

Summary of compliance 2008/09

Overview of the Human Tissue Authority's regulatory activity 2008/09

Working together to drive up standards

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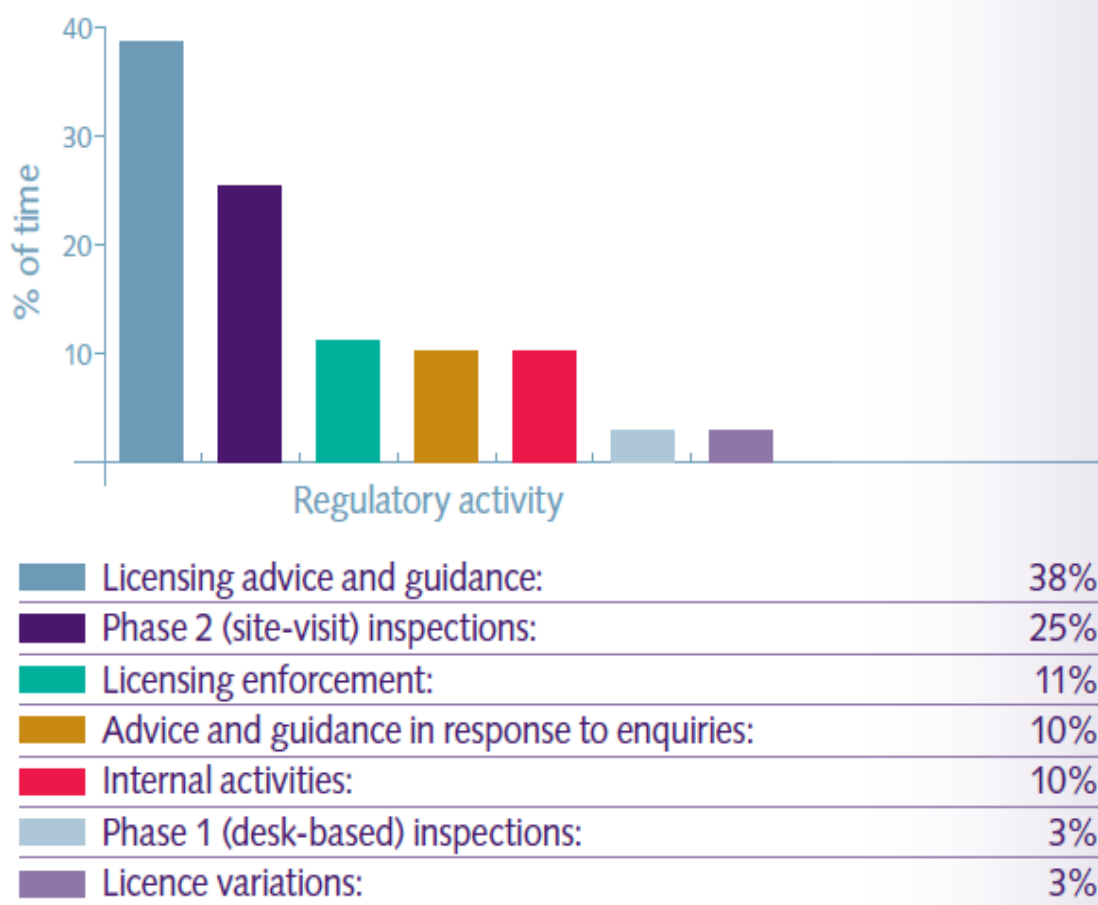
Introduction

1. In September 2008, the HTA published a set of five summary inspection reports, reviewing each sector's compliance with HTA standards and highlighting relevant learning points. This year, we have launched five reports, covering the 2008/09 business year, which aim to give a clear summary and update of the extent of regulatory compliance and activity in each sector. It is hoped that the information and guidance provided in these reports will enable individuals to benchmark their establishments against others in their sector and to drive up their own establishment's standards. Copies of all the reports can be found on our website:
www.hta.gov.uk/publications/summaryinspectionreports.cfm.
2. The aim of this report is to provide an overview of the HTA's regulatory activities across all sectors between 1 April 2008 and 31 March 2009, reviewing and comparing the findings with those of the previous business year. Since the first period of phase 2 site-visit inspections, the HTA has gained a better understanding of the strengths and weaknesses of each sector.
3. During the 2008/09 business year, we assessed applications to license 90 new premises and conducted 102 phase 2 site-visit inspections. Overall, we have seen a decrease in the number of additional conditions imposed and an increase in advice and guidance given during this period, compared with the previous business year.

Regulatory activity: what does it involve?

4. The HTA's regulatory activities can be separated into seven categories (figure 1).
 - phase 1 desk-based inspections
 - phase 2 site-visit inspections
 - licensing advice and guidance
 - licensing enforcement
 - licensing variations
 - advice and guidance in response to enquiries and
 - internal activities

Figure 1 Breakdown of the time spent on regulatory activities



5. Licensing advice and guidance takes up the largest proportion of the HTA's regulatory activities (38%). This involves analysing all of our licensing, inspection and enforcement activity, and subsequently sharing the learning with those working in the sectors that we licence and inspect. The aim is to drive up standards across all of our licensed sectors.

6. Advice and guidance is shared via:
 - the annual publication of summary of compliance and regulatory activity reports:
www.hta.gov.uk/publications/summaryinspectionreports.cfm
 - bimonthly publication of our e-newsletter:
www.hta.gov.uk/newsandevents/e-newsletter.cfm
 - frequently asked questions:
www.hta.gov.uk/licensingandinspections/faqs.cfm
 - Designated Individual (DI) training events and
 - the written interpretation of legislation:
www.hta.gov.uk/legislationpoliciesandcodesofpractice/policies.cfm

7. In addition to this, 10% of time spent on regulatory activities involves the provision of tailored advice and guidance in response to direct enquiries, from individuals working in licensed establishments and members of the public.
8. During this time period, the completion of phase 1 desk-based and phase 2 site-visit inspections accounted for 28% of time spent on regulatory activities. All new applications undergo a phase 1 desk-based inspection, resulting in a decision to grant or refuse a licence. The HTA undertakes a risk-based schedule of phase 2 site-visit inspections (table 1), which also lead to licensing decisions.
9. For the human application sector, there is a requirement for establishments to undergo a phase 2 site-visit inspection every two years. Inspections for this sector are therefore scheduled taking this and each establishment's risk level into account. More information about our inspection processes can be found on our website: www.hta.gov.uk/licensingandinspections/inspections.cfm.
10. Between 1 April 2008 and 31 March 2009, the HTA conducted 102 site phase 2 site-visit inspections across the five licensed sectors as follows:

Table 1: Number of phase 2 site-visit inspections 2007/08 vs 2008/09

Sector	2007/08	2008/09
Post mortem	49	37
Human application	51	44
Research	10	15
Anatomy	4	4
Public display	2	2
Total	116	102

11. Regulatory action may result from non-compliances identified during a site-visit inspection or after an investigation of a complaint or allegation reported to the HTA. We estimate that enforcement occupies 11% of time spent on regulatory activity. More information on the significant regulatory action taken during this period can be found in paragraphs 27 – 31 of this report.

12. During the 2008/09 business year, we received and assessed 550 licence variation applications.

13. Licence variations fall into the following categories:

- changes to an establishment's DI
- changes to an establishment's licence holder or corporate licence holder contact
- minor changes to a premises (e.g. the addition of a room to an existing site)
- major changes to a premises (e.g. the addition of a new licensed activity, move to a new building or significant change to the premises)
- the submission of an application to add a satellite site

14. The relevant application forms and more information about how to make changes to a licence can be found on our website:

www.hta.gov.uk/licensingandinspections/peopleatlicensedestablishments/howtomakechangestoyourlicence.cfm.

What changes have there been to the number of licensed establishments since 1 April 2008?

15. Between 1 April 2008 and 31 March 2009, the HTA received 71 new licence applications for a total of 90 premises (including 18 satellites), spread between the five licensed sectors as follows:

Table 2: Number of new applications between 1 April 2008 and 31 March 2009

Sector	Applications	Newly licensed premises (including satellites)
Post mortem	7	8
Human application	44	54
Public display	6	7
Anatomy	1	1
Research	13	20
Total	71	90

16. These applications contributed to an overall growth of 8% in the number of licensed premises, with the highest proportion of these applications (61%) from establishments within the human application sector.

17. Overall growth in the number of licensed premises was seen in both the public display and human application sectors, with numbers increasing by 69% and 25% respectively (table 3).

Table 3: Number of HTA licensed premises as at 31 March 2008 and 31 March 2009, grouped by sector

Sector	2007/08	2008/09
Post mortem	298	296
Human application	212	266
Public display	13	22
Anatomy	45	45
Research	236	236
Total	804	865

18. The licensing of 40 procurement organisations contributed substantially to the growth of the human application sector during this period.

19. The growth of the public display sector is largely due to an increase in the number of temporary licences granted. However, despite a growth of 69%, public display remains the smallest of our sectors (table 3); currently making up 3% of total licensed premises.

What did we find on phase 2 site-visit inspections during 1 April 2008 to 31 March 2009?

20. Between 1 April 2008 and 31 March 2009, the HTA conducted 102 phase 2 site-visit inspections across the five licensed sectors (table 1). These inspections resulted in the imposition of 151 additional conditions to the licences of 54 establishments and of a total of 1,001 individual items of advice and guidance offered.
21. Of the phase 2 site-visit inspections carried out in 2008/09, 10 were considered to be non-routine inspections. The majority of these (seven, 70%) were within the post mortem sector, two were within the public display sector and one was of an anatomy sector establishment. More details of these can be found in the individual reports published for each sector.
22. Fewer phase 2 site-visit inspections were carried out in 2008/09 as compared with 2007/08 (table 1). This decrease was the result of a decision to suspend inspections for a three month period to allow staff to effectively deal with the influx of applications from procurement organisations.
23. In the period from 1 April 2008 to 31 March 2009, compared with the previous business year, the HTA imposed fewer additional conditions and offered more items of advice and guidance, as demonstrated in table 4. These changes are significant and take into account the 12% decrease in the number of site-visit inspections. This equates to a real decrease in additional conditions of 25% and an increase of 21% in the number of individual items of advice and guidance.
24. All sectors except anatomy experienced a decrease in the number of additional conditions imposed after phase 2 site-visit inspections. Only the human application and research sectors experienced an increase in the number of items of advice and guidance given.
25. As in the previous summary period, the highest proportion of both additional conditions and advice and guidance were provided in relation to the standards of governance and quality systems. The lowest number of conditions and advice and guidance were provided in relation to the disposal standards (table 4).

26. Between August 2008 and March 2009, we received 36 inspection feedback forms (a return rate of 50%), with 95% of respondents finding the overall inspection process very good or excellent.

Table 4: Summary of additional conditions and advice and guidance for all sectors: 2008/09 vs 2007/08

	Consent	Governance and quality systems	Premises, facilities and equipment	Disposal	Total
Additional conditions 2008/09	16 (-36%)	94 (-33%)	30 (-44%)	11 (-45%)	151 (-37%)
Additional conditions 2007/08	25	142	54	20	241
Advice and guidance 2008/09	96 (+10%)	614 (+13%)	241 (-3%)	50 (+25%)	1001 (+9%)
Advice and guidance 2007/08	87	541	248	40	916

What significant regulatory action has been taken since 1 April 2008?

27. The HTA is responsible for ensuring that establishments comply with the requirements of the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007. If non-compliance is identified, regulatory action may be taken; this may include the refusal to grant a licence, imposition of additional conditions to an existing licence, issuing of special directions or the suspension or revocation of a licence.

28. Regulatory Action Panels (RAP) are set up whenever significant regulatory action needs to be considered. RAPs are used by the HTA to consider complex regulatory issues and to ensure that a fair, proportionate and justifiable licensing decision is made in line with the HTA's enforcement policy. More information about regulatory enforcement policy can be found on our website:

29. Between 1 April 2008 and 31 March 2009, we convened 19 RAPs, resulting in five non-routine inspections and the issue of three special directions (table 5). This represents a 46% increase in the number of RAPs compared with the previous business year, although we issued fewer sets of special directions.

Table 5 Number of RAPs held per business year

Sector	2007/08	2008/09
Anatomy	1	1
Human application	5	6
Post mortem	4	9
Research	3	1
Public display	0	0
Unlicensed establishments		2
Total	13	19
Special directions issued	8	3

30. There are several possible reasons for the number of RAPs increasing. The HTA's public profile has increased since 2007, resulting in an increased volume of individuals and whistleblowers contacting the HTA to report allegations of potential poor compliance or non-compliance with the relevant legal and regulatory requirements. Examples of this include: allegations that procurement activities were being carried out on unlicensed premises and that unsuitable practices were taking place in a post mortem establishment.

31. As the HTA's professional profile has grown, other organisations and agencies have gained a better understanding of the HTA's remit and powers. This has resulted in an increase in the number of matters referred to us from organisations such as the Department of Health and the police. For example, the Health and Safety Executive contacted us with a complaint that they had received from an anonymous source alleging unsuitable practices at a mortuary. In response to this, we carried out one unannounced site-visit inspection, which was

subsequently followed up by a joint inspection of the premises with the Health and Safety Executive.

What next?

32. In October 2009, the HTA is hosting a post mortem conference to support DIs in understanding their statutory responsibilities. Delegates will be encouraged to share good practice and explore how improvements can be achieved.
33. We are planning to hold a training event in November 2009 to support DIs from human application establishments that distribute acellular material.
34. Throughout the 2009/10 business year, a new approach to optimise the number and usefulness of feedback forms returned to the HTA after phase 2 site-visit inspections is being piloted. This feedback allows us to continually improve our inspection processes.
35. We will continue to engage with stakeholders and work collaboratively with professional bodies, addressing relevant issues as they arise. New advice and guidance will continue to be issued via our e-newsletter and on our website.
36. We hope that, having read this overview of our regulatory activity during the 2008/09 business year, you will go on to read the individual summary of compliance and regulatory activity reports for each sector that are referenced in this report. Copies of these reports can be found on our website:
www.hta.gov.uk/publications/summaryinspectionreports.cfm.

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