

Sectors (type of licence)	Post mortem sector (PM)	Research sector	Public display sector	Anatomy sector	Human application sector	Organ donation and transplant	Licence for Removal
Main Licence fee:	£3,200	£3,300	£1,225	£2,380	£5,350	£3,950	£780
PM activities:							
• Making of a PM	£2,250	-	-	-	-	-	-
• Storage	£320	-	-	-	-	-	-
• Removal	£320	-	-	-	-	-	-
HA activities:							
• 5 or more tissue types	-	-	-	-	£995	-	-
• Processing	-	-	-	-	£2,850	-	-
• Procurement	-	-	-	-	£995	-	-
• Testing	-	-	-	-	£995	-	-
• Storage	-	-	-	-	£995	-	-
• Distribution	-	-	-	-	£500	-	-
• Import	-	-	-	-	£500	-	-
• Export	-	-	-	-	£500	-	-
ODT - two or fewer organs	-	-	-	-	-	£2,950	-
ODT - three organs	-	-	-	-	-	£5,890	-
ODT - four organs	-	-	-	-	-	£7,850	-
ODT - five or more organs	-	-	-	-	-	£9,750	-
Organisation responsible for procuring organs from deceased donors	-	-	-	-	-	£28,290	-
Satellite licence fees: (First 4 satellites)	£1,450	£780	£300	£380	£3,400	-	-
Satellite licence fees: (Each satellite over 4)	£750	£390	£150	£190	£1,900	-	-
Application fees:							
Main licence	£3,100	£3,100	£3,100	£3,100	£4,000	£3,100	£320
Satellite	£790	£790	£790	£790	£850	-	-

## **Explanatory notes – Licence fees 2018/19**

### **Background**

In 2010, the HTA developed a new licence fee structure which has been in operation since 1 April 2011. In 2016, a further review of our fees model was conducted and a consultation undertaken which focused on minor structural changes to our fees. The revisions to the structure are detailed by sector below:

#### ***Human Application***

Introduction of an additional fee for establishments that undertake activities on more than five tissue types

#### ***Post Mortem***

Storage only fee has been removed and we have introduced activity based fees with a main fee for all establishments and additional fees for each of:

- Making a post mortem
- Removal of relevant material for a scheduled purpose
- Storage of relevant material for a scheduled purpose

#### ***Organ Donation and Transplantation***

Introduction of a base fee for all establishments and an additional fee for the number of organ types as detailed on establishment licences

#### ***Public Display***

Removal of the fee for establishments that hold less than twenty items

#### ***Research***

No changes

#### ***Anatomy***

No changes

#### ***Satellite Bandings***

Applicable to all sectors; previous bandings of 1-3 4-10 and 11+ replaced with two bandings of 1-4 and 5+

### **Activities funded by licence fees**

HM Treasury requires the HTA to set fees to recover the costs of licensing and there can be no cross-subsidisation between sectors. The main costs are:

- Evaluating licence applications and issuing licences
- Site visit inspections
- Licence activities (gathering and maintaining data, updating compliance information, agreeing and monitoring corrective and preventative action (CAPA) plans)
- Processing variations to licences
- Preparation Process Dossier assessments
- Holding regulatory decision meetings (RDMs)
- Taking enforcement action to ensure compliance (hearings and appeals)
- Providing advice and guidance to establishments

- Responding to phone and email queries
- Giving views on relevant legislation
- Providing workshops and events for establishment staff
- Development of licensing standards and Codes of Practice
- Working with other organisations to streamline regulation
- Reporting to government and the European Commission
- Paying for proportion of overheads

## **Licence fee structure**

### ***Application fee***

The application fee reflects the work undertaken by the HTA in processing an application for a licence. It is:

- charged for new establishments, and those re-applying after revocation of their licence
- charged for a new licence application where an existing establishment changes its governance **and** premises. This reflects the work the HTA needs to do to assess the new arrangements. There would be no charge for a change of name, or where other arrangements remained similar, even if premises changed.
- (for new establishments with satellites) based on a charge for the main site and a smaller charge for each satellite
- establishments who already hold a licence and are applying for new satellites will be charged the satellite fee for each new satellite (even if that satellite was licensed previously as a main site in its own right, or if that satellite was previously a satellite on another licence.)
- establishments who wish to make one of their own satellites the main site, and the main site a satellite, would not be charged a fee
- the same for all sectors, as the HTA's work on new applications is similar regardless of the sector. However a licence for removal is charged at a lower rate, reflecting the work required.

- charged when the application is received, regardless of whether the application results in a licence (this means that the cost of the HTA's work is recovered even if a licence offer is not taken up) if an application is rejected and a satisfactory revised application is submitted again within three months of the rejection, no charge will be made

### **Annual fee**

The annual fee covers all the other activities set out previously. It is:

- different for each sector, reflecting the cost of the HTA's work for different sectors
- derived from a fee for a main site and for the number of satellites, to fairly reflect economies of scale when dealing with organisations with a large number of satellites. Satellites are charged for in bands: 1–4, and 5+. The satellite fee for each of the first four satellites is the same, reflecting the resource regulating satellites in each sector consume, the fee for each satellite thereafter reduces to around 50% of the first satellite fee. These proportions reflect the HTA's costs associated with licensing organisations with many satellites. A definition of what constitutes a satellite is on our [website](#).
- charged at the times of the year that the legislation came into effect (April for human application establishments, September for all others) although the fee covers the cost of licensable activities for the financial year (from 1 April to 31 March)
- applied to new establishments and for satellites on a pro rata basis for the remaining part of the financial year in which they are first licensed (in addition to the application fee). New establishments will be invoiced at the usual time (as above) or if that month has passed, when the licence is accepted
- reduced on a pro rata basis if an establishment ceases to hold a licence during the year, or if a satellite is removed

Pro rata charges or refunds are calculated for whole months, so a whole month's fee is charged for the month in which the change happens.

Examples of pro-rata charging:

1. An establishment granted a new licence on 12 May will be charged the annual fee for 1 May – 31 March (11/12ths of the annual fee). If the new establishment is in the human application sector, the annual fee would be charged for May – March, in May. If the new establishment is in the post mortem sector, the annual fee would be charged for May - March in September.
2. A post mortem establishment granted in November will be charged the annual fee for November – March (5/12ths of the annual fee), in November.
3. An establishment revoking in the human application sector on 28 April will be charged the annual fee for 1 April – 30 April (1/12ths of the annual fee). If they had already paid the fee for the full year (due in April), they would be refunded for May to March (11/12ths).
4. An establishment revoking in the post mortem sector on 12 June will be charged the annual fee for 1 April – 30 June. **They would be invoiced at the point of revocation and would need to pay before the revocation is finalised.**

5. An establishment revoking in the post mortem sector in December will be charged the annual fee for April – December. They should have already paid the full annual fee in September and would be refunded for January to March (3/12ths of the annual fee).

Information on sectors that have more than one rate of annual fee is set out below

### ***Public display***

- There is a separate, individual fee for each temporary public display exhibition. This avoids the significant costs of dealing with these temporary displays being passed onto other organisations within the sector that have small static displays. The HTA will calculate the cost of issuing these temporary licences on a case by case basis. The fee will be based on the costs for conducting activity around the temporary licence, based on component parts such as application, site visit, and advice and guidance.

### ***Human Application***

- The annual fee is determined by the licensed activities undertaken by each establishment, to reflect the amount of HTA resource applied to establishments, particularly on site visits (since each activity is inspected independently) and to an extent on advice and guidance and other regulatory activity.
- There is a fixed part charged to all establishments plus an incremental or variable part, built up depending on the individual activities on the licence. The activities are procurement, testing, processing, storage, distribution, import and export and number of tissue types greater than five. This gives a more transparent charging structure, and more fairly reflects HTA effort involved for different profiles of establishments. Processing attracts a higher fee relative to other activities and distribution, import and export would each attract lower relative fees.
- For establishments with satellites, the satellite fee does not depend on activities – it is derived from the average cost of the main licence fee for organisations in the sector.

### ***Organ Donation and Transplantation***

- There are four fee levels and a separate fee for the national organisation responsible for procuring organs from deceased donors – NHS Blood and Transplant (NHSBT).
- The four fee levels reflect the regulatory resource consumed for different types of establishments depending on their complexity, including the number of different types of organs they transplant. Each establishment is notified of the level of fee appropriate to them.