Licence application assessment report on compliance with HTA licensing standards
Assessment dates: **9 April 2025 (remote) and 17 April 2025 (site visit)**

Mast Group Limited

Proposed HTA licensing number 12800

Application for a licence under the Human Tissue Act 2004

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
Mast Group Limited	Application made	Application not made

Summary of findings

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

Although the HTA found that Mast Group Limited ('the establishment') had met the majority of the HTA's standards, four minor shortfalls were found against standards for Governance and quality systems and 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 shortfalls identified during the assessment

Compliance with HTA standards

Minor Shortfalls

Standard	Inspection findings	Level of shortfall
GQ1 All aspects of the establishments work are governed by documented policies and procedures as part of the overall governance process		
a) Ratified, documented and up-to-date policies and procedures are in place, covering all licensable activities.	Although the establishment does not intend to seek consent for donations directly, there was no documented procedure in place to detail how the establishment will ensure that consent is obtained in accordance with the requirements of the HT Act and the HTA's Codes of Practice by third parties. Furthermore, there was no documented procedure in place to cover how the establishment will manage consent limitations or what to do in the event of consent withdrawal.	**Minor**
GQ2 There is a documented system of audit		
a) There is a documented schedule of audits covering licensable activities.	The audit schedule did not cover licensable activities.	**Minor**
GQ6 Risk assessments of the establishment's practices and processes are completed regularly, recorded and monitored		
a) There are documented risk assessments for all practices and processes requiring compliance with the HT Act and the HTA's Codes of Practice.	Although information relating to risk management and blank risk assessment templates were provided, no risk assessments relating to licensable activities were submitted for assessment.	**Minor**
PFE2 There are appropriate facilities for the storage of bodies and human tissue		
d) There are documented contingency plans in place in case of failure in storage area.	The contingency plan is not documented.	**Minor**

Advice

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

Number	Standard	Advice
1.	GQ1(a)	The *Clinical Specimen Handling SOP (SOP248)* contains some inaccurate statements relating to- 1) Licensing exemptions (paragraphs 1.2, 4.8 and 4.17). 2) DIs being trained by the HTA (paragraph 3.6). These points were discussed during the assessment process. The proposed DI is advised to remove or correct these references in line with the HTA's Codes of Practice.
2.	GQ1(b)	The review dates of most documents are automatically defaulted to 3 years from the approval date. As the processes relating to licensed activities are new, the proposed DI is advised to undertake earlier initial review.
3.	PFE1(b)	The laboratory area is secured by a coded door lock. The code is infrequently changed. To improve security, the proposed DI is advised to consider implementing a regular change of the code.
4.	T1(b)	The establishment intends to use a *'Clinical Specimen Record'* to facilitate the traceability of samples. The practicalities of using a form for each sample were discussed with the proposed DI, and it is advised that a spreadsheet may be an easier-to-use format.

Background

Mast Group Limited ('the establishment') is a manufacturer and supplier of diagnostic products. The establishment has applied for a HTA licence for the storage of relevant material, which has come from a human body, for use for the scheduled purpose of 'research in connection with disorders, or the functioning, of the human body'.

Description of activities undertaken during assessment

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

Standards assessed
38 out of 47 HTA licensing standards were covered during the assessment (standards published 3 April 2017).
Some standards relating to consent were not applicable as the establishment does not intend to seek consent directly from donors (C1(a), C1(b), C1(d), C1(e), C1(f), C2(a), C2(b) and C2(c)). Furthermore, PFE2(b) was not relevant as the establishment does not intend to store the deceased.

Review of governance documentation
Policies and procedural documents relating to all licensable activities including an overarching quality manual, standard operating procedures and risk assessments were assessed. Documents detailing the plans for staff training, incident management, governance meetings and audits were reviewed. The establishment's plans for the traceability of material were also assessed.

Visual inspection
The Regulation Manager undertook a visual inspection of the premises which included the laboratory storage area, office area and the contingency storage area. The security arrangements and the suitability of the storage areas were assessed. The temperature monitoring and alarm systems, maintenance plans and cleaning schedule were also reviewed.

Meetings with establishment staff
The Regulation Manager met with staff involved in the proposed licensed activities including managers of different departments including the Molecular Development Manager who is the proposed DI, and the Director who is the proposed Corporate Licence Holder contact.

Report sent to proposed DI for factual accuracy: 21 May 2025

Report returned from proposed DI: No factual accuracy or request for redaction comments were made by the DI

Final report issued: 9 June 2025

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, and;
- 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, or;
   - 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 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 site visit inspection;
- a request for information that shows completion of actions;
- monitoring of the action plan completion, or;
- 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.