

Summary of compliance 2008/09

Regulating the post mortem sector

Working together to drive up standards



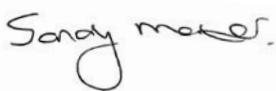
Foreword

The work of the Human Tissue Authority (HTA) is determined by a combination of statutory obligations and accepted good practice. The principles which frame the HTA's work are similar to those which frame the work of post mortem (PM) establishments. As a regulatory body, our approach to regulating the PM sector is determined by the Human Tissue Act 2004 (HT Act) and the good practice derived from key Government reports, particularly the Regulators' Compliance Code: www.berr.gov.uk/files/file45019.pdf.

This report is the second of its kind and is one of a set that the HTA has produced for each of the sectors that we license and inspect. The main aim is to give a clear summary and update about the extent of regulatory compliance in the PM sector. The information and guidance in this report should be used by staff working under the authority of PM licences, particularly Designated Individuals (DIs), who may then be able to rate their establishments against others in the sector and use the information to raise their establishment's standards.

In December 2008, the Hampton Implementation Review (HIR) measured our compliance against the principles of Better Regulation: www.betterregulation.gov.uk. The HIR team found that we function in a risk-based, proportionate and transparent manner. The HIR report validates our approach in taking regulatory action only when it is needed, with an emphasis on providing advice and guidance, with the aim of preventing future non-compliance. This report indicates that non-compliance in the PM sector has not changed significantly in the last 12 months. This is of concern to the HTA and we have allocated more resources to inspect the PM sector in 2009/10, and we expect DIs to use this report to improve standards.

Although we expect licensed establishments to comply with our standards, we would also like staff at these establishments to feel that they have the knowledge and the confidence to achieve more than minimal compliance and to demonstrate good practice to us, other professionals and members of the public.



Dr Sandy Mather
Director of Regulation

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Executive summary

This report provides a summary of findings from the 37 phase 2 site-visit inspections of PM establishments, which were carried out between 1 April 2008 and 31 March 2009. As a result of the phase 2 site-visit inspections, we placed 52 additional conditions on 22 establishments' licences and offered 224 items of advice and guidance. During this same period, the HTA experienced a significant increase in complaints about establishments, which originated either from the staff working within our licensed establishments or from other sources, such as members of the public. Approximately one in five of our PM establishment site-visit inspections took place, and were prioritised, following receipt of information, including complaints.

The PM sector is the largest of the sectors we regulate. Much of its regulatory complexity relates to the diversity of staff, from different organisations, who work within the sector. The legislation, or professional guidelines, that influence the work of one individual within the sector might be different from those that influence the work of another. When the duties of these individuals overlap and conflict, there is a potential for regulatory non-compliance.

Phase 2 site-visit inspections demonstrated that the majority of PM establishments had a good understanding of the consent requirements of the HT Act, although there were deficiencies in the documents that supported the consent process and in consent training. In relation to governance and quality systems, quality management systems remain of a variable standard, although some were excellent. Complete traceability is a continuing issue; retained relevant material on microscope slides was often not accurately recorded.

In our summary inspection reports for 2007/08, we commented on the frequent uncertainty about a family's wishes regarding disposal of retained material removed during a PM examination. Our inspection findings demonstrated that this problem was still present. We believe this is a result of inadequate communication between families, establishments and coroners. In some areas, communication is excellent and systems have been put in place to ensure that establishments are left in no doubt as to when the tissue must be disposed of. In other areas, staff at our licensed establishments are still struggling to implement and maintain good lines of communication, which has resulted in establishments holding material which has fallen outside the authority of the coroner and is not being stored with consent for a scheduled purpose under the HT Act.

Executive summary (continued)

The HTA continues to work with establishments and coroners to try to resolve these communication issues. The revised code of practice on PM examination gives further information on this and we provide a model communication flowchart on our website: www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm.

Introduction

1. The findings in this summary report are mainly drawn from our phase 2 site-visit inspection reports. However, these data are also supported by information drawn from licensing records and documents relating to regulatory action.
2. As part of the process following a site-visit inspection, the inspection report and any licensing decisions are reviewed by the DI responsible for supervising licensable activities. In accordance with statutory requirements, the HTA gives each Licence Holder (LH) and DI clear reasons for proposed licensing decisions and gives the establishment the opportunity to make representations about a proposal to add conditions before the HTA makes the final licensing decision. In this way, the HTA demonstrates transparency about the judgements and licensing decisions that have been made and the reasons for them. In addition, all individual licensing decisions made as a result of the findings included in inspection reports are carefully considered with input from legal advisors and, where appropriate, a senior member of the HTA's regulation directorate.
3. It is important to note that the additional conditions, and advice and guidance, are establishment- and context-specific, and do not always lend themselves to be easily or appropriately transferred to another licensed establishment. Each licensing decision the HTA makes is specific to the facts of the case and only relevant information is considered. The HTA exercises its discretion reasonably and aims to make regulatory decisions that are transparent, accountable, proportionate, consistent and targeted to where action is needed. We do not routinely apply the same decision to each establishment. This means that, although the HTA aims to be consistent in its decision-making process, decisions will vary from establishment to establishment depending on the circumstances.

Introduction (continued)

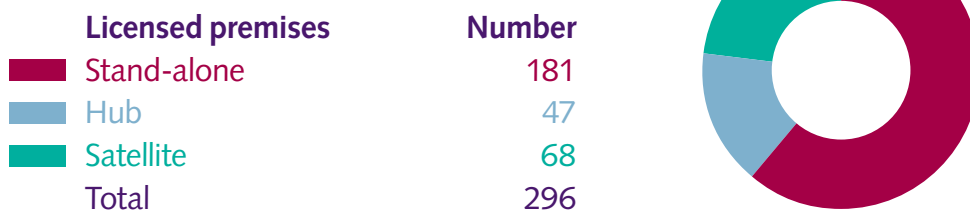
Using a risk-based regulatory approach

4. The HTA uses a risk-based regulatory approach to inform how we prioritise phase 2 site-visit inspections. Risk has different meanings according to context. The risk the HTA refers to is regulatory risk, which is the risk of non-compliance with the requirements of the legislation that the HTA was set up to implement. In the PM sector, the primary document that informs the framework for regulatory risk is the HT Act. The HT Act is augmented by other documents that are developed by the HTA with input, where appropriate, from those we regulate. These documents include our codes of practice, Directions and licensing standards.
5. We bring the core elements of the legislation and other documents together in the licensing standards that form the basis of the compliance report licence application.

Overview of the PM sector and inspections 2008/09

- At the end of the business year 2008/09, there were 296 PM premises, including satellite sites, within our licensing framework. Satellite sites are smaller establishments engaged in the same licensable activities as their hub sites. They are under the same governance as the hub establishment and are included in the hub's main application for licences.
- Although a small number of establishments either joined or left our licensing framework during the year, the total number of establishments (296) remained similar to the previous year's figure of 298 establishments. Figure 1 shows the numbers of stand-alone, hub and satellite establishments.

Figure 1: The numbers of stand-alone establishments, hubs and satellites



- The majority of licensed premises are within NHS Trusts. Twenty-six (9%) of the 298 establishments are public mortuaries, under the management of local authorities.
- Thirty-seven establishments received a phase 2 site-visit inspection between 1 April 2008 and 31 March 2009 (see Appendix 1 for a full list of establishments visited). 34 of these establishments were within NHS Trusts, two were public mortuaries and one was a private facility which stored blocks and slides. This report contains the results of all 37 inspections.
- Two of the inspected establishments had a satellite site. The governance arrangements of satellite sites were assessed and the premises were inspected.

Overview of the PM sector and inspections 2008/09 (continued)

11. The HTA has a statutory responsibility to make judgments about the suitability of the LH and DI. Although the suitability of DIs is assessed by the HTA during its assessment of applications for licensing, on four phase 2 site-visit inspections, the HTA recommended or advised that the DI be substituted for a more suitable person. None of the suitability issues was related to qualifications or professional competence. They were all because DIs are too far removed from the operational management of regulated activities. Three of the four DIs were subsequently replaced with someone more suitable to perform the expected duties. In the remaining case, the HTA invited the LH to consider whether another DI more closely linked with regulated activities might be more suitable. In that particular case, the DI remains in place.

Non-routine phase 2 site-visit inspections

12. Most phase 2 site-visit inspections are planned and scheduled according to each establishment's risk score, which is calculated using a sector-specific risk matrix. The HTA refers to the majority of phase 2 site-visit inspections as 'routine' inspections. A minority of phase 2 site-visit inspections are described as 'non-routine'; these are usually brought forward in response to increased risk scores, typically resulting from one of the following:
 - an adverse incident, which might have been reported to us by any person or which we heard about via other means, or
 - a complaint, originating from any person
13. We advise that complaints from members of the public concerning services within NHS establishments do not fall within the remit of the HTA, but should first be referred to the relevant Trust through its formal complaints process. However, if complaints suggest the possibility of unsuitable practices or a regulatory breach at one of the HTA's licensed establishments, we seek to establish the facts so we can decide on the best regulatory approach to take.
14. A non-routine inspection may also be undertaken following a valid request from the establishment. These are considered on a case-by-case basis.
15. Of the 37 phase 2 site-visit inspections carried out during 2008/09, eight (22%) were non-routine. Seven of the eight non-routine inspections were prioritised and scheduled following receipt of information. Five of the eight non-routine inspections – 14% of the total number of phase 2 site-visit inspections – were carried out in response to a complaint from someone internal or external to the establishment.

Non-routine phase 2 site-visit inspections (continued)

Regulatory Action Panels

16. A Regulatory Action Panel (RAP) is an internal panel, convened to consider complex regulatory issues which may require significant regulatory action. The purpose of the RAP is to ensure that all relevant considerations are taken into account, leading to a fair, proportionate and justifiable decision. This panel is usually chaired by a Head of Regulation and includes the Regulation Manager responsible for making the licensing decision under discussion and a legal advisor. Regulatory action resulting from these panels can take the form of licence suspensions, Special Directions, revocations, variations, additional conditions or verbal and written advice and warning. Alternatively, a non-routine inspection may be the most appropriate course of action.
17. During 2008/09, a total of 19 RAPs were convened: nine (47%) were convened in relation to 10 PM establishments (one was a satellite of the main establishment). Of these RAPs, five were convened in response to complaints we received about practices at HTA-licensed establishments. One of these complaints was from a member of the public and appeared in a national newspaper.
18. Table 1 shows the three main reasons that RAPs were convened for PM sector establishments during the 2008/09 business year and the numbers of RAPs convened for each reason.

Table 1: the numbers and reasons for the RAPs pertaining to PM establishments

Reason for the RAP	Complaint	Unmet additional conditions	Following a phase 2 site-visit inspection
Number of RAPs	5	3	1

Analysis of additional conditions and advice and guidance

19. We recognise that the small sample size of establishments that received a phase 2 site-visit inspection (37) limits the statistical significance of some of the conclusions that could be drawn from the collated data. We have been mindful of this when we have drawn conclusions in this report.
20. When comparing this report's findings with those of last year's report, it is also important to exercise a degree of caution as there are factors which may confound any potential conclusions drawn from direct comparison. First, because we schedule routine inspections according to establishments' risk scores; many of the PM establishments we had deemed as the highest risk had already been inspected before the 2008/09 business year commenced. Second, fewer phase 2 site-visit inspections were carried out and, third, it may be argued that the HTA's increased understanding of the PM sector could influence our approach in resolving deficiencies in regulatory compliance.
21. Following phase 2 site-visit inspections, we placed 52 additional time-bound conditions on 22 establishments' licences. In addition, we offered 224 items of advice and guidance, which demonstrates the importance we place on supporting our licensed establishments during the inspection process (see table 2).
22. We group our licensing standards in four categories:
 - consent
 - governance and quality systems
 - premises, facilities and equipment
 - disposal

Analysis of additional conditions and advice and guidance (continued)

Table 2: Distribution of additional conditions and advice and guidance following site-visit inspections, grouped by category of standard

	Consent (C1–C3)	Governance and quality systems (GQS1–GQS8)	Premises, facilities and equipment (PFE1–PFE5)	Disposal (D1–D2)	Totals
No. of additional conditions	9	21	13	9	52
No. of establishments affected	9 (24%)	13 (35%)	8 (22%)	8 (22%)	N/A*
No. of items of advice and guidance	31	119	53	21	224
No. of establishments affected	21 (57%)	36 (97%)	26 (70%)	13 (35%)	N/A*

***NB:** An establishment may have a condition against more than one category of standards (e.g. a condition relating to consent and a condition relating to disposal). Such establishments have been included in the figures more than once (i.e. an establishment with conditions relating to consent and disposal will be included in the figures for consent and disposal).

Compliance with HTA standards

23. In this section of the report, compliance data for each of the four categories of the HTA standards have been extracted from the 37 phase 2 site-visit inspection reports and summarised. Where appropriate, references are made to the findings in last year's report.
24. For each category of HTA standards, general observations, comments and comparisons with previous findings are given. Data which may be of practical use to staff at establishments or licence applicants are presented in three ways:
 - Areas for improvement: these are linked to the additional conditions that were placed where compliance deficiencies were identified. These will allow staff working at licensed establishments to compare their level of regulatory compliance with other establishments in the PM sector.
 - Learning points: these are linked to the standard-specific items of advice and guidance we have provided to establishments in our phase 2 site-visit inspection reports. We provide these to help staff raise standards in their own establishments.
 - Good practice: these are examples of good practice that we have noted during phase 2 site-visit inspections. We provide them so that good practice is recognised and shared so that others may benefit.
25. The HTA is careful not to be too prescriptive so that DIs may be empowered to develop tailored solutions to achieve regulatory compliance. Therefore, the pieces of information contained within the learning points and good practice subsections are not 'one-size-fits-all' solutions but support efforts to improve compliance with HTA standards.

Consent standards (C1–C3)

26. Consent is the founding principle of the HT Act; consequently, the HTA places a great deal of importance on the consent standards being met. The requirements of the three consent standards are shown in table 3.

Table 3: Requirements of the consent standards

Consent standard (C1–C3)	Requirement of the standard
C1	Consent is obtained in accordance with the requirements of the HT Act and as set out in the code of practice
C2	Information about the consent process is provided and in a variety of formats
C3	Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

27. In last year's inspection summary report, we commented on our observation that the majority of establishments had a good understanding of the consent requirements of the HT Act and had policies and procedures outlining how consent should be taken. Again, we have found this to be the case.
28. In England, Wales and Northern Ireland, there remains a stark mismatch between the relatively small numbers of 'hospital' (or 'consented') PM examinations being undertaken each year and the much larger numbers of PM examinations being undertaken under the authority of a coroner. Given that few hospital PM examinations take place, in some cases we found that there may have been reluctance within NHS Trusts to set aside resources to update consent documentation and provide consent training. We believe that the relative scarcity of hospital PM examinations makes it more important that robust consent processes are in place to ensure that, when consent is sought and obtained, it is done so in accordance with the HT Act and codes of practice. Despite these challenges faced within their own organisations, establishments demonstrated a willingness to fully implement the consent requirements. Several establishments showed creativity in the way that training had been delivered and the proficiency of those seeking consent maintained.

Consent standards (C1–C3) continued

29. Following a phase 2 site-visit inspection, nine (24%) establishments had at least one additional condition relating to consent placed on their licences. Table 4 shows the comparison with last year.

Table 4: The number of additional conditions and advice and guidance placed on licences in relation to the consent standards after a phase 2 site-visit inspection

Business year	No. of establishments inspected	No. of conditions	No. of items of advice and guidance
2007/08	47	11	37
2008/09	37	9	31

30. Overall, establishments demonstrated an awareness of the cultural diversity of their local population, so that information about the consent process for hospital PM establishments was readily available. Any deficiency was usually addressed by using translators. One NHS Trust had researched the possibility of printing leaflets in an extended range of different languages, but had found this to be too impractical.

Consent standards (C1–C3) continued

Areas for improvement

31. Where we found deficiencies, we highlighted areas in which establishments needed to improve and imposed additional conditions to ensure compliance of the establishments with the consent standards. Box 1 details these areas for improvement.

Box 1: Areas for improvement (HTA standards, C1–C3)

- documents supporting the consent process, including forms, information leaflets, policies and procedures, needed to be updated to reflect the requirements of the HT Act and HTA codes of practice on Consent and PM examinations, (HTA standard C1)
- staff seeking consent for hospital PM examinations needed to undergo documented training to ensure that consent was obtained in accordance with the HT Act and HTA codes of practice (HTA standard C3)

NB. Where clinicians sought consent for PM examinations, it was typical to find that, although they might have received general training in consent, they had not been trained in the consent requirements of the HT Act and HTA codes of practice. The HTA does not consider proficiency or experience in seeking and obtaining consent in other circumstances to be a substitute for specific consent training.

Learning points for establishments

32. Following an analysis of the advice and guidance we offered to staff at establishments to help them improve their compliance with the consent standards, we have produced the following learning points for establishments (box 2).

Box 2: Learning points for establishments (HTA standards on consent)

- when consent forms are updated, they should be made available to all staff involved in the process of obtaining consent
- when more than one consent form is used, consideration should be given to whether a unified form could be developed
- staff at establishments should consider whether it is inappropriate for relatives to be used as translators in the consent process
- records of consent training should be reviewed and maintained

Consent standards (C1–C3) continued

Good practice observations

33. Several establishments demonstrated excellence in meeting the requirements of the consent standards. We have assembled some of our good practice observations in box 3.

Box 3: Good practice observations (HTA standards on consent)

- the use of nominated members of staff to support the clinicians seeking consent. These nominated members of staff have documented evidence of consent training
- the development of excellent, in-house training courses on consent
- the development of refresher training on consent, with opportunities for the staff involved to review, reflect and feedback on their experiences

Governance and quality systems standards (GQS1–GQS8)

34. This category of licensing standards comprises the largest number of component standards (eight) and so it is unsurprising that the most additional conditions were proposed in relation to them (13 additional conditions, representing 40% of all additional conditions imposed). Thirteen (35%) establishments that were inspected had at least one additional condition placed on their licences relating to the governance and quality systems (GQS) standards. In addition, we offered 119 items of advice and guidance, representing 53% of all advice and guidance, to establishments in relation to the GQS standards. The requirements of the eight GQS standards are shown in table 5.

Table 5: Requirements of the governance and quality systems standards

Governance and quality systems standard (GQS1–GQS8)	Requirement of the standard
GQS1	All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process
GQS2	There is a documented system of quality management and audit
GQS3	Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills
GQS4	There is a systematic and planned approach to the management of records
GQS5	There are documented procedures for donor selection and exclusion, including donor criteria
GQS6	A coding and records system facilitates traceability of bodies, body parts, tissue and cells, ensuring a robust audit trail
GQS7	There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly
GQS8	Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

Governance and quality systems standards (GQS1–GQS8) *continued*

35. The GQS standards are the category of standards most directly linked to the day-to-day work of PM establishments. As previously mentioned, the HTA has a statutory remit to assess the suitability of practices at licensed establishments and so there is an observed association between low levels of compliance with the GQS standards and establishments where practices were found to be sub-optimal. Two of the five additional conditions placed following the five phase 2 site-visit inspections undertaken in response to a complaint were directly related to the GQS standards. Although these are small numbers, more conditions were placed in relation to GQS than the consent, premises, facilities and equipment or disposal standards (table 6).

Table 6: The number of additional conditions and advice and guidance placed on licences in relation to the governance and quality systems standards after a phase 2 site-visit inspection

Business year	No. of establishments inspected	No. of conditions	No. of items of advice and guidance
2007/08	47	41	169
2008/09	37	21	119

36. Where PM practices were found to be sub-optimal, it was often the case that the practices did not conform to accepted good practice as opposed to being regulatory breaches. In these circumstances, we provided advice and guidance in preference to imposing additional conditions.
37. A key component of a phase 2 site-visit inspection by the HTA is a review of an establishment's documentation. We scrutinise documents such as standard operating procedures (SOPs), service level agreements, transport arrangements and policies which cover key procedures such as training and disposal of samples.

Governance and quality systems standards (GQS1–GQS8) *continued*

38. Mortuaries in NHS trusts are often linked to pathology laboratories that have Clinical Pathology Accreditation (CPA). Laboratories that have CPA are familiar with quality management. However, in many cases, mortuaries within the same Trust are not covered by the same policies and governance procedures as the pathology laboratories, even though their practices are closely linked. In these cases, the integration of SOPs and policies relating to both the mortuary and the pathology department would help to ensure that mortuaries are compliant with standards GQS1 and GQS2. Within NHS Trusts, mortuaries are often covered by Trust-wide policies which require adaptation to accurately reflect practices within the mortuary.
39. In some mortuaries, PM examinations are carried out by visiting pathologists. It is a requirement that DIs exercise supervisory control of activities which take place in the establishment under the HT Act but very few mortuaries have agreements with these pathologists, which would help to ensure that they are aware of local practices.
40. HTA inspectors review minutes of governance meetings where mortuary issues are discussed. We observed that mortuary staff did not often attend formal meetings and relied on informal arrangements to keep up-to-date with any changes. We gave advice and guidance to encourage establishments to include the mortuary in formal meetings to ensure that all staff are engaged effectively. Equally, mortuary staff should endeavor to attend such meetings when invited.
41. In contrast to last year, we did not identify lone working as a problem area during phase 2 site-visit inspections carried out during the business year 2008/09. Many mortuaries had carried out risk assessments of lone working and developed procedures to ensure that the safety and security of staff, and the safety and security of the bodies of the deceased people in their care, were not compromised.

Governance and quality systems standards (GQS1–GQS8) *continued*

42. DIs are responsible for ensuring that all staff working under a licence are trained and that their training is kept up-to-date. During phase 2 site-visit inspections, the HTA looks for evidence of training such as training records, attendance at external meetings and other ongoing training opportunities provided to staff. In some mortuaries, the role of the Anatomical Pathology Technologist (APT) has extended to supporting bereavement staff and this has given them an increased understanding of the consent requirements of the HT Act, particularly if they are involved in the seeking of consent for PM examinations. Some establishments did not have training records for staff that received training in consent and were involved in taking consent.
43. We have observed that pathologists usually have opportunities to access further professional training, and opportunities for APTs are often limited. Many APTs have not joined a professional body or registered with the Voluntary Registration Council for Healthcare Science professions.
44. It is common for hospital porters to deliver bodies to the mortuary outside of normal working hours, and sometimes to be responsible for arranging viewings. It is therefore important that their involvement in mortuary practices is recognised and that they are provided with adequate training.
45. In some cases, mortuary staff did not have access the HTA website and their establishment did not keep them informed of changes in policy or alerts issued by the HTA.

Governance and quality systems standards (GQS1–GQS8) *continued*

46. Removal of tissue for transplantation takes place in some mortuaries. Since July 2008, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations) require tissue removal for transplantation – which is typically carried out by tissue retrieval teams from NHS Blood and Transplant (NHSBT) – to take place on premises under the authority of an HTA licence which covers procurement, or under a Third Party Agreement with a suitably-licensed establishment. NHSBT is the UK's main provider of human tissue for transplantation: www.nhsbt.nhs.uk. Its role is to coordinate, recover, process, bank and supply human tissue grafts for use in surgery within the NHS and independent hospitals. In addition to emphasising the licensing requirements of such arrangements, staff at PM establishments were given advice and guidance relating to the implications for traceability that visits from tissue retrieval teams might have. For example, staff were advised to record the details of such visits, particularly the relevant material removed. Any PM establishments involved in these activities should contact the HTA for further advice.
47. Robust traceability systems are essential for establishments to be confident that all relevant material is used, disposed of or retained in accordance with the consent given. During phase 2 site-visit inspections, the HTA carries out audits to determine whether establishments have effective procedures in place to facilitate traceability from consent to disposal. In mortuaries, the HTA checks entries in the mortuary register together with labels on bodies and fridges. In pathology laboratories, records on tissues received from the mortuary and slides prepared from those tissues are also checked. In several cases, there were inconsistencies in the recording of the number of slides which were stored or disposed of, which appeared to arise from a failure of staff to appreciate the status of the slides as relevant material. These observations suggested that these establishments did not have robust systems to ensure full traceability. The HTA has been made aware that many pathology staff regard microscope slides prepared from tissues as different to the tissues or organs themselves, because of the slides' size, shape and format. This perception does not alter the HTA's view of cell deposits or tissue sections on microscope slides, which are considered to be relevant material. This is because they are likely to contain whole cells or are intended to be representative of whole cells.

Governance and quality systems standards (GQS1–GQS8) *continued*

48. Most PM examinations are carried out under the authority of a coroner. When the pathologist has informed the coroner of the details of any tissues removed, the coroner's officer should obtain the wishes of the next of kin for retention of tissue for a scheduled purpose, return of tissue either to the body or to the family or disposal of the tissue when the coroner's authority has ended. The coroner or coroner's officer should provide this information to the pathologist so that all tissue has been dealt with in accordance with the wishes obtained and that, for any tissue that has been retained, there is the required consent. All other tissue must be sensitively disposed of. The HTA recommends that a nominated person is identified to handle the communication channels between the coroner's office and the pathology department and between the coroner's office and the bereaved person's next of kin: www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm.
49. Most establishments within NHS Trusts follow trust policies and procedures when an untoward incident occurs. HTA inspectors found that these procedures were usually followed in response to health and safety incidents or in response to external complaints. In several cases, untoward incidents or near misses which could have resulted in a breach of the HT Act were not perceived as falling within the adverse incident reporting system. These required the HTA to take action, typically in the form of advice and guidance.
50. Risk assessments help staff at establishments to develop robust procedures. Most establishments undertake risk assessments of practices which are focused on staff safety rather than on the risks of breaching the requirements of the HT Act or not complying with the HTA's standards, such as inadvertently releasing the wrong body or the risk of retaining tissue unlawfully. We also observed that some members of staff did not have adequate training to enable them to carry out risk assessments.
51. Additional conditions highlighted six main areas of non-compliance in relation to the GQS standards. These areas were also reflected in the items of advice and guidance provided to establishments. The highest numbers of non-compliances were in traceability (GQS6), followed by risk assessments (GQS8), audit (GQS2), SOPs (GQS1), staff training (GQS3) and incident reporting (GQS7).

Governance and quality systems standards (GQS1–GQS8) *continued*

52. Areas where establishments needed to improve were highlighted where deficiencies were found and additional conditions were imposed to ensure that establishments complied with the GQS standards. Deficiencies in traceability related to the largest number of additional conditions. Risk assessments were also another area of significant non-compliance. Box 4 details these areas for improvement.

Box 4: Areas for improvement (HTA standards, GQS1–GQS8)

- all licensable activities needed to be supported by documented SOPs which should be followed by all relevant staff who had undergone training in their use (HTA standard GQS1)
- a documented quality management system needed to be implemented (HTA standard GQS2)

NB. Only one establishment did not have a complete quality management system

- a scheduled programme of audits covering licensable activities, needed to be implemented and the audits properly documented (HTA standard GQS2)
- all members of staff needed to receive regular appraisal and documented training in mortuary practices to allow them to suitably carry out activities under the licence (HTA standard GQS3)

NB. It was not uncommon for HTA inspectors to find training records which had not been updated, due to lapses in appraisal processes or poor record-keeping. During a traceability audit carried out on one phase 2 site-visit inspection, HTA inspectors found that a body that had been delivered out-of-hours by non-mortuary staff had not been labelled in accordance with the mortuary's documented procedure. The inspection team did not see any evidence that non-mortuary staff involved in mortuary procedures, such as labelling bodies, placing bodies in storage or dealing with relatives, had received any training in the procedures.

Governance and quality systems standards (GQS1–GQS8) continued

Box 4: Areas for improvement (HTA standards, GQS1–GQS8) continued

To ensure robust traceability, establishments needed to:
(HTA standard GQS6)

- Accurately record the numbers of blocks and slides made from tissue removed during a PM examination
- Put in place a system to label and track the movement of relevant material after it had been removed during a PM examination, including material which had been transferred elsewhere for special analysis or research
- A SOP for recording and reporting adverse incidents needed to be put in place (HTA standard GQS7)
- Adverse incidents needed to be identified and an approach to ensure that staff working under the licence knew which incidents to report needed to be determined. The types and trends of reported incidents needed to be discussed with staff, raising the awareness of any corrective and preventative actions (HTA standard GQS7)
- Risk assessments needed to cover all practices, processes and premises involved in licensable activities. The risk assessments needed to be available to relevant staff and subject to regular review

The range of specified risks to be assessed included: (HTA standard GQS8)

- The possibility that relevant material could be returned to the wrong body or not returned at all
- The pathologist taking full responsibility for PM examinations, even when tasks such as external examination were delegated to APTs
- The possibility that some mortuary practices might have a negative impact on the dignity of the deceased
- The risks posed to staff transferring stored bodies to fixed-height PM tables
- The practice of storing perinatal, paediatric and adult bodies together, including high-risk cases
- The transportation of bodies between different sites
- The practice of carrying out more than one PM examination in the PM room at the same time
- The use of chemicals and reagents in the mortuary
- The layout of the mortuary and the PM room and how this might have a negative impact on mortuary practices

Governance and quality systems standards (GQS1–GQS8) continued

Learning points for establishments

53. Following an analysis of the advice and guidance we offered to staff at establishments to help them improve their compliance with the GQS standards, we have produced the following learning points for establishments (box 5).

Box 5: Learning points for establishments (HTA standards on governance and quality systems)

- SOPs should be reviewed regularly
- consideration should be given to whether meetings with other DIs in the local area might benefit the delivery of staff training and improve compliance with HTA standards
- where appropriate, documented agreements with visiting pathologists and funeral directors should be put in place and kept under review
- quality management in a mortuary might be improved by incorporating the mortuary into the quality management system used by the pathology department
- audits should cover a number of different areas, including patient records, mortuary registers, relevant material stored under the licence and disposal records
- establishments that undertake PM examinations under the authority of a coroner should consider auditing stored relevant material to ensure that it is not being retained unlawfully after a coroner's authority has ended
- the training in mortuary practices should be subject to regular review, to ensure it is fit for purpose and is being delivered to all appropriate staff
- professional development of staff should be encouraged
- individual staff training records should be kept up-to-date
- where several tissue registers exist, traceability might be improved by unification
- staff should consider maintaining records of all visitors to the mortuary, including tissue retrieval teams
- the property of the deceased should be fully recorded
- written amendments to records should be legible, signed and dated

Governance and quality systems standards (GQS1–GQS8) continued

Box 5: Learning points for establishments (HTA standards on governance and quality systems) continued

- although complaints from the public, including bereaved relatives, should be dealt with through the establishment's complaints system, staff should consider whether complaints are linked to adverse incidents and should be investigated as such
- risks other than those related to health and safety should be considered when staff carry out risk assessments; for example, the possibility of inadvertently releasing the wrong body or where a deviation from published good practice is possible, such as the evisceration of bodies by APTs prior to the arrival of the pathologist

Good practice observations

54. Several establishments demonstrated excellence in meeting the requirements of the GQS standards. We have assembled some of our good practice observations in box 6.

Box 6: Good practice observations (HTA standards on governance and quality systems)

- informing the HTA of adverse incidents and their investigation
- the implementation of well-developed incident reporting systems, which fully record the details of the incident, together with the identification of the root cause, and the corrective and preventative actions that have been implemented
- a person, fulfilling the formal role of Quality Manager, whose job description guarantees dedicated time for the role
- competency-based induction training for new staff
- questionnaires, inviting feedback from funeral directors about the quality of reconstruction of bodies that have undergone PM examinations

Premises, facilities and equipment standards (PFE1–PFE5)

55. The HTA acknowledges that there is a broad range of mortuaries, from the very new to the very old. Even when facilities have been updated, the design and layout of older mortuaries might still make it difficult to implement and maintain accepted standards of good practice. Where age and structural factors affect the suitability of premises, we encourage staff to develop solutions to improve compliance despite the fixed constraints of the physical environment in which they work.
56. During phase 2 site-visit inspections, HTA inspectors expect all equipment in the mortuary to be in a good condition and appropriate for use. HTA inspectors need to assure themselves that staff have the equipment they need to undertake their work, free of unnecessary risk or discomfort and that the bodies of people who have died are treated with respect. We therefore inspect fridges and freezers, trolleys, PM tables and equipment such as hoists, weighing scales, oscillating saws, personal protective equipment (PPE) and ventilation systems.
57. The requirements of the five PFE standards are shown in table 7.

Table 7: Requirements of the premises, facilities and equipment standards

Premises, facilities and equipment standard (PFE1–PFE5)	Requirement of the standard
PFE1	The premises are fit for purpose
PFE2	Environmental controls are in place to avoid potential contamination
PFE3	There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records
PFE4	Systems are in place to protect the quality and integrity of bodies, body parts, tissues and cells during transport and delivery to a destination
PFE5	Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

Premises, facilities and equipment standards (PFE1–PFE5) continued

58. Following a phase 2 site-visit inspection, eight (22%) establishments had at least one condition placed on their licences relating to the PFE standards (table 8).

Table 8: The number of additional conditions and advice and guidance placed on licences in relation to the premises, facilities and equipment standards after a phase 2 site-visit inspections

Business year	No. of establishments inspected	No. of conditions	No. of items of advice and guidance
2007/08	47	29	108
2008/09	37	13	53

59. It is rare for the HTA to decide that licence revocation is the best course of action; however, during one phase 2 site-visit inspection, the DI was informed that the mortuary premises at a satellite site were not suitable. The NHS Trust was aware that the premises were unsuitable and had planned to close the facilities within three months. The HTA was concerned that the planned closure could be postponed, as it had been before. After the phase 2 site-visit inspection, a RAP was convened, resulting in the HTA issuing Special Directions to immediately stop licensable activities at the satellite site. The issuing of Special Directions was partnered with a legal notice of proposal to revoke the satellite site's licences.

60. Additional conditions highlighted three main areas of deficiencies in meeting the PFE standards. These were:

- storage – including temperature monitoring and the appropriateness of storage facilities
- documented agreements – including those with providers of facilities and transportation services
- maintenance of equipment

Premises, facilities and equipment standards (PFE1–PFE5) continued

Deficiencies are explained by the following areas for improvement (box 7).

Box 7: Areas for improvement (HTA standards, PFE1–PFE5)

- an agreement needed to be put in place between the NHS Trust and the provider of the PM facilities. The agreement needed to detail the roles and responsibilities of both parties and their respective members of staff (HTA standard PFE1)
- in addition to a DI ensuring that the planned refurbishment of mortuary premises deemed unfit for purpose was completed on time, the DI needed to provide monthly updates to the HTA on the status of the refurbishment (HTA standard PFE1)
- rugs, which were soiled, unhygienic and prevented the underlying floor being cleaned effectively, needed to be removed from the mortuary (HTA standard PFE2)
- a cleaning procedure needed to be developed and implemented, to include:
 - a periodic deep clean of all mortuary facilities
 - the cleaning of the inside of refrigeration units with bactericidal and fungicidal cleaning products
 - the cleaning of body trays with bactericidal and fungicidal cleaning products after the release of each body
 - a cleaning rota and regimen
 - the disinfectants to be used
 - the frequency of cleaning
 - records of cleaning and decontamination, which needed to be maintained

The DI also needed to ensure that staff were appropriately trained in cleaning the mortuary (HTA standard PFE2)

Premises, facilities and equipment standards (PFE1–PFE5) continued

Box 7: Areas for improvement (HTA standards, PFE1–PFE5) continued

- the temperature of body storage units needed to be adequately monitored and recorded, even if they appeared to be operating within normal limits. Temperatures exceeding a predetermined normal range needed to activate a regularly tested alarm system (HTA standard PFE3)
- one refrigerated storage unit was unsuitable in one establishment and needed to either be replaced or decommissioned; it was decommissioned (HTA standard PFE3)
- the contract between an establishment and a private company that managed the establishment's mortuary needed to be updated to include the details of the transportation services provided by the company (HTA standard PFE4)
- a documented agreement, setting out the responsibilities of both parties involved, needed to be put in place to protect the quality and integrity of relevant material during its transportation and delivery to another site (HTA standard PFE4)
- all critical equipment needed to be monitored and validated, and contracts with maintenance providers needed to be put in place (HTA standard PFE5)

Learning points for establishments

61. Following an analysis of the advice and guidance we offered to staff at establishments to help them improve their compliance with the PFE standards, we have produced the following learning points for establishments (box 8).

Box 8: Learning points for establishments (HTA standards on premises, facilities and equipment)

Security and safety: establishments should consider reviewing whether: (HTA standard PFE1)

- access to the mortuary by non-mortuary staff is adequately secure
- health and safety information for staff and visitors is available and adequate

Premises, facilities and equipment standards (PFE1–PFE5) continued

Box 8: Learning points for establishments (HTA standards on premises, facilities and equipment) continued

Repair and renovation: establishments should consider reviewing whether: (HTA standard PFE1)

- any minor repairs are required
- privacy screening in the areas of the mortuary such as viewing rooms and entrances is adequate
- signposting could be improved
- demarcation of clean and dirty areas could be improved
- DIs should investigate whether there might be other areas in the establishment where removal of relevant material from the deceased might take place; for example, in a hospital's Accident and Emergency department. Where this is found to be the case, the HTA needs to be informed (HTA standard PFE1)
- to minimise environmental contamination and improve standards of hygiene, wooden head blocks and other porous materials used in the mortuary should be substituted by non-porous replacements (HTA standard PFE2)
- related to the previous point, staff at establishments should check that risk assessments of potential contamination hazards have been undertaken and environmental controls put in place to minimise them (HTA standard PFE2)
- to minimise environmental contamination and improve security, windows in PM suites should be kept shut and consideration should be given to whether they should be screened and / or sealed (HTA standards PFE2 and PFE3)
- if tracking sheets are used by undertakers, to record the transfer of material from the establishment, consideration should be given to whether copies should be kept by the establishment to improve traceability (HTA standard PFE4)
- in several NHS Trusts, all maintenance records – including those relating to equipment in the mortuary – were held only centrally. The HTA advises that it might be beneficial for copies of equipment maintenance records to be kept in the mortuary (HTA standard PFE5)

Premises, facilities and equipment standards (PFE1–PFE5) continued

Good practice observations

62. Several establishments demonstrated excellence in meeting the requirements of the PFE standards. We provide some of our good practice observations in box 9.

Box 9: Good practice observations (HTA standards on premises, facilities and equipment)

- the involvement of mortuary staff, such as APTs and pathologists, in the design and planning of new facilities
- when and where appropriate, visitors being offered personal protective equipment

Disposal standards (D1–D2)

63. The HT Act, HTA codes of practice and our licensing and inspection processes aim to ensure that relevant material from the deceased is not removed, or retained for future use, without appropriate consent and that, where relevant, it is disposed of in accordance with the wishes of the individual or next of kin. The codes of practice are here: www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm.

64. Requirements of the two disposal standards are shown in table 9.

Table 9: The requirements of the disposal standards

Disposal standard (D1–D2)	Requirement of the standard
D1	There is a clear and sensitive policy for disposing of human organs and tissue
D2	The reasons for disposal and the methods used are carefully documented

65. Following a phase 2 site-visit inspection, eight (22%) establishments had at least one condition placed on their licences relating to the Disposal standards (table 10).

Table 10: The number of additional conditions and advice and guidance placed on licences in relation to the disposal standards after a phase 2 site-visit inspections

Business year	No. of establishments individuals	No. of conditions	No. of items of advice and guidance
2007/08	47	17	25
2008/09	37	9	21

66. Interviews with staff during phase 2 site-visit inspections revealed that, in several cases, there was a lack of awareness that relevant material included material on microscope slides as well as organs and tissues. This lack of awareness has the potential to lead to unlawful retention of relevant material.

Disposal standards (D1–D2) continued

67. Many establishments were not informed when the coroner's authority had ended and so had inadvertently retained relevant material: www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm. Clear and effective communication between establishments and coroners is required if establishments are to comply with the consent and disposal standards. In some establishments, the coroner's officers were based within the mortuary or visited the mortuary regularly. In these cases, there was usually good communication between coroner's officers and staff at the establishment. The HTA recommends that a nominated person is identified to handle the communication channels between the coroner's office and the pathology department and between the coroner's office and the bereaved person's next of kin: www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm.
68. The HTA codes of practice should be followed in respect of the methods used for disposal. Disposal of human tissue should be done in a sensitive manner and in accordance with consent given by the next of kin. The codes are available on our website: www.hta.gov.uk/legislationpoliciesandcodesofpractice/codesofpractice.cfm.
69. Tissue removed during PM examinations should be disposed of separately from other clinical waste. During phase 2 site-visit inspections, the HTA found that most establishments did dispose of human tissue in a sensitive manner.

Disposal standards (D1–D2) continued

70. Additional conditions highlighted three main areas of deficiencies in meeting these standards. These were:

- the absence of suitable disposal policies
- inadequate disposal records
- the continued storage of relevant material in the absence of communication from the coroner regarding the retention period for material from coroners' cases

Box 10 details these areas for improvement.

Box 10: Areas for improvement (HTA standards, D1–D2)

- a clear and sensitive disposal policy, reflecting the requirements of the HT Act and HTA codes of practice, needed to be put in place (HTA standard D1)

NB. In some establishments, a disposal policy did not exist at all; in others, the policy was inadequate or in a draft format

- the disposal policy needed to be implemented by SOPs which ensured that the methods and reasons for disposal were recorded (HTA standard D2)
- relevant material which had been retained without consent needed to be disposed of (HTA standard D2)

Disposal standards (D1–D2) continued

Learning points for establishments

71. Following an analysis of the advice and guidance we offered to staff at establishments to help them improve their compliance with the disposal standards, we have produced the following learning points for establishments (box 11).

Box 11: Learning points for establishments (HTA standards on disposal)

- staff at establishments should consider developing an agreed protocol or pathway for communication between coroners, establishment staff and relatives of the deceased, setting out roles and responsibilities. For further guidance on this, please refer to the model communication flowchart on the HTA's website: www.hta.gov.uk/licensingandinspections/sectorspecificinformation/postmortem.cfm.
- where multiple systems for documenting disposal are in place, staff at establishments should consider whether traceability could be improved by unifying disposal records
- to confirm that disposal is undertaken in accordance with the consent given, staff at establishments should consider including regular audits of disposal records in their audit schedule

Good practice observations

72. Several establishments demonstrated excellence in meeting the requirements of the disposal standards. We have assembled some of our good practice observations in box 12.

Box 12: Good practice observations (HTA standards on disposal)

- the development and implementation of documented agreements, protocols or pathways for communication between coroners and establishments, setting out roles and responsibilities
- where a commercial incineration company had been contracted to provide disposal services, staff from the establishment visited the facilities to assure themselves that suitable practices took place

Appendix 1:

List of establishments that received an HTA phase 2 site-visit inspection during business year 2008/09

- Arrowe Park Hospital (12027)
- Barnsley Hospital NHS Trust (12346)
- Bedford Hospital (12324)
- Birmingham Heartlands Hospital (12366)
- Birmingham Women's Hospital (12255)
- Chesterfield Royal Hospital (12029)
- East Surrey Hospital (12117)
- Finchley Coroners Mortuary (12287)
- Graphic Data (12486)
- Great Ormond Street Hospital (11026)
- Hope Hospital Salford (12134)
- James Paget University Hospitals (12127)
- Leeds Teaching Hospital NHS Trust (12231)
- Manchester Royal Infirmary (12221)
- Mayday Healthcare Trust (12305)
- Newcastle upon Tyne Hospitals NHS Trust (12341)
- Norfolk and Norwich University Hospital (11208)
- Northwick Park and Central Middlesex (12386)
- Pathlinks Diana Princess of Wales Hospital (12310)
- Pinderfield General Hospital (hub) and Dewsbury District Hospital (satellite) (12086)
- Poole Hospital (12398)
- Princess Royal University Hospital (12300)
- Queen Elizabeth Hospital NHS Trust (12238)
- Queen Elizabeth Hospital, Kings Lynn (12298)
- Queen's Hospital, Burton Hospitals NHS Foundation Trust (12317)
- Queens Hospital, Romford (12154)
- Queens Medical Centre and Nottingham City Hospital (12258)
- Royal Bournemouth Hospital (11129)
- Royal Surrey County Hospital (12222)
- South Tyneside NHS Trust (12380)
- St George's Healthcare NHS Trust London (12387)

Appendix 1:

List of establishments that received an HTA phase 2 site-visit inspection during business year 2008/09 (continued)

- State Pathologist's Department, Belfast (12493)
- University Hospital of Wales, Department of Histopathology (12488)
- University Hospital, Bristol (12151)
- Victoria Hospital, Blackpool (12133)
- Weston General Hospital (12156)
- Whiston Hospital (12043)

Details of all licensed establishments are listed on the HTA website at http://www.hta.gov.uk/licensing/licensed_establishments.cfm

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