

Summary of inspections 2007–2008

Post-mortem

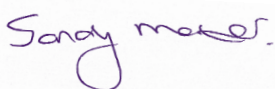
Foreword

This summary inspection report is one of a set of five that the Human Tissue Authority (HTA) has produced for each of the sectors that we license and inspect: anatomy, human application, post-mortem, public display and research. The reports summarise the key learning points from a range of information that we hold about the establishments that we regulate. They are vital reading for anyone who works in these sectors, so that lessons may be learnt and standards improved.

The HTA's regulatory methods are framed by the requirements of the Human Tissue Act 2004 (HT Act) which places a specific obligation on the HTA to follow the principles of Better Regulation and to carry out regulatory activities in a way that is transparent, accountable, proportionate, consistent and targeted. The proportionate, risk-based regulatory system that we use is also informed by the good practice from key Government reports: Reducing administrative burdens: effective inspection and enforcement (Philip Hampton, 2005) and Regulation – less is more, reducing burdens, improving outcomes (Better Regulation Task Force, 2005). In April 2008 the statutory code of practice for regulators (the Regulators' Compliance Code) came into force. This provides further guidance on Better Regulation and will form the basis of an external inspection of the HTA's regulatory systems by the Better Regulation Executive during the 2008/09 business year.

The HTA works with those who need to be licensed by acting as “coach” not “cop” to bring them into the licensing framework, and to provide advice and guidance to help them to improve standards. This compliance-based approach to regulation is partnered with the HTA's proportionate approach to enforcement, which is aimed at deterring future non-compliance.

These summary inspection reports are the next steps on the path to improving standards for the regulation of human tissue. We hope that all those working in the sectors we license and inspect will review this information, and reflect on how it could be applied to their own practice to improve standards.



Dr Sandy Mather
Director of Regulation



Ms Caroline Browne
Head of Regulation

Contents

Executive summary	4
Introduction	6
Overview of the post-mortem sector and inspections 2007–2008	9
Analysis of additional conditions, and advice and guidance	11
Compliance with HTA standards	
• Consent standards	15
• Governance and quality systems standards	19
• Premises, facilities and equipment standards	35
• Disposal standards	44
Appendix 1: Licensing and inspection processes	48
Appendix 2: List of establishments which received an HTA phase 2 inspection in 2007–2008	52

Executive summary

In the period 1 April 2007 to 31 March 2008, the HTA carried out 49 site visit inspections of 47 post-mortem establishments.

As a result of the site visit inspections, 98 additional conditions were placed on 34 establishments' licences and nearly 340 items of advice and guidance were offered.

We have seen many examples of good practice and a genuine commitment by staff to care for the deceased and bereaved families. This report highlights areas of weakness across the sector, which are evidenced by non-compliance with our standards. The post-mortem sector is the largest sector we regulate, is unused to regulation, involves a number of professional groups working for different organisations and, because of the nature of mortuary work, has the potential for significant personal distress to bereaved relatives and friends when things go wrong.

Our inspections showed that mortuaries around the UK vary enormously in age and condition, and some are in need of investment and upgrade. In addition, the design and layout of some of the busiest mortuaries makes it difficult to implement standards of good practice.

Anatomical Pathology Technologists (APTs), many of whom have worked in the same establishment for many years, appear to have had insufficient opportunity for professional development and reflection on practice. During the site visit inspections, we found that many mortuary staff were unfamiliar with concepts such as governance, quality management and standards compliance, which have become commonplace in other areas of healthcare.

Risk assessment of mortuary practices is underdeveloped. For example, lone working, which in some establishments is routine practice, has not been subject to risk assessment and is not always governed by documented procedures developed to mitigate risks identified.

Executive summary (continued)

There is often uncertainty about families' wishes regarding disposal of material retained during the post-mortem or indeed about whether the coroner has completed his investigation. We believe this may result in pathologists retaining tissue samples simply because they do not know whether or not they should dispose of them.

There needs to be improvement in communications and interactions between pathologists, APTs, coroners and their officers to ensure that the requirements of the HT Act are met and in particular, that the consent provisions are complied with.

Our inspections have helped us develop a much better understanding of the post-mortem sector, the professionals who work in it and the challenges they face on a daily basis.

The inspection process has highlighted the opportunities for HTA to support this sector and drive up standards.

Introduction

1. This summary inspection report is one of a set of five. Each report is specific to one of the sectors we license and inspect. The findings in the report are drawn from two main sources of existing knowledge that are held by the HTA:
 - information and data submitted by an establishment (i.e. as part of the compliance report licence application process and during the site visit inspection process)
 - documents that we have issued to establishments (i.e. drawn from site visit inspection reports and licensing decisions)
2. This report brings all the information together in one place and provides an analysis of trends and themes for the post-mortem sector so that lessons can be learnt. The individual site visit inspection reports and proposed licensing decisions have each been reviewed by the Designated Individual (DI) responsible for supervising licensable activities in the establishment concerned. 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 have been carefully considered with input from legal advisors and, where appropriate, a senior member of the regulation directorate. This summary report therefore draws on a wide range of pre-existing information and data that are currently held by the HTA. It is intended to provide a review and analysis of the findings from the post-mortem sector so that the reader may consider them and, where appropriate, apply them to their own practice to enable standards to be raised across the sector.

Introduction (continued)

3. It is important to note that the conditions and advice and guidance the HTA gives to an establishment are 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 where action is needed. Therefore we do not routinely apply the same decision to each establishment. This means that while the HTA aims to be consistent in its decision making process, decisions will vary from establishment to establishment depending on the particular set of circumstances. So, the conditions and advice and guidance are context specific and are not always transferable to other establishments. They should be read with this in mind.

Using a risk-based regulatory approach

4. The HTA uses a risk-based regulatory approach to inform how we prioritise the phase 2 site visit inspections (see Appendix 1 for more information about our inspection process). Risk means different things to different people, according to context. So it is relevant at this point to explain what we mean by risk when referring to how we regulate. In this context, the risk the HTA refers to is regulatory risk, i.e. the risk of non-compliance with the requirements of the legislation that the HTA was set up to implement. The primary documents that inform the framework for regulatory risk are: the HT Act and the associated Regulations, including for the human application sector, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). These are therefore mandatory requirements. The legislation is supported by other documents that are developed by the HTA. Where possible, we develop this additional guidance with input from those we regulate. These documents include: codes of practice, Directions, and licensing standards.

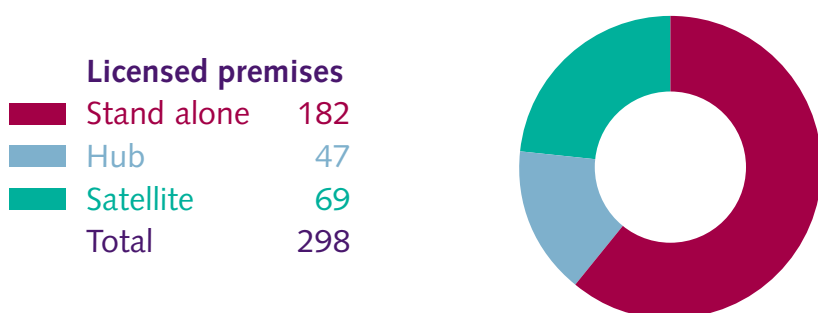
Introduction (continued)

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 for each sector. The specificity and detail of regulation required for each sector is set out in the relevant legislation. Some sectors have much more detailed requirements than others. Generally, the detail of standards and requirements increase when there is a direct risk to patient safety if they are not met. The corollary is that where there are more standards with greater specificity, there is an increased risk they will not be met. Therefore the HTA focuses resources on where this is most likely to occur so that advice and guidance can be offered to help professionals achieve regulatory compliance. This means the regulatory risk of the sectors we license and inspect varies from low risk, where there is minimal regulation and a lighter touch approach can be used, to high risk, where there is detailed regulation with specific requirements and a more direct regulatory approach is employed.

Overview of the post-mortem sector and inspections 2007–2008

6. There are 298 post-mortem premises within our licensing framework, grouped as follows.

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



7. The majority of the 298 licensed premises are NHS Trust mortuaries and associated pathology laboratories; 23 are public mortuaries, under the management of local authorities rather than NHS Trusts.
8. There are 69 satellite sites attached to a main hub (they are smaller establishments engaged in the same licensable activities and operating under the same governance as the hub). Although satellite sites are licensed individually, they are included in the main application for licences made by the hub establishment.
9. All establishments received a phase 1 inspection and 47 establishments received a phase 2 site visit inspection during 2007/08 (see Appendix 1 for more information about our inspection process). Of those receiving a phase 2 site visit inspection, 35 were NHS Trusts, 11 were public mortuaries and one, the Forensic Science Service, provides toxicology analysis of post-mortem tissue (see Appendix 2 for a full list of establishments visited).

Overview of the post-mortem sector and inspections 2007–2008 (continued)

10. Some of the establishments had one or more satellite sites (11 had one satellite, one had two satellites and one, the Forensic Science Service, had eight satellite sites.) The governance arrangements of satellite sites were assessed during inspection, and most premises were visited to ensure suitability (which means that the HTA actually visited around 60 premises).
11. Of the 49 site visit inspections, one was scheduled following receipt of information about inappropriate storage of fetal specimens, and one was an unannounced site visit inspection of a previously inspected mortuary in response to information received from an anonymous source alleging inappropriate practices (and subsequently followed up by a joint inspection of the premises with the Health and Safety Executive).
12. During the period, the HTA held four Regulatory Action Panels (RAPs) relating to four establishments and issued three sets of Special Directions.

Analysis of additional conditions, and advice and guidance

13. Of the 47 establishments visited, 35 had time-bound additional conditions already placed on their licences where standards were found to be not met or only partially met after the phase 1 inspection. Comparison of the numbers of additional conditions placed at phase 1 and phase 2 shows that both phases of our inspection process have identified shortfalls in standards compliance, and reveals common areas of weakness across the sector. In particular, the disposal standards appear to have presented the greatest challenge for this sector (see the section on disposal later in this report for further detail).

14. Following site visit inspections, 98 additional time-bound conditions were placed on 34 establishments' licences. In addition, nearly 340 items of advice and guidance were offered, demonstrating the importance we place on supporting our licensed establishments through the inspection process (see table 1 and Figure 2).

Analysis of additional conditions, and advice and guidance (continued)

Table 1: Distribution of additional conditions, and advice and guidance following phase 2 inspection, grouped by category of standard

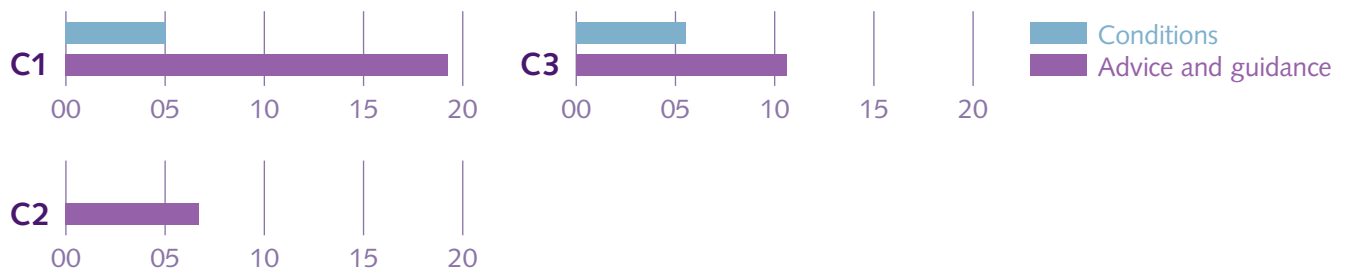
	Consent	Governance and quality systems	Premises, facilities and equipment	Disposal	Totals
No of standards	3	8	5	2	18
No of additional conditions	11	41	29	17	98
No of establishments affected	11 (23%)	22 (47%)	19 (40%)	17 (36%)	N/A*
No of items of advice and guidance	37	169	108	25	339
No of establishments affected	24 (51%)	47 (100%)	44 (94%)	22 (47%)	N/A*

***NB:** An establishment may have a condition against more than one category of standard (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).

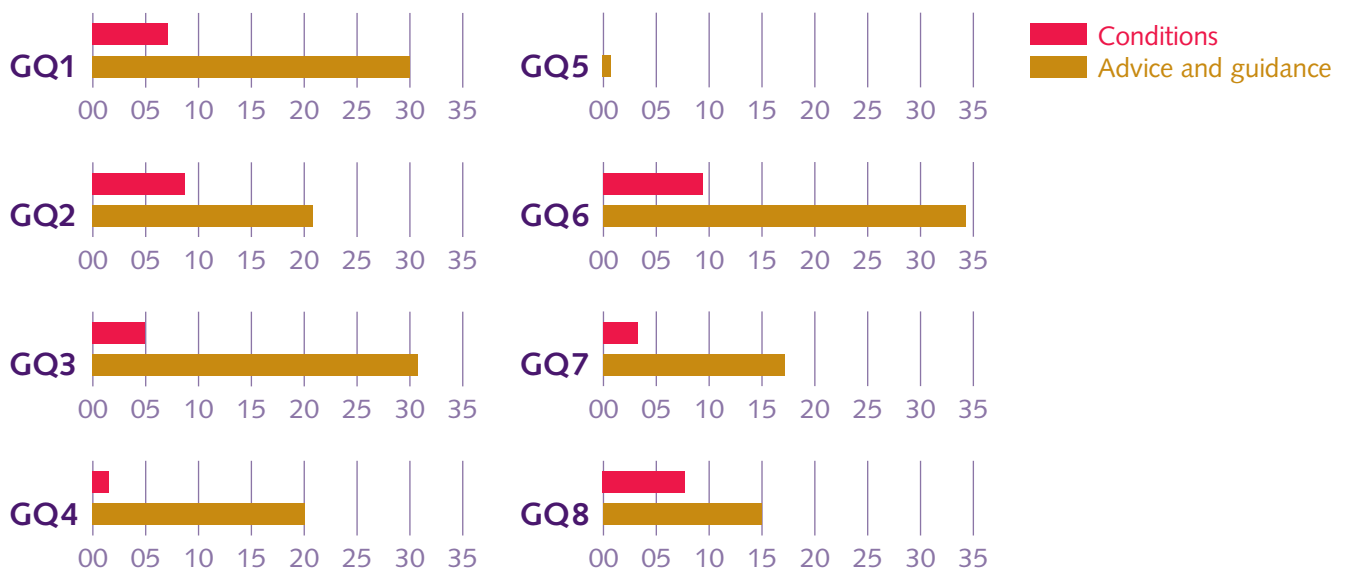
Analysis of additional conditions, and advice and guidance (continued)

Figure 2: Distribution of additional conditions, and advice and guidance following phase 2 inspection, by individual standard

Consent

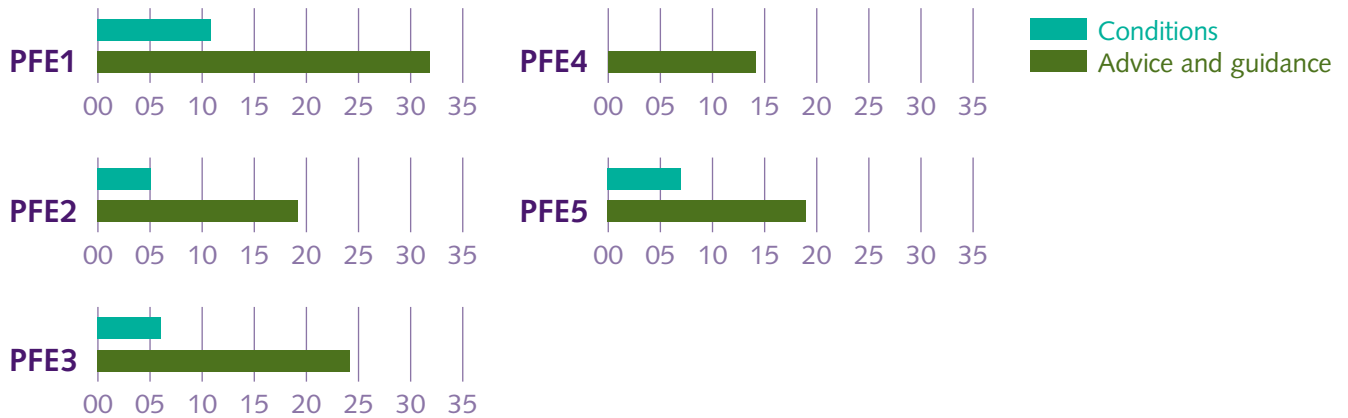


Governance and quality systems

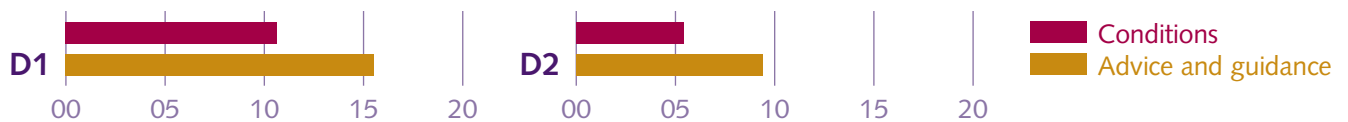


Analysis of additional conditions, and advice and guidance (continued)

Premises, facilities and equipment



Disposal



- Summary findings are given for each group of standards, followed by more in-depth discussion of individual standards. Because additional conditions often address more than one area of deficiency, we have calculated the incidence of each of these deficiencies to indicate where the greatest areas of weakness lie. The results are tabulated in each section for quick and easy reference. When reviewing the data, remember that they relate to the 47 establishments that were subject to a site visit inspection.

Compliance with HTA standards

Consent standards (C1–C3)

Key findings

16. Additional conditions highlighted three main areas of deficiency in meeting the consent standards. These related to standard operating procedures (SOPs), availability of information on consent and training for staff on how to take consent (see Table 2).

Table 2: Key areas of deficiency in meeting the consent standards

Deficiency	No of establishments
Standard operating procedures	9
Availability of information	2
Training for staff on obtaining consent	10

17. In the vast majority of cases, post-mortem examinations are undertaken on the authority of the coroner, so consent from the next of kin is not required. Where a post-mortem is requested by a clinician for the purposes of learning more about the nature or progress of a disease following notification of the cause of death, 'appropriate' consent must be obtained from a person in a 'qualifying relationship'. The HTA code of practice on Consent provides more detailed guidance to help establishments understand and meet the statutory requirements. We expect establishments' policies and procedures on consent to reflect these requirements.
18. Overall, there was a reasonable level of compliance with the consent standards, although some establishments were required to review and update their policies and procedures on consent. Standard C3, the requirement that regular training on consent be provided for staff, presented the greatest difficulty (see C3 below).

Consent standards (C1–C3) (continued)

C1 Consent is obtained in accordance with the requirements of the HT Act and as set out in the code of practice

19. Despite the very small number of hospital post-mortems which now take place, 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.
20. Where there were serious deficiencies, additional conditions required establishments to update their consent procedures to ensure that they fully met the requirements of the HT Act and the HTA code of practice. Other establishments were advised simply to review their procedures and associated forms and to ensure that staff were aware of their content. The model consent form developed by the HTA and available on the website had been adopted in some cases, but in many cases establishments were continuing to use the Department of Health consent form, which predates the HT Act and has now been withdrawn.
21. Advice and guidance offered to establishments to help them improve their systems and processes recommended that:
 - consideration is given to involving bereavement officers in the consent process, to support medical staff who may not be used to obtaining consent for hospital post-mortems because of their infrequency
 - the consent process covers the reasons for and benefits of consenting to the retention of material, for example that it may be of use to other family members
 - the consent process ensures that consent for a hospital post-mortem, once given, can be withdrawn, albeit within a specific timescale

Consent standards (C1–C3) (continued)

C2 Information about the consent process is provided and in a variety of formats

22. Information about the consent process for hospital post-mortems was found to be generally available, although it was often limited to printed leaflets in English only. This deficiency was addressed by an additional condition in three cases (and linked to a standard C1 condition), which required information to be available to reflect the needs of the patient population.
23. In addition, advice and guidance recommended that:
- information is updated to include more detail about the removal of samples and the options for retention and disposal
 - information leaflets about the consent process are made available in other languages as appropriate for the patient population
 - the use of other formats (for example, Braille) is considered
 - the services of a translator are used where necessary, rather than having to depend on relatives

C3 Staff involved in seeking consent receive training and support in the implications and essential requirements of taking consent

24. During inspection, establishments are asked to demonstrate that they have procedures in place that identify staff trained and able to take consent for hospital post-mortem, and that this information is documented in staff training records.

Consent standards (C1–C3) (continued)

25. Assessment of compliance with this standard highlighted that there is inadequate training and support for staff in how to obtain consent in compliance with the HT Act and uncertainty about who should be able to seek consent for hospital post-mortems and what to include in training. This is largely due to the very small number of hospital post-mortems that currently take place which, it might be argued, makes it difficult to justify resources spent on training. A counterargument, and a view held by the HTA, is that the more infrequent the activity, the more likely it is that proficiency in it will weaken. Therefore, additional conditions relating to standard C3 required the development and delivery of training on consent.
26. A range of advice and guidance was given, recommending:
- relevant members of staff are identified and trained in how to take consent
 - records of consent training are maintained
 - the subject of consent is added to existing training and development or seminar programmes
 - consideration is given to training bereavement officers in the requirements of valid consent in order that they can support medical staff (by identifying a smaller number of people with this responsibility, on-going training may be managed more effectively)
 - documented procedures on consent should detail the consent process, who is able to take consent and what training they should receive initially and on an ongoing basis
27. In addition, where establishments had difficulty developing training, we advised that they work through the relevant sections of the HT Act and the code of practice to ensure that the key issues are covered. As a minimum, training should include:
- what constitutes valid consent
 - who is able to take consent and also give it
 - cultural / religious considerations
 - the provision of information about the post-mortem itself, as well as about the retention, storage and disposal of material
 - what information should be documented and where

Governance and quality systems standards (GQ1–GQ8)

Key findings

28. Additional conditions highlighted six main areas of deficiency in meeting the governance and quality systems standards. These related to: SOPs, quality management (including audit and document control), training, appraisal and professional development, traceability of tissue, risk management (including incident reporting, risk assessment and corrective action) and lone working (see Table 3). Many of these deficiencies were also picked up in relation to other standards, for example those on premises, facilities and equipment, and they were also reflected in the extensive advice and guidance that was offered to establishments.

Table 3: Key areas of deficiency in meeting the governance and quality systems standards

Deficiency	No of establishments
Standard operating procedures	10
Quality management	11
Training, appraisal and PDPs	5
Traceability	9
Risk management	18
Lone working	3

29. Establishments are expected to have in place documented procedures for all licensable activities. On inspection we check that documents are controlled in order to ensure that only current, authorised documents are in use. The need to review and update SOPs was identified in several cases; this is unsurprising since quality management systems remain work in progress for many establishments.

Governance and quality systems standards (GQ1–GQ8) (continued)

30. The HTA was somewhat surprised and concerned to find that as a professional group, APTs do not appear to have benefitted from regular appraisal or training opportunities (see section on standard GQ3). This may, in part, account for the underdeveloped systems of quality and risk management in mortuary settings, both of which could be improved by training and professional development. We hope that, through continuing to work towards full compliance with the HTA standards, and by responding to the advice and guidance we have given, there will be significant improvements in the forthcoming months and years. In addition, we understand that the Association of Anatomical Pathology Technologists (AAPT) is working with Skills for Health in consultation with the Royal College of Pathologists (RCPath) to develop a modern professional educational programme for APTs, which, if implemented, will help bring about positive change in this area.
31. We have come across very few examples of practice requiring the HTA to take urgent regulatory action. The most serious was evisceration of bodies the day before post-mortem examination – the bodies sometimes being left in the post-mortem room overnight to accommodate an early start by the pathologists. The HTA considered this to be an unsuitable practice and took immediate action to stop the practice by issuing Special Directions and a range of additional conditions, including a change of DI and the submission of a monthly activity report to the HTA, signed by the APTs and the pathologists working at the mortuary. We are satisfied that this practice has now ceased.
32. The potential for serious error always exists. Establishments therefore need to develop their systems of risk assessment and review to ensure that risks are minimised as far as possible, particularly as lone working appears to be prevalent in the sector.

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ1 All aspects of the establishment's work are supported by ratified documented policies and procedures as part of the overall governance process

33. When assessing compliance with this standard, the HTA checks that up-to-date policies and procedures are in place, that staff are aware of their content and that they adhere to them. Where practice does not match the written procedure, this is highlighted.
34. Additional conditions related to a need for more robust systems of review and update of procedures or to the need for procedures on specific activities. The conditions required that the policies and procedures cover all licensable activities, that they be disseminated to staff, that there is a system for recording that staff have read new documents on release and are adhering to them. The HTA frequently recommended that staff involved in carrying out specific activities should be involved in the creation and review of documentation, which may help to ensure that all SOPs accurately reflect working practices.
35. Specific procedures identified as needing review across a number of establishments included those relating to cleaning and decontamination of all areas of the mortuary and equipment, manual handling, particularly by staff working alone, and lone working itself. 13 establishments were given either a condition or specific advice relating to procedures on lone working.
36. In one case, the review of documentation and subsequent interviews with staff highlighted that mortuary staff were not having occupational health assessments and reviews of immunisation status in accordance with the establishment's own policies.

Governance and quality systems standards (GQ1–GQ8) (continued)

37. Advice and guidance related to a range of issues, in some cases overlapping with other standards, but in many cases it focused on the need for documented procedures to be developed where none existed, for example on:

- the delivery of bodies out-of-hours, ensuring that funeral directors and porters enter the mortuary for legitimate reasons only and their attendance is logged
- access to the mortuary by NHS Blood and Transplant (NHSBT) tissue retrieval teams
- transfer of samples / bodies for specialist examination
- the management of toxicology samples
- the disposal and retention of tissue blocks and slides
- the acceptance and management of the obese
- the management of high risk post-mortems and associated cleaning procedures
- out-of-hours viewing

38. Finally under this standard, the HTA recommended that mortuary staff are involved more regularly in governance meetings to ensure good communication and common understanding of key issues. This has applied particularly to NHS Trusts with split sites, and to public mortuaries, where staff report to management at council offices in a different location from that of the mortuary. We recommended that agendas and minutes of meetings are recorded and made available to all relevant staff for reference.

GQ2 There is a documented system of quality management and audit

39. From the establishments inspected to date, it appears that formal systems of quality management are not common in the post-mortem sector. Although many of the establishments we inspected had participated in Clinical Pathology Accreditation (CPA) – with seven accredited, nine receiving conditional approval and 12 awaiting assessment – it appears that this has not always been extended to mortuaries and staff are often unfamiliar with the principles of quality management and its practical application.

Governance and quality systems standards (GQ1–GQ8) (continued)

40. Taking a proportionate and pragmatic approach, we have built on what individual organisations have in place rather than requiring all to reach the same level of achievement at the same pace.
41. Linked to the finding that a number of establishments have not put in place a robust quality management system, is the finding that establishments are not carrying out regular internal audits of licensable activities or are adopting an ad-hoc approach. Whilst additional conditions required establishments to implement a schedule of internal audits and a document control system, the emphasis has been on ensuring that mortuary procedures are reviewed and brought up-to-date and that they reflect the requirements of the HTA codes of practice.
42. Where an NHS Trust has implemented a quality management system in its laboratories, e.g. Q-Pulse, we required this to be extended to include the mortuary. In some cases, we recommended that staff be given access to IT systems to enable them to access existing systems.
43. Advice and guidance was offered where establishments needed particular assistance in taking forward work on quality management. This can largely be grouped under two headings: document control and audit. Examples are as follows:
 - operational procedures should have an author, an authorising person, a published date, a review date and a version number
 - there should be a system to ensure that review dates are adhered to and that new documents are disseminated to staff and read and understood by them
 - where electronic document control systems are in use, they should include all documented procedures and be accessible to all staff, who should be trained in how to use them
 - there should be a planned schedule of vertical and horizontal audits, which involves the mortuary and staff working there; topics to include: consent, sample tracking, record content (to ensure that traceability has been maintained in the mortuary and in laboratories) and compliance with procedures

Governance and quality systems standards (GQ1–GQ8) (continued)

- staff involved in audits should be trained
- the action points from audits should be recorded, along with the person responsible and the date by which they should be completed, and followed up to ensure they are completed
- feedback should be given to staff on the results of audits and actions arising from them

44. Finally, in one case the establishment asked for specific advice on what might be contained in its quality manual. The advice given is included here for the benefit of other establishments that are planning to develop a quality manual. The HTA recommended that the quality manual includes:

- a statement or policy of the scope of the quality management system
- an organisational chart showing interactions between linked departments and the committee / meeting structure
- reference to operational procedures, i.e. a master list, and an overview of the document control procedures, including the change control system for implementing new procedures
- a schedule of audits, including how topics are identified and planned and who is responsible for carrying them out
- reference to the incident reporting, complaints and risk-management systems
- links to training and reference manuals

45. The HTA advises that establishments keep their quality management system proportionate to the size and activity of the establishment and the number of staff, concentrating on making the system manageable, functional and useful.

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ3 Staff are appropriately qualified and trained in techniques relevant to their work and are continuously updating their skills

46. One of the key statutory responsibilities of a DI is to ensure that other persons working under the licence are suitable. Suitability of staff can be assessed against a range of criteria, the most obvious being that they possess relevant qualifications. However, it is also important to ensure that staff are suitable to conduct activities at the establishment by ensuring that they receive a thorough induction into the establishment's systems and that they have access to continuing professional development.
47. Mortuary staff attrition rates appear to be very low; whilst this ensures consistency of service, it appears that where APTs have worked in the same establishment for many years there has often been little opportunity, or indeed incentive, for professional development and reflection on practice. Also, it means that there has been little requirement for review of local induction programmes.
48. Whilst efforts are being made to raise the professional status of APTs, the findings from our inspection process indicate that mortuary staff may not benefit as much as other staff groups from training opportunities. We have found evidence of irregular appraisal of staff and lack of ongoing learning and development. In addition, staff do not routinely attend mandatory training sessions (see Table 3) and it is unclear whether they are not invited or they are unable to attend when invited.
49. Few additional conditions were placed on licences as the deficiencies did not always trigger the HTA's power to add conditions. In addition, most establishments had recognised the need to address the issue and were able to evidence plans to implement systems of appraisal and development as a matter of priority.

Governance and quality systems standards (GQ1–GQ8) (continued)

50. Where additional conditions were proposed against this standard, they required establishments to:

- establish a system of regular appraisal and personal development plans
- maintain staff training records
- develop a documented training programme to ensure that all mandatory training takes place (for example, health and safety, manual handling, infection control)
- identify and respond to specific training needs, for example the removal of pacemakers from the deceased and immediate training for staff in cleaning and decontamination
- develop a local induction programme for mortuary staff

51. An issue that was identified in eight cases is that of professional boundaries, and in particular the apparently common practice of APTs eviscerating bodies before the arrival of the pathologist, which has been found in some cases to be contrary to the establishment's own documented policy. RCPATH guidance published in 2002 (Guidelines on autopsy practice: Report of a working group of The Royal College of Pathologists) recommends that the pathologist must identify and examine the body before evisceration and supervise evisceration. We recommended that where RCPATH guidance is not followed, the practice should be reviewed and risk assessed. Where the DI, in consultation with colleagues, agrees that senior and experienced APTs can proceed routinely without the presence of the pathologist, there should be documented criteria for when APTs should deviate from this procedure and instead wait and defer to the pathologist.

52. A key part of the APT's role is the reconstruction of bodies following post-mortem examination. The HTA inspection process has found the quality of reconstruction work to be variable and in a very small number of cases we found mortuary staff using inappropriate packing materials (e.g. hospital gowns). We recommended that establishments consider implementing quality checks of reconstruction work, perhaps using a system of peer review, or engaging pathologists.

Governance and quality systems standards (GQ1–GQ8) (continued)

53. More than 30 establishments were given advice and guidance relating to this standard. This recommended:
- APTs are offered the opportunity to attend courses and conferences as part of ongoing professional development
 - a system of competency-based training for new staff is introduced
 - IT and internet access is made available to staff, enabling them to keep up-to-date with new developments and websites such as those of the HTA and the Royal Institute of Public Health
 - APTs consider joining their professional body, the Association of Anatomical Pathology Technologists, or registering with the Voluntary Registration Council for healthcare science professionals
 - porters accessing the mortuary should be trained by mortuary staff in relevant mortuary procedures
54. The HTA has developed a DI e-learning course. This resource can be accessed by any member of staff and may constitute a useful element of training for all staff working under a HTA licence. Staff knowledge of regulation can also be enhanced by ensuring that staff have access to the HTA e-newsletter as it contains up-to-date information on a range of issues affecting licensed establishments.
55. The HTA does not involve itself in detailed operational issues to avoid the risk of micro-managing establishments and thus disempowering the DI. Nor does it usually provide advice on staffing levels. However, in a small number of cases where concerns have been raised, establishments have been advised to complete a risk assessment of staffing levels to establish whether they are sufficient to ensure that suitable practices can be maintained and regulatory requirements complied with. The use of locums or the recruitment of additional staff should be considered to address any shortages identified and mitigate the risk of compromised service delivery due to the unexpected long-term absence of key staff.

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ4 There is a systematic and planned approach to the management of records

56. Compliance with this standard was good, with the majority of establishments providing evidence of a systematic and planned approach to the management of records, supported by documented procedures which reflected practice.
57. Additional conditions required only two establishments to review their records management systems and procedures for the creation, amendment, retention and destruction of records, to ensure clarity about what records are kept, how long they will be kept and where they will be kept.
58. There were some deficiencies relating to the recording of disposal details, which are covered in more detail in standard D2.
59. Advice and guidance recommended:
 - regular audit of records, to ensure completeness, legibility and accuracy
 - clarity on the records to be kept relating to bodies brought in out-of-hours
 - consideration of means of safekeeping paper records, for example by storing them in lockable cabinets and ensuring their protection against fire, flood or theft
 - review of record keeping procedures to ensure they reflect guidelines set by relevant professional bodies such as the RCPATH
 - amendments to records are signed and dated
 - policies on data protection, confidentiality and public disclosure are made available to staff
 - duplicate copies of key records are stored in a secure place to mitigate the risk of records being lost or damaged
 - development of a procedure for the creation and management of electronic records

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ5 There are documented procedures for donor selection and exclusion, including donor criteria

60. Removal of tissue for transplantation by mortuary staff was found to be uncommon, this largely being the domain of NHSBT. NHSBT is the UK's main provider of human tissue for transplant. Its role is to coordinate, recover, process, bank and supply human tissue grafts for use in surgery within the NHS and independent hospitals within the healthcare sector.
61. A condition was proposed in one case, requiring the introduction of a standard procedure for the removal of material for transplantation.
62. As of July 2008, removal of tissue for transplantation (procurement) is a licensable activity under the Human Tissue (Quality and Safety for Human Application) Regulations 2007, and is only permitted under a licence from the HTA or a third party agreement with a licensed establishment. Any establishments that are involved in this activity should contact the HTA for further advice.

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ6 A coding and records system facilitates traceability of bodies, body parts, tissues and cells, ensuring a robust audit trail

63. Effective coding and traceability systems are crucial to ensuring that material is not retained without the necessary consent, that it is disposed of in accordance with the wishes of the next of kin and that there is no scope for mistaken identity leading to errors. Compliance with this standard was fair, with definite room for improvement to systems of traceability.
64. During inspection, the HTA seeks to assure itself that bodies are labelled effectively and that there are systems to track each body from receipt into the mortuary to release for burial or cremation. Organs or tissue samples taken during the post-mortem examination must be similarly traceable.
65. The HTA undertakes an audit of random samples to check that systems work as described by mortuary and laboratory staff and as documented in SOPs.
66. Additional conditions required review of and improvements to establishments' coding and record systems to facilitate the full traceability of bodies and tissue blocks and slides.
67. These included:
 - the use of at least one unique identifier for each sample
 - the maintenance of transport and delivery records for material that is moved between sites
 - centralisation of histology records
 - third party agreements with recipients of tissue for research, ensuring traceability, responsibility for maintaining the integrity of tissue during transportation and disposal in line with the consent given.
 - the development of procedures to ensure that material taken from a body during post-mortem examination is returned to the body before burial or cremation, where this is requested by the next of kin

Governance and quality systems standards (GQ1–GQ8) (continued)

68. Advice and guidance recommended:

- recording the number of blocks and slides produced from each sample and the type and quantity of material subsequently disposed of
- the use of unique numbers as well as names, to identify bodies in storage, to minimise the risk of mixing up bodies with the same or similar name
- rationalisation of forms and paperwork to avoid duplication
- the use of fridge labels to augment the blackboard containing the names of the deceased
- access by APTs to computerised records held on centralised pathology systems (e.g. Telepath) to enable the mortuary to track the movement and storage of samples retained
- the introduction of a log to track the number and types of material sent and returned from microbiology or histology testing, to facilitate full traceability and ensure material is returned to the body, where this has been requested
- review and update of the referencing system for still births to include the mortuary unique number as well as the mother's name

Governance and quality systems standards (GQ1–GQ8) (continued)

GQ7 There are systems to ensure that all adverse events, reactions and / or incidents are investigated promptly

69. The HTA found that there is widespread use of NHS Trust or corporate incident reporting systems, but in the establishments inspected the use of these systems was largely limited to reporting of health and safety or security incidents. In three cases, establishments were required to introduce a mortuary-specific procedure on adverse incident reporting, including guidance on what types of incident to report and how to instigate a root cause analysis or follow-up investigation.
70. Incident reporting systems should ensure that corrective actions are identified, completed and reported back to staff, and this is checked by discussion with staff during interview.
71. Advice and guidance was offered to 17 establishments which recommended:
 - widening the scope of the incident reporting system so that it took into account the full range of incidents possible in the mortuary environment and included incidents that may pose a risk to or result in harm to bodies and body parts
 - consideration of the use of a 'trigger' list of incidents that must routinely be reported
 - the introduction of a method of recording at a local level when an incident has been reported and how it has been followed up. This might include noting the corrective and preventative actions identified after an adverse incident, as well as the person responsible for taking forward the actions, the date by which actions should be completed and the date for completion
 - training for staff to ensure common understanding of what and how to report
 - the use of untoward incident information to inform and develop risk assessments (see GQ8)

Governance and quality systems standards (GQ1–GQ8) (continued)

72. The HTA requires that any incidents that have been defined by the establishment as 'severe' in nature must be reported to the HTA. This is so that we can provide appropriate advice and guidance and, in the future, share the learning gained from investigation of these incidents.

GQ8 Risk assessments of the establishment's practices and processes are completed regularly and are recorded and monitored appropriately

73. Risk assessment is another activity that was identified on inspection as requiring further work, with 18 establishments requiring an additional condition to rectify this deficiency. Although the establishments inspected were found to have a good understanding of health and safety practices, including control of substances hazardous to health (COSHH) requirements and the need for regular assessment to ensure compliance, risk assessment of other activities was infrequent.
74. Additional conditions were applied to seven establishments' licences, requiring that they undertake risk assessments of all licensable activities and that staff are updated on the results.
75. In a number of cases, also picked up when assessing compliance with standard GQ1, there was concern about the practice of lone working, which could be addressed through formal risk assessment. In one case the HTA advised that risk assessments should consider manual handling and accidents, as well as the personal safety of staff who may have to deal with distressed relatives. Establishments were also required to ensure that risk assessments inform lone working policies and associated procedures.

Governance and quality systems standards (GQ1–GQ8) (continued)

76. Advice and guidance recommended:

- the development of guidelines for how risk assessments should be carried out, including how to document the results and take forward any actions
- clarity about the definition of a 'high-risk' post-mortem examination, and the procedures to follow
- improvement of the risk assessment process by clearer definition of potential risks and adoption of a formal model of risk assessment
- dissemination of risk information to all staff working under the licence, ensuring that they understand how risk ratings are applied to individual procedures
- where required, risk assessments should include specialist advice, for example on infection control and COSHH, to ensure that all risks are identified and acted upon

Premises, facilities and equipment standards (PFE1–PFE5)

Key findings

77. Additional conditions highlighted six main areas of deficiency in meeting these standards. They related to: the condition of premises and equipment (including maintenance), storage (including contingency planning and temperature monitoring), infection control (including demarcation of clean, transitional and dirty zones and the use of personal protective equipment), cleaning and decontamination and security (see Table 4).

Table 4: Key areas of deficiency in meeting the premises, facilities and equipment standards

Deficiency	No of establishments
Condition of premises and equipment	13
Storage	9
Infection control	8
Cleaning and decontamination	6
Security	3

78. In December 2007, the HTA met the Health and Safety Executive (HSE) to discuss the role of each organisation and how we might work together. Although it undertakes annual inspections, targeting organisations based on information gathered from a range of sources, it very rarely visits mortuaries and is content for the HTA to lead on this.
79. The HTA, through its statutory remit to ensure suitable premises, seeks to assure itself that mortuary storage areas and post-mortem rooms provide an environment that is safe for staff and preserves the dignity of the deceased. We have completed one joint inspection with the HSE and will continue to do this where appropriate. We also use the HSE publication *Safe working and the prevention of infection in the mortuary and post-mortem room* (2003) to inform the judgements we make about suitability of premises.

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

80. 19 establishments, around 40% of those visited, had conditions proposed relating to their premises or the condition of their equipment, and in some cases these required investment in new equipment or repairs to the fabric of the building.

PFE1 The premises are fit for purpose

81. Many mortuaries are housed in buildings that are decades old; in the case of public mortuaries, some date back to the 19th Century. Although upgrades have been made, often the design and layout of some of the busiest mortuaries makes it difficult to implement standards of good practice.
82. Along with disposal standard D1, this standard warranted the most advice and guidance and additional conditions.
83. The HTA has taken a proportionate and risk-based approach and proposed additional conditions only where these are required on the basis of the evidence obtained and where improvements can be made so that HTA is satisfied that the premises are suitable. Where the constraints of the building have not allowed physical changes to the environment to allow the establishment to meet the standard fully, the HTA has highlighted the issues and worked with staff to come up with a solution that is an improvement rather than a complete rectification.
84. In three cases, the premises were deemed to be unfit for purpose and more serious regulatory action was taken in the form of special directions requiring immediate remedial action to be taken or preventing the continued use of the mortuary for post-mortem activity. In one case the mortuary was able to continue operating as a body store, pending results of a risk assessment.

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

85. Following their HTA site visit inspection, 11 establishments had a condition placed on their licence relating to this standard. They required:
- separation of clean, transitional and dirty zones by the use of floor markings and / or wall signs. In one establishment, the HTA required that a door be installed to close off the post-mortem room from the body store
 - regular maintenance of ventilation equipment and refrigerated storage units to ensure that equipment is working effectively and the post-mortem room has the required number of air changes
 - repairs to cracked and broken work surfaces and flooring
 - actions to address inadequate security, including risk assessment of the site, the introduction of standard operating procedures on access and lone working, the use of CCTV and a review of measures that could be put in place to ensure that staff are sufficiently protected from risks associated with distressed relatives visiting the premises, particularly out-of-hours
 - immediate risk assessment of the air ventilation system and necessary remedial action
86. In some cases, maintenance was carried out by the hospital's central engineering department rather than under contract with an external service provider and the DI had no records or information relating to maintenance of the equipment.
87. In one organisation, building works gave rise to serious concern about possible unauthorised access to the main body store and a full review of security arrangements was required in order that steps could be taken to mitigate this risk. In another there was a risk that relatives visiting the mortuary might inadvertently see the bodies of the deceased being brought to the mortuary by hospital porters, and the establishment was required to review procedures and implement a system to prevent this from happening.

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

88. Broadly, advice and guidance fell into four categories:

- security and lone working: a number of establishments were advised to review their lone working policies, to risk-assess the practice of lone working and mitigate any risks by the introduction of additional security measures, for example CCTV, intercoms or intruder alarms
- health and safety: establishments were advised to consider the development of health and safety information for staff and visitors. One was advised to expand mortuary procedures to ensure that overshoes and outer garments were removed when leaving the post-mortem room and to prevent staff working in the mortuary from taking the more convenient route to the shower via the office area. Another was advised to assess the manual handling risk to staff when lifting bodies onto trolleys for viewing purposes
- repair and renovation: areas identified included cracked tiles in the post-mortem room and body-store area, stained and chipped enamel sinks and the use of formica worktops, which present an infection risk because they are prone to surface damage and the underlying wooden material is porous
- care of the bereaved: the HTA looks at facilities for the bereaved when inspecting mortuary premises. For the most part, the establishments inspected took great efforts to meet the needs of distressed relatives. In a small number of cases, the HTA advised establishments to consider removing specific religious artefacts from viewing rooms (unless they are specifically requested)

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

PFE2 Environmental controls are in place to avoid potential contamination

89. Overall, compliance with this standard was good, with only five additional conditions requiring action to rectify non-compliances. In most cases, the HTA found well developed understanding of infection control practices supported by comprehensive procedures for each working area of the mortuary, however this was not always the case. The treatment of possible high risk post-mortems serves as a good example of the variation in practice we have observed. In a very small number of cases, where the history of the deceased is unknown, post-mortem examination does not take place until the results of a blood test have been obtained (with the authority of the coroner), or the body is transferred to an alternative mortuary and handled as a high risk case. In others, no such assessment is made and staff proceed as usual, taking minimal extra precautions (for example, the use of full-face visors).

90. Additional conditions required:

- critical equipment to be readily available for high risk post-mortems
- replacement of damaged and unsuitable pieces of equipment such as dissection boards, wooden head-rest blocks, wooden measuring sticks, body trays and post-mortem tables
- development of a thorough and documented procedure on cleaning and decontamination of the mortuary, to include the use of disinfectants and the frequency of cleaning
- risk assessment of the ventilation system, drainage in the post-mortem room and the movement of the body trolley between areas to ensure minimal risk of contamination.

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

91. Advice and guidance recommended:

- development of a procedure for identifying the correct movement through areas of the mortuary to minimise the risk of cross-contamination, and the correct protective equipment required within each
- the introduction of visual reminders within areas where personal protective equipment (PPE) is required, outlining what should be worn and by whom, to reinforce the importance of health and safety, and the use of appropriate PPE
- review and update of the mortuary cleaning schedule, including refrigerated units, with reference to the HSE's Safe working and the prevention of infection in the mortuary and post-mortem room
- review of disinfection procedures for high risk post-mortems
- more regular cleaning of floor drainage channels and training in effective cleaning
- introduction of a sign-off sheet logging when cleaning tasks have been completed

92. In a small number of mortuaries, mortuary staff, who were already stretched by their workload, were responsible for cleaning non-mortuary areas, for example the office and waiting room. The HTA suggested that alternative arrangements should be made to relieve them of this duty.

PFE3 There are appropriate facilities for the storage of bodies, body parts, tissues and cells, consumables and records

93. As mentioned earlier, the age and condition of mortuary buildings varies enormously; this applies also to their storage facilities and in particular refrigerated units.

94. Although overall compliance was generally good, additional conditions were required in some cases, relating to the need for continuous monitoring of body storage fridges and freezers and contingency plans to be put in place in the event of power failure.

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

95. One NHS Trust informed the HTA that it was holding a small number of fetal specimens that had been in the Trust for many years, and asked for advice. The specimens were contained in individually wrapped glass jars and stored in an inappropriate location with no plans for their use. A condition placed on the licence required that the specimens stored be itemised and either used for one of the scheduled purposes defined in the HT Act (e.g. education and training) or arrangements made for respectful disposal in line with HTA code of practice on Disposal.
96. Advice and guidance related mostly to storage and included the recommendation that, where possible, refrigerator temperature-monitoring systems be linked to the main switchboard to ensure an out-of-hours response to alarms. Also highlighted was the need to maintain fridge temperatures at an optimum level of 3–6°C and to implement a system of testing of the alarm system when temperature levels are breached. One establishment was advised to replace damaged fridge door seals and another was advised to store cleaning equipment separately from blocks and slides.
97. Finally, the HTA considers the storage of unshrouded bodies to be inappropriate practice; where this was found to be the case the establishment was advised to take steps to ensure that bodies are always shrouded whilst stored in fridges and freezers.

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

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

98. This standard applies both to bodies coming in and out of the mortuary and to organ and tissue samples removed during post-mortem and sent elsewhere for analysis, or for use for other purposes in line with the consent given by the next of kin.
99. There were no serious examples of non-compliance and the following advice and guidance was given:
 - putting systems in place to ensure that any material removed during post-mortem and transferred to another establishment for analysis is subsequently disposed of in line with the relatives' wishes or stored for further use with appropriate consent
 - risk-assessing the practice of APTs transporting tissue samples in their own vehicles and taking reasonable measures to mitigate any risks identified, or ceasing this practice
 - ensuring that histology sample pots state clearly the type of tissue they contain
 - including in mortuary records the date and time of collection and the details of the receiving organisation, where tissue samples are transferred or taken off site by the police or forensic pathologists
100. In NHS Trusts it is common practice for portering staff to bring bodies from ward areas to the mortuary. The HTA recommended that mortuary staff could be involved in training porters to ensure that they are aware of relevant mortuary procedures, particularly when delivering bodies out-of-hours.

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

PFE5 Equipment is appropriate for use, maintained, quality assured, validated and where appropriate monitored

101. During site visit inspections, the HTA seeks to assure itself that all equipment in the mortuary environment is in a good condition and appropriate for use; that staff have the equipment they need to undertake their work free of unnecessary risk or discomfort; and that the bodies in their charge should be protected from harm. During a site visit inspection, we therefore inspect fridges and freezers, hydraulic trolleys, post-mortem tables and equipment (for example hoists, weighing scales, oscillating saws and PPE such as respiratory masks and visors), drainage channels and ventilation / air conditioning systems.

102. Additional conditions required:

- regular and routine maintenance of critical equipment, including fridges, freezers, trolleys and air exchange systems
- fridges and freezers to be fitted with temperature alarms, ensuring that critical storage temperatures are maintained
- contingency plans for the loss of critical equipment and the movement of bodies in emergency situations

103. In addition, advice and guidance recommended:

- a schedule of equipment maintenance is established, detailing how often the service is required, who it is provided by (whether an internal or external service), and when the next service is due
- records of equipment maintenance are kept in the mortuary
- lone worker alarms are tested on a regular basis
- staff have adequate and accurate scales for the weighing of bodies

Disposal standards (D1–D2)

Key findings

104. Additional conditions highlighted three main areas of deficiency in disposal practice. These related to: SOPs, compliance with relatives' wishes and record keeping relating to the details of the disposal, including the reason and method for disposal of tissue (see Table 5).

Table 5: key areas of deficiency in meeting the disposal standards

Deficiency	No of establishments
Standard operating procedure	14
Compliance with relatives' wishes	16
Record keeping	8

105. The change in the legislation that resulted in the HT Act stemmed largely from two public inquiries that took place in England between 2000 and 2003. These were the Kennedy and Redfern inquiries, and the subsequent Isaacs Report, all of which established that the removal, storage and use of organs and tissue from adults and children during post-mortem examination, without sufficient disclosure or consent, was widespread. The HT Act, the codes of practice and our licensing and inspection process aim to ensure that tissue is no longer deliberately retained indefinitely, without consent, for future use.

106. However, our inspection process has highlighted that many establishments continue to retain material because they simply have not received instruction from the family on whether or not they would like it retained, and they are uncomfortable disposing of material without the knowledge of the next of kin. Where this has been indicated on inspection, we have encouraged improved communication with coroners and their officers and, on occasion, changes to standard operating procedures and forms in use (see D1 below for further detail).

Disposal standards (D1–D2) (continued)

107. A better understanding of the operational issues facing mortuary staff, the working relationships between APTs, pathologists and coroners' officers, and the key responsibilities of each of these groups during the post-mortem process has led to a significant rewrite of the HTA code of practice on Post-mortem. In particular, emphasis has been placed on the importance of effective communication. The code of practice on Disposal is also a useful resource.

D1 There is a clear and sensitive policy for disposing of human organs and tissue

108. The disposal standards have presented a challenge to some of the licensed establishments inspected, as indicated earlier. This may be partly due to inadequate communication between the coroner's office, pathologists and the mortuary, which means that there is sometimes uncertainty about whether the coroner's authority has ended and also about the disposal, or retention, wishes of the next of kin.

109. Additional conditions required establishments to set up formal arrangements with coroners, agreeing lines and methods of communication. The aim is to avoid the prolonged and unnecessary retention of tissue samples caused by poor communication flows. So, for coroners' post-mortems, we have encouraged improved, and where possible, more formalised procedures with the coroner to ensure that mortuary staff are notified both of the cessation of the coroner's investigation and the wishes of the next of kin with regard to retention or disposal of tissue.

110. Also, establishments were expected to review and update their local policies and procedures on disposal, where they were found to be inconsistent with the requirements of the HTA code of practice, for example with regard to the disposal of fetal remains.

Disposal standards (D1–D2) (continued)

111. Advice and guidance recommended:

- reacquaintance with the HTA codes of practice on Consent and Disposal, particularly with regard to the disposal of retained material
- closer working with coroners and their officers to ensure that forms detailing options for the retention of tissue blocks and slides reflect all the options available, are fully completed and are passed to mortuary staff
- inclusion in the mortuary operations manual of the documented agreement with the coroner
- modification of the mortuary disposal policy to include reference to return to body request
- the development of an information leaflet for bereaved relatives outlining the disposal options and the possible benefits of retaining material
- an audit of retained material stored on the premises to establish whether material is being held without authorisation or consent for its storage, and whether it should be disposed of

D2 The reasons for disposal and the methods used are carefully documented

112. As indicated earlier in this report, by and large compliance with the record-keeping standard (GQ4) was good. Where there were deficiencies, they related to the requirement to record the details of disposal of tissue.

113. Establishments that failed to comply fully with this standard were required to review their standard operating procedures to ensure that disposal records are routinely kept. Additional conditions required:

- the development of a standard operating procedure that reflects the requirements of the HTA code of practice on Disposal and ensures that disposal is in line with the relatives' wishes and ensures that material is reunited with the body where this has been requested

Disposal standards (D1–D2) (continued)

- electronic and / or paper records of disposal should include the date, method and reason for disposal
- liaison with the coroner to ascertain the status of retained material no longer required and the respectful disposal of material held without consent

114. Advice and guidance focused on improved working with coroners' officers, and recommended:

- improved communication to ensure that mortuary staff are made aware when the coroner's authority has ended and disposal of material retained can take place
- efforts to encourage coroners' officers to familiarise themselves with the HTA codes of practice on Post-mortem examination and Disposal
- joint review and amendment of forms used by coroner's officers to record the disposal / retention wishes of the next of kin and offering the family the option of disposal of the material by the establishment

Appendix 1:

Licensing and inspection processes

The HTA defines inspection as a process encompassing desk-based review, site visit assessment and analysis of relevant written, numerical, verbal and visual information to evaluate an establishment's compliance with expected standards. Desk-based reviews are described as phase 1 inspections and site visit assessments are described as phase 2 inspections. Phase 2 inspections are primarily used to gather information that can only be gathered by going on site. Both phase 1 and phase 2 inspections lead to licensing decisions.

Phase 1 inspections

Phase 1 inspections involve a thorough analysis and evaluation of the compliance report licence application submitted by the proposed LH and the proposed DI. This information is often supplemented with additional verbal or written information requested by HTA during telephone interviews and email exchanges with the proposed DI and / or LH, as part of the process. Phase 1 inspections lead to a licensing decision including whether to grant or refuse a licence.

Phase 2 inspections

Phase 2 site visit inspections are conducted based on the findings from a phase 1 inspection plus any other relevant information. The focus during a phase 2 inspection is on review of an establishment's operational policies and procedures, inspection of its premises and scrutiny of its practices. This involves interviews with a range of staff at the premises. This allows the HTA to follow up any areas of non-compliance, and evaluate progress against any licence conditions imposed at a phase 1 inspection.

A risk-based approach to inspections

The HTA targets phase 2 site visit inspections at those establishments deemed to be at highest risk both across sectors and within sectors (please note, as described above, all establishments have a mandatory phase 1 desk based inspection). Risk is context-specific and we refer here to the risk of regulatory non-compliance.

Appendix 1:

Licensing and inspection processes (continued)

We also conduct phase 2 site visit inspections at low-risk establishments. This is to assess the validity of the risk assessment process we use when scheduling inspections, which helps ensure that the assessment of risk is appropriate. The phase 2 inspections also allow the HTA to gather knowledge from high performing (low-risk) organisations and to share learning about this across the sector.

Occasionally, the HTA may carry out a 'reactive' inspection. This may be announced or unannounced. The decision to carry out a reactive inspection is usually based upon receipt of information about an establishment that raises concerns regarding regulatory compliance.

The role of the HTA in making licensing decisions

The HTA has a statutory responsibility to make judgements about the suitability of the proposed Designated Individual (DI), Licence Holder (LH), premises and practices in relation to the licensed activities. This means that during a phase 1 inspection and before issuing a licence, the HTA must be satisfied that the applicant is a suitable person or entity to be the LH, and that the premises are suitable for the activities to be authorised.

The HTA must also be satisfied that the DI is a suitable person and can supervise the activities authorised by the licence. This requires the DI to have a sound knowledge and understanding of licensed activities and associated operational procedures. The HTA helps DIs to understand their statutory responsibilities by providing advice and guidance via meetings, email, workshops and training events, as well as the DI e-learning course: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders.cfm and a guide for DIs and LHs: www.hta.gov.uk/licensing/designated_individuals_and_licence_holders/dls_under_the_ht_act.cfm

Appendix 1:

Licensing and inspection processes (continued)

Although a DI's statutory responsibilities cannot be delegated, operational responsibility can be: the HTA advises DIs to identify key staff within each licensed area that can act as Persons Designated (PD) under the licence to support them in fulfilling their statutory role.

To enable the HTA to make effective judgements, we have developed standards with input from the professionals working in the sectors we license. These licensing standards form the basis of the compliance report licence application and are in four broad themes:

- consent
- governance and quality systems
- premises, facilities and equipment
- disposal

Compliance with the HTA standards is assessed through inspection, using a four-point numerical scale.

1 = standard not met

2 = standard partially met

3 = standard almost met

4 = standard fully met or exceeded

Where the inspection process identifies that a standard is not being met, formal advice and guidance may be offered or formal regulatory action may be taken where the non-compliance triggers the HTA's power to vary a licence. There are several different types of regulatory action which may be considered by the HTA: variation of licences through, for example, the imposition of additional conditions; issue of Special Directions; suspension of a licence or revocation of a licence. In the vast majority of cases, the HTA will take regulatory action by varying a licence to impose additional conditions. Additional conditions are time-bound and DIs are required to inform the HTA when they have taken appropriate action to comply with them. The HTA then assesses this information to decide whether the establishment has met the condition or whether further regulatory action should be taken.

Appendix 1:

Licensing and inspection processes (continued)

Complex regulatory issues are normally brought before a Regulatory Action Panel (RAP), to ensure that all relevant considerations are taken into account and that a fair, proportionate and justifiable licensing decision is made. RAPs are normally chaired by the Director of Regulation and consist of a Head of Regulation, a Legal Advisor and the Regulation Manager responsible for making the licensing decision.

The difference between advice and guidance and licence conditions

The HTA works as a compliance-based regulator, which means we place a strong emphasis on the value of providing advice and guidance to professionals working within the sector. This is so that they understand regulatory requirements and are better equipped to meet standards. Where enforcement is necessary, we aim to make evidence-based, justifiable and proportionate decisions. Phase 2 inspections also lead to advice and guidance from the HTA on how the establishment can improve its practices.

The HTA provides verbal and written advice and guidance in a wide variety of ways. We provide a great deal of written advice and guidance during phase 2 site visit inspections in the spirit of continuous quality improvement, and these recommendations are for the DI and staff to consider to make improvements to their systems, processes and practices. Whilst these are not statutory requirements, any advice and guidance made by the HTA is carefully considered and is intended to help establishments reflect on their practice and make improvements.

Regulatory sanctions imposed on an establishment (most frequently in the form of licence conditions) hold statutory weight and failure by the DI to comply with a licence condition is a breach of the DI's statutory duties, which gives HTA the power to revoke a licence.

Appendix 2:

List of establishments which received an HTA phase 2 inspection in 2007–2008

- Addenbrooke's Hospital, Cambridge University Hospitals NHS Foundation Trust, Cambridge
- Burnley General Hospital, East Lancashire Hospitals NHS Trust, Burnley
- Central Mortuary, Birmingham City Council, Birmingham
- City of Westminster Public Mortuary, Westminster City Council, London
- Colchester General Hospital, Essex Rivers Healthcare NHS Trust, Colchester
- Conquest Hospital, East Sussex Hospitals NHS Trust, Hastings
- Cumberland Infirmary, North Cumbria Acute NHS Trust, Carlisle
- Darent Valley Hospital, Dartford and Gravesham NHS Trust, Dartford
- Darlington Memorial Hospital, County Durham and Darlington Foundation Trust, Darlington
- East Ham Public Mortuary, London Borough of Newham, London
- Eastbourne District General Hospital, East Sussex Hospitals NHS Trust, Eastbourne
- Forensic Science Service, Sheffield
- Friarage Hospital, South Tees Hospitals NHS Trust, Northallerton
- Great Western Hospital, Swindon and Marlborough NHS Trust, Swindon
- Hackney Public Mortuary, London Borough of Hackney, London
- Hornsey Public Mortuary, London Borough of Haringey, London
- James Cook University Hospital, South Tees Hospitals NHS Trust, Middlesbrough
- John Radcliffe Hospital, Oxford Radcliffe Hospitals NHS Trust, Oxford
- Kent and Sussex Hospital, Maidstone and Tunbridge Wells NHS Trust, Maidstone
- Kettering General Hospital, Kettering General Hospital NHS Trust, Kettering
- Medico-Legal Centre, Sheffield City Council, Sheffield
- Miller House Mortuary, Greenwich Council, London
- Morriston Hospital, Swansea NHS Trust, Swansea
- Neath / Port Talbot Hospital, Swansea NHS Trust, Swansea
- Ormskirk and District General Hospital, Southport and Ormskirk Hospitals NHS Trust, Southport

Appendix 2:

List of establishments which received an HTA phase 2 inspection in 2007–2008 (continued)

- Pathlinks, Lincoln County Hospital, North Lincolnshire and Goole Hospitals NHS Trust, Lincoln
- Pathlinks, Pilgrim Hospital, North Lincolnshire and Goole Hospitals NHS Trust, Boston
- Peterborough District Hospital, Peterborough and Stamford Hospitals NHS Foundation Trust, Peterborough
- Prince Philip Hospital, Carmarthenshire NHS Trust, Llanelli
- Public Mortuary, Cannock Chase Council, Cannock
- Public Mortuary, City of Stoke on Trent Council, Stoke On Trent
- Royal Cornwall Hospital, Royal Cornwall Hospitals NHS Trust, Truro
- Royal Devon and Exeter NHS Foundation Trust, Exeter
- Singleton Hospital, Swansea NHS Trust, Swansea
- Southampton General Hospital, Southampton University Hospitals NHS Trust, Southampton
- Southport & Formby District General Hospital, Southport and Ormskirk Hospitals NHS Trust, Southport
- The Calderdale Royal Hospital, Calderdale and Huddersfield NHS Foundation Trust, Halifax
- University Hospital of North Durham, County Durham and Darlington Foundation Trust, Durham
- University Hospital of North Tees, North Tees and Hartlepool NHS Trust, Stockton on Tees
- Waltham Forest Public Mortuary, London Borough of Waltham Forest, London
- Wednesfield Public Mortuary, Wolverhampton City Council, Wolverhampton
- West Cumberland Hospital, North Cumbria Acute NHS Trust, Carlisle
- West Middlesex Hospital, West Middlesex Hospital NHS Trust, Isleworth
- West Wales General Hospital, Carmarthenshire NHS Trust, Carmarthen
- Withybush General Hospital, Pembrokeshire and Derwen NHS Trust, Haverford West
- Worthing Hospital, Worthing and Southlands Hospitals NHS Trust, Worthing
- Ysbyty Gwynedd Hospital, North West Wales NHS Trust, Bangor

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

Human Tissue Authority

Finlaison House

15–17 Furnival Street

London EC4A 1AB

Tel 020 7211 3400

Fax 020 7211 3430

Email enquiries@hta.gov.uk

Web www.hta.gov.uk