

Anatomy sector compliance updates report - 2017/2018



A short summary of selected compliance update findings & learning points



Introduction

All establishments licensed in our Anatomy, Post-Mortem, Public Display and Research sectors are required to provide us with periodic updates of licensing information and to complete a compliance questionnaire. The data from this collection helps us to maintain oversight of the sectors we regulate, guide our regulatory approach for each sector, and inform the scheduling of site-visit inspections. We call these 'compliance updates' and we collect them every two years.

In October 2017, we completed a collection of compliance updates for the Anatomy sector. Anatomy sector establishments include organisations that use donated bodies or body parts for education and training, including medical schools and surgical training centres in England, Wales and Northern Ireland.

This report presents a snapshot of the key findings from the data collection, identifying trends and themes we found from Anatomy sector submissions. We hope that this report will be useful to people working in the sector, as well as to members of the public who have an interest in body donation.

The data we collected in the 2017 round of compliance updates shows information from all 37 establishments licensed in this sector. This includes two establishments newly licensed during the 2016/2017 period.

HTA-licensed Anatomy establishments reported high levels of compliance with our standards. This corresponds with the low levels of shortfalls identified during the inspection of Anatomy establishments and our view that there is a widely-held respect for the gift of body donation and a genuine commitment to uphold the dignity of the deceased. This view is supported by feedback provided to HTA staff during inspections, workshops and conferences.

How we gather compliance data

We carefully analyse the data we receive from compliance updates. If we require further clarification on any aspects of the data, we follow these up with individual establishments. Compliance data is evaluated along with information such as the length of time since the last inspection to prioritise establishments for future HTA inspections.

Compliance updates are submitted electronically, through the HTA Portal. As part of the submission, we ask establishments for feedback on the process. In 2017, the feedback we received from the Anatomy sector was positive, with the majority of establishments indicating that they found both the portal and submission process to be user-friendly. We will continue to monitor this feedback as part of our commitment and focus on continuous improvement for future compliance updates.



Key findings

Profile of establishments

The majority of Anatomy establishments are licensed as a single facility; a small number have satellite sites (Figure 1). Satellite sites allow for licensable activities to take place at another facility under the governance and oversight of the [Designated Individual](#) for the main site. You can find out more about how we regulate satellite premises [here](#).

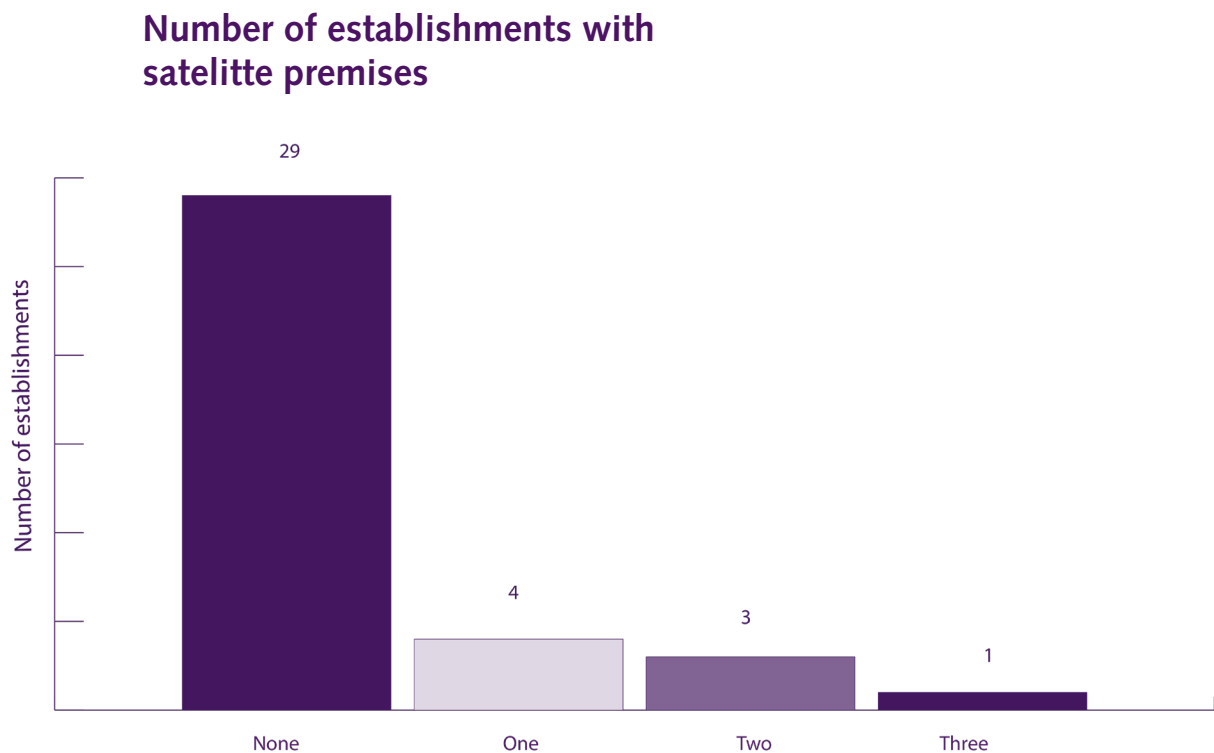


Figure 1. The number of establishments with either no satellite facilities, or one or more satellite facilities

Key findings

Loaning material

The data we received shows that 21 (54%) Anatomy establishments loan or transfer specimens to other locations, ensuring that the widest group of individuals can benefit from the donated material (Figure 2).

Specimens are loaned for varying reasons. This can include establishments that loan material:

- within their own institution;
- to branches of their institution located in other countries and regions; or,
- to external medical establishments to support clinical training.

Percentage of establishments that loan material

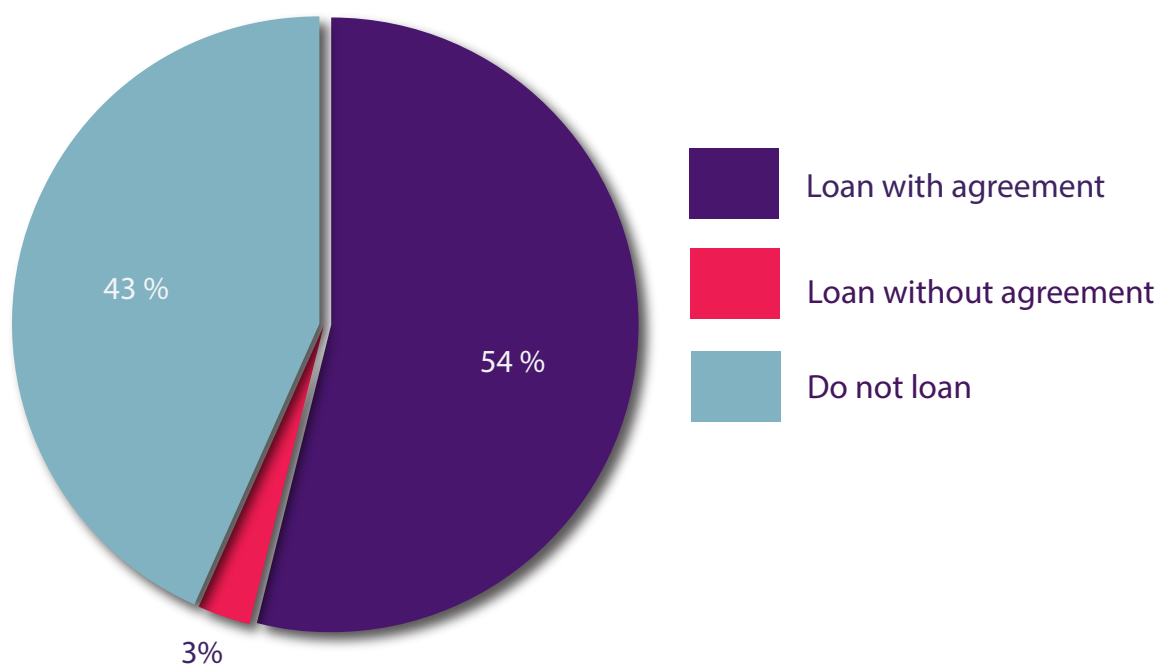


Figure 2. The number of establishments that either loan material or do not loan material

Key findings

Storage

In addition to storing material for anatomical examination, education, and training, 15 (41%) of establishments reported that they store relevant material for research studies 'in connection with disorders, or the functioning of the human body', another 'scheduled purpose' under the Human Tissue Act 2004. In the 2015 compliance updates, two of the 37 licensed establishments at that time reported that they included RTBs under their Anatomy licence. However, none of the establishments reported that they include a Research Tissue Bank (RTB) facility in this compliance update as the two previously reported RTBs were subsequently transferred to different governance arrangements.

Number of bodies received

The compliance data shows that Anatomy establishments can vary quite widely in the number of donated bodies they receive each year (Figure 3). For example:

- Eight establishments did not receive any donated bodies in 2017;
- Two establishments received only a single body; and,
- One establishment received 95-100 donated bodies per year.

This contrast indicates the varying needs of the different establishments, and may be influenced by the type of training they undertake.

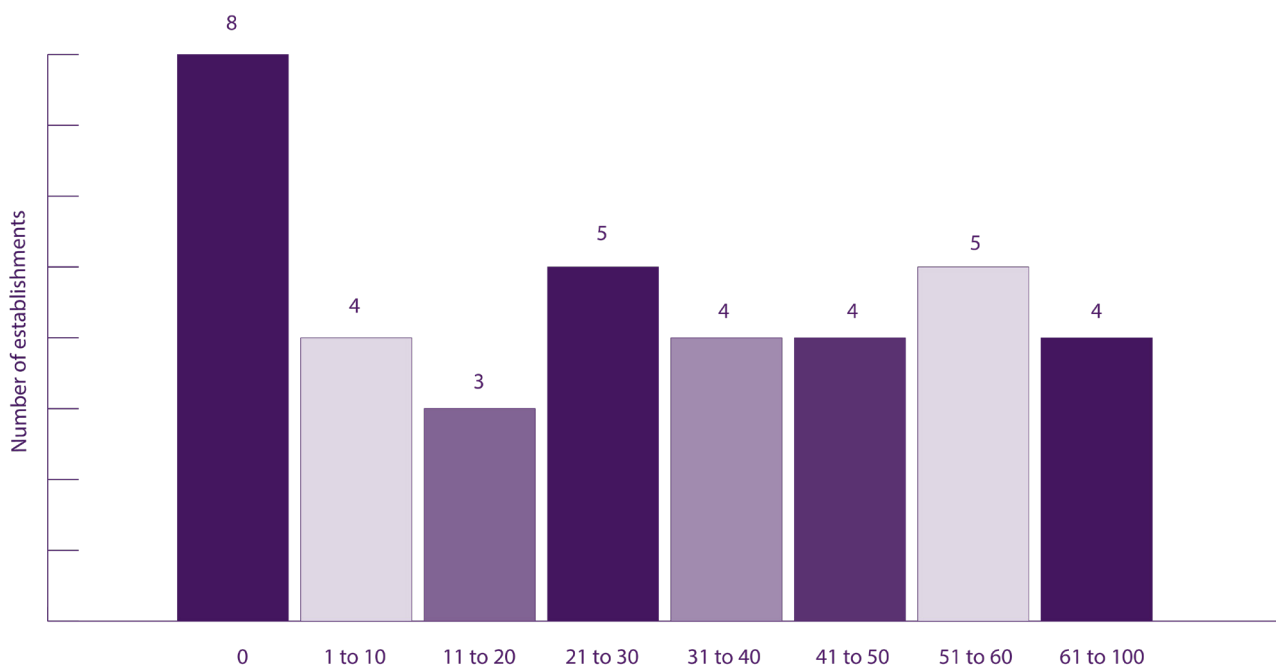


Figure 3. The number of licensed establishments (number on top of the bar) and the number of bodies they receive per year (number indicated under the bar)

Key findings

Preservation methods

Seven of the 37 (14%) Anatomy establishments do not undertake any preservation on site. We found that a range of methods are undertaken at the remaining 30 establishments, with most establishments utilising several different methods for preserving bodies and tissue (Figure 4).

Eleven establishments indicated that individuals other than staff, such as students, might be involved in the preparation of bodies. This was only conducted under the close supervision of establishment staff.

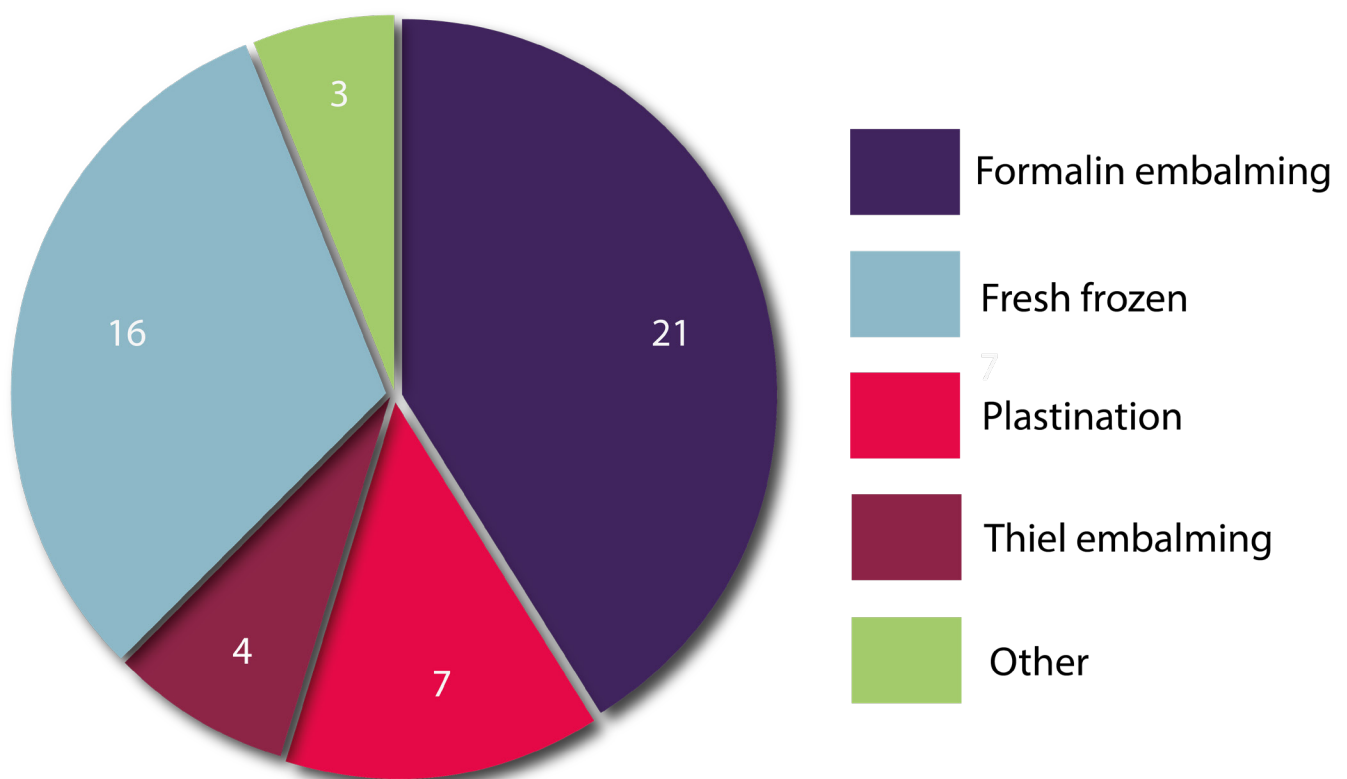


Figure 4. The number of establishments (number on each pie slice) that utilise the indicated preservation methods. Establishments may utilise more than one method

Key findings

Fresh frozen material

In the previous round of compliance updates, 14 establishments indicated they used fresh frozen material. In the 2017 update, this number increased to 19.

Of the 19 establishments using fresh frozen material, 14 reported where they sourced material. Nine obtain fresh frozen material exclusively from the USA. Three obtain fresh frozen material within the UK and two establishments source material from both the UK and the USA.

Whilst all of these establishments confirmed donors of fresh frozen material had a low risk status, only 17 establishments relied on testing to confirm this. Establishments reported that they tested for a range of potential infections, such as HIV, Hepatitis B and C, and CJD.

Of the establishments that did not carry out testing, three reported that they relied on the medical record of the donor or opinion of the clinician signing the death certificate to confirm that there was low risk of infection.

Governance and quality arrangements

The majority of licensed establishments in the Anatomy sector reported that they have good quality management and governance systems in place. 36 establishments reported that they regularly undertake traceability audits.

We asked Anatomy establishments if they undertook any new activities, since the last compliance update, on their premises. 17 establishments indicated that they had, all of which were described as new training courses.

All Anatomy establishments reported that they had risk assessments in place. Seven establishments indicated they did not have three or more of the risk assessments listed in the compliance update question. We followed up with these establishments and confirmed that they either had other governance documents addressing the potential risks, or did not undertake activities associated with the risks outlined in the question.

Key findings

Types of material used

We found that there is a range of 'relevant material' being stored and used across Anatomy establishments (Figure 4). The most common specimens are:

- bones or skeletons;
- potted specimens; and,
- embalmed bodies.

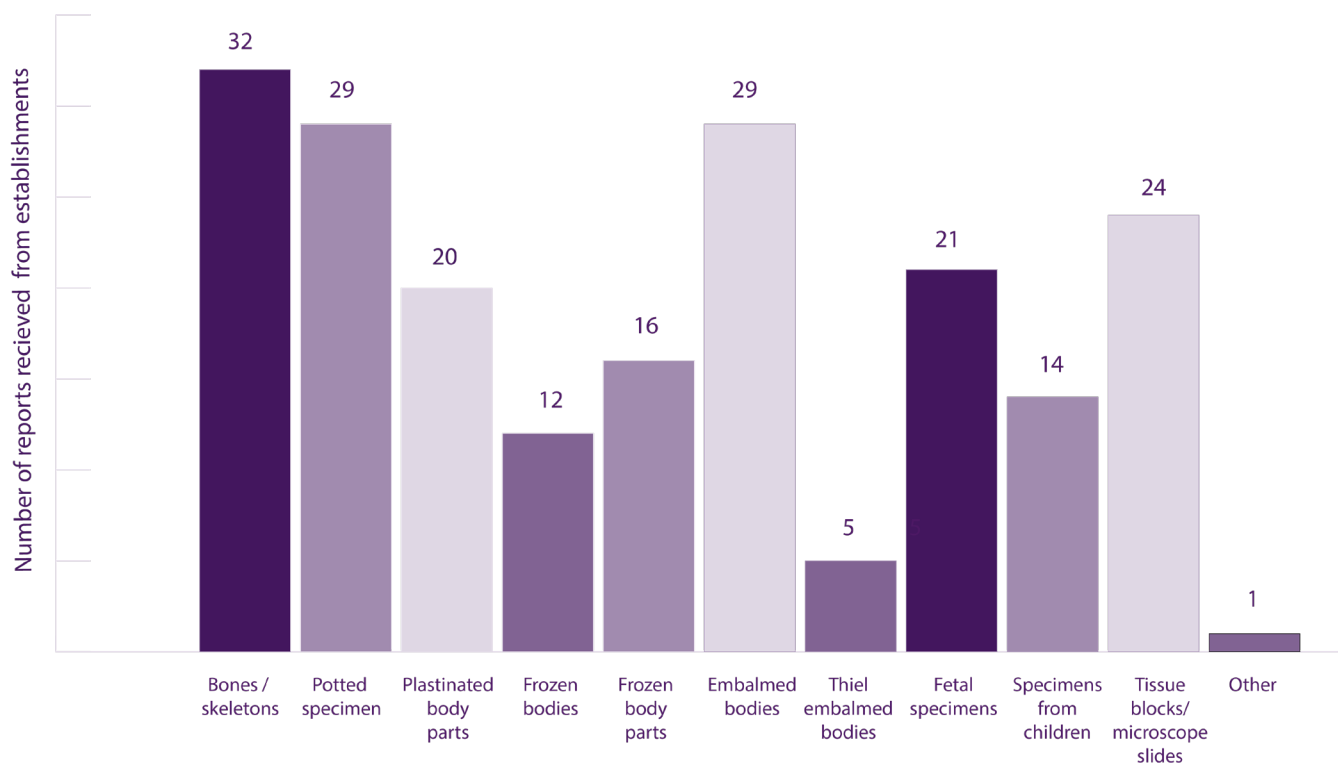


Figure 5. The number of establishments that use each of the indicated types of tissue. Establishments generally use multiple types of tissue

Twenty-one (56%) of Anatomy establishments stated that in addition to human tissue, they also store animal tissue for research and teaching purposes.

We hope you found this short report useful. The next round of compliance updates is being planned for 2019/20.

If you have any comments or questions, please contact us at enquiries@hta.gov.uk or visit our website.