Inspection report on compliance with HTA licensing standards
Inspection date: **17 August 2022**

Cryo-Store Ltd

HTA licensing number 12568

Licensed under the Human Tissue Act 2004

Licensed activities

Area	Storage of relevant material which has come from a human body for use for a scheduled purpose	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
Cryo-Store Ltd	Licensed	Not 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 Cryo-Store Ltd ('the establishment') had met the majority of the HTA's standards, one minor shortfall was found against a standard for Traceability (disposal documentation).

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 during the inspection.

Compliance with HTA standards

Minor Shortfall

Standard	Inspection findings	Level of shortfall
T2 Bodies and human tissue are disposed of in an appropriate manner		
b) The date, reason for disposal and the method used are documented.	Samples are returned to clients if disposal is required; however, the establishment occasionally disposes of non-conforming consignments. The disposal procedure, and associated form, do not result in the documentation of the method of disposal or the reason.	**Minor**

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.

Advice

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

Number	Standard	Advice
1.	C1(c)	There is an agreement with each client, confirming that appropriate and valid consent is in place. The DI is advised to consider additionally holding copies of blank client donor information and consent forms to provide ongoing assurance of the scope of the consent.
2.	GQ2(a)	There is a schedule of horizontal and vertical audits carried out by establishment staff, clients and the quality assurance auditor. The DI is advised to consider including procedural audits in this schedule to widen the scope of activities that will be subject to review.
3.	GQ5(b)	Adverse events relating to human tissue are captured in several different documents (e.g., the standard operating procedures (SOPs) SMP-01: 'Sample handling procedure' and FEQ-04: 'Alarm response'). The DI is advised to consider developing a separate SOP for all adverse events relating to human tissue to ensure consistency in their management.
4.	GQ6(a)	The establishment has a matrix of identified risks associated with licensed activities. This covers the likelihood and consequences of recurrence of each risk. However, the matrix has not been completed to evaluate the final risk rating. The DI is advised to ensure that the final risk rating is completed in each case so that all risks can inform risk management as intended.

Background

Cryo-Store Ltd is a private, purpose-built facility that stores biological and clinical material for the pharmaceutical, biotechnology and healthcare industries. The establishment currently stores a wide range of products, including small quantities of relevant material (peripheral blood mononucleocytes) from living donors. Material is stored under the terms of a 'master service contract' with each client; this ensures that appropriate and valid consent is in place.

The establishment has been licensed by the HTA within the Research sector since September 2010. From September 2006 until September 2010, it held a Human Application sector licence (HTA licensing number 11136). This was the second inspection of the establishment since it became licensed within the Research sector; the last one took place in June 2017.

Since the previous inspection, there have been no changes to the licensing arrangements.

Description of inspection activities undertaken

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

Standards assessed against during inspection

37 out of 47 HTA licensing standards were covered during the inspection (standards published 3 April 2017). Some standards are not applicable as establishment staff do not directly seek consent [standards C1(a)(b)(d)-(f), C2(a)-(c)], accommodate visiting staff [standard GQ3(c)] or store bodies or body parts [standard PFE2(b)].

Review of governance documentation

The following documents were reviewed: policies and procedural documents relating to the activity to be licensed, temperature monitoring records, contracts for servicing of equipment and records of servicing, contingency arrangements, and agreements.

The review of information relating to the quality management system included: document control, minutes of meetings, the management of complaints, staff training records, and risk assessments.

Two of the establishment's audits and two recorded adverse events were reviewed.

Visual inspection

Although no visual inspection was undertaken as part of this assessment, the DI shared a video tour of the facilities.

Audit of records

No formal audit of records was carried out by the HTA.

Meetings with establishment staff

The inspection included virtual meetings with the DI and Operations Manager. The meetings covered: consent, distribution and disposal; quality management; traceability; and premises, facilities and equipment.

Report sent to DI for factual accuracy: 14 September 2022

Report returned from DI: 28 September 2022

Final report issued: 18 October 2022

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: 16 February 2023

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 the 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.