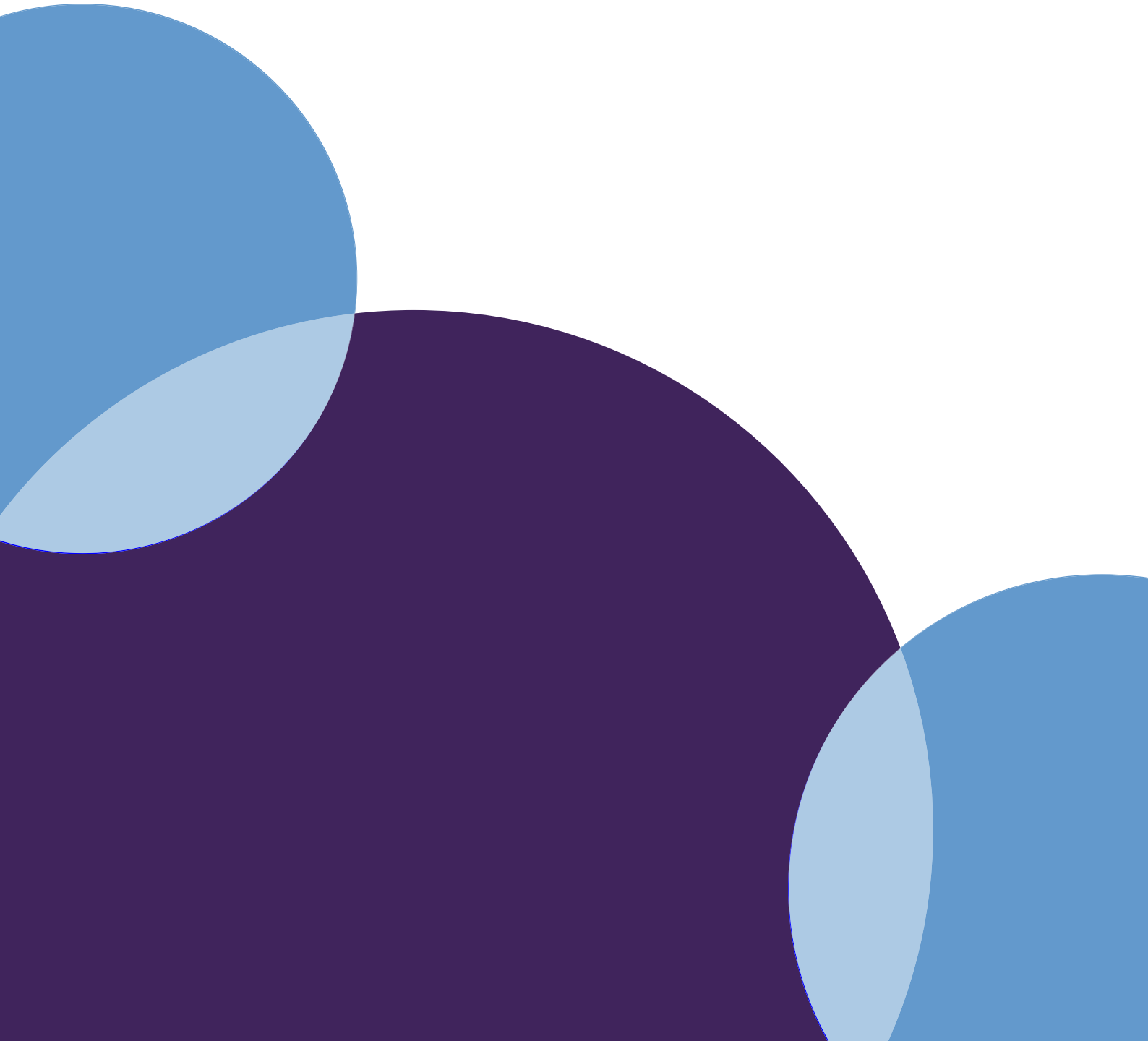
HTA
Human Tissue Authority

2024/25 review

Human Tissue Authority



A message from Lynne Berry, Chair

I am pleased to reflect on the work of the Human Tissue Authority (HTA) and proud of the achievements of our colleagues and partners during the last year. It has been an important period for the HTA as we have focused on maintaining trust in the use of human tissue and cells at a time of considerable public interest in many aspects of our work.

We remain committed to our vision for the safe and trusted use of human tissue and to our mission of being an excellent and proportionate regulator, basing our approach on principles of consent and safety, and on sustaining public and professional confidence in our work.

We launched a new three-year strategy in July 2024 which now underpins our activities. We can already see the results of this approach, for example, by continuing to deliver against an increased target of inspections for the third year running, introducing new compliance models and undertaking unannounced visits in the Post Mortem sector.

The strategy builds on these achievements and signals our intention by the end of this period to be:

- more outcome focused and proportionate in our approach and more able to use our authoritative and expert voice to bring about change in areas of concern
- more consistent and evidence-based both in our risk assessments and the corrective action taken
- recognised as an invaluable partner in the regulation and growth of the life sciences
- less reliant on manual processes, with strengthened digital capacity and capability
- able to demonstrate a continuing commitment to investing in and developing our workforce.

We have already made considerable progress, as shown in this review, and the Board and I look forward to seeing continuing progress in the next period as the HTA delivers the next stages of the strategy.

Lynne Berry CBE
Chair, Human Tissue Authority

Maintaining trust in the safe use of human tissue

The HTA is a regulator set up in 2005 following events in the 1990s that revealed a culture in hospitals of removing and retaining human organs and tissue without consent. The legislation that established us not only addressed this issue but also updated and brought together other laws that relate to human tissue and organs.

Patient safety and maintaining public trust and confidence in the use of human tissue and cells is at the heart of what we do. To achieve this, we license and inspect organisations that remove, store and use human tissue for research, medical treatment, post-mortem examination, education and training, and display in public. We also work to ensure organ and stem cell donations from living people for the purpose of transplantation do not involve any reward or coercion.

We are funded in part from Grant-in-Aid from the Department of Health and Social Care (DHSC) and the Devolved Administrations. However, the majority of our funding comes from fees paid by the establishments we license. It is therefore important that the HTA operates in a lean and proportionate fashion, ensuring we offer good value to taxpayers and our licensed establishments, whilst remaining a resolutely robust regulator.

Last year's annual review highlighted how, over the preceding three years, we had improved efficiency and productivity by increasing our target for the number of annual inspections on existing licences from 140 to 222 per year, up by over 50%.

Building on this, in July 2024 we launched a new three-year strategy, setting out our vision for regulating the safe and trusted use of human tissue, cells and organs. This strategy sets out four key priorities:

Approach to regulation: to deliver effective, proportionate regulation which protects confidence in the use of human tissue and organs. This involves being risk-based and responsive to changes and adaptable to future challenges

Trust and confidence: to be a trusted and expert voice on the storage and use of human tissue, cells and organs. The HTA's credibility enables it to shine a light on performance and practices in the sectors it regulates, underpinned by our principles of equality, diversity and inclusion

Use of information: to use data and intelligence to inform regulatory actions and improve standards. This involves applying insights from data and expertise to strengthen regulation and support the sectors the HTA oversees

Efficiency and effectiveness: to ensure resources are used wisely, delivering value for money whilst maintaining high standards. This includes modernising systems and processes to maximise impact and improve the regulatory experience for stakeholders

This year's review highlights the progress we have made in the first year of our new strategy, underpinned by our four core values of collaboration, openness, respect and excellence.

Key metrics

Inspections carried out

223

We inspected around a quarter of all of our licensed establishments during 2024/25

Shortfalls identified

902

We identified 902 shortfalls in 2024/25 as part of our ongoing assessment of compliance

Licence Variations

874

We processed 874 updates to existing licences and reviewed 28 new applications

Average number of shortfalls per inspection

4

On average, we found 4 shortfalls per inspection. However, this varied between sector, with more being found in Post Mortem (6.4) and Human Application (4.1)

Shortfalls levels

63%

Almost two thirds of all shortfalls identified we classed as “minor”

Living organ donations

1,115

We approved 1,115 living organ donations – or on average, around 3 every day of the year

General enquiries

1,278

General enquiries were received in 2024/25

Stakeholder newsletter

10,000

Our quarterly newsletter is sent to over 10,000 individuals and organisations across all regulated sectors.

Key highlights

Q1

- We published revised guidelines on reporting incidents in the Post Mortem sector to ensure establishments are informed of updated protocols and to adjust their policies and procedures accordingly.

- We published guidance and updated key stakeholders and clinicians of the changes brought in by the new Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024, which came into force on 1 April 2024.

Q2

- We published the HTA's review of 2023/24 and our annual report and accounts.

- We launched our new three-year strategy for 2024-2027, setting out our ambitions and priorities for the period.

- We hosted a Stakeholder Event focused on the safe and trusted use of human tissue. This event brought together our Board, senior management team, and sector colleagues to share insights, challenges, and future plans.

- In response to the Independent Pregnancy Loss Review, we reviewed and updated our guidance on the disposal of pregnancy loss remains. To inform this we carried out extensive stakeholder consultation with over 40 organisations

- We commenced our unannounced inspection programme in the Post Mortem sector.

Q3

- We presented at the British Transplant Society's Annual Congress on the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024.

- We shared our first annual horizon scanning report with the HTA Board, identifying a number of high-priority topics which have helped inform our work and resource allocation for 2025/26.

- We launched RIMI, our Regulatory Insight Model and Index, an internal data tool to aid regulatory oversight.

Q4

- We worked with the baby loss charity, Sands, to support them to update their Post Mortem consent form in line with current perinatal Post Mortem practices and policies and revised professional guidelines.

- We joined law enforcement experts and academics at a conference hosted by the Metropolitan Police on trafficking in persons for organ removal.

- We updated our Memorandum of Understanding (MoU) with the UK Accreditation Service (UKAS) as part of our ongoing commitment to strengthening our collaboration with others in the system to improve the experience of those we regulate.

Approach to regulation

Assessing compliance, identifying shortfalls and serious incidents

Sustaining public and professional confidence in the safe and trusted use of human tissue is at the core of what we do. Our approach to regulation and superintending compliance with legislation and the standards we set is geared around delivering this.

To maintain this public and professional confidence and to retain our reputation as an excellent regulator, we recognise that our approach to regulation needs to continually evolve and adapt to ensure we are able to anticipate and respond proportionately to new and emerging technologies or practices, and to changes in levels of risk across the sectors we regulate.

Engaging with our licensed establishments and sectors, together with other stakeholders, is a vital aspect of this. Throughout 2024/25 we continued to focus on maintaining a high level of direct engagement with the 992[1] establishments we license, so that we remain well-connected with the sectors we regulate and continue to gain assurance that our standards are being met. See Figure 1 for information on the number of main and satellite licences in each of the sectors we regulate and the number of inspections we undertook in each of them in 2024/25.

One way in which we achieve this direct engagement is through our inspections. In the three years preceding 2024/25, we increased our target for the number of annual inspections on existing licences by over 50% - from 140 to 222 per year. We continued to deliver this ambitious target in 2024/25, delivering 223 inspections (including 25 unannounced inspections) on existing licences over the course of the year as shown in Figure 2. The majority of these inspections (69%) were of establishments in the Post Mortem and Human Application sectors, reflecting the sectors we consider at greatest risk of non-compliance with our standards.

Of these 223 inspections, 100 were full inspections; 93 were focused inspections; 13 were Evaluated Self Assessments; and 17 were other types of inspections, including follow-ups to corrective and preventative actions (CAPA) plans.

We welcome and actively seek feedback as part of our inspection process. We regularly review this feedback, examples of which are highlighted throughout this annual review, to learn from and improve our regulatory approach and inspection processes.

[1] the figure of 992 includes main and satellite licenses and is correct as of 31 March 2025.

Figure 1: Number of inspections and licences in each sector, 2024/25

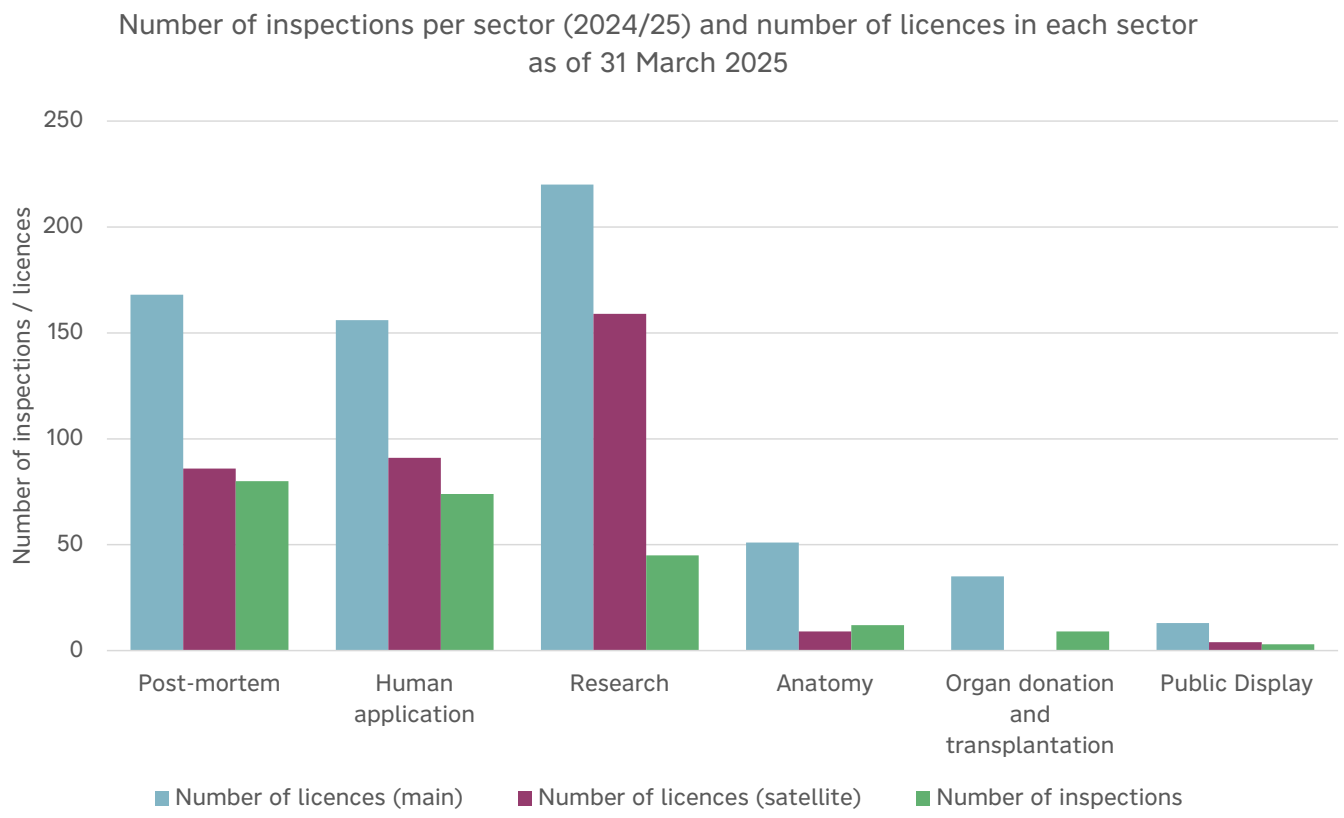
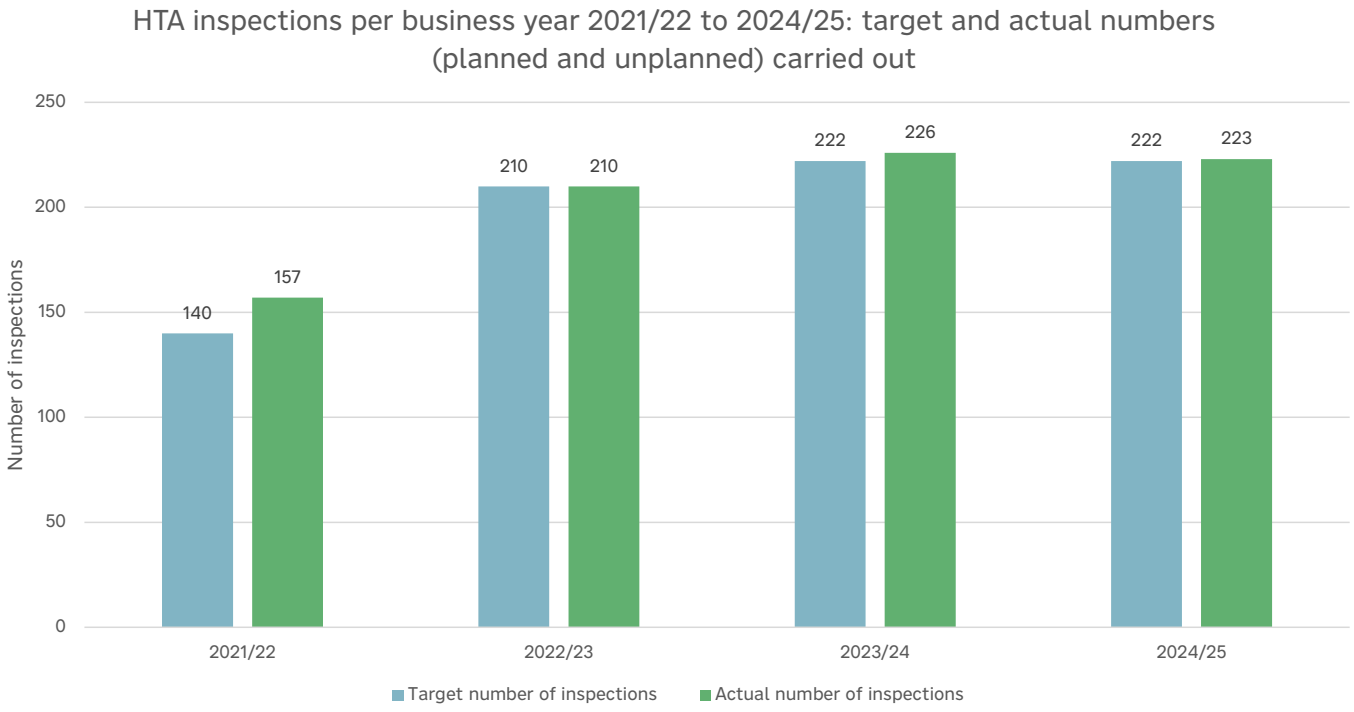


Figure 2: Actual and target number of inspections carried out 2021/22 to 2024/25



In addition to delivering 223 inspections, we also managed 874 changes to existing licences, including licence variations requiring formal assessment. We also carried out 28 new licence application assessments. Assessing these new applications, including carrying out site visits, is a vital part of our regulatory function to ensure that establishments cannot carry on licensable activity unless they meet our standards. This ensures unsuitable premises are not licensed and that those which are licenced are set off on a sound regulatory footing thereby reducing future non-compliance risks.

> Despite it feeling like a friendly inspection, I was also very satisfied that we were being challenged appropriately, but also given advice/ having things pointed out that, despite not within the scope of the investigation, were relevant to other standards – this was very helpful.
>
> – Feedback from an inspection

Shortfalls

When we inspect an establishment, we review operational policies processes and procedures to assess compliance against our licensing standards. This can include reviewing documentation, incident and consent records and carrying out sample testing of holdings of tissue to check consent, maintenance of traceability and suitability of storage arrangements. We also assess the suitability of premises and practice, including by observing activities as carried out (as compared to how they are documented) and conducting interviews and discussions with a range of staff.

> The Regulation Manager was very open throughout the inspection both pre and on site. They explained to each group clearly what the process was, and explained shortfalls, and advisories throughout the process.
>
> – Feedback from an inspection

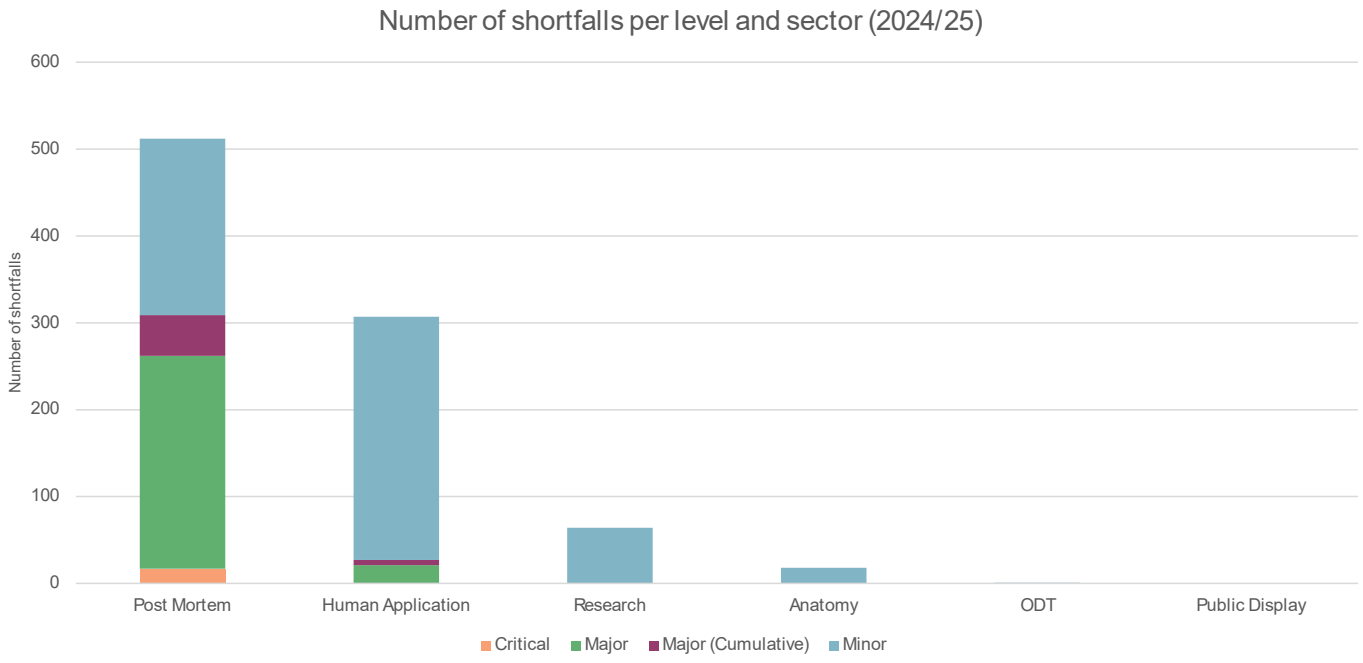
Where we identify that standards are not met, we assess the criticality of shortfalls, which we categorise as minor, major or critical.

In 2024/25, we identified 902 shortfalls during the 223 inspections we carried out and worked with our licensed establishments to identify the steps they needed to take to meet our standards. We also gave practical advice on matters within our remit that do not amount to a failure to meet our standards but where we identify that practice could be improved.

Across all sectors, almost two thirds (63%) of the 902 shortfalls were classified as ‘minor’. No ‘major’ or ‘critical’ shortfalls were found during our inspections of Research, Anatomy, Public Display or Anatomy sector establishments.

In line with previous years, most of the major or critical shortfalls were identified in the Post Mortem sector, with a smaller number also identified in Human Anatomy, as highlighted in Figure 3.

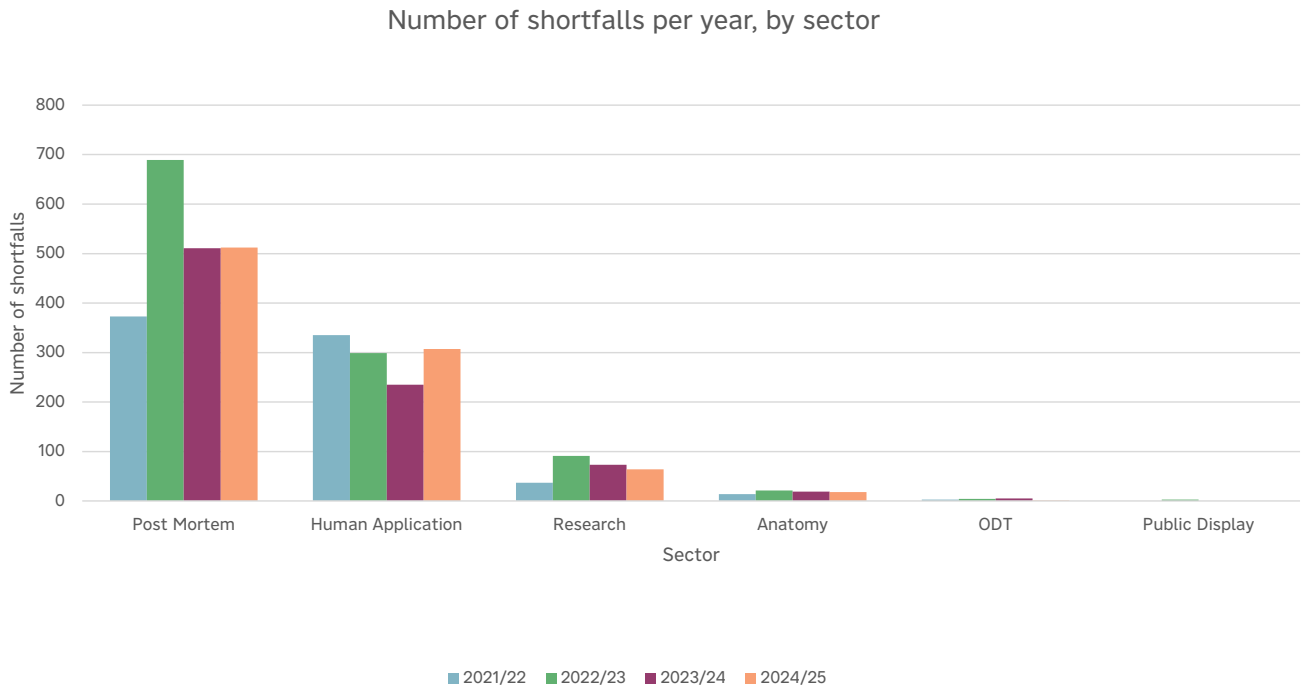
Figure 3: Number and level of shortfalls by sector (2024/25)



Overall more shortfalls (of any category) are found on average per inspection in these two sectors than all sectors as shown in figures 4 and 5. This underpins our approach to focus the majority of our inspections in these sectors and to continue to take action to drive up standards in the Post Mortem sector in particular, as described later in this Annual Review.

> “As the Designated Individual, I was interviewed alone towards the end of the day. However, the inspection had slightly over-run therefore I was mindful of time restrictions which did not leave as much time as would have been ideal for open discussion.”
>
> – Feedback from an inspection

Figure 4: Number of shortfalls by sector 2021/22 to 2024/25



> I would suggest including not only shortfalls but good practice on the reports as they can be a learning tool for other establishments to set up new practices and pathways.
>
> – Feedback from an inspection [2]

[2] We use feedback from our inspections to continually review our inspection processes and regulatory approach. Our inspection reports remain exception based, but we share best practice and learnings on our website in guidance, through blogs and in our quarterly newsletter. This ensures our inspections remain robust whilst supporting sector-wide learning and development.

Figure 5: Average number of shortfalls per inspection 2024/25

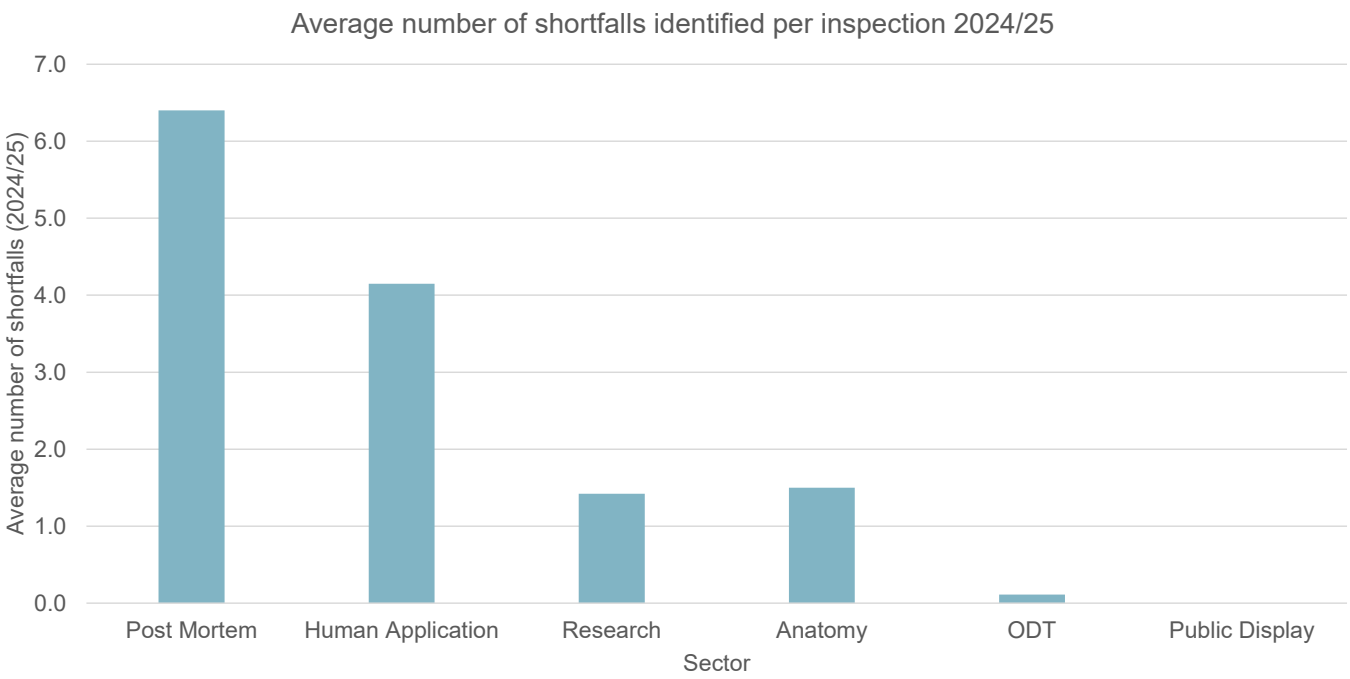
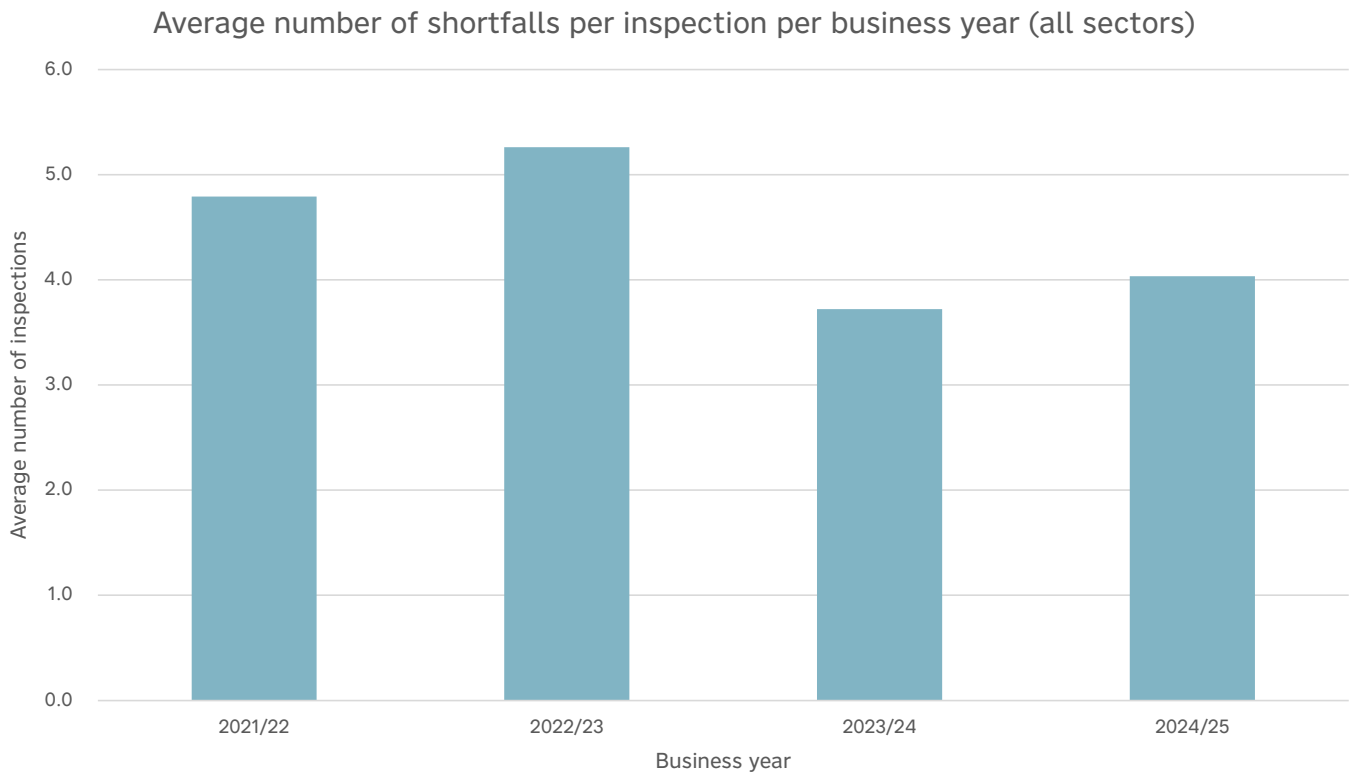


Figure 6: Average number of shortfalls per inspection 2021/22 to 2024/25



The complexity of HTA-regulated activities and of the broader regulatory landscape means we are not regulating in isolation. Collaborating with other regulators and organisations helps ensure our approach is proportionate, avoids duplication, supports the achievement of standards and does not hinder or stifle innovation or development.

During 2024/25 we undertook a data collection exercise to help better understand who else regulates, licences and/or accredits our licenced establishments. We will use this information to continue to strengthen how we work with others to reduce regulatory and administrative burden. As part of this, we have been reviewing and updating Memorandums of Understanding with a number of key organisations, including the Care Quality Commission (CQC) and the United Kingdom Accreditation Service (UKAS).

Case study: Maintaining research excellence through compliance: A case study in addressing HTA inspection findings

During a routine inspection of a research sector establishment, the HTA inspector identified three minor shortfalls. The inspection took place during a period of significant operational changes, including the appointment of a new Designated Individual (DI), Corporate Licence Holder contact, 18 new Persons Designate and the addition of a satellite site.

The inspection revealed three specific areas requiring improvement in the establishment's compliance with HTA standards relating to their standard operating procedures (SOPs), gaps in sample traceability and risk assessments.

The establishment responded promptly to our findings and addressed all the shortfalls before the inspection report was finalised. Their timely corrective actions significantly enhanced governance arrangements across the establishment and effectively restored complete sample traceability thereby reducing the risk of loss or misuse of human tissue.

Building on this experience, the establishment's DI has committed to implementing several proactive measures to prevent similar issues in the future. These include introducing a formal mechanism to monitor SOP review cycles, improving systems to track Research Ethics Committee approval expiry dates, and enhanced training provision for both staff and visitors handling human tissue.

The case demonstrates how timely, constructive responses to regulatory findings can drive meaningful improvements in research governance. It also highlights the importance of robust oversight mechanisms, particularly during periods of operational change and staff transition.

Serious incidents

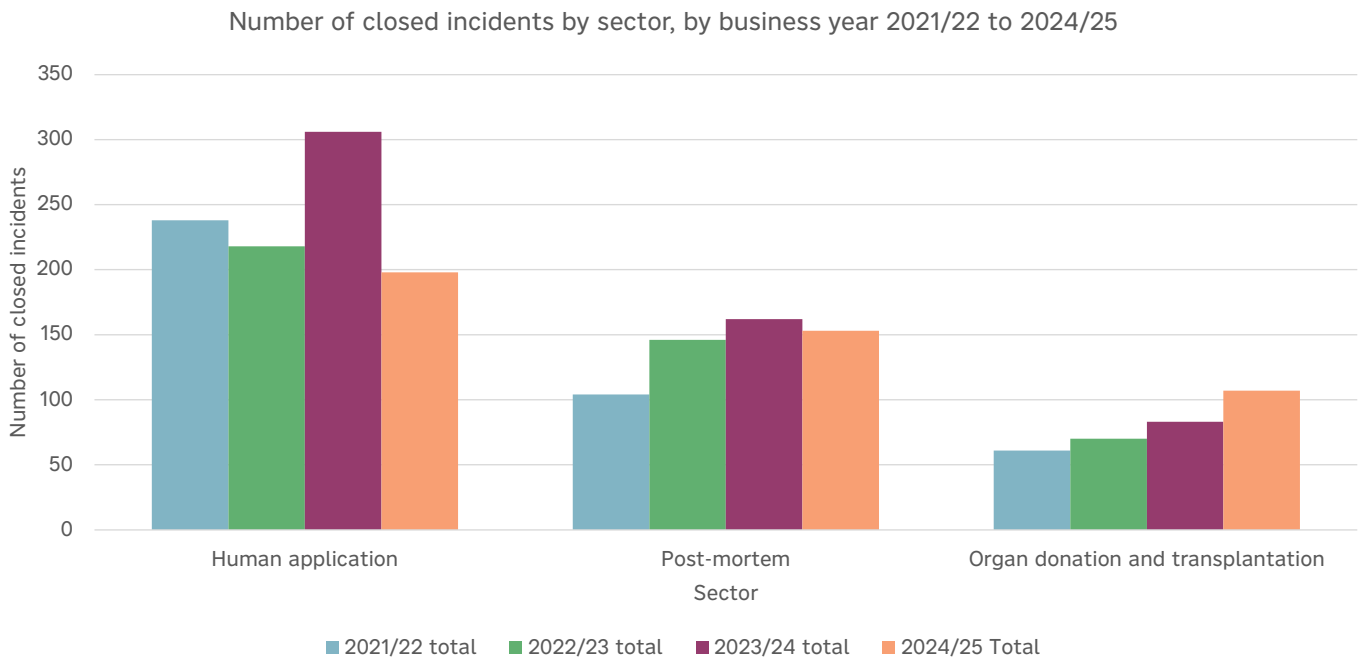
To maintain public confidence in the safe use of organs and tissues, and in the dignified treatment of the deceased, licensed establishments should embed a culture of openness and continuous learning. To ensure that incidents reportable to the HTA are investigated thoroughly and that appropriate actions are taken, licensed establishments in those sectors where this framework exists (currently Human Application (HA), Organ Donation and Transplantation (ODT) and Post Mortem are required to report certain categories of incident to the HTA.

We review incidents routinely when we inspect an establishment to ensure they have robust systems and processes in place for identifying and reporting them. We also use the data to look for trends in the types of HTA-reportable incidents to inform risk profiling.

In the ODT sector, establishments are required to report incidents to NHS Blood and Transplant (NHSBT) who carry out an investigation on the HTA's behalf under a Service Level Agreement. Where an incident has been deemed to be a Serious Adverse Event or Serious Adverse Reaction (SAEAR), a final report is submitted to the HTA for consideration.

As shown in Figure 7, a total of 458 reported incidents were closed during 2024/25 across these three sectors: 198 SAEARs in the HA sector, 107 SAEARs in the ODT sector, and 157 HTA Reportable Incidents (HTARIs) in the Post Mortem sector.

Figure 7: Number of closed incidents per sector 2021/22 to 2024/25



Developing and strengthening our regulatory toolbox

To increase productivity and maintain inspection levels, we have continued to adapt our approach to regulation in line with our strategy. Throughout 2024/25 we have increasingly focused our resources on areas at greatest risk of non-compliance, taking a more proportionate approach in areas and sectors of lower risk. For example, we continued to make use of Virtual Regulatory Assessments (VRAs) and Evaluated Self Assessments in our Research sector.

Since Autumn 2024, audits conducted in the Organ Donation & Transplantation sector have had a focus on the living donation pathway and ensuring that transplant centres understand the obligations of relevant clinicians under '*The Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024'*, which came into effect on 1 April 2024.[3] This is in addition to assessing compliance with '*The Quality and Safety of Organs Intended for Transplantation Regulations 2012'*.[4]

Areas of higher risk include the Post Mortem sector, where we introduced Evidential Compliance Assessments (ECAs) (see below) and trialled the routine use of unannounced visits. This has helped strengthen safety measures across this sector, as we seek the highest standards of safety, dignity and respect.

Driving improvements within the Post Mortem sector

Part of our role is to ensure Post Mortem examinations and related activities, such as storage of relevant material, are undertaken on suitable, licensed premises with appropriate consent or under the authority of the coroner. Last year we recognised that further action was required in the Post Mortem sector to further embed understanding of and compliance with our updated guidance on security-related standards, aimed at increasing the protection and dignity of the deceased. This was identified through a data-collection exercise, our shortfall and incident data, and the findings from the Phase 1 report of Sir Jonathan Michael's independent inquiry into David Fuller's offending.

In April 2024, we published revised guidance for establishments in the sector to clarify requirements about the submission and completion of HTA Reportable Incidents (HTARIs). In March 2024 we delivered a series of mandatory webinars on security standards for all Designated Individuals in the Post Mortem sector whose establishments store bodies. This was in preparation for introducing Evidential Compliance Assessments (ECAs) in the first two quarters of 2024/25.

The newly developed ECA process required establishments to provide evidence to demonstrate compliance with a sub-set of standards, in this case, those relating to security and quality and governance. Establishments' submissions were assessed as being either 'compliant', 'compliant with advice and guidance' or 'non-compliant'. Follow-up work in the second half of the year included on-site inspections of those establishments assessed as having been 'non-compliant' in their ECA, with continued oversight where relevant of establishment Corrective and Preventative Action Plans if the inspections resulted in findings of shortfalls.

[3] https://www.legislation.gov.uk/uksi/2024/262/made, 2024 SI No. 262
[4] https://www.legislation.gov.uk/uksi/2012/1501/introduction/made, 2012 SI No. 1501

Finally, we notified all establishments that from September 2024, on a trial basis, the inspections in the Post Mortem sector would routinely be carried out on an unannounced basis, with further information provided to enable establishments to be prepared for inspections, including guidance about documentation they should be able to produce.

> It's always a shock to get a call and drop everything, but the HTAs inspectors made the process easy. My mortuary manager commented that she would rather have this system.
>
> – Feedback from an inspection

Case Study: Unannounced inspection – Post Mortem licenced establishment

In October 2024, we carried out an unannounced inspection at a licensed establishment in England, where all 72 Post Mortem Standards were inspected. As part of this, we identified that an extension lead was being used for the electrical supply for the bone saw. The lead was being trailed from the post mortem room to the body store and there was a risk both of cross contamination, as well as of electrocution due to the cable sitting in water.

This shortfall would not have been identified during an announced inspection as historically the establishment did not undertake post mortem examinations on the day of an announced inspection.

The shortfall was discussed with the Designated Individual on the day of inspection, reflected in our published inspection report where after it was managed through our corrective and preventative actions (CAPA) process to ensure appropriate action was taken to rectify it.

Unannounced inspections have largely been well received by Designated Individuals. Shortfalls were discovered that may not have been identified in inspections conducted with prior notice. These have included the discovery of serious security breaches, risks of injury to staff due to issues with electrical equipment and the absence of a Designated Individual at one establishment that had failed to notify the HTA when the staff member left.

> Unannounced visits have reinforced the need to maintain high standards.
>
> – Feedback from an inspection

The HTA is working to support Designated Individuals through regular dialogue (including at a newly established sector-led forum) and consideration of further developing guidance in key areas, along with specific support for new Designated Individuals. In addition, through regular engagement with the funeral sector, we maintain awareness of matters that are outside of the HTA's remit but can be relevant to those working in the Post Mortem sector, given the role of Funeral Directors in receipt and release of bodies and, on occasion, in providing contingency storage.

> Although a broad update was issued a couple of weeks prior to the unannounced inspection, there was not time to organise staff availability to ensure time was well spent facilitating the inspection whilst ensuring service delivery continuity.
>
> – Feedback from an inspection [5]

[5] We use feedback from our inspections to inform changes to our inspection processes and regulatory approach. Feedback such as this helps us to continue to adapt and improve our scheduling of inspections.

Case study: Ensuring regulatory compliance in the Post Mortem sector

Following findings of non-compliance relating to security in an Evidential Compliance Assessment (ECA) in July 2024 we brought forward a scheduled inspection of a Post Mortem establishment by six months to November 2024 and assessed against all 72 Post Mortem standards. In doing so, the inspection team discovered that the Designated Individual (DI) had stepped down a fortnight previously and that no application had been made for a replacement. This created a significant regulatory gap, as it is a legal obligation for there to be a DI in post to ensure there is a responsible person able to oversee day-to-day activities under the licence. The absence of a DI meant there were significant risks of inadequate oversight of activities, including the management of any HTA Reportable Incidents (HTARIs). This may have negatively impacted the establishment's ability to maintain and protect the dignity of the deceased. There was also no Mortuary Manager in post.

Nine major and two minor shortfalls were identified at the inspection, with a major shortfall against standard PFE1(e) relating to the oversight of staff and visitors entering the mortuary. The HTA team took immediate action, including requiring the licence holder to urgently identify a proposed new DI, whose suitability could then be assessed by the HTA, in line with usual practice.

The establishment recognised the importance of regulatory compliance and responded positively to the HTA's intervention. A new DI was proposed and assessed by the HTA as suitable, with the relevant formal licence variation having been implemented before the draft inspection report was issued. This enabled legal obligations to be met and meant the new DI was able to agree and oversee the establishment's corrective and preventative actions from the outset.

Sir Jonathan Michael's Independent Inquiry Phase 2 report has highlighted the importance of clear routes of escalation on HTA Post Mortem licences from the operational level to organisational Board level.[6] With no DI in post, it was unclear how escalation of serious incidents and concerns, including the shortfalls identified at inspection, would be accomplished. The ECA process was instrumental in identifying the regulatory risks, resulting in the accelerated unannounced inspection and the constructive responses to that inspection by the establishment.

The shortfalls identified are being addressed, with progress being overseen by the HTA through the Corrective and Preventative Action (CAPA) process.

[6] Phase 2 – Independent Inquiry into the issues raised by the David Fuller case

Sir Jonathan Michael's Independent Inquiry into the issues raised by the David Fuller case published its final report (Phase 2) in July 2025.

The Government is considering the recommendations made and has committed to providing an interim response in Winter and a final response next year.[7]

The HTA is carefully examining the findings and recommendations and will continue to actively seek opportunities to address risks to the dignity of the deceased within our remit and to support the implementation of any recommendations that are accepted by Ministers.

Meanwhile, we continue to keep under review our approach to ensuring that licensed establishments appropriately safeguard the dignity of the deceased in line with our regulatory requirements. For example, over recent years, we have:

- revised our guidance to relevant licensing standards in the Post Mortem and Anatomy sectors to clarify our expectations on how to ensure there are suitable security measures in place and effective oversight of access;
- implemented the Evidential Compliance Assessment process and carried out a security-focused Data Collection Exercise (in 2022 and 2024);
- introduced unannounced inspections;
- at the request of the Welsh Government, carried out a limited series of voluntary advisory inspections of unlicensed body stores under Health Boards in Wales whilst carrying out inspections of licensed premises.

The HTA remains committed to learning lessons and playing our part to improve practice in the management and storage of the deceased to help licensed establishments prevent anything similar happening again.

Supporting innovation

We use our expertise to support licensed establishments' use of the latest technologies in accordance with human tissue legislation. Throughout all our regulatory activities, we aim to drive up standards whilst actively supporting innovation. In the Human Application (HA) sector, we do this by adapting our licensing approach to keep pace with innovation and changing practice.

We also work with other organisations to help shape the UK's approach to new and emerging technologies and science. An example of this is in relation to xenotransplantation. While the Human Tissue Act (2004) is centred on human tissue and consent principles, as a member of DHSC's xenotransplantation steering group, the HTA is bringing its regulatory expertise to inform any potential future regulation in this area.

In the HA sector, we license and inspect establishments that procure, process, store, distribute, import and export tissue for human use, or carry out donor testing. These include a range of organisations such as hospitals, stem cell laboratories and tissue banks that can use a variety of tissues and cells (such as bone, skin, heart valves and stem cells). It is a diverse sector where there has been considerable innovation and growth.

[7] Fuller Inquiry Phase 2 Report - Hansard - UK Parliament

Our proportionate and effective regulation supports the UK's position as a global leader in life sciences innovation. By providing a trusted regulatory framework that is respected internationally, we help create an environment where research and development can thrive, ultimately bringing new treatments to UK patients faster while maintaining essential safety standards.

Avoiding delays in patient treatment

Under legislation, establishments are required to notify us before they start new licensable activities or vary methodologies. This is to ensure that tissue used for patient treatment meets regulatory requirements for quality and safety.

In 2024/25, we received 303 licence variation requests relating to patient treatment within the Human Application sector. While the majority were routine, where requests were considered time-critical they were prioritised to avoid any material delays to patient treatment. By collaborating at pace with establishments, we were able to rapidly authorise licence variations and enable patients to access the urgent care they needed.

In emergencies, we can directly authorise any person to distribute, import or export tissue for human use outside of the usual licensing framework. These unforeseen events can be brought about by factors such as a change in a patient's circumstances or the availability of highly matched human tissue. To do this, we worked closely with establishments to gain assurance about the planned treatment, ensure any risks to patient safety were appropriately considered and managed, and ensure patients were appropriately informed and provided proper consent.

By prioritising urgent requests to amend licences or providing emergency authorisations, we continue to ensure that establishments meet legislative requirements. This approach also enables the use of innovative procedures without compromising patient treatment and care.

Case study – Human Application storage licensing

Under the Human Tissue (Quality & Safety for Human Application Regulations) 2007 (as amended), establishments need to hold an HTA licence in order to store, for more than 48 hours, any human tissue or cells intended for human application.

This requirement exists to help ensure that establishments have suitable equipment and procedures in place for the storage of tissue and cells that are used to treat patients.

When the legislation was introduced, the HTA worked with a range of stakeholders to establish which storage activities fell within the scope of this licensing requirement. The upshot of that work was a position that exempted the storage of acellular products by end users from this licensing requirement.

Over the last 18 months, the HTA has been exploring whether additional products could be similarly exempted on the basis that they do not need to be maintained under carefully controlled conditions for defined periods of time, with the aim of reducing the regulatory burden where it is safe to do so.

In September 2024, following a comprehensive review of the legislation and stability data provided by a UK manufacturer of a tissue product that can be stored at room temperature for extended periods prior to end use, the HTA agreed that the product could be stored on unlicensed premises for up to seven days.

Although this is a relatively modest extension to the period for which a licence isn’t needed, in the short-term this position will address some of the logistical challenges that stem from current ‘just in time’ supply models, whilst not increasing risks to patients. In the future, additional extensions may be possible, further reducing costs to establishments, reducing wastage and increasing treatment options for patients.

Trust and confidence

We are an effective regulator that maintains public confidence through our licensing, inspection and authorisation processes and by being open and transparent. Through our approach to regulation and inspection, patients and families can be confident that their organs and tissue will be used in line with their wishes and handled with care.

We use the confidence and trust in us to highlight where things are working well and where they can improve. As part of this, we have continued through 2024/25 to publish biannual open datasets on inspections, shortfalls, incidents and enquiries. By routinely publishing these datasets, we increase transparency in how human tissue and cells are used.

Collaboration with others in the system to improve the experience of those we regulate is a key tenet of our approach and strategy. For example, during 2024/25 we:

- supported the work of various UK advisory committees, including the Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee; the Advisory Committee on the Safety of Blood, Tissues and Organs; and the Standing Advisory Committee for Tissues and Cell Therapy Products;

- contributed to Royal College of Pathologist's (RCPath) Pathology Delivery Board and attended the NHS Pathology Conference in February 2025, which provided an opportunity to engage with key stakeholders and gain insight into developments in Post Mortem pathology for consideration in any future update of HTA guidance;

- provided guidance about HTA licensing requirements to the Northern Ireland Pathology Blueprint programme;

- provided guidance on licensing and regulatory requirements in the lead up to a Parliamentary roundtable event looking at apheresis capacity in the UK and its impact on Advanced Therapy Medicinal Products (ATMP) manufacture;

- worked closely with NHS England and the baby loss charity, Sands, to support them to update their perinatal Post Mortem consent package, and

- undertook several activities relating to ocular tissue supply, including:
    - granting licences to enable ocular tissue to be imported from third countries;
    - meeting with suppliers from the US and the EU to help them better understand UK regulatory and licensing requirements; and
    - liaising with NHS England on supply issues, service delivery and emergency import authorisations.

> Sands undertook a collaborative process to update the template perinatal post-mortem consent form. We welcomed input from clinical, NHS and Royal College stakeholders alongside bereaved parents and the HTA. Our joint working with the HTA to finalise and share the form has been constructive, thoughtful and positive. We have greatly appreciated the sensitivity to the needs of parents alongside those of professionals, and openness to finding ways to improve this very difficult process within the regulatory requirements. Many thanks for your support and generosity with your time.
>
> - Sands

Approving living organ donations

We have a unique role as a regulator where we assess all cases of living organ donation in the UK against legislative criteria. To make a decision to approve a donation we need to be satisfied that:

- a donor has not been and will not be given a reward for their donation;
- a donor has not been coerced or placed under duress to donate; and
- a donor has provided valid consent for the removal of their organ.

In 2024/25, we approved 1,115 living organ donations, a comparable number with the previous business year (of 1,119) as highlighted in Figures 8 and 9. As noted in last year's annual review, the number of living organ donations approved has recovered after the number of living organ donations reduced to 561 during 2020/21 due to the Covid-19 pandemic.

Figure 8: Proportion of approved living organ donations, by country 2024/25

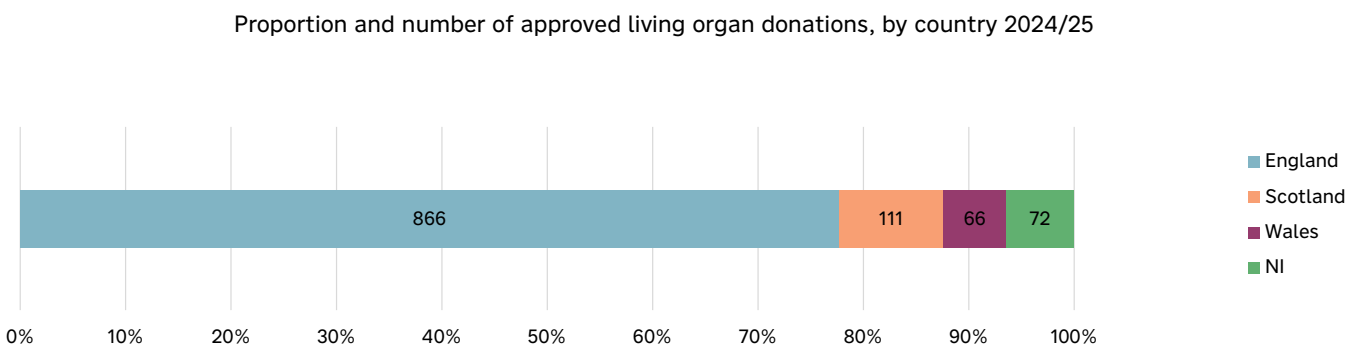
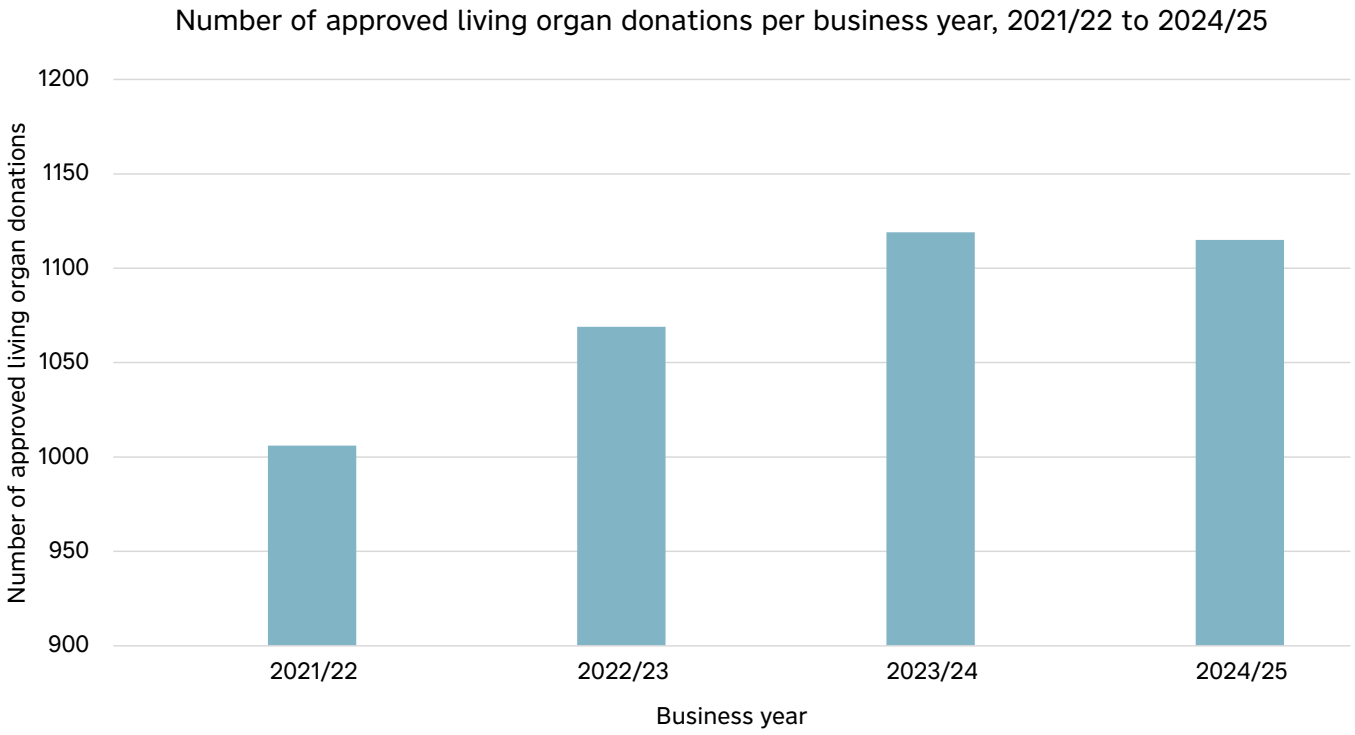


Figure 9: Number of approved living organ donations 2021/22 to 2024/25



On 1 April 2024, the Government introduced the Human Tissue Act 2004 (Supply of Information about Transplants) Regulations 2024. These Regulations place a duty on 'relevant clinicians' in England, Wales and Northern Ireland to inform the HTA:

- if they have a reasonable suspicion that an organ donation and transplantation-related offence may have taken place; or
- if they are made aware that a patient has received an organ transplant outside the UK.

The HTA considers information reported by clinicians under the Regulations. In instances where we believe an offence may have been committed, the case is referred to the police.

The HTA has published guidance to support clinicians and throughout the year we have attended various events to help raise awareness and answer questions about the Regulations.

We have also delivered further training and education sessions during 2024/25 in collaboration with the Metropolitan Police to Independent Assessors (who interview donors and recipients on behalf of the HTA to explore whether legislative requirements are met) and other specialist NHS staff. This has helped ensure that frontline healthcare staff have the opportunity to improve their knowledge and understanding of the signs and indicators of human trafficking.

> The Transplant team at the HTA consistently work in tandem with the clinical community to ensure timely regulatory compliance, ensuring donors and recipients receive optimum care. Evolving regulatory changes are highlighted appropriately and due consideration to the impact on donation and transplantation explored. Regular interaction ensures continued confidence for both the public and health care professionals.
>
> - Associate Medical Director of an Arm's Length Body

The HTA has received a regular flow of cases reported to us under these Regulations since their introduction. As of 31 March 2025, we had received 39 reports. Each of these cases required consideration as to whether referral to the police was warranted. We also received a number of reports that pre-date the introduction of the Regulations.

Since the implementation of the Regulations we have continued to build on existing relationships with law enforcement and clinical colleagues across England, Wales and Northern Ireland, such as the Modern Slavery and Organised Immigration Crime Unit and NHSBT. We also continued to forge new relationships to help further understanding of the requirements of the Regulations, both with colleagues in the UK and across Europe.

> Collaborating with the HTA on the implementation of these Regulations has led to improved understanding on the issue of organ trafficking. The HTA's professionalism and commitment has driven significant and timely changes while also strengthening the relationship between healthcare professionals and law enforcement.
>
> – Police Force stakeholder

SoHO regulation implementation

The Regulation on Standards of Quality and Safety for Substances of Human Origin (SoHO) Intended for Human Application came into force in the European Union (EU) in August 2024.

Under the Windsor Framework[8], the SoHO Regulation will apply in Northern Ireland but not Great Britain. The regulation expands quality and safety standards for substances of human origin with full implementation by August 2027. This represents a key shift that affects many healthcare providers and associated organisations across Northern Ireland.

We are actively preparing for the implementation of these regulations and in 2024/25 established a multi-phase project to support the introduction of this new regulatory framework in Northern Ireland. The first 'scoping' phase of the project focused on producing a gap analysis between existing and new requirements and raising awareness of the upcoming changes through various stakeholder engagement activities. This work has been undertaken in close partnership with DHSC and other relevant organisations affected by this regulatory change, reflecting our commitment to effective collaborative working.

The HTA is also working closely with DHSC to support them with their work in advising Ministers as to whether wider changes are required to UK legislation to align with EU regulations.

> "I really think the HTA are setting the standard on this work and being incredibly supportive to other organisations who are in this space as well."
>
> – Deputy Branch Head: Central Government Department

[8] The Windsor Framework - GOV.UK

Updating guidance for disposal of pregnancy loss remains

In response to the Independent Pregnancy Loss Review commissioned by DHSC and published in July 2023, the HTA supported work to review guidance on the disposal of pregnancy loss remains. This important update ensures that women are central to decision-making about what happens to their pregnancy remains following loss or termination before 24 weeks gestation. The revised guidance places particular emphasis on ensuring women have a clear understanding of the disposal options available to them and the importance of their wishes being respected and acted upon. This reinforces the HTA's core principles of dignity and consent in the handling of human tissue, while recognising the deeply personal nature of pregnancy loss.

To make sure the guidance was informed by diverse perspectives, the HTA ensured extensive stakeholder consultation with over 40 organisations representing various groups including faith communities, pregnancy centres, abortion providers, and professional medical bodies. This broad engagement was critical in developing guidance that is sensitive to different cultural, religious, and personal needs.

The updated guidance applies in England, Wales and Northern Ireland, providing consistent standards for healthcare professionals while still allowing flexibility to respond to individual circumstances. By establishing clear expectations for service providers responsible for the disposal of pregnancy loss remains, the HTA has created a framework that balances regulatory requirements with compassionate, person-centred care. By placing women's choices at the centre of care processes and working collaboratively across the healthcare system, the HTA continues to fulfil its mission of ensuring tissue is handled with dignity, proper consent, and in accordance with the highest standards of care.

Communicating with the public and professionals

The HTA has developed an annual communications and engagement plan focused on three key objectives: increasing awareness of our regulatory role in ensuring the safe handling of tissue, demonstrating our commitment to raising standards across the sectors we regulate, and showcasing our collaborative approach within the broader healthcare system.

Throughout 2024/25, we delivered a comprehensive stakeholder engagement programme to continue to help deliver our aim to maintain and enhance public and professional understanding and trust. Our quarterly newsletter reached over 10,000 subscribers, providing valuable updates on regulatory developments and guidance. We have organised sector-focused forums for the Post Mortem, Anatomy, Research and Public Display sectors, creating spaces for direct engagement with stakeholders.

A notable success was our September in-house engagement event, attended by representatives from across all the sectors we regulate. The event received excellent feedback, with 96% of attendees indicating they would attend future HTA events. Participants particularly valued the roundtable discussions, which provided opportunities to share experiences and discuss challenges. The Board noted that attendees praised the HTA's balanced regulatory approach, with staff members commended for their responsiveness and professional attitude.

To validate the feedback received at the event, we conducted a broader stakeholder survey, receiving over 300 responses from establishments across all sectors. Results showed that 84% of respondents felt clear about their roles and responsibilities. The survey highlighted stakeholder preferences for engagement channels and timing, with strongest support for quarterly engagement through webinars, newsletters, and annual conferences. Some areas for improvement were identified, with 26.8% of respondents mentioning training and development needs, and 17% suggesting the need for greater consistency in our guidance and documentation.

Number of website visits in 2024/25: 397,554 by 171,530 users

Popular web pages in 2024/25: Find a medical school (20,387 visits) and Relevant Material Under Human Tissue Act (17,544 visits)

Number of social media posts, views and reactions in 2024/25

Platform	Posts	Views	Average engagement rate
X	190	42,300	4.79
LinkedIn	117	42,761	7.23%
Facebook	68	5,874	5.25%

Our low cost digital communication activity delivers online and social media content to explain our role and share positive stories from our work and the establishments we regulate. This approach is proving effective, with an 87% increase in media enquiries since implementing our communications strategy. Connection across our social media channels remains stable, with strong engagement with our visual content.

Number of general enquiries

Category	2024/25 total	2022/23 total	2022/23 total	2021/22 total
Post Mortem	461	407	446	396
Human application	312	326	387	507
Research	261	325	294	292
Anatomy	140	79	75	79
Public display	18	18	24	27
Organ donation and transplantation	27	9	21	34
Other	59	98	59	50
Total	**1,278**	**1,262**	**1,306**	**1,385**

We are also enhancing our website accessibility, converting key guidance documents from PDF to HTML format to improve searchability. Converting into HTML also improves overall experience for the user. For example, after converting Code A to HTML, we saw a 58% reduction in PDF downloads as users chose to access the HTML content instead.

Use of information

Information and data from a range of sources provides valuable insight into risk and opportunities for improvement. The HTA's strategy for 2024-27 sets out how we aim to strengthen our use of information and intelligence to be more responsive and targeted in our regulatory activities and to highlight opportunities to be more efficient and lever changes in performance and practice.

Regulatory Insight Model & Index (RIMI) tool

As highlighted in our review of the previous business year, we have been developing a regulatory insight model to transform how we use data to regulate. Following a period of development and testing, we launched our new Regulatory Insight Model & Index (RIMI) tool in March 2025. This is a real step forward and provides us with greater insight into both individual establishments and themes and trends in the sectors we regulate.

Version 1 of the RIMI tool has initially been developed for internal use in three of our sectors. It uses data from six key indicators taken from our regulatory activities. Feedback from users has highlighted the benefits of providing consistent, useful information in a readily accessible way. We will build on this initial version through further development in 2025/26. In addition, the launch of RIMI has highlighted further opportunities to continue to explore the data we generate from our regulatory activities so that we can further develop our analysis of risk and targeted use of our resources in future years, in line with our strategic ambitions.

Horizon scanning

The UK is at the forefront of life sciences innovation, with the sector playing a vital role in the national economy and health strategy. Government initiatives, such as the UK Innovation Strategy, outline the need for a culture of innovation across all sectors, including healthcare.

In order to remain efficient and effective, regulators need to keep pace and adapt to scientific and technological innovations and developments without compromising standards or public safety.

During 2024/25, the HTA developed and introduced a streamlined horizon scanning process to help understand our position within this changing regulatory landscape. This process aims to identify current and emerging topics that could impact on the work of the HTA and our licensed establishments over the immediate, medium and longer-term. A first annual horizon scanning report was presented to the Board in March 2025. This identified a number of topics classified as high priority based on the HTA's prioritisation process which has helped inform our work and resource allocation for 2025/26.

Our horizon scanning process enables us to anticipate and appropriately regulate emerging technologies in tissue and cell therapies, ensuring UK citizens have safe access to cutting-edge medical treatments that can transform lives.

Efficient and effective

The HTA strives to operate in the most efficient and effective way, seeking an evidence-based positive impact on the regulation of human organs, tissues and cells. As highlighted above, during 2024/25 we have continued to adapt and develop our regulatory approach, taking an increasingly targeted and proportionate approach which focuses on areas of greatest risk.

As an executive non-departmental public body, the HTA is funded in part from Grant-in-Aid from DHSC and devolved administrations but the main source of income comes from licence fees charged to licensed establishments. Licence fees are set to recover the HTA's costs and whilst every effort has been made to streamline where possible, our costs have risen due to price rises as well as an increase in employer's National Insurance Contributions. This, plus the reduction in Grant-In-Aid, resulted in a need to increase above inflation the total fees recovered by the HTA from regulated sectors in 2024/25.

Recognising this, during 2024/25 we worked with our licensed establishments to rationalise licences to ensure they are not paying for any licensable activities they are not utilising. Within the Human Application sector, we have also introduced reduced main licence and satellite fees for:

- establishments located in Great Britain that are only licensed to import relevant material from suppliers based in the EU; and
- establishments located in Northern Ireland that are only licensed to import relevant material from suppliers based in Great Britain.

During 2024/25, we worked towards ensuring that our licence fees were paid in a timely manner. We have a robust credit control process that allows us to be flexible where our smaller establishments may struggle to pay their fees within our 28-day timeframe. In order not to over-burden them, we have on occasion offered a payment plan that allows establishments to pay their licence fees within a 6-month period. This is usually after much discussion with the establishment to gain an understanding of the issues they may be having. At the end of the 2024/25 business year, less than 1% of licence fees remained unpaid.

We are also committed to learning from other regulators experiences and to working with them to enhance how the wider system protects patient safety and the dignity of the deceased so that we are working in the most effective and impactful ways. In September 2024, the Boards and Senior Management Teams of the HTA and the Health Services Safety Investigation Body (HSSIB) met to share learning and experiences. We also undertook a Board Effectiveness Review in Quarter 4 2024/25. The actions identified will support us, alongside the four new HTA Board members recently appointed, to continue to strengthen and sustain our approach over the coming years during a time of potential change and opportunities for the HTA and health sector Arm's Length Bodies (ALBs) as a whole.

Digital & IT Strategy:

The HTA recognises the vital role that digital transformation will have over the coming years, as highlighted in the Government's *10 year health plan for England*[9] and in the Department for Science, Innovation and Technology's *Blueprint for modern digital Government*[10]. During 2024/25, we outlined an ambitious three-year Digital & IT Strategy to advance improvements in the delivery, management and compliance of IT systems across the HTA. This strategy is underpinned by a drive to ensure we have excellent cyber security and secure IT systems in place across the business.

The replacement of unsupported systems was a key focus during the 2024/25 business year and we have progressed vital work to ensure that our IT systems remain supported and patched against known vulnerabilities. This work has helped set firm foundations for ongoing improvements which will help us continue to make better use of data and ensure that our systems are more efficient and secure. The changes we have introduced will also enable us to progress our ambitions to digitalise more of our processes in the future and to standardise and simplify the collection of data from our licensed establishments used across our regulatory activities.

The investment in IT continues to be a primary objective of our Digital and IT Strategy, with improvements and upgrades identified in other areas to enhance our Cyber Security. In doing so, we will continue to work closely with our ALB counterparts to deliver a collaborative service, share working practices and experiences to best drive forward an IT system that utilises next-generation technologies.

People strategy

[9] 10 Year Health Plan for England: fit for the future - GOV.UK
[10] A blueprint for modern digital government - GOV.UK

We recognise the vital impact our staff have. Our People Strategy for 2025-2028, launched in March 2025, seeks to help support improvements and enhance staff experience at the HTA, supporting our people to be and to feel their best.

At its heart are the HTA's core values of collaboration, openness, respect and excellence. A positive, inclusive and collaborative environment is essential to the success of our organisation, and we recognise that our culture is the foundation upon which everything else is built. We have brought in expert resource to oversee and facilitate initial strategy roll-out and, in January 2025, we introduced a new staff forum to encourage and facilitate communication and engagement with everyone that works for the HTA.

Human Resources (HR) support shared services

The HTA continues to have a service level agreement in place for HR shared services with the Care Quality Commission (CQC). This includes support with recruitment, onboarding, advice and guidance, learning and development, organisational design and HR business partnering. We have recognised that further work is required to support the efficient use of the resources available. We have agreed with CQC new improvements to the way we work in partnership with them, whilst in parallel, managed to reduce the cost of the service provision.

We are alive to working constructively with health organisations in other areas, provided there is no conflicts of interest, such as other Arms Length Bodies, and where there is mutual benefit and the opportunity for better value for money.

Looking ahead

A message from Dr Colin Sullivan, our Chief Executive

Reflecting on the priorities we set ourselves and the measures of success outlined in the three-year strategy we published last year, it is clear that we have already made good progress:

Approach to regulation

We have maintained historically high inspection numbers for the third year running, by continuing to deploy and expand a range of different inspection approaches to achieve a greater degree of direct contact with the establishments we license. This has included introducing Evaluated Self Assessments in the Research sector, and Evidential Compliance Assessments and unannounced inspections in the Post Mortem sector.

Trust and confidence

A key focus during 2024/25 has been to continue to work collaboratively with partners to deliver public protection and build public trust and confidence in the use of human tissue.

We have worked in tandem with numerous partners throughout the year on issues which directly impact the sectors we regulate. This has included close working with law enforcement agencies and others in relation to new regulations (effective from April 2024) relating to the supply of information about transplants. We have also continued to work closely with DHSC and relevant organisations impacted by the Regulation on Standards of Quality and Safety for Substances of Human Origin (SoHO).

Use of information

We routinely publish quarterly datasets to promote openness and transparency in our activities. We have also taken steps to enhance our use of data to provide insight into the sectors we regulate. Our new Regulatory Insight Model & Index (RIMI) tool, launched in March 2025, now enables us to better tailor our inspection approach to target areas of greatest risk.

The introduction of a new horizon scanning process within the HTA will also enhance our responsiveness to new innovations and emerging scientific and technological developments.

Efficient and effective

We have continued striving to deliver proportionate yet robust regulation throughout 2024/25, in the most efficient and cost-effective way. Underpinning this is the vital role our staff play and we have recognised this through the introduction of a new People Strategy which will support us to develop and retain our most valuable asset.

Our ambitious three-year Data and IT strategy will also enable continued improvements in the HTA's internal systems.

Looking forwards, in 2025/26 we will maintain our focus on delivering in these priority areas. We will continue to prioritise frontline delivery, which involves maintaining regular touch points with our licenced establishments through proportionate and risk-based regulation, remaining responsive to the ever changing nature of the sectors we regulate.

In parallel, we will progress the change agenda arising from several reform initiatives recently announced. These include generic reforms for Arms Length Bodies and regulators and those which more specifically impact the HTA, such as the Sir Jonathan Michael inquiry, where we stand ready to support the implementation of any recommendations accepted by Ministers.

I look forward to working alongside DHSC, our staff, our licensed establishments and other key players as we seek to serve the public through the effective regulation of human tissue.

Dr Colin Sullivan
Chief Executive, Human Tissue Authority

Data note:

The HTA routinely publishes data on shortfalls as part of our commitment to transparency. This data is a snapshot in time taken at the end of each quarter and there are occasions where data on shortfalls is captured on our systems after the data has been published. For this Annual Review of 2024/25 we have refreshed the data quoted for previous years to account for this and there may therefore be some minor differences between the numbers quoted here and those previously published. Furthermore, data on shortfalls in 2024/25 may be subject to revision when published in due course.

Glossary of acronyms used

Advanced Therapy Medicinal Products (ATMP)
Arm's Length Bodies (ALBs)
Care Quality Commission (CQC)
Computed Tomography (CT)
Corrective and Preventative Action (CAPA)
Department of Health and Social Care (DHSC)
Designated Individual (DI)
Evaluated Self Assessments (ESAs)
Evidential Compliance Assessments (ECAs)
Health Services Safety Investigation Body (HSSIB)
HTA Reportable Incidents (HTARI)
Human Application (HA)
Human Resources (HR)
Human Tissue Authority (HTA)
Memorandums of Understanding (MoUs)
NHS Blood and Transplant (NHSBT)
Organ Donation and Transplantation (ODT)
Post-mortem (PM)
Regulatory Insight Model & Index tool (RIMI)
Royal College of Pathologists (RCPath)
Serious Adverse Event or serious Adverse Reaction (SAEAR)
Standard Operating Procedure (SOP)
Substances of Human Origin (SoHO)
The UK Accreditation Service (UKAS)
Virtual Regulatory Assessments (VRAs)