

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 - Neston	Not licensed	Not licensed	Licensed
Satellite site Restore PLC - Oldham	Not licensed	Not licensed	Licensed
Satellite site Restore PLC - Salford	Not licensed	Not licensed	Licensed

Summary of assessment findings

The HTA found the Designated Individual (DI) and the Licence Holder (LH) to be suitable in accordance with the requirements of the legislation.

Restore PLC Document Services Division ('the establishment') was found to have met all HTA standards.

The HTA has assessed the establishment as suitable to be licensed for the activities specified.

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.	GQ1(a)	The 'Operations Training Manual' covers all procedures relating to licensable activities. The DI is advised to include information on which of the establishments 56 sites are licensed by the HTA. Furthermore, a summary of the HTA's licensing requirements in this primary training document may increase staff awareness.

2.	GQ1(h)	There is a monthly meeting attended by all Persons Designated (PDs) on the licence. The DI is advised to include HTA related matters as a standing agenda item.
3.	GQ2(a)	Annual audits take place at all licensed sites, not all sites formalise the 'stock-check' part of the audit. The HTA advises that all licensed sites conduct a formalised audit of 'record' to 'storage location' and vice versa.
4.	GQ5(a)	The DI and PDs do not have accounts set up on the HTA Portal which would allow the submission of HTA reportable incidents (HTARIs). Although many of the HTARI categories are not applicable to the establishment, some, such as 'serious security breach' could be relevant and the DI is advised to set up HTA portal accounts for named persons.

Background

Restore PLC Document Services Division has been licensed by the HTA since September 2014. This was the second inspection of the establishment; the last inspection took place in September 2015.

Since the previous inspection, there have been some significant changes to the licence arrangements including the addition of five satellite sites.

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

32 out of the HTA's 72 standards were covered during the Virtual Regulatory Assessment (VRA). Standards covered at this inspection are listed in Appendix 3. As the establishment store 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. PFE1(a) could not be assessed as no site visit took place.

Review of governance documentation

The assessment team reviewed the establishment's self-assessment document provided by the DI in advance of the VRA and associated documentation including policies and procedural documents.

Visual inspection

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

Meetings with establishment staff

The assessment team met virtually with staff carrying out activities under the licence. This included the DI and group quality manager of the hub site, and the PD and site manager at one of the satellite sites.

Report sent to DI for factual accuracy: 04 November 2021

Report returned from DI: 05 November 2021

Final report issued: 05 November 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.

Its programme of site visit 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 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.

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

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.