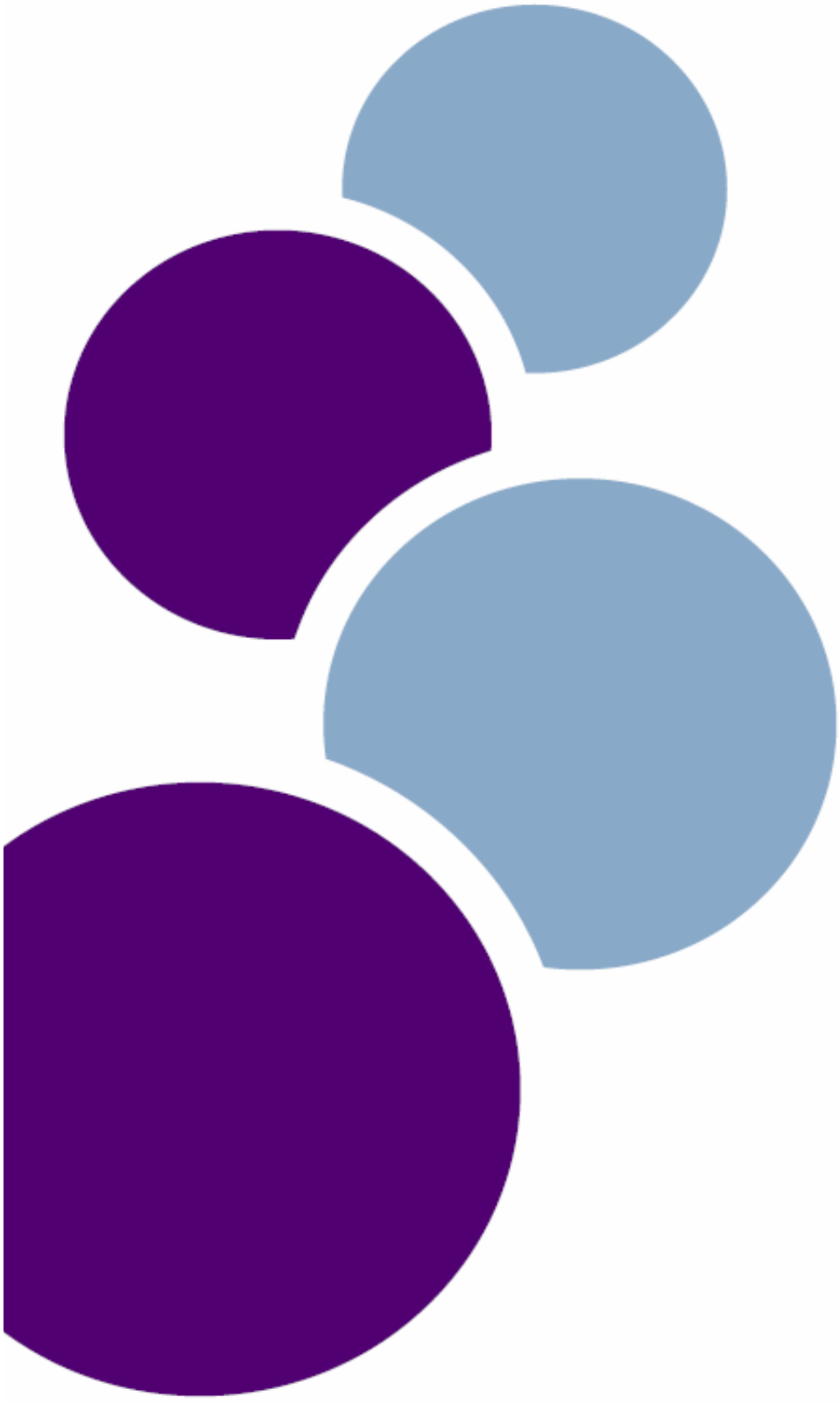


Human Tissue Authority

2009/10 summary report of performance against HTA standards for all sectors

Contents

Introduction

For the previous two business years, the HTA has published separate reports summarising regulatory activity in each of its sectors: human application (patient treatment), post mortem, research, anatomy and public display. For the 2009/10 business year, a single report has been compiled in which we present findings based on site-visit inspections and other regulatory activities we undertook in order to fulfil our statutory obligations under the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. The report summarises how licensed establishments have performed against HTA quality standards for protecting the public, and ensuring public and professional confidence in safe and ethical use of human tissue with proper consent.

In this report, we provide information about our regulatory activity and inspection findings. Where relevant, we have drawn conclusions and highlighted good practice. In doing so, we aim to create opportunities for learning that will support the people whose work we regulate and help to further improve standards.

The report contains brief summaries of site-visit inspection findings for the public display, anatomy and research sectors, which undertake relatively low levels of licensed activities. For the post mortem (PM) and human application (HA) sectors, there are more comprehensive sections due to the greater numbers of licensed establishments inspected, greater range of regulatory activities undertaken by the HTA and the wider range of licensed activities taking place, particularly in the HA sector.

We recognise that, in some sectors, the small sample size of establishments that received site-visit inspections limits the validity of some of the conclusions that could be drawn.

When comparing this report's findings with those of last year's report, we also recognise that it is important to exercise a degree of caution as there are factors which may confound any potential conclusions drawn from direct comparison. For example, in some sectors, substantially different number of site-visit inspections were carried out.

The format and content of this report reflect the results of our recent stakeholder survey, conducted by Ipsos MORI[1]. More than 80% of those who commented on the last summary reports found them useful. We have responded to feedback for improving them, by including more example scenarios and making the report shorter.

In each sector-specific section of the report, we have included 'Example scenarios of good practice'. The intention is that these will provide staff working at HTA-licensed establishments with ideas on how to address common shortfalls in meeting HTA standards. In order to make these scenarios applicable to the widest range of establishments within each sector, these scenarios have been combined from

elements of good practice identified during site-visit inspections. Alongside good practice, these scenarios also cover the subjects of the most common enquiries we received for each sector during the period.

We recommend that those working at establishments should be familiar with the information we provide on our website for licensed establishments. At the end of this report, we have included a section containing links to the HTA's Frequently Asked Questions pages, codes of practice and other relevant documents.

Main Messages

Three main messages are evident from the findings presented in this report:

- The majority of establishments had met the HTA's licensing standards, demonstrating that human material was used safely, ethically and with proper consent.

- Inspection findings from previously inspected establishments indicate that standards rose in the safe and ethical use of human tissue.

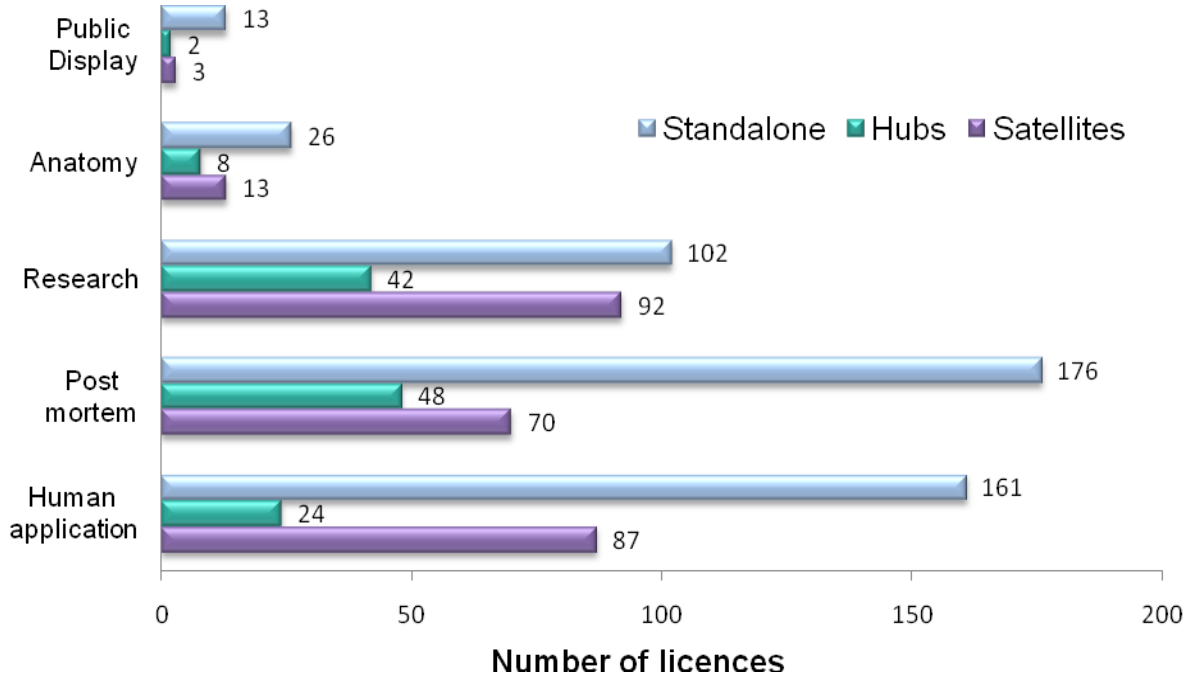
- The most common areas for shortfalls across all sectors continued to be related to our Governance and Quality systems standards, which was anticipated due to the largest number of standards in this category.

Overview of regulatory activity

The HTA licensed 602 main establishments and 265 satellite sites across all sectors in the 2009/10 business year.

Standalone establishments are those with no attached satellite sites. Satellites are smaller establishments, engaged in the same licensable activities and operating under the same governance of a central site, referred to as a hub. Satellites are licensed individually but are included in the application for licences made by the hub establishment.

Figure 1: Breakdown of licences per sector 2009/10

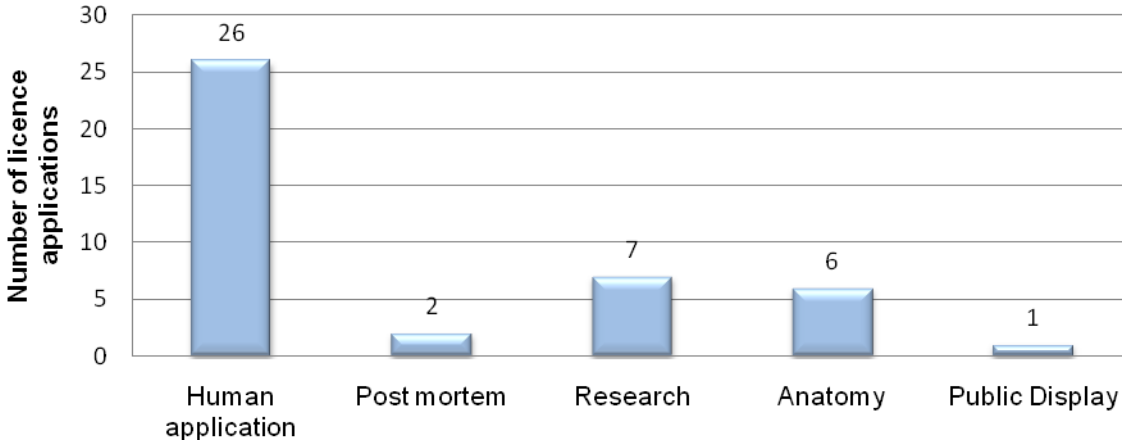


Although we have a separate research sector, our licensing framework allows establishments in our post mortem, human application (patient treatment) and anatomy sectors to store relevant material for a scheduled purpose, including for research, at no extra cost. In licensing this way, we aim to minimise regulatory burdens and, in particular, facilitate research. This has been an effective approach, as evidenced by the majority of our establishments needing or choosing to keep this storage licence.

Licence applications

Forty-two licence applications were made in 2009/10. The HTA did not refuse to grant any licences during this period.

Figure 2: Licence applications 2009/10



Site-visit inspections

One hundred and eighty-nine site-visit inspections, both routine and non-routine, were undertaken between 1 April 2009 and 31 March 2010, compared with 102 in the previous year (Figure 3). This is due to the increase in inspections carried out in the human application (HA) and post mortem (PM) sectors. The increase in HA inspections was planned to enable the HTA to meet its obligations under the Human Tissue (Quality and Safety for Human Application) Regulations 2007. In the PM sector, there was evidence of continuing common areas of shortfalls in meeting HTA quality standards and the HTA wanted to ensure that all establishments in the sector had received at least one site-visit inspection within the three business years from 2008 to 2011.

It is a statutory duty of the HTA to follow the principles of best regulatory practice, including the need to act in a proportionate and consistent way and to target regulatory action where it is most needed. The HTA prioritises site-visit inspections according to the risk of not meeting the HTA quality standards, focusing on establishments where known or suspected shortfalls in meeting the standards have, or are likely to have, the most significant impact.

The HTA considers a range of factors that indicate the extent to which the establishment is effectively mitigating and managing the risks associated with the licensable activities undertaken. In addition to this, the HTA conducts a proportion of site-visit inspections at low-risk establishments, in order to assess the validity of the risk assessment process we use when scheduling inspections. The HTA also meets its obligation under the Human Tissue (Quality and Safety for Human Application)

Regulations 2007 by inspecting all human application establishments at least once every two years.

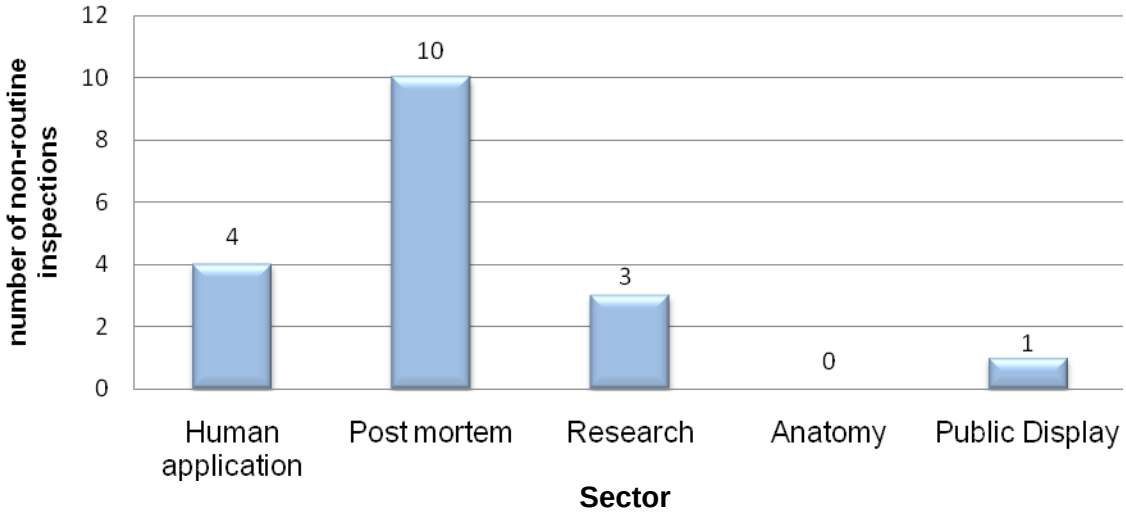
Figure 3: Number of site-visit inspections 2008/09 versus 2009/10

Non-routine site-visit inspections

Several factors can bring a site-visit inspection date forward or lead to a non-routine site-visit inspection. Eighteen non-routine site visit inspections were undertaken during the 2009/10 business year across all sectors other than Anatomy (Figure 4). These were undertaken because of allegations, whistle-blowing and other information which raised potential concerns about shortfalls against our standards.

These non-routine inspections are discussed in more detail within the individual sector sections of this report.

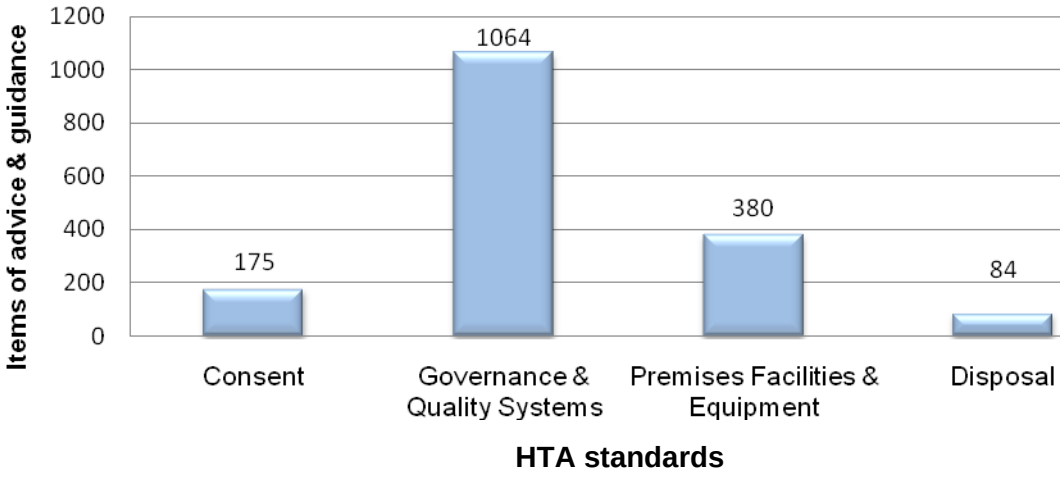
Figure 4: Non-routine site-visit inspections 2009/10



Advice and guidance

Advice and guidance is provided to establishments during licence application assessments and site-visit inspections. Advice and guidance offered as a result of site-visit inspections during the 2009/10 business year is summarised in Figure 5.

Figure 5: Advice and guidance offered during site-visit inspections during 2009/10



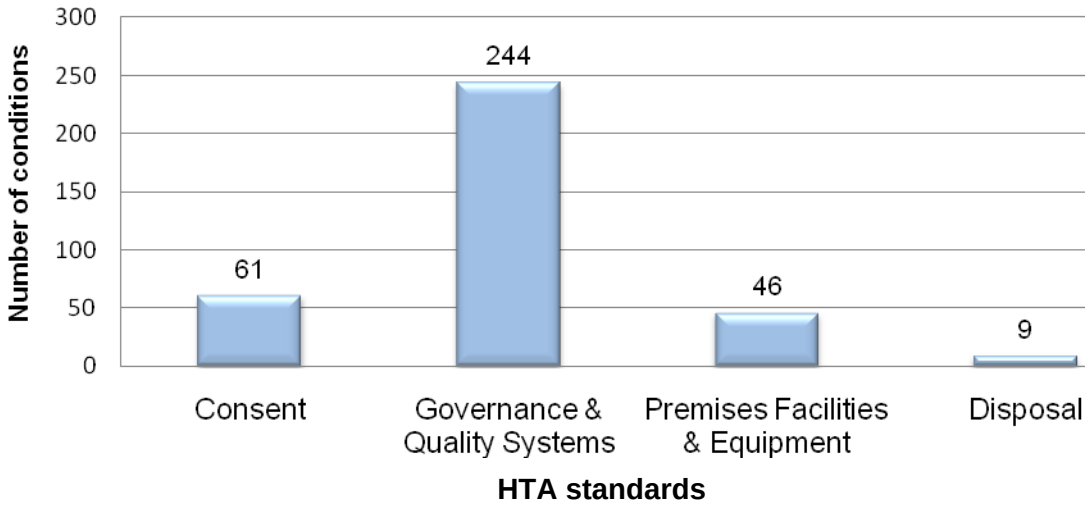
Consistent with previous reports, the largest amount of advice and guidance was given in relation to our Governance and Quality Systems standards. This is expected due to the larger number of standards in this category. Trends in the advice and guidance offered are discussed in the individual sector sections of this report.

Additional conditions placed on licences

During 2009/10, additional conditions were applied to licences where site-visit inspections identified shortfalls in meeting HTA's quality standards[3]. Conditions are time-bound and evidence must be provided to the HTA which demonstrates that a condition has been met before it is removed from a licence. Figure 6 shows the additional conditions placed on licences as a result of site-visit inspections during the 2009/10 business year.

As noted above, the large number of additional conditions applied in relation to our Governance and Quality Systems standards can be expected due to the larger number of standards in this category. Trends in the additional conditions placed on licences are discussed in the sector-specific sections of this report.

Figure 6: Additional conditions placed on licences during site-visit inspections during 2009/10



Regulatory enforcement action

The HTA follows the Better Regulation Executive's Statutory code of practice for Regulators[2] in carrying out its functions. Where regulatory breaches are identified, action is taken in line with our Regulation Enforcement Policy[4]. The primary aim of this policy is to reduce the likelihood of future breaches by taking action that is proportionate to the potential or actual harm associated with the breach.

There are several forms of regulatory enforcement action. As mentioned above, additional conditions may be applied to licences. Directions may also be issued, which require establishments to take specific and immediate actions to rectify significant shortfalls in meeting HTA quality standards. Licences may be suspended immediately when the HTA identifies significant or critical shortfalls in meeting its standards and considers that a licensed activity should immediately cease until the standards are fully met, because of the risks to patient safety or the dignity of the

deceased. Depending on the nature and severity of the shortfalls, licence revocation (a permanent removal of a licence) may also be considered.

During the 2009/10 business year:

- four sets of Directions were issued to three of the 185 licensed establishments in the HA sector
- four sets of Directions were issued to three of the 224 licensed establishments in the PM sector
- licences were suspended at four of the 185 licensed establishments in the HA sector
- two licences were suspended at one of the 224 licensed establishment in the PM sector

The reasons for each of these regulatory enforcement actions are discussed in the individual sector sections of this report.

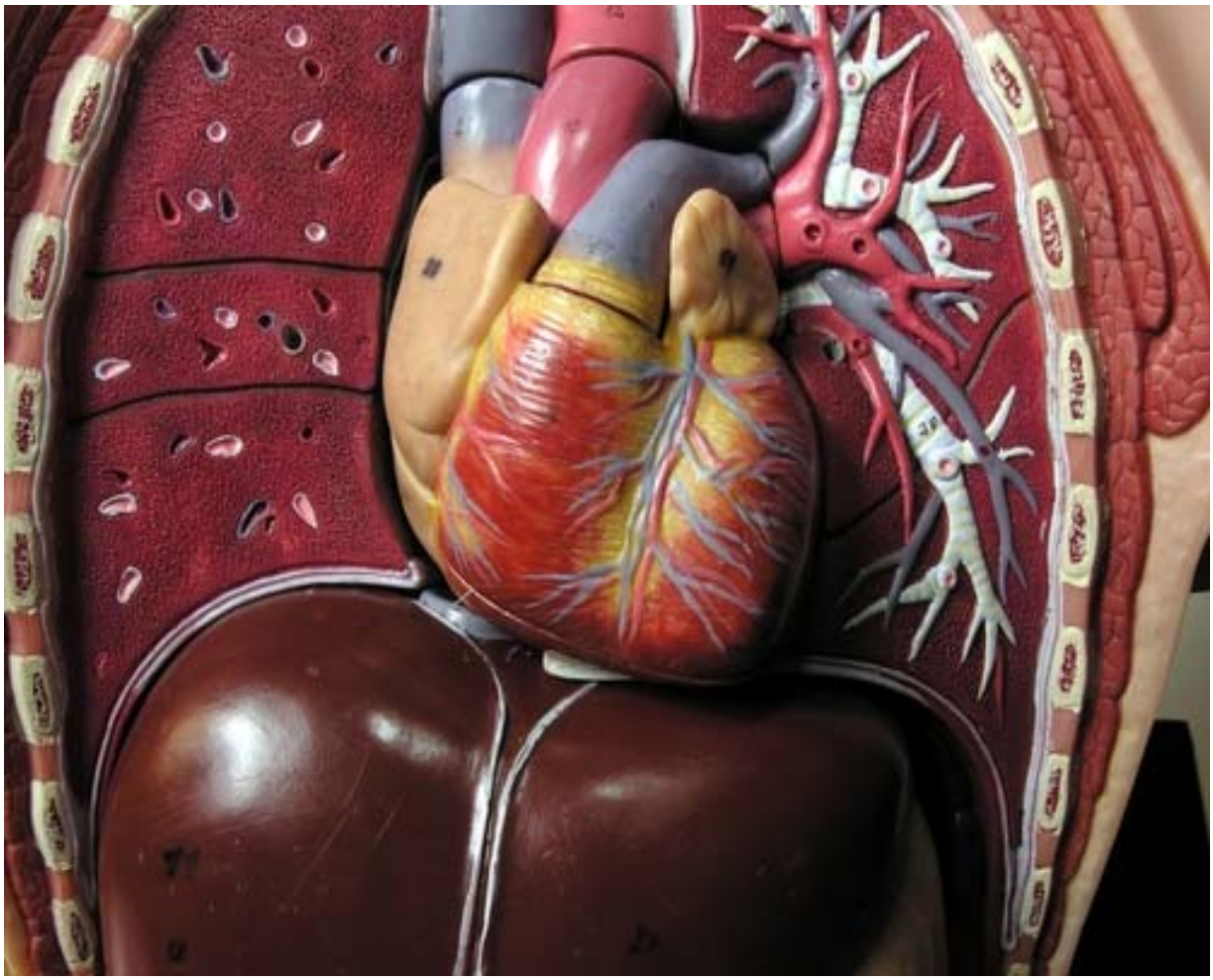
We did not revoke any licences during the 2009/10 business year. One Notice of Proposal to revoke a licence was made to a PM establishment following a site-visit inspection. Representations were made against this decision because the establishment judged it had made substantial improvements following the site-visit inspection. Following a thorough review, the HTA accepted the evidence of improvements provided and the revocation did not proceed.

Publication of revised HTA codes of practice[5]

In September 2009 the HTA published revised versions of the following codes of practice:

- Consent
- Donation of solid organs for transplantation
- Post-mortem examination
- Anatomical examination
- Disposal of human tissue
- Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

A code of practice for public display was published for the first time; this had previously been a guidance document. Additionally, a code of practice for the research sector was published for the first time. Our code of practice on import and export was published in May 2007 and has not been revised.



Anatomy

Sector overview

1. The number of licensed premises in the anatomy sector increased by two, to 47, during the 2009/10 business year. This was comprised of 26 standalone premises and eight hub sites with 13 satellite sites attached. Three new applications were received and processed; two of these were from higher education establishments and one was received in response to a complete change of premises from an already-licensed establishment. One licence was made inactive because it was no longer required by the establishment.

Summary of site-visit inspections

2. As with previous years, establishments within the anatomy sector were generally found to meet HTA standards and several areas of good practice were identified.

3. None of the new premises licensed in 2009/10 had additional conditions placed on their licences following the assessments of their licence applications. Routine site-visit inspections were carried out at two establishments and no additional conditions were placed on either licence as a result. However, we offered 14 items of advice and guidance (Table 1). There were no non-routine inspections carried out in the anatomy sector in this period.

4. The advice and guidance provided to both establishments at which site-visit inspections were carried out was similar to that provided during site-visit inspections carried out in previous years and predominantly related to the Governance and Quality (GQ) Systems standards.

5. Only one item of advice and guidance was offered in relation to a lack of documented policies and procedures (standard GQ1). This was an improvement on previous years, while audit schedules and risk assessments (which related to standards GQ2 and GQ7 respectively) continued to be the main subjects for advice and guidance.

Table 1: Advice and guidance offered during site-visit inspections of anatomy sector establishments (four inspections were carried out in 2008/09 and two in 2009/10)

	Consent	Governance & Quality Systems	Premises, Facilities & Equipment	Disposal	Total
Number of items of advice and guidance 2008/09	2	16	3	2	23
Number of items of advice and guidance 2009/10	1	7	4	2	14

Guidance to address common areas for improvement identified during site-visit inspections

6. This section highlights the common areas where shortfalls in meeting HTA standards were identified during site-visit inspections and provides information on how Designated Individuals (DIs) can avoid these shortfalls in their own establishments.

7. In relation to standard GQ2, which requires a documented system of quality management and audit, the types of audit we would typically expect to see included in an audit schedule are as follows:

    - *records audit* to ensure records are legible, complete and accurate
    - *process audit* to ensure staff are adhering to documented standard operating procedures (SOPs)
    - *traceability audit* to ensure that the establishment can trace specimens from the donor's consent, or point of receipt if supplied by a third party, to storage, use and disposal

8. In relation to standard GQ7, documented risk assessments must cover the premises where licensed activities are carried out and all processes and procedures which relate to the licensed activities. This standard is intended to ensure that in addition to consideration of health and safety hazards, establishments assess and mitigate risks which may affect the dignity of the deceased and the integrity of human tissue.

9. Staff working under licences can be involved in risk assessments and should, at a minimum, be made aware of risks associated with the licensed activities and what measures are in place to mitigate them. Risk assessments should be reviewed whenever a process is changed.

Example scenarios of good practice

As explained in the *Introduction*, the following section provides example scenarios of good practice.

Scenario 1: A Designated Individual (DI) wished to audit the disposal procedures and records at their establishment.

The first part of the audit followed three items, which were due for disposal, as they progressed through the establishment's disposal procedures. The second part of the audit reviewed the documentation associated with two of the 'critical steps' in the

disposal procedure, for a group of randomly selected items which had been disposed of.

Deviations from the establishment's disposal standard operating procedure (SOP) and any errors in the documentation were recorded. A corrective and preventative action plan was developed in order to improve practice and the plan was shared with staff working under the licence.

Scenario 2: Filming cadavers and anatomical specimens

A film company contacted the DI of an anatomy establishment to request permission to film cadavers and other anatomical specimens as part of a documentary. The film company assured the DI that the identity of any material filmed would be concealed.

The HT Act is silent about the use of images which means that images, both static and moving and in any medium, are not within the HTA's remit. It is at the DI's discretion whether they wish to allow filming on their premises by an external party. The HTA endorses the guidance on use of images provided by the General Medical Council in its publication *Making and using visual and audio recordings of patients*[6].

The DI ensured that systems were in place at the establishment to ensure that the dignity of the deceased was respected by the film crew when they visited the licensed premises. Before making a decision about permitting the filming, the DI communicated with the film company about the purpose of the documentary, in order to prevent the inappropriate use of images.

Research

Sector overview

10. The overall number of licensed premises in the research sector (236) did not change from the previous business year. During 2009/10, there were 102 standalone premises and 42 hub sites, with 92 satellite sites attached. Seven new applications were received and processed between 1 April 2009 and 31 March 2010 and several licences were made inactive due to consolidation of licences and where licensable activities were no longer being carried out.

Summary of site-visit inspections

11. During 2009/10, 12 routine site-visit inspections and three non-routine site-visit inspections were carried out at research sector establishments. Two non-routine site-visit inspections were carried out as a result of allegations that relevant material was being stored for use for research on unlicensed premises; one of these allegations included concerns about inappropriate use and disposal of research material. The third non-routine site-visit inspection was undertaken as a result of a breach in the DI training requirement. No further significant regulatory enforcement action was taken as a result of these non-routine inspections. Results from the non-routine inspections are included within the inspection data presented in Table 2.

12. Eighteen (18) additional conditions were placed on licences as a result of these inspections, which is an increase from 2008/09. There was a slight decrease in the number of items of advice and guidance offered during site-visit inspections in 2009/10 compared to 2008/09 (Table 2).

Table 2: Additional conditions applied and advice and guidance offered to research sector establishments during site-visit inspections (there were 15 site-visit inspections in 2008/09 and 2009/10)

	Consent	Governance & Quality Systems	Premises, facilities & equipment	Disposal	Totals
Number of additional conditions 08/09	2	5	1	0	8
Number of additional conditions 09/10	6	11	1	0	18
Number of items of advice and guidance 08/09	11	50	21	5	87
Number of items of advice and guidance 09/10	12	53	11	2	78

13. The standards against which additional conditions were placed and advice and guidance offered during site-visit inspections in 2009/10 were similar to those of previous years. Most of these related to Governance and Quality (GQ) systems standards (see below). However, compared with 2008/09, more establishments were found to be meeting quality standard GQ1, which is about documented policies and standard operating procedures (SOPs).

Guidance to address common areas for improvement identified during site-visit inspections

14. This section highlights the common areas where shortfalls in meeting HTA standards were identified during site-visit inspections and provides information on how DIs can avoid these shortfalls in their own establishments.

15. In relation to consent documentation and training (standards C1 and C3 respectively) DIs are expected to ensure that:

- consent policies and SOPs are documented, reflecting current practice and incorporating the requirements of the HT Act and the HTA's code of practice on Consent
- staff who seek consent are suitably trained about the requirements of the HT Act and the HTA's code of practice on Consent. The HTA recommends that this training is documented
- training is regularly reviewed to ensure it reflects current practice and relevant legislation and professional guidelines
- refresher training is considered in cases where consent is not taken often enough for staff to otherwise maintain their knowledge about the process

16. In relation to standard GQ2, research sector establishments are required to have a documented system of quality management and audit. The types of audit the HTA would typically expect to see included in an audit schedule are as follows:

- *records audit* to ensure records are legible, complete and accurate
- *process audit* to ensure staff are adhering to documented SOPs
- *traceability audit* to ensure that the establishment can trace specimens from the donor's consent, or point of receipt if supplied by a third party, to storage, use or disposal.

17. The HTA considers it good practice for individuals from different work sections or research groups to be involved in conducting audits carried out in relation to the licence. This provides an independent approach to audits and creates opportunities for shared learning about areas for improvement and good practice.

18. It is also considered good practice for a centralised register of materials to be held for all research groups at an establishment because this facilitates access to information and material for all staff. Copies of paper records should be considered where they are not backed up electronically.

19. In relation to standard GQ6, a robust coding and traceability system for tracking research material from donors to storage, use and disposal must include:

    - a unique identifier assigned to each item
    - securely-held records of internal and external movements of research material (to and from, and within, the establishment)

20. In relation to standard GQ8, documented risk assessments must cover all processes and procedures carried out under the HTA licence, including but not limited to:

    - transportation of material
    - use of critical equipment

21. Risks associated with not meeting the HTA's standards must be considered in addition to health and safety issues. Risk assessments should be reviewed whenever a process or procedure is changed or reviewed.

Example scenario of good practice

As explained in the *Introduction*, the following section provides an example scenario of good practice.

The Designated Individual (DI) of an HTA-licensed research establishment wanted to improve practices in accordance with the HTA's standards for governance and quality systems.

The DI identified individuals in each of the research groups working under the licence to act as Persons Designated (PDs). These individuals formally directed others, within each group, on behalf of the DI. The PDs also carried out audits on behalf of research groups other than their own, which allowed them to become

familiar with how the other groups carried out their activities and helped them to raise standards in their own groups.

The DI held regular meetings with the PDs and other staff working under the licence to discuss matters relating to the licence in order to ensure that issues were raised and addressed in a timely manner. Minutes were kept for each meeting, which are circulated to staff including those who were unable to attend.

A centralised register of material held across the establishment's research groups was created, using a coding system to uniquely identify each item and distinguishing between material currently being held under the licence and that which was being held under approval from a recognised research ethics committee. The register made it easier to identify ethically-approved projects that were nearing their completion, which included material that would either need to be disposed of or would revert to being held under the HTA licence. All staff working under the licence had access to the register.

Public display

Sector overview

22. During the 2009/10 business year, the HTA licensed 13 standalone public display sector premises and two hub sites with a total of three satellite sites attached. This is a reduction of one establishment (to 18 licensed premises in total) from the previous year. Changes in the number of public display establishments from year to year are expected as some are licensed for temporary exhibitions.

23. Only one new application was received for a public display sector licence during 2009/10, which was for a temporary exhibition.

Summary of site-visit inspections

24. The HTA considers temporary exhibitions to pose a higher risk of not meeting HTA standards. Therefore all temporary exhibitions of relevant material receive a site-visit inspection before they open to the public. In line with this policy, we carried out two site-visit inspections prior to an exhibition opening to the public; the second inspection to assure ourselves that additional conditions that had been placed on the licence following the earlier inspection had been met before the exhibition opened to the public.

Guidance to address common areas for improvement identified during site-visit inspections

25. Only one public display establishment received site-visit inspections during 2009/10. Additional conditions placed on this licence following the initial site-visit inspection required the DI to:

- ensure that the establishment's procedures for managing visitors (including protecting exhibits from accidental damage by visitors) and for managing damage to exhibits were sufficiently developed and were documented (GQ1)
- ensure that an appropriate incident management system was in place including sharing information about incidents among staff (GQ5)
- ensure that risk assessments were carried out for all procedures relating to the licensed activities (GQ6)
- ensure that there was effective risk management of specimens immersed in formaldehyde solutions (PFE2)

26. Advice and guidance was given in relation to the Governance and Quality (GQ) standards which recommended:

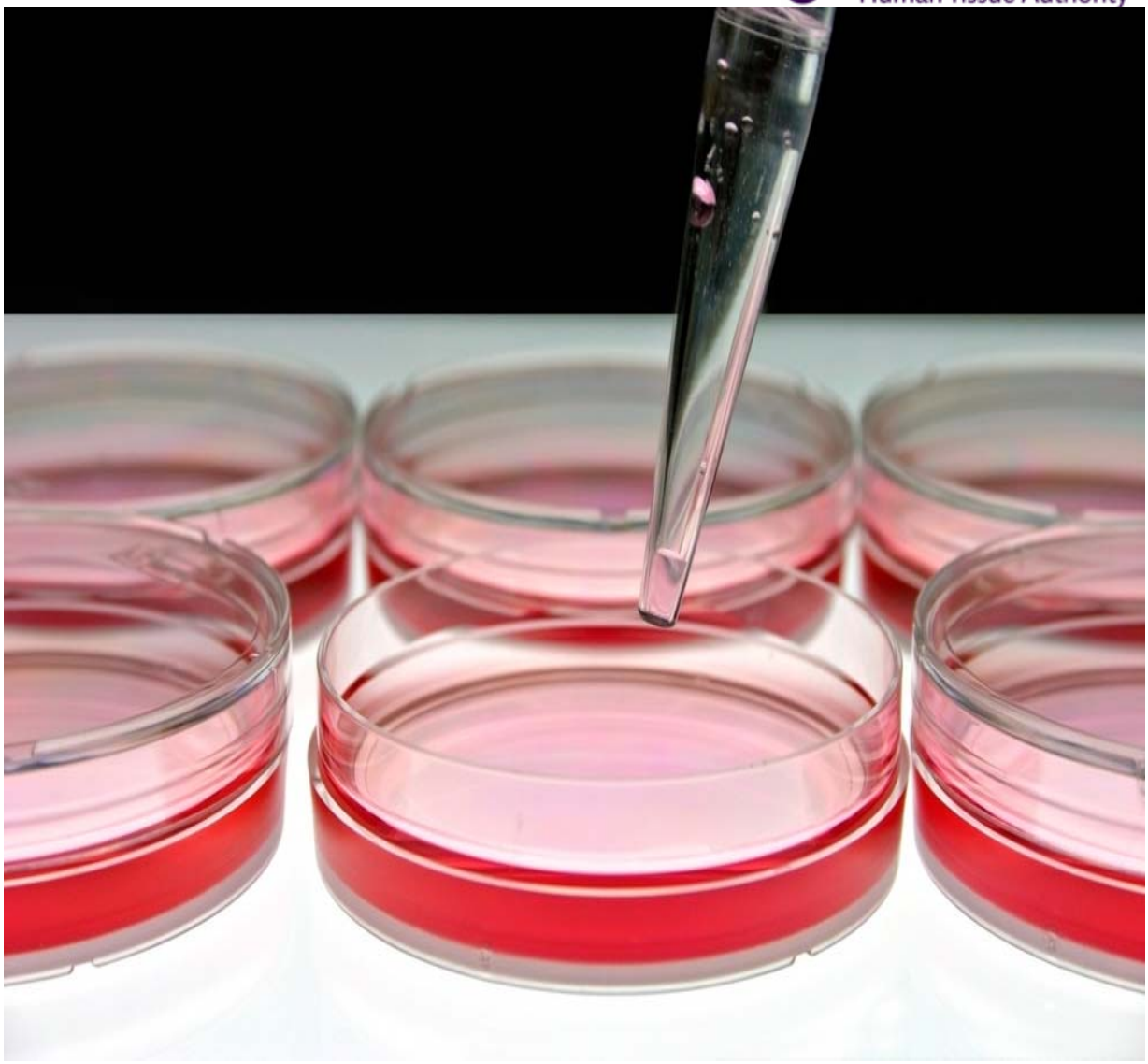
- improvements to documentation of processes and procedures and of control of these documents (GQ1)
- changes to staffing arrangements to ensure adequate numbers of staff on duty to provide adequate protection of specimens on display and the provision of training and updates (GQ2)
- review of the risk assessments carried out prior to opening the exhibition to the public, to ensure the assessments remained adequate after the commencement of the exhibition (GQ6)
- improvements to systems which ensured that exhibits were kept secure and safe from damage and were maintained in an acceptable condition (PFE3)

Example scenario of good practice

As explained in the *Introduction*, the following section provides an example scenario of good practice.

A museum which exhibits human tissue for public display wanted to ensure they had an adequate system for tracking items.

The DI implemented a system where a unique identifier was assigned to each item. This identifier was used in a password-protected central register which recorded the movement of each item from storage through preparation and exhibition. At any time, all staff at the establishment could access the register to locate a specific item. The register was computerised and backed up by a validated and secure server.



Human application

Sector overview

27. The overall number of licensed premises in the human application (HA) sector increased by six, to 272, during the 2009/10 business year. The number of main sites increased by 14, to 185 and the number of satellites fell by eight, to 87.

28. Although, the overall number of licensed premises increased by only six, 26 new HA licence applications were received and approved by the HTA. The HTA has noted that an increasing number of HA establishments are amalgamating licences across sites and implementing our hub and satellite model more widely.

29. Licence restructuring is often undertaken at the suggestion of the HTA and has helped establishments reduce licence fee costs. This contributed to the 25 HA licences that were made inactive during the 2009/10 business year. Other reasons for making licences inactive were because establishments were no longer carrying out licensable activities or had identified that licensable activities could be carried out under third party agreements with other licensed establishments.

Key findings

- The majority of licensed establishments had met the HTA's licensing standards
- Previously inspected establishments were found to have raised standards when inspected again
- The standards against which additional conditions were placed and advice and guidance offered, after site-visit inspections, was similar to previous inspection periods
- There was an increase in the reporting of serious adverse events and reactions (SAEARs), which was probably due to an increased understanding of reporting requirements, and improvements to the reporting systems at licensed establishments

Summary of site-visit inspections

30. Ninety-nine (99) routine and non-routine site-visit inspections were carried out at HA establishments during 2009/10 which is more than double the inspections carried out during 2008/09. This increase was planned to enable the HTA to carry out an inspection of each HA establishment at least every two years. Taking the increase in inspections into account, we confirmed our prediction that there would

be an increase in the number of conditions and items of advice and guidance given during this period.

31. In 2009/10, approximately half (46 out of 99) of the establishments which received a site-visit inspection had previously been inspected, compared to a quarter of those inspected in 2008/09 (Table 3).

Table 3: Site-visit inspections of establishments in the human application sector

	2008/09	2009/10
Number of site-visit inspections	44	99
Number of inspected establishments visited previously	10	46
Non-routine inspections	2	5

32. Five non-routine site-visit inspections were carried out in the HA sector during 2009/10. Of the non-routine inspections:

- one was in response to an allegation made by a member of the public that unlawful procurement of cord blood had taken place
- two were repeat visits to assess progress made towards meeting additional conditions which had been placed on the licences following previous site-visit inspections
- one was as a result of the DI's failure to provide the HTA with evidence which demonstrated that additional conditions which had been placed on the licence during a site-visit inspection had been met
- one followed assessment of a new licence application and was carried out to ensure that the premises were suitable for the complex range of licensed activities which would be taking place under the licence

Results from the non-routine inspections are included within the inspection data presented in Table 4.

33. The majority of HA establishments which received site-visit inspections in 2009/10 demonstrated that they were meeting the HTA's quality standards. Establishments which had previously been inspected were generally found to have raised the standards of their practices in line with advice and guidance provided during those inspections. Table 4 shows that additional conditions placed on HA licences and advice and guidance offered during site-visit inspections in 2009/10 were similar to previous years. Most of the additional

conditions and advice and guidance related to the Governance and Quality (GQ) standards.

Table 4: Advice and guidance offered and additional conditions placed on human application sector licences during site-visit inspections (44 inspections were carried out in 2008/09 and 99 in 2009/10)

	Consent	Governance & Quality Systems	Premises, Facilities & Equipment	Disposal	Total
Number of additional conditions applied 2008/09 (%)	2 (3)	59 (81)	11 (15)	1 (1)	73
Number of additional conditions applied 2009/10 (%)	23 (11)	154 (75)	27 (13)	3 (1)	207
Number of items of advice & guidance 2008/09 (%)	52 (8)	424 (64)	162 (25)	22 (3)	660
Number of items of advice & guidance 2009/10 (%)	78 (6)	801 (69)	243 (21)	42 (4)	1164

Guidance to address common areas for improvement identified during site-visit inspections

34. This section highlights the common areas where shortfalls in meeting HTA standards were identified during site-visit inspections and provides information on how DIs can avoid these shortfalls in their own establishments.

35. During 2009/10, the most common areas of shortfalls in meeting the HTA quality standards at HA establishments related to Consent standard C1 and Governance and Quality Systems standards GQ1, GQ2, GQ4, GQ7 and GQ8.

36. In relation to standard C1, consent forms must be clearly separated from contractual agreements and obligations. Additionally, forms should be reviewed regularly (for example, annually) to ensure that they reflect regulatory requirements. Documented consent policies and procedures must also be reviewed and updated to ensure they meet regulatory requirements as well as applicable professional guidelines.

37. Establishments should have a system in place to confirm that consent is in place before licensed activities begin. Written agreements maintained by establishments which receive tissue and/or cells procured by third parties outside the UK must include the provision that all those involved in the taking of consent adhere to local legal requirements.

38. In relation to standard GQ1, which requires policies and standard operating procedures (SOPs) relating to the licensed activities to be documented, establishments must

    - implement and review policies and SOPs as required by the HTA's Directions (the Directions were updated in 2010 by the release of the *Guide to quality and safety assurance for human tissues and cells for patient treatment,* as implemented by HTA Directions 003/2010[6])

    - have documented contingency plans for the transfer of stored tissues and/or cells and all relevant documentation in case of emergency or cessation of licensed activities

    - ensure that third party agreements require third parties which procure tissues and/or cells on behalf of the establishment to carry out risk assessments of premises where procurement takes place.

39. Additionally, it is considered good practice for establishments to ensure that written agreements include an obligation for third party premises and staff to meet regulatory requirements and to provide a template risk assessment document to third parties that procure tissues and /or cells on behalf of the establishment.

40. In relation to standard GQ2, which requires a documented system of quality management and audit, the requirement for an independent audit can be achieved by ensuring that those carrying out the audit are not involved in the day-to-day operations. This can include individuals from other departments within the licensed establishment (e.g. clinical audit department, another ward or unit), other departments within the parent organisation (e.g. from another hospital within a Trust), an external organisation (e.g. DIs in similar establishments but who have no conflict of interest in the establishment's practices), and professional auditors.

41. In relation to standard GQ4 a robust record-management system requires certain information to be included in all written agreements with third parties, end users and other licensed establishments as specified in the sub-standards associated with GQ4 and the HTA's *Guide to quality and safety assurance for human tissues and cells for patient treatment,* as implemented by HTA Directions 003/2010[6]. Records management must be based on documented policies and SOPs.

42. It is a requirement for a unique identifier to be assigned to each record in order to facilitate traceability. Additionally, access to records should be limited in order to prevent unauthorised disclosure of information.

43. In relation to standard GQ7, DIs must ensure the establishment has in place documented procedures for the management of adverse events and reactions which includes the reporting of them to the HTA. These procedures must include an outline of the roles and responsibilities of individuals working at the establishment in the event of an incident and should include arrangements for reporting to the HTA in the DI's absence. Agreements with third parties, end users, service providers and other licensed establishments must include communication protocols for the appropriate and timely reporting of adverse events and reactions to the DI.

44. In relation to standard GQ8, DIs must ensure that risk assessments:

- cover all practices and processes relating to licensed activities
- include risks to staff, visitors, patients and the quality and safety of tissues and/or cells
- are regularly reviewed (at a minimum this must be annually or when any changes to practice are made)
- are made available for staff reference

45. Where changes are made to donor-selection and testing requirements, a risk assessment in relation to patient safety (standards GQ1h and GQ8d) must be completed for all tissues and cells which are in storage before these can be released for treatment (human application) .

Summary of other regulatory activity

46. This section describes the regulatory enforcement action and other regulatory activities, unique to the human application sector, which the HTA carried out in 2009/10.

Regulatory enforcement action

47. Two HA establishments were issued with Directions between 1 April 2009 and 31 March 2010. One set of Directions was issued to suspend some of the licensed activities at an establishment after information was received that brought the quality and safety of tissues into question. The establishment subsequently applied to revoke its licence. The second set of Directions was issued to prevent an establishment from releasing tissue and/or cells for treatment (human application) until the HTA agreed they had met an additional condition which had been placed on the licence. The additional condition was met within the agreed

timeframe, the Directions were removed and the establishment resumed their normal activities.

48. The HTA suspended licences at four HA establishments during 2009/10; all issues which led to the suspensions were resolved and these establishments have resumed activities.

    - the licences were suspended at each of two establishments due to the failure of the DIs to adequately demonstrate that these establishments were meeting the HTA quality standards, where shortfalls had been identified during site-visit inspections

    - one licence was suspended due to the failure of the DI to ensure that the practices and premises were suitable

    - the fourth licence suspension resulted after the HTA identified that an establishment was operating without a DI and the proposed replacement DI was deemed unsuitable.

2009 annual activity data collection

49. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the HTA has a duty to collect an annual data return regarding the licensable activities of establishments within this sector.

50. During February 2010, 179 HA establishments submitted data about their licensed activities to the HTA for the 2009 calendar year (1 January to 31 December 2009). Six establishments were not asked to submit this information as they were licensed close to the end of the reporting period and had not carried out any licensable activities during this time. The reporting time period is set by the European Commission (EC) and the HTA reports on the data to the EC in an anonymised format[7].

51. The HTA uses annual activity data to identify trends, update our licence management systems and improve the advice and guidance provided on our website. The data is also referred to in preparation for site-visit inspections.

Serious adverse events and reactions reporting

52. Under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, the HTA is also required to monitor, investigate and respond to reports of serious adverse events or reactions relating to the use of human tissue for patient treatment.

53. During 2009/10, 75 serious adverse events and reactions (SAEARs) were reported to the HTA, which is an increase from 2008/09 (Table 5). This increase

appears to be due to the improvement of reporting systems at licensed establishments. A further indication of these improvements can be seen in the reduction of average initial reporting and follow-up report submission times.

54. The HTA introduced new reporting time requirements for SAEARs in 2010, with the introduction of the *Guide to quality and safety assurance for human tissues and cells for patient treatment,* as implemented by HTA Directions 003/2010[8]. Establishments are required to submit initial notifications within 24hrs of identifying a SAEARs and submit follow-up reports within 90 days. The purpose of the new reporting requirements is to enable the HTA to provide timely information and advice to establishments and EU partners about any actions that need to be taken.

Table 5: Number of notifications and reporting times of serious adverse events and reactions

	Serious Adverse Reactions	Serious Adverse Events		
	number of notifications	number of notifications	average notification time* (days)	average time to follow-up report** (days)
2008/09	8	34	41	73
2009/10	16	59	24	39

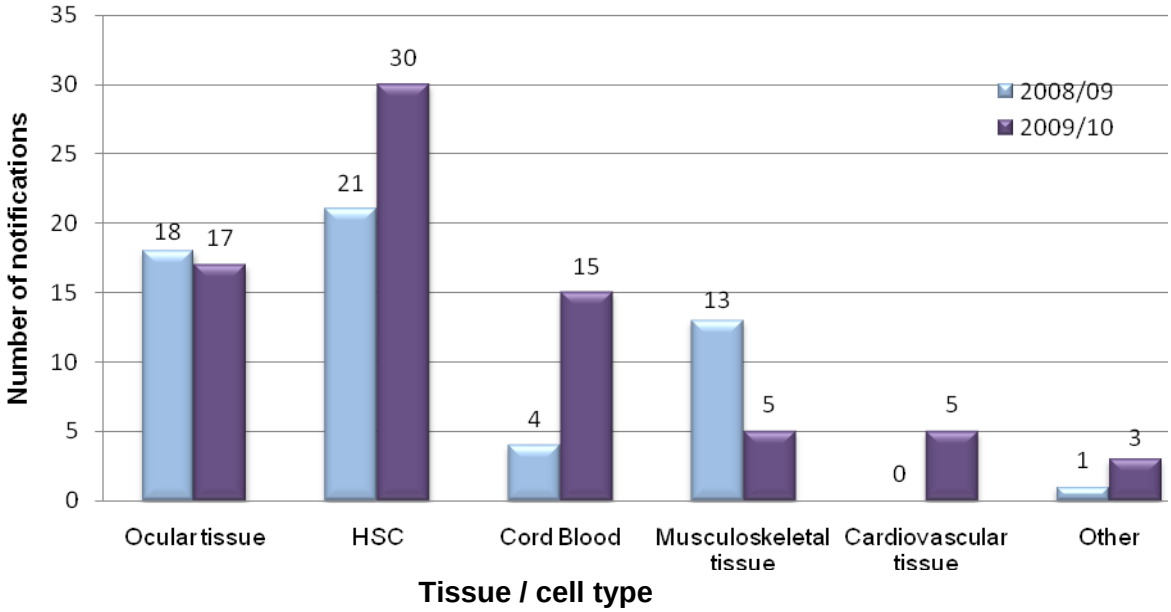
*notification times were calculated as the number of days between the SAEARs occurring and the report submission to the HTA

**follow-up report times are calculated as the number of days between the initial report and the HTA receiving a follow-up report submission

55. As stated above, new reporting requirements were introduced in 2010 and were not in place during the periods set out in Table 5. Although the notification times are longer than might be expected, this is partly explained by establishments reporting the time elapsed since the event, rather than since it was discovered or reported to the establishment, or the event iniatially being classified as not serious and only reported at a later date when an internal review escalated its status.

56. Establishments which work with haemopoetic stem cells and ocular tissues contributed the largest number of SAEARs in 2009/10. This is similar to our findings in 2008/09 and most likely reflects the level of vigilance and volume of activity within these types of establishments (Figure 7).

Figure 7: Number of serious adverse events and reactions submitted per tissue type



*(HSC stands for haemopoetic stem cells)

57. Further information on the reporting of SAEARs can be found in Appendix 2 at the back of this document[9].

Example scenarios of good practice

As explained in the *Introduction*, the following section provides example scenarios of good practice.

Scenario 1: *A licensed establishment wished to import tissue and/or cells for use for patient treatment (human application) from a company outside of the European Economic Area (EEA). The testing, processing and storage were to be performed by the licensed establishment in the UK.*

The DI ensured that the written agreement between the establishment itself and the external company included the provision that all those involved in taking consent were trained in local consent requirements, and that consent documentation was maintained. The agreement also required a documented risk assessment of each procurement site to be provided to ensure that the premises were suitable.

The DI provided the company with a template consent form, template risk assessment document and standard operating procedures (SOPs) which contained the same information as those used by the licensed establishment.

The DI arranged to visit the company to obtain an assurance that the staff and premises were suitable and that staff were adhering to the written agreement.

Scenario 2: *A DI needed to undertake an independent audit to assess how the establishment is meeting the HTA quality standards but was unable to find someone at the establishment who was sufficiently separate from the day-to-day operations under the licence to be considered independent.*

The DI contacted the establishment's parent company and a suitable individual was identified elsewhere in the company. An audit was arranged and the DI further agreed with the parent company that a suitable person would be made available for audit purposes on a biennial basis.

The DI recorded the choice of the auditor in the audit documentation. The audit was performed to assess the establishment's compliance with HTA standards; findings were documented and distributed to the DI and all staff working under the licence. Corrective and preventative actions identified during the audit were shared with staff and assigned to specific individuals for completion by a target date.

Scenario 3: *A DI discovered that a company supplying the licensed establishment with pre-packaged demineralised bone matrix (DBM) putty had failed to carry out full donor testing on several lots over the last six months. The establishment had received at least one of the lots and it was likely that the products had already been distributed to a variety of end users.*

The DI used the establishment's coding and records system to identify that three end users had received the affected material. The establishment's recall SOP was enacted and a recall was issued to the three end users for the return of any unused packets of DBM putty. An internal investigation was initiated in conjunction with the supplier. The DI of the licensed establishment reported this to the HTA as a serious adverse event.

In accordance with their written agreement with the licensed establishment, the end users investigated whether any of the material had been transplanted into patients. If so, the affected patients were to be monitored by the end user and appropriate actions taken. Relevant information on patient outcomes were provided to the licensed establishment and the DI passed this information on to the HTA. If the material had been transplanted into patients, then this would have been reportable to the HTA as a serious adverse reaction.

The DI followed the establishment's SOP on the reporting of serious adverse events and reactions to the HTA, which included the provision of as much of the following information as possible to the HTA within 24 hours of the incident's discovery:

- types of tissues and/or cells affected
- quantity of affected tissues and/or cells

- list of unique identifiers of the affected tissues and/or cells
- potential consequences of the event
- action(s) taken in response to the event

When the internal and end user investigations were completed, the DI submitted a follow-up report to the HTA which included:

- a root cause analysis
- a corrective and preventative action plan which identifies the responsible parties and the action deadlines

Post mortem

Sector overview

58. During 2009/10, our post mortem (PM) sector's 294 licensed premises were comprised 176 standalone premises and 48 hubs sites with 70 associated satellite sites. This is almost identical to the total of 296 licensed premises in 2008/09.

59. Most PM establishments (89%) and their associated satellites were part of an NHS trust. Nine percent were public mortuaries, managed by Local Authorities. The remaining licensed establishments were commercial organisations which stored PM material under their own licence for other establishments, for example forensic science laboratories and storage-only facilities which stored tissue blocks and slides as part of NHS archives.

60. During 2010, we collected audit information about retained material from our PM establishments. These results will be published early in the 2011/12 business year.

Key findings

- Inspections carried out in 2009/10 noted that there were improvements in the number of establishments meeting HTA licensing standards for the Premises, Facilities and Equipment and Disposal standards

- The most common shortfalls in meeting HTA standards were related to the Consent and Governance and Quality Systems Standards

Summary of site-visit inspections

61. In the PM sector, there was evidence of continuing common areas of shortfall in meeting HTA quality standards. The HTA wanted to ensure that all establishments in the sector had received at least one site-visit inspection within the three business years from 2008 to 2011. As a result, 72 site-visit inspections were carried out in the sector during 2009/10, almost double the 37 conducted in 2008/09. Sixty-two of these inspections were routine and none of the premises inspected in the period had previously undergone an HTA site-visit inspection. By the end of the 2010/11 business year, we will have met our objective of inspecting all PM sector establishments within the three year period.

62. Ten non-routine site-visit inspections were carried out at nine establishments. Five were undertaken following the discovery of organs or tissues retained without consent. Of these incidents, three were reported to the HTA by the establishments concerned, while two were brought to our attention by journalists.

63. Two non-routine site-visit inspections were carried out after establishments reported that licensable activities were taking place in the absence of an HTA licence. The remaining two non-routine inspections were carried out at the same establishment; the first was undertaken following findings of major shortfalls in meeting the HTA's standards at another site within the Trust and the second was a follow-up visit to assess the improvements which had been made after the first inspection. The outcomes of the non-routine inspections are included within the inspection findings set out in Table 6.

64. Compared to the previous year, in 2009/10 a larger proportion of establishments appeared to meet the Premises Facilities and Equipment and Disposal standards. Conversely, a smaller proportion of establishments appeared to meet the Consent and Governance and Quality Systems standards. (Table 6).

Table 6: Additional conditions applied to licences and advice and guidance offered to post mortem sector establishments during site-visit inspections (37 site-visit inspections were carried out in 2008/09 and 72 in 2009/10)

	Consent	Governance & Quality Systems	Premises, Facilities & Equipment	Disposal	Total
Number of additional conditions applied 2008/09 (% of total)	9 (17)	21 (41)	13 (25)	9 (17)	52
Number of additional conditions applied 2009/10 (% of total)	31(26)	64 (54)	17 (15)	6 (5)	118
Number of items of advice & guidance 2008/09 (% of total)	31 (14)	119 (53)	53 (24)	21 (9)	224
Number of items of advice & guidance 2009/10 (% of total)	89 (16)	300 (54)	126 (23)	39 (7)	554

Guidance to address common areas for improvement identified during site-visit inspections

65. This section highlights the common areas where shortfalls in meeting HTA standards were identified during site-visit inspections and provides information on how DIs can avoid these shortfalls in their own establishments.

66. Additional conditions and advice and guidance were used to address areas for improvement identified during site-visit inspections (Figure 8). The most common areas of shortfall identified during 2009/10 related to the Consent standards C1 and C3 and Governance and Quality Systems standards GQ1, GQ2, GQ6 and GQ8.

67. In relation to standard C1, consent forms, standard operating procedures (SOPs) and information for families about the PM examination should reflect the requirements of the HT Act[9] and HTA codes of practice[4] to ensure:

    - appropriate and valid consent is obtained in order to carry out a hospital PM examination

    - consent is obtained to retain and use any tissue removed during PM examination (including tissue which is made into blocks and slides). Please note that: consent for retention is separate from that for a PM examination to take place.

68. Consent processes can be improved by:

    - identifying the relationship between the consent giver and the deceased on the consent form and documenting, where appropriate, that the consent giver has been confirmed as the highest position in the hierarchy of qualifying relationships as defined by the HT Act 2004[10]

    - separating consent for retention and use of whole organs from consent for retention and use of other tissues retained during PM examination

    - listing on the consent form the scheduled purposes for which PM material may be used if it is stored in as part of the "medical record" (which in itself is not a scheduled purpose)

    - documenting whether the consent giver has any objection to observers attending the PM examination for educational purposes, for example on the consent form.

69. Establishments are encouraged to refer to the HTA's model consent form[11] and our recently published policy and position statement[12] in relation to consent for PM examination and retention of tissue removed during PM.

70. In relation to standard C3, consent training should be provided to individuals who seek consent or who accompany those who seek consent for hospital PM examinations and retention and use of tissue taken during hospital or coronial PM examinations. Training should, at a minimum, cover the requirements of the HT Act[9] and HTA code of practice on Consent[4], including:

    - when consent must be sought

- who can give consent
- what information must be provided to those giving consent
- how to document consent

71. It is considered good practice for both the consent training programme contents and attendance to be documented. Where there are low numbers of hospital PM examinations, it may be difficult for staff to maintain their knowledge about consent processes. In these cases refresher training will ensure that those involved in the consent process maintain their knowledge.

72. Standard GQ1 requires processes and procedures relating to licensed activities to be documented in policies and standard operating procedures (SOPs), including (as applicable):

    - consent for PM examination and retention of tissue retained during PM
    - admission and release of bodies to and from the mortuary
    - movement of bodies and tissue between the mortuary and any other internal areas or external organisations (e.g. to a lab for analyses or to a referral site for examination)
    - PM examination
    - records management
    - incident reporting and management
    - disposal of tissue retained during PM examination.

73. Policies and SOPs may be written and controlled ("owned") by the mortuary or by the Directorate or Department within which it sits. Alternatively they may be centrally owned, for example within an NHS Trust clinical governance framework or by a Local Authority.

74. In relation to standard GQ2, which requires a documented system of quality management and audit, as a minimum, policies and SOPs should be controlled in order to ensure that only current versions are in use. Additionally, audits should be carried out of activities taking place under an HTA licence and cover all key processes, procedures and records. Audit findings and any corrective and preventative actions taken as a result of the audit should be documented. The

types of audits that we would typically expect to see at a PM establishment are as follows:

- process audits where processes, policies, and SOPs are audited for accuracy and compliance on a regular basis (for example, on a rotating basis every one to three years)

- traceability audits, which follow bodies from admission to the mortuary to release, including any tissue removed during PM to repatriation with the body, release for burial or cremation, disposal or retention with consent

- audits of retained material, which should be carried out regularly to ensure that establishments are aware of all material they are storing, and for which scheduled purpose(s)

75. In relation to standard GQ6, the HTA requires establishments to have a robust system in place which ensure bodies and tissues are uniquely and unambiguously labelled and traceable from the time of admission to release from the establishment or disposal. The system should enable bodies and tissues (including blocks and slides) that have moved around or left the establishment for analyses or examination to be traced, and it is considered good practice for establishments to record that bodies and tissue have been delivered elsewhere, whether to another area on-site (e.g. laboratory) or to an external person or organisation.

76. In relation to standard GQ8, documented risk assessments should cover all processes and procedures which relate to the licensed activities. These should include health and safety as well as risks to the integrity of bodies and tissue, and the dignity of the deceased. Examples of these types of risks are misidentification of a body, mislabelling of bodies or tissues, and incorrect or inaccurate record-keeping.

Summary of other regulatory activity

77. This section describes the regulatory enforcement action and investigations into serious untoward incidents, unique to the post mortem sector, which the HTA carried out in 2009/10.

Regulatory enforcement action

78. Directions were issued to three PM establishments in 2009/10:

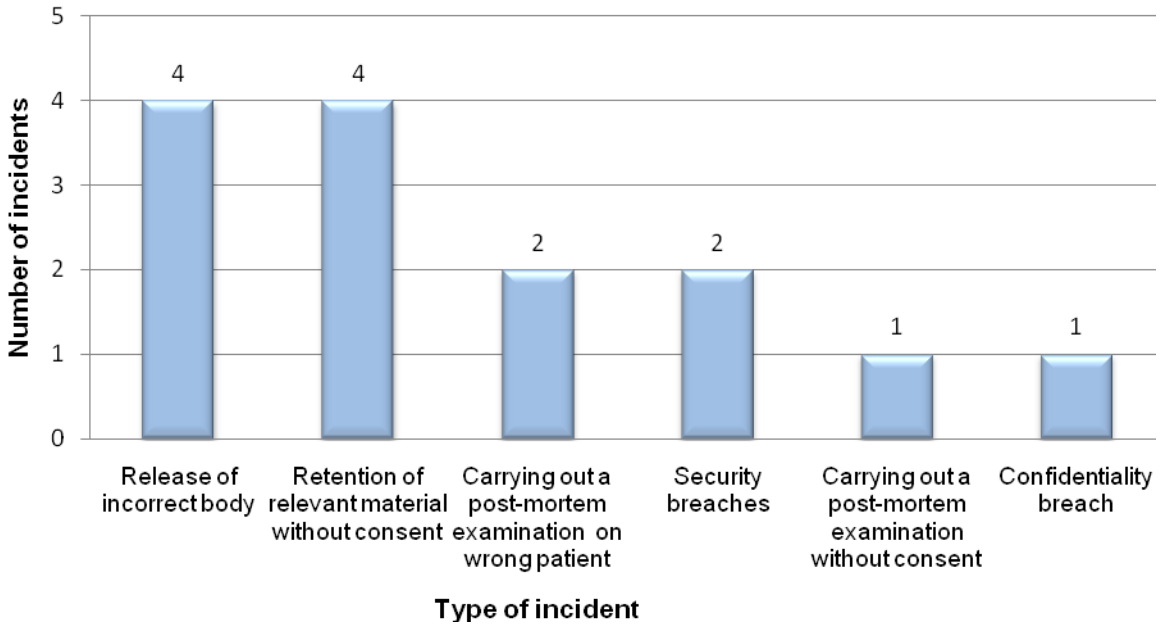
- to bring establishments into the licensing framework where licensed activities were being carried out on unlicensed premises
- to ensure that a suitable DI was in place at licensed establishments
- to ensure that relevant material was stored on licensed premises

79. Regulatory enforcement action was taken in relation to one establishment. Two licences were suspended and a notice of proposal was issued to revoke a licence. This action was the result of a non-routine site-visit inspection that revealed that the majority of HTA quality standards were not being met and that the DI had failed in his statutory duty to ensure that suitable practices were being carried out at the establishment. A follow-up non-routine site-visit inspection was undertaken five weeks after the first, in order to assess the progress which had been made towards meeting the HTA standards. The establishment had invested substantial amounts of time and resources and had made significant improvements, satisfying the HTA that appropriate systems had been put in place. As a result, the suspended licences were reinstated.

Investigations

80. Incidents were brought to the HTA's attention during 2009/10 from a variety of sources, including voluntary reporting by establishments, concerns or complaints from members of the public, media interest and site-visit inspections. The HTA investigated incidents with the intention of supporting establishments with their internal investigations and to ensure demonstrable remedial action was taken. Those which were considered to warrant investigation are summarised in Figure 10.

Figure 10: Incidents investigated by the HTA which occurred in PM establishments during 2009/10



81. It should be noted that the number of reported incidents is very small in comparison with the estimated 111,000 PM examinations undertaken each year in England, Wales and Northern Ireland.

82. Since May 2010, reporting of serious untoward incidents in the PM sector is mandatory. A report summarising incidents reports during the first eight months of the system (1 May – 31 December 2010) will be published early in the 2011/12 business year.

Example scenarios of good practice

As explained in the *Introduction*, the following section provides example scenarios of good practice.

***Scenario 1**: A Designated Individual (DI) wanted to extend the scope of their establishment's HTA licence to include premises where removal of tissue from a deceased child would occasionally take place, including the Accident and Emergency Department, maternity ward and paediatric ward.*

The DI confirmed that the premises were fit for purpose by carrying out a documented risk assessment of the different areas. The risk assessment considered the risks to the samples and the equipment and area available to take the samples, to ensure that the dignity of the person who had died is maintained and the needs of the family accompanying the child were taken into account.

The DI nominated a Person Designated (PD) in each of the areas where the licence would be extended. This assured the DI that appropriate individuals had oversight of the licensed activity in each area and that they were kept up-to-date on all relevant matters. The PDs were identified to all staff in each area as having the authority to act under the HTA licence on the DI's behalf.

The DI ensured that staff in the additional areas read and understood the HTA's policy on the removal of relevant material from deceased children and that all relevant policies and SOPs were amended to include reference to the policy. The DI also ensured that relevant local policies and SOPs were amended to reflect any changes in practice in the additional areas which resulted from the carrying out of regulated activities.

Staff in the areas where the licence was extended were trained on any changes in practice and the risks associated with the regulated activities. Particular attention was paid to issues related to consent, traceability, disposal and the reporting of incidents to the DI. The training was documented.

Scenario 2: *A licensed establishment did not have a histopathology laboratory on the same site and sent all post mortem tissue which required analysis off-site.*

The DI put in place a written agreement with the courier company which transported tissue between the establishment and other laboratories. This agreement outlined the responsibilities of each party, the storage parameters for tissue during transport and the record-keeping requirements. The courier was required to provide the establishment with a receipt upon collection of tissue, and to record the name and job title of the person who took delivery of the tissue at each off-site laboratory.

The establishment created a template form, which was used to record what tissue was sent in each delivery to an external laboratory. Written agreements were put in place with each of the off-site laboratories, which outlined the responsibilities of each party. The agreements put an emphasis on record-keeping: laboratories were required to fax the form which accompanied tissue deliveries back to the establishment to confirm each delivery was received. Additionally, the external laboratories provided disposal dates if tissue was not being returned to the establishment for repatriation, burial or cremation, or retention for use for a scheduled purpose.

The establishment used a log to record tissue types and quantities which were sent off-site for analysis including the date they are sent, a unique identifier (PM number), the name and address of the laboratory, whether tissue would be returned to the establishment and the courier receipt number. If tissue was returned to the establishment, the same log was used to record when it was received and when it

was repatriated, released for burial or cremation, disposed of or stored for future use for a scheduled purpose.

The DI ensured that all practices relating to tissue being sent off-site for analyses were contained in controlled documents and included documented risk assessments. The practices and risk assessments were subject to audit and regular review.

Appendix 1: Establishments receiving a site-visit inspection between 1 April 2009 – 31 March 2010

Establishments marked with a * have been inspected previously.

Anatomy

- Department of Anatomy –Robert Jones and Agnes Hunt Orthopaedic and District Hospital (12073)
- University Hospitals of Coventry and Warwickshire NHS Trust (30019)

Research

- Southmead Hospital (12415)
- John James Laboratories, University of Bristol (12273)
- Belfast Health and Social Care Trust (12278)
- University of Wales Institute Cardiff (12408)
- Brunel University (12543)
- Centre for Emergency Preparedness and Response (30007)
- Liverpool School of Tropical Medicine (12548)
- University of Bradford (12191)
- University of Southampton (12009)
- Institute for Science & Technology in Medicine (ISTM), Keele University (12349)
- King's College London (12521)
- London Neurodegenerative Diseases Brain Bank (12293)
- Glaxosmithkline (12202)
- Central Manchester University Hospitals NHS Foundation Trust (12552)
- King's College London (12223)

Public display

- Space 2 (12540)

Human application

- SCI Bristol (11039)
- NHSBT Bristol (22518)
- James Paget University Hospitals NHS Foundation Trust (22504)
- MTS Cryo Stores UK Ltd (22499)
- UK Stem Cell Bank (22502)
- Wycombe Hospital (12247)
- European Collection of Cell Cultures, Centre for Emergency Preparedness & Response (12114)
- University Hospitals of Coventry and Warwickshire NHS Trust (12319)
- Queen Alexandra Hospital (11128)
- Welsh Blood Service (22497)
- DRWF Islet Isolation Facility (22496)
- Future Health Technologies (22503)
- Hospital Innovations Limited (22512)
- Leicester Bone Bank, University Hospitals of Leicester NHS Trust (11011)
- London Centre for Aesthetic Surgery (LCAS) (11112)*
- King's Cell Isolation Unit (11062)*
- Anthony Nolan Cord Blood Bank (22527)
- Stem Cell Derivation Facility (22510)
- CryoLife Europa, Ltd. (22498)
- University Hospital North Staffordshire (12417)*
- Birmingham Children's Hospital (11005)*
- St George's Healthcare NHS Trust (12462)*
- Bristol Tissue Bank (11045)*
- Birmingham and Midland Eye Centre (11061)*
- Alder Hey Children’s NHS Foundation Trust (22595)
- East of Scotland Blood Transfusion Centre (11086)*
- Edith Cavell Hospital (12484)*
- Princess Grace Hospital (11069)*
- Royal Free Hospital (12406)*
- Wolfson Cellular And Gene Therapy Unit (11025)*

- Southmead Hospital (11143)
- Robert Jones and Agnes Hunt Orthpaedic and District Hospital (11064)*
- Bone Bank (11134)*
- Royal Gwent Hospital (11130)
- NHS London Cord Blood Bank (SCI CBB Edgware) (11007)
- Wrightington Hospital (11089)
- Ysbyty Gwynedd (11110)*
- Frenchay Hospital (12444)*
- Belfast Health and Social Care Trust (11087)
- Poole Hospital (11133)
- SCI Sheffield (11036)
- London Bridge Hospital (12431)*
- Microbiology, Northern General Hopsital (11030)
- SCI Manchester (11028)
- SCI Birmingham (11041)
- SCI Oxford (11042)
- Gartnavel General Hospital (11065)
- Royal Liverpool University Hospital (11055)*
- Stem Cell Laboratory, Addenbrooke's Hospital (11066)
- Smart Cells International (22522)
- Royal Bournemouth Hospital (11129)*
- Salisbury District Hospital (11102)*
- Royal Manchester Children's Hospital (22596)
- University Hospital of North Staffordshire (22593)
- Newcastle Bio-Manufacturing Facility (22516)
- SCI Leeds (11017)*
- CTS-Manchester Eye bank (11056)*
- Trycare Ltd (22587)
- Surgi C Limited (22578)
- UK Cord Blood Bank (22576)
- Broomfield Hospital (12404)*
- Norfolk & Norwich University Hospital NHS Trust (11019)*

- Belfast City Hospital Stem Cell Bank (11024)*
- Swindon & Marlborough NHS Trust (11014)*
- Virgin Health Bank (22514)
- Roslin Cells Ltd (22515)
- Forth Medical Limited (22583)
- Royal National Orthopaedic Hospital (11135)*
- Chase Farm Hospital Bone Bank (11044)*
- The John Goldman Centre for Cellular Therapy (11118)*
- Piam Brown Ward (22567)
- Fisher BioServices (11074)*
- Nuffield Orthopaedic Centre NHS Trust (22545)
- Bioeden Limited (12478)*
- University Hospital of North Durham (12428)*
- Weston General Hospital (12156)
- Royal Cornwall Hospital (12439)*
- Moorfields Eye Hospital NHS Foundation Trust (11040)*
- Paediatric Haematology/Oncology Unit (22561)
- Queen Victoria Hospital NHS FT (11091)*
- Altrika Limited (ne York Pharma) (11020)*
- Stepping Hill Hospital (12410)*
- City Hospital (22563)
- BMI The Priory Hospital (22551)
- Royal Alexander Hospital (22568)
- Frimley Park Hospital (12294)
- Great Ormond Street Hospital Cell therapy Laboratory (Immunology and Haematology) (11026)*
- Basingstoke Hospital, Orthopaedic Department (11119)*
- BioVault (11063)*
- Royal Devon & Exeter Hospital (11132)*
- Cells 4 Life Limited (11083)*
- South East Tissue Services (SNBTS) (11010)*
- Addenbrooke’s Hospital (11072)*

- The London Clinic (11052)*
- The Christie Hospital Foundation Trust (11081)*
- St Bartholomew's Hospital (11099)*
- Anthony Nolan Trust (22513)
- BMI Alexandra Hospital (22542)

Post mortem

- Uxbridge Mortuary, Civic Centre (12435)
- North Cheshire Hospitals NHS Trust (Warrington Hospital) (12024)
- Wrexham Maelor Hospital (12150)
- Department of Cellular Pathology, Kent and Sussex Hospital (12211)*
- Sunderland Royal Hospital (12281)
- Trafford General Hospital (12234)
- Royal Liverpool University Hospital (11055)
- Miller House Mortuary (12125)
- Brighton & Hove City Mortuary (12007)
- Salisbury District Hospital (12047)
- King's College Hospital (12377)
- Bournemouth Borough Mortuary (12405)*
- Haringey Public Mortuary (12263)*
- Leicester Royal Infirmary (12337)*
- Croydon Public Mortuary (12081)
- Ashford & St Peter's NHS Trust (12542)
- Scarborough General Hospital (12395)
- Cemeteries & Crematoria Service (12033)
- St Pancras Public Mortuary (12445)
- University Hospital of Wales (12163)
- Brent & Harrow Public Mortuary (12017)
- Fulham Public Mortuary (12489)
- Poplar Public Mortuary (12087)
- University Hospitals of Coventry and Warwickshire NHS Trust (12319)
- The Coroner's Court (12536)

- Lewisham Public Mortuary (12407)
- Public Mortuary - Public and Forensic Science Centre (12046)
- Royal Derby Hospital (12537)
- Medway Maritime Hospital (12090)
- William Harvey Hospital Mortuary (12147)
- Queen Elizabeth the Queen Mother Hospital (QEQMH) Mortuary (12147)
- Bradford Royal Infirmary (12244)
- Sandwell Hospital (12131)
- Hull Royal Infirmary (12170)
- Royal Manchester Childrens Hospital (12554)
- Stoke Mandeville Hospital (12246)
- Wycombe Hospital (12245)
- The Royal London Hospital (12187)
- Cellular Pathology Department, Milton Keynes General Hospital (12201)
- Pathology - St Helier Hospital (12345)
- Airedale General Hospital (12138)
- Dorset County Hospital - Department of Histopathology (12449)*
- Birmingham Children's Hospital (12132)
- St. Richard's Hospital (12143)
- Hinchingbrooke Hospital (12205)
- University Hospital of North Staffordshire (12224)
- Wexham Park Hospital (12323)
- Royal Berkshire NHS Foundation Trust (12232)
- The Ipswich Hospital NHS Trust (12308)
- Gloucestershire Royal Hospital (12126)
- Alder Hey Childrens NHS Foundation Trust (12213)
- Royal Hampshire County Hospital, Winchester (12014)
- Glan Clwyd Hospital (12153)
- Guy's & St Thomas' Hospitals, Cellular Pathology (12243)
- Queen Elizabeth II Hospital (12110)
- Southend University Hospital NHS Foundation Trust (11068)
- The Princess Alexandra Hospital NHS Trust (12458)

- Bronglais Hospital (12396)
- Bournemouth Borough Mortuary (12405)
- Royal Blackburn Hospital (12309)
- The Pennine Acute Hospitals NHS Trust (12342)
- Mid Essex Hospitals Trust (12441)
- South Devon Healthcare Trust (12181)
- Royal Preston Hospital (12037)
- Sheffield Children's Hospital (12001)
- West Suffolk Hospital NHS Trust (12242)
- Luton and Dunstable Hospital NHS Foundation Trust (12348)
- Belfast Health and Social Care Trust (12229)
- Altnagelvin Hospital (12025)
- Frimley Park Hospital (12294)
- George Eliot Hospital (12171)

Appendix 2: Relevant website links

References cited in the text (numbering refers to their reference in the text)

1. Ipsos MORI evaluation 2010
   www.hta.gov.uk/publications/evaluations/publicevaluation2010.cfm

2. Better Regulation Executive code of practice
   www.bis.gov.uk/policies/better-regulation/code-of-practice-on-guidance-on-regulation

3. HTA standards for all sectors – see appendix 2

4. HTA Regulatory Enforcement Policy

   http://www.hta.gov.uk/legislationpoliciesandcodesofpractice/regulatoryenforcementpolicy.cfm

5. HTA codes of practice
   www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

6. GMC publication *Making and using visual and audio recordings of patients*
   www.gmc-uk.org/guidance/ethical_guidance/making_audiovisual.asp

7. EUROCET
   www.eurocet.org

8. HTA Legal Directions
   www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm

9. Adverse event and reaction reporting
   www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm

10. Human Tissue Act 2004
    www.legislation.gov.uk/ukpga/2004/30/contents

11. HTA model post-mortem examination consent form
    www.hta.gov.uk/legislationpoliciesandcodesofpractice/modelconsentforms.cfm

12. Position statement on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004
    www.hta.gov.uk/legislationpoliciesandcodesofpractice/positionstatementonconsentforpost-mortemexaminationandtissueretentionunderthehumantissu.cfm

    Policy on consent for post-mortem examination and tissue retention under the Human Tissue Act 2004

www.hta.gov.uk/legislationpoliciesandcodesofpractice/policyonconsentforpost-mortemexaminationandtissueretention.cfm

Legislation

Human Tissue Act 2004

www.legislation.gov.uk/ukpga/2004/30/contents

Human Tissue (Quality and Safety for Human Application) Regulations 2007 - www.legislation.gov.uk/uksi/2007/1523/contents/made

Licensing under the Quality and Safety Regulations - www.hta.gov.uk/licensingandinspections/licensingunderthequalityandsafetyregulations.cfm

HTA Legal Directions - www.hta.gov.uk/legislationpoliciesandcodesofpractice/htalegaldirections.cfm

HTA publications

Codes of practice - www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm

Summary compliance reports 2008/09 - www.hta.gov.uk/publications/summarycompliancereports2008-09.cfm

Summary inspection reports 2007/08 - www.hta.gov.uk/publications/summaryinspectionreports2007-08.cfm

Licensing information

HTA licence standards can be downloaded as compliance report licence applications from - http://www.hta.gov.uk/licensingandinspections/licenceapplicationstep-by-stepguide/compliancereportlicenceapplications.cfm

Licence application step-by-step guide - www.hta.gov.uk/licensingandinspections/licenceapplicationstep-by-stepguide.cfm

Do I need a licence? - www.hta.gov.uk/licensingandinspections/licenceapplicationstep-by-stepguide/doineedalicence.cfm

People at licensed establishments - www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments.cfm

Reporting to the HTA

- Human application adverse event and reaction reporting - www.hta.gov.uk/licensingandinspections/reportingtothehta/adverseeventandreactionreporting.cfm
- Post mortem serious untoward incident notification - www.hta.gov.uk/licensingandinspections/reportingtothehta/seriousuntowardincidentreporting.cfm

Frequently asked questions (FAQs)

Research sector:

Research FAQs - www.hta.gov.uk/licensingandinspections/sectorspecificinformation/research/researchfaqs.cfm

Anatomy sector:

FAQs on the disposal of anatomical specimens, former anatomical specimens, and body parts - www.hta.gov.uk/legislationpoliciesandcodesofpractice/faqsonthedisposalofanatomicalspecimensformeranatomicalspecimensandbodyparts.cfm

Public display sector:

Public display FAQs - www.hta.gov.uk/licensingandinspections/sectorspecificinformation/publicdisplay/publicdisplayfaqs.cfm

Post mortem sector:

PM General Directions April 2010 FAQs - www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem/pmgeneraldirectionsapril2010faqs.cfm

Human application sector:

Licensing of procurement organisations FAQs - www.hta.gov.uk/licensingandinspections/licensingunderthequalityandsafetyregulations/licensingofprocuremen/licensingofprocurementorganisationsfaqs.cfm

Quality and Safety Regulations FAQs-
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/qualityandsafetyregulationsfaqs.cfm

Advanced Therapy Medicinal Product FAQs-
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/advancedtherapymedicinalproductsfaqs.cfm

Distribution, Import, Export FAQs-
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/distributionandimportexportfaqs.cfm

Third Party Agreement FAQs-
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/thirdpartyagreementfaqs.cfm

Regulation of stem cell lines FAQs-
www.hta.gov.uk/licensingandinspections/sectorspecificinformation/humanapplication/regulationofstemcelllinesfaqs.cfm

Serious Adverse Events and Serious Adverse Reactions FAQs-
www.hta.gov.uk/licensingandinspections/faqsonsaears.cfm

FAQs for distributors of acellular material-
www.hta.gov.uk/aboutus/frequentlyaskedquestions/faqsfordistributorsofacellularmaterial.cfm