Not licensed	Not licensed	Licensed
Satellite site Restore Plc -Salford	Not licensed	Not licensed	Licensed

Satellite site Restore Plc - Oldham	Not licensed	Not licensed	Licensed
Satellite site Restore Plc - Neston	Not licensed	Not 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.

Although the HTA found that Restore Plc Document Services Division ('the establishment') had met the majority of the HTA's standards two minor shortfalls were found against standards for Governance and quality systems.

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

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishment's work are governed by documented policies and procedures		
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.	The incident reporting procedure does not include information about which incidents require reporting to the HTA.	**Minor**

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	Although staff are aware of how to report incidents, they do not necessarily know which types of incidents relevant to their work require reporting the HTA.	**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.	GQ1(a)	Due to the increased number of requests from establishments to dispose of tissue blocks and slides, the DI is advised to develop a disposal SOP which outlines how these requests are managed and the process for staff to follow. The SOP should include how disposal is confirmed/recorded and how records of disposal are shared with establishments requesting disposal.
2.	GQ1(h)	The DI advised to increase senior management meetings to twice a year to help ensure senior managers are aware of regulatory matters more frequently.
3.	GQ3(a)	The DI is advised to include information regarding HTARIs in staff training at induction and on an ongoing basis to refresh awareness.
4.	GQ6(a)	The establishment do not currently check the condition of tissue blocks and slides on receipt for storage, in damaged boxes or otherwise. The DI is advised to assess the risk of not performing checks as assurance the tissue blocks and slides have been received in an undamaged condition.

5.	PFE	Should the establishment decide to undertake the storage of fresh and/or frozen post mortem (PM) tissue in the future, the DI should review HTA standards relevant to storing tissue in this manner and inform the HTA to ensure licensing standards are met.

Background
Restore Plc Document Services Division has been licensed by the HTA since September 2014. This was the third inspection of the establishment; the most recent previous inspection took place in October 2021.

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 inspection team covered the following areas during the inspection:

Standards assessed against during inspection
33 out of the HTA's 72 standards were covered during the inspection. Standards covered at this inspection are listed in Appendix 3. As the establishment store tissue blocks and slides on behalf of other establishments, 39 standards relating to consent, post-mortem and body storage were not applicable. These standards have been deleted from the table.

Review of governance documentation
The assessment team reviewed the establishment's self-assessment document provided by the DI and associated documentation including policies and procedural documents. Other documentation was reviewed electronically during interviews and on-site, for example, the risk register spreadsheet, an example of meeting minutes and SOP sign-off sheets.

Visual inspection
A visual inspection of the satellite site at Goole was undertaken which included the storage arrangements for PM tissue blocks and slides.

Audit of records
An audit was undertaken of two boxes of PM tissue blocks and slides already requested for return by an establishment. Traceability details including box and location barcodes were taken from the computer tracking system and printed. The location of the boxes was identified and the barcode details checked and scanned, ready for dispatch. No discrepancies were identified.

Meetings with establishment staff
The assessment team met with staff carrying out processes under the licence, including Service Delivery Managers, a Service Supervisor and the DI.

Report sent to DI for factual accuracy: 7 May 2024

Report returned from DI: 7 May 2024

Final report issued: 14 May 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: 6 August 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.

Appendix 3: Standards assessed during VRA

Governance and quality systems
GQ1 All aspects of the establishment's work are governed by documented policies and procedures
a) Documented policies and SOPs cover all mortuary/laboratory procedures relevant to the licensed activity, take account of relevant Health and Safety legislation and guidance and, where applicable, reflect guidance from RCPath.
d) Policies and SOPs are reviewed regularly by someone other than the author, ratified and version controlled. Only the latest versions are available for use.
e) There is a system for recording that staff have read and understood the latest versions of these documents.
f) Deviations from documented SOPs are recorded and monitored via scheduled audit activity.
g) All areas where activities are carried out under an HTA licence are incorporated within the establishment's governance framework.
h) Matters relating to HTA-licensed activities are discussed at regular governance meetings involving establishment staff.
GQ2 There is a documented system of audit
a) There is a documented schedule of audits.
b) Audit findings document who is responsible for follow-up actions and the timeframe for completing these.
GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and demonstrate competence in key tasks
a) All staff who are involved in mortuary duties are appropriately trained/qualified or supervised.

b) There are clear reporting lines and accountability.
c) Staff are assessed as competent for the tasks they perform.
d) Staff have annual appraisals and personal development plans.
e) Staff are given opportunities to attend training courses, either internally or externally.
f) There is a documented induction and training programme for new mortuary staff.
g) Visiting / external staff are appropriately trained and receive an induction which includes the establishment's policies and procedures.
GQ4 There is a systematic and planned approach to the management of records
a) There is a system for managing records which includes which records must be maintained, how they are backed up, where records are kept, how long each type of record is retained and who has access to each type of record.
b) There are documented SOPs for record management which include how errors in written records should be corrected.
c) Systems ensure data protection, confidentiality and public disclosure (whistleblowing).
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.
b) The incident reporting system clearly outlines responsibilities for reporting, investigating and follow up for incidents.
c) The incident reporting system ensures that follow up actions are identified (i.e. corrective and preventative actions) and completed.

d) Information about incidents is shared with all staff to avoid repeat errors.
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored
a) All procedures related to the licensed activities (as outlined in standard GQ1) are risk assessed on a regular basis.
b) Risk assessments include how to mitigate the identified risks. This includes actions that need to be taken, who is responsible for each action, deadlines for completing actions and confirmation that actions have been completed.
c) Significant risks, for example to the establishment's ability to deliver post-mortem services, are incorporated into the Trust's organisational risk register.

Traceability
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). The traceability system ensures that the following details are recorded: i. material sent for analysis on or off-site, including confirmation of arrival ii. receipt upon return to the laboratory or mortuary iii. the number of blocks and slides made iv. repatriation with the body v. return for burial or cremation vi. disposal or retention for future use
h) There are documented procedures for transportation of bodies and tissue anywhere outside the mortuary, (such as to the lab or another

establishment), including record-keeping requirements.

Premises, facilities and equipment
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.
c) There are documented cleaning and decontamination procedures and a schedule of cleaning.
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).
e) Security arrangements protect against unauthorized access and ensure oversight of visitors and contractors who have a legitimate right of access.
PFE2 There are appropriate facilities for the storage of bodies and human tissue
b) There is sufficient capacity for storage of bodies, organs and tissue samples, which takes into account predicated peaks of activity.
PFE3 Equipment is appropriate for use, maintained, validated and where appropriate monitored
d) Staff have access to necessary PPE.