

Human Tissue Authority

A Hampton Implementation Review Report

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July 2009

## **Human Tissue Authority**

This review is one of a series of reviews of regulatory bodies focusing on the assessment of regulatory performance against the Hampton principles and Macrory characteristics of effective inspection and enforcement. It was carried out by a review team drawn from the Better Regulation Executive, from the Gambling Commission and the Pensions Regulator, in December 2008. Further information about the reviews can be found at: <http://www.berr.gov.uk/whatwedo/bre/inspection-enforcement/implementing-principles/reviewing-regulators/page44054.html>

## EXECUTIVE SUMMARY AND CONCLUSIONS

Key findings from the review: The Review Team found that the Human Tissue Authority (HTA) was, to a high degree, compliant with the Hampton principles. The review team rated the HTA highly on provision of advice and guidance and minimisation of inspection and data-collection burdens. In the future, the HTA should continue to work with stakeholders and the Department of Health (DoH) to overcome any perceived inconsistencies with the legislation it is responsible for enforcing.

Key findings are:

- The HTA was established in the same year that the Hampton Review was published. The team setting up the HTA successfully used the Hampton principles and recommendations when designing the new regulatory framework, ensuring that it is risk-based, proportionate and transparent.
- As a compliance-based regulator, the HTA's main focus is on advice and guidance, and it always tries to bring establishments back into compliance before resorting to regulatory action. Stakeholders value HTA staff members' openness and desire to help, and the willingness of the organisation as a whole to engage on the development of the regulatory framework.
- While the HTA does a good job in helping establishments understand what is required of them, there remains scepticism among some stakeholders about aspects of the underlying legislation. The HTA should continue to work with professional stakeholders to clarify any perceived inconsistencies in the legislation as it stands, and gather ideas for future reforms of the legislation. At the same time, the HTA should continue to demonstrate to stakeholders the benefits of improved public confidence in the handling of human tissue.
- In the post-mortem, research, anatomy and public display sectors, the HTA has very nearly minimised data-collection and inspection burdens at present. The HTA is in the process of revising its regulatory framework for all sectors for implementation in 2009,

and has decided that the level of burden in the future may be minimised by using an open-ended (“continuous”) licensing system.

- In June 2007, the HTA published research on the levels of public confidence in the handling of human tissue in the UK. The HTA should continue to commission similar surveys at regular intervals, so that it may determine if its regulatory activity is having an impact on this key outcome measure.

Issues for follow-up identified during the review:

The key follow-up issues identified during the review are:

- The HTA should work with the DoH in the near future to amend/update the Human Tissue Act, using the feedback and experience gained from the first years of its implementation.
- The HTA should continue to work with establishments it regulates and its scientific panel to provide clarity on the definition of types of human tissues and whether they are in or out of scope of the legislation.
- The HTA regularly reviews the effectiveness of individual pieces of guidance material. At some point in the future, the HTA may wish to consider a more strategic approach to measure the certainty, accessibility, clarity and consistency of its suite of guidance materials across all sectors it regulates.
- The HTA should continue its discussions with stakeholders on how best to make use of the activity data it collects from establishments in the human application sector.
- With respect to on-site inspections, the HTA should continue to focus its resources on establishments with the highest risk scores.
- The HTA should continue to explore options for further collaborative inspection activity with other regulators, particularly those with technical expertise that may be relevant to the work of the HTA.
- The HTA should monitor the effectiveness of its regulatory activity by commissioning surveys of public perception around handling of human tissue at regular intervals.

## INTRODUCTION

Introductory background information about the regulator such as the rationale for establishing it:

The Human Tissue Authority (HTA) was established on 1 April 2005 under the Human Tissue Act 2004 to regulate the removal, storage, use and disposal of human tissue in England, Wales and Northern Ireland. It is an Executive Non-Departmental Public Body sponsored by the Department for Health.

The HTA is the competent authority in the UK for regulating tissues and cells for human application under the EU Tissue and Cells Directive (EUTCD). The HTA is also responsible for approving donation of solid organs and bone marrow from living donors.

The origins of the HTA go back to public concerns over organ-retention at The Royal Liverpool Children's Hospital (Alder Hey) and The Bristol Royal Infirmary, which brought issues of consent, and organ and tissue use and storage under the spotlight. The scale of these issues across the health service was highlighted in February 2001 when an investigation led by Liam Donaldson, the Chief Medical Officer, found that 105,000 organs, body parts and fetuses had been retained in 210 English NHS trusts and medical schools. Over 16,000 organs had been kept illegally. Michael Redfern QC examined Alder Hey pathology practices and found that organs had been stockpiled and then processed as clinical waste between 1970 and 1990. He concluded that there was a 'weak and poorly understood legal framework that allowed bad practice to flourish'.

When the HTA was established, it was the Government's intention for it to merge with the Human Fertilisation and Embryology Authority, forming the Regulatory Authority for Tissue and Embryos. However, following the report of a Joint Parliamentary scrutiny committee in 2007, the Government decided that the merger should not go ahead and that both organisations would continue as stand-alone regulators.

While the HTA was established in April 2005, it only began regulating the human application sector in April 2006, and the remaining licensable sectors (post-mortem, research, anatomy and public display) in September 2006. Therefore, at the time at which this review was conducted the HTA had only completed two full operational business

years.

The legislation establishing the regulator:

The Human Tissue Act 2004 repeals and replaces the Human Tissue Act 1961, the Anatomy Act 1984 and the Human Organ Transplants Act 1989 as they relate to England and Wales, and the corresponding Orders in Northern Ireland. In addition, the Unrelated Transplant Regulatory Authority (ULTRA) and the post of HM Inspector of Anatomy were abolished and their functions transferred to the HTA.

The regulator's statutory remit or objectives:

The HTA has two principal statutory functions. The first is to provide advice and guidance on all matters within its statutory remit. The second is to regulate the removal, storage, use and disposal of human bodies, organs and tissues for a number of Scheduled Purposes – such as research, transplantation, and education and training – set out in the Human Tissue Act 2004. To this end, the HTA regulates through licensing:

- the carrying out of an anatomical examination and the storage of human bodies and anatomical specimens for anatomical examination;
- the making of a post-mortem examination;
- removal of tissue from the body of a deceased person for Scheduled Purposes except transplantation;
- storage and use of human bodies or parts for public display;
- storage of human tissue for other scheduled purposes, for example research;
- donation of organs or part organs by living donors; and
- donation of bone marrow by certain donors.

The HTA is also responsible for enforcing the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations), which transpose new pieces of European legislation (Directives 2004/23, 2006/17 and 2006/86).

This review considered the majority of the HTA's work, with the exception of its responsibilities in the area of live tissue transplants.

The regulator's budget:

The HTA derives its income from two sources: grant-in-aid drawn down from the Department of Health (used for supporting administrative costs) and licence fees. The total annual expenditure was nearly £4.6 million in 2007/08, with over half of this (59%) being staff costs.

The HTA estimates that about 75% of its operating costs will be met by licence fees. The HTA is not a profit-making organisation.

Number of staff (including breakdown of policy and frontline staff):

The HTA is made up of two parts – the Authority and the Executive.

The Authority currently consists of a Chair and 14 members who have been appointed by the Secretary of State for Health. The members come from a variety of medical, scientific, legal, administrative and political backgrounds.

The Executive implements the policy and strategic goals set by the Authority. The Executive currently has 42 staff. This review focused on the activities of the Executive.

The sectors and number of businesses regulated either directly or indirectly:

The HTA is responsible for licensing and inspecting over 800 premises across five diverse sectors:

<b>Sector</b>	<b>Number of licensed public sector establishments</b>	<b>Number of licensed private businesses</b>	<b>Total</b>
Human application	170	42	212
Post-mortem	290	8	298
Research	184	52	236
Anatomy	45	0	45
Public display	11	2	13
<b>Total</b>	<b>700</b>	<b>104</b>	<b>804</b>

Figures above are as of March 2008. Since then, the HTA has licensed an additional 43 procurement establishments.

The HTA has defined the term 'private businesses' as establishments that are not subject to public law. Only 13% of HTA licensed establishments fall within the category of private businesses, with the remaining 87% being public sector establishments, such as NHS Trusts and universities. The HTA states that it applies the Principles of Better Regulation to all its licensed establishments, regardless of whether they are businesses or public sector organisations. All methodologies are therefore consistent across all five of

the licensed sectors.

## THE HAMPTON VISION

*Both the Hampton and Macrory reports are concerned with effective regulation – achieving regulatory outcomes in a way that minimises the burdens imposed on business. Key to this is the notion that regulators should be risk-based and proportionate in their decision-making, transparent and accountable for their actions and should recognise their role in encouraging economic progress.*

Any findings relevant to whether the regulator is risk-based:

The HTA assigns different levels of risk to the different sectors that it regulates based on a number of factors, including the type of activity undertaken by the establishments in those sectors. It then assigns a particular risk score to each of the establishments within each sector.

Across four of the five sectors regulated by the HTA (post-mortem, research, anatomy and public display), establishments with lower risk scores receive a lighter-touch in terms of data-collection and inspection than those with higher risk scores, in keeping with the Hampton vision. The Review Team is satisfied that this light-touch approach will be continued as a result of the HTA's decision to move to a system of open-ended licensing (see section on 'data requests'), and further focussing of resources on higher-risk establishments in the HTA's on-site inspection planning (see section on 'inspections').

The highest risk sector is the human application sector, and here establishments are faced with regular reporting (every year) and regular inspection (every 2 years) after licences have been granted. There is less scope for a risk-based approach in this sector because European Union requirements (the Q&S Regulations) provide the HTA with no flexibility.

The HTA's approach to sanctioning is risk-based in all sectors, with tailored sanctions underpinning a pragmatic approach designed to bring establishments back into compliance rather than penalise them. Where evidence suggests that the non-compliance is serious and/or deliberate, appropriate, but proportionate, regulatory action is taken.

The only area of concern for the Review Team was around the primary legislation and the codes of practice that flow from it. In some sectors (particularly the research

sector), stakeholders felt that the original legislation was disproportionate to the level of risk posed by the sector. Given that the legislation is unlikely to be reviewed for a few years, the HTA may be able to overcome this scepticism by continuing to ensure that the burden imposed is an absolute minimum. In doing so, the HTA should ensure that regulated establishments understand the distinction between minimum standards and good practice, building on the new codes of practice issued in 2009 that go some way towards achieving this.

Any findings relevant to whether the regulator is transparent and accountable:

In its Annual Report, Annual Review and Summary Inspection Reports for each sector (all available on the HTA website), the HTA provides all interested parties with a comprehensive picture of its regulatory activity. In these documents the HTA publishes output measures, such as the number of licences issued and the number of inspections undertaken, and data on levels of non-compliance. Comparing the levels of non-compliance over time gives an indication of whether the HTA is achieving its strategic objectives. Therefore, by publishing this information and its enforcement policy, the HTA is achieving high-levels of transparency and accountability. However, the key outcome for the HTA is around public confidence in the handling of human tissue by the establishments it regulates. The HTA commissioned Ipsos MORI to do work in this area and a report was published on public perception in June 2007, but this has not yet been repeated (although the HTA plans to conduct a second evaluation in 2009/10, and further measurements every two years thereafter). Therefore, it would be difficult to say with certainty at present that any increase in compliance levels is having the desired effect on public trust. This will become clearer over time (the HTA has only been regulating across all five licensable sectors for two and a half years).

With regard to individual decisions, the HTA provides lots of feedback to establishments it regulates throughout the licence application process and during inspections. This transparent approach was welcomed by stakeholders, who also praised the openness and consultation process of the HTA when making changes to the regulatory framework (e.g. new codes of practice and the Developing Regulatory Methodology workshops).

The HTA is accountable to the Secretary of State for Health for the delivery of its strategic and business plans and the HTA balanced scorecard is provided to the Department of Health each quarter. All HTA staff were

involved in the production and development of these performance indicators.

Any findings relevant to whether the regulator encourages economic progress:

The HTA was set up in 2005 to regulate sectors that had previously been largely unregulated and has to date licensed over 800 establishments. In terms of the administrative burdens imposed on these establishments (form-filling and inspection burdens), the HTA has greater flexibility to minimise the costs to establishments in the post-mortem, research, anatomy and public display sectors than it does in the human application sector, where additional EU regulations prescribe higher levels of enforcement activity. Where flexibility exists, the HTA goes a long way to minimise the administrative burden by taking a risk-based approach to data-collection and inspection, but some stakeholders in the research sector still feel the burden of the legislation is disproportionate to the benefits. However, the Review Team's view was that the HTA has done a lot to keep costs to a minimum by adopting this risk-based approach, using online methodology where possible, and creating simple regulatory systems and processes.

The HTA also seeks to minimise the burden by nearly always trying to bring those establishments that are not up to standard back into compliance through advice and guidance, rather than taking a heavy-handed approach. This was commended by stakeholders.

The HTA sets its licence fees at the level required to recoup its costs (it receives around 75% of its funding from licence fees). Fees are varied between sectors according to the inherent risks associated with each of the sectors, and therefore the level of regulatory intervention anticipated. Within a given sector, fees can also be varied according to the amount of activity undertaken by an establishment. At the time of this review, the HTA were undertaking a full public consultation on its licence fees, giving all licensed establishments the opportunity to comment on the proposed licence fee structure.

## DESIGN OF REGULATIONS

### **Hampton Principles**

*All regulations should be written so that they are easily understood, easily implemented, and easily enforced, and all parties should be consulted when they are being drafted*

*When new policies are being developed, explicit consideration should be given to how they can be enforced using existing systems and data to minimise the administrative burden imposed.*

Key findings on  
Design of  
Regulations:

- The HTA's codes of practice interpret complex new legislation, providing greater clarity and certainty for those establishments it regulates.
- The HTA had no influence over the design of the majority of the regulations it is responsible for enforcing, as most of them predate the organisation, but is aware of the concerns that some stakeholder groups have about the legislation. The HTA should work with the Department of Health at an appropriate time in the near future to amend the Act, using the feedback and experience gained from the first years of its enforcement.
- The HTA should continue to work with establishments it regulates and its scientific panel to provide clarity on the definition of types of human tissues and whether they are in or out of scope of the legislation. In establishing these definitions, the key driver should be designing a proportionate and consistent regulatory framework.
- The HTA issues new directions only twice a year, as required, rather than on an *ad hoc* basis, to reduce uncertainty for those it regulates.

Background  
information such  
as the regulator's  
role in developing  
regulations:

The HTA is responsible for implementing two significant pieces of legislation – the Human Tissue Act 2004 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007 (Q&S Regulations). This legislation is supported by policies and guidance that are developed by the HTA in consultation with stakeholders.

Under the Human Tissue Act, the HTA has the power to issue its expected standards (or Directions) to

establishments. This means that the HTA can issue general Directions to establishments to take into account changes in policy and legislation. The HTA may also make Directions that are specific to a particular establishment.

The HTA aims to issue Directions twice each year (April and September) rather than on an *ad hoc* basis. To date, seven sets of Directions have been issued by the HTA.

The HTA has developed nine codes of practice to explain the legislation and provide advice and guidance. A failure on the part of any person to observe any provision of a code of practice does not, of itself, render the person liable to any proceedings. However, the HTA may take into account any relevant observance of, or failure to observe, a code of practice when making a licensing decision.

Examples of good regulatory practice:

#### **Delaying enforcement of the Q&S Regulations until clear guidance was available**

The HTA put a moratorium on licensing procurement establishments for one year after the Q&S Regulations came into force. This was because the new legislation raised complex issues of interpretation, particularly for procurement establishments. During the moratorium, the HTA was in dialogue with the Department of Health, the European Commission, businesses and other stakeholder organisations to seek further information and clarification of the issues. In this way, the HTA avoided a situation in which new requirements came into force before sufficient guidance was in place to help ensure compliance.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principles:

The two significant pieces of legislation for which the HTA has enforcement responsibility are complex. By issuing codes of practice, the HTA has effectively interpreted the legislation on behalf of those it regulates, increasing clarity and certainty around the regulations.

Stakeholders were complimentary about the codes of practice, and particularly about the high levels of consultation during their development, but some (particularly in the research sector) had concerns about various aspects of the underlying legislation. For example, some complained of lack of clarity around the scope of the legislation in terms of type of tissue (e.g. among research professionals there was some confusion around the status of tissues from which DNA is extracted). In the months since the Review Team spoke to stakeholders, the HTA has updated its guidance on

“relevant material” in response to queries from regulated establishments. The HTA should continue its efforts to provide increased clarity in this area.

The HTA is not responsible for the legislation it enforces, and was not able to influence its design (the legislation created the regulator). However, it is aware of the concerns of some stakeholders about the Human Tissue Act, has kept records of these issues, and is ready to work with the Department of Health to amend the legislation at an appropriate point in the future.

In response to the queries of regulated establishments, the HTA has revised its existing codes of practice and issued an additional code for the research sector. This responsive approach was praised by stakeholders, though the HTA should take care to ensure that the establishments it regulates do not interpret revised and additional codes as an attempt to continually raise minimum standards. This could lead to over-compliance and disproportionate costs for these establishments.

Under the Act, the HTA issues standards (‘Directions’). These are only introduced twice a year in order to reduce uncertainty and prevent establishments looking for new regulatory requirements where none exist. The Review Team regarded this as an example of good practice, as it is in line with the government policy of Common Commencement Dates.

## ADVICE AND GUIDANCE

### *Hampton principle*

*Regulators should provide authoritative, accessible advice easily and cheaply*

Key findings on Advice and Guidance:

- The HTA's stakeholders praised the wide range of advice and guidance available.
- The HTA's staff put great emphasis on bringing establishments back into compliance using advice and guidance rather than immediate sanctions.
- The HTA's staff were often referred to as supportive, friendly and approachable.
- The HTA regularly reviews the effectiveness of individual pieces of guidance material. At some point in the future, the HTA may wish to consider a more strategic approach to measure the certainty, accessibility, clarity and consistency of its suite of guidance materials across all sectors it regulates.

Background information such as the means by which the regulator provides advice and guidance

The HTA provides advice and guidance to a range of different establishments and individuals, in a variety of different ways:

- codes of practice (mentioned above);
- tailored advice and guidance during the licence application process, during inspection visits and as and when stakeholders require it;
- the HTA website (receives around 300,000 hits and 2,500 visits per month);
- the e-newsletter is the HTA's main tool for communicating policy changes to its stakeholders (distributed every 2 months to around 5000 subscribers);
- regular training events and conferences for the staff of regulated establishments;
- e-learning packages available on the HTA website;
- a central telephone enquiries line for regulated establishments and members of the public (body donation enquiries from recently bereaved people are handled sensitively by trained members of HTA staff);
- development of FAQs; and
- the HTA email enquiries mailbox (over 90% of

general queries are answered within 20 working days).

Examples of good regulatory practice:

### **The HTA facilitates informal sharing of good practice**

The sharing of good practice among stakeholders and the HTA is undertaken through personal contact at various conferences, subject-specific workshops, and via telephone and email helplines. Mutual problem-solving and the sharing of ideas is encouraged, and feedback processes have been set up to enable stakeholders to engage.

Review findings:

The HTA was set up as a compliance-based regulator – the founding legislation sets out that the HTA’s main role is to provide advice and guidance to those establishments within the scope of the legislation. This advice and guidance is provided by a wide variety of means (see above).

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

Nearly all stakeholders encountered by the Review Team said that HTA are enormously helpful in providing clear and timely advice. The staff of the HTA were described as highly approachable and many stakeholders said that if they need advice they know that all they have to do is pick up the phone. The HTA’s staff provide tailored advice and guidance during the licence application process, during inspections of premises and as and when stakeholders require it. Stakeholders praised these staff for always seeking to bring establishments back into compliance by giving advice, rather than clamping down on every small infringement.

The HTA’s codes of practice were widely praised, and new codes will shortly be issued in response to the concerns and queries of stakeholders (see previous section).

The HTA should be praised for the manner in which it is constantly seeking to improve its advice and guidance, and engage with its stakeholders to raise awareness and increase understanding. The HTA runs regular consultation events, conferences and workshops, and the Review Team found that these act as excellent networking opportunities for regulated establishments to learn from both the HTA and each other.

The HTA are very receptive to feedback on their guidance, and regularly use *ad hoc* feedback and dedicated reviews to measure and improve the effectiveness of individual pieces of guidance material. At some point in the future,

the HTA may wish to consider a more strategic approach to measure the certainty, accessibility, clarity and consistency of its suite of guidance materials across all sectors it regulates (in line with the Code of Practice on Guidance on Regulation and the Government Response to the Anderson Review).

## DATA REQUESTS

### ***Hampton principle***

*Businesses should not have to give unnecessary information or give the same piece of information twice.*

- Key findings on Data Requests:
- In the post-mortem, research, anatomy and public display sectors, the HTA has minimised data-collection burdens at present. The HTA is ensuring that the burden will be kept to a minimum in the future by moving to a system of open-ended licensing (“continuous licensing”).
  - In the human application sector, the HTA is required by the Q&S Regulations to collect data annually and has little flexibility to reduce this burden. The HTA has held discussions with stakeholders on how to make best use of this data and communicate it back out to regulated establishments in a meaningful and useful way. The HTA plans to continue these discussions in the future.

Background information such as the data required by the regulator; the means by which business can return data, etc:

The HTA collects the following data from the establishments it regulates:

- information from licence applications (largely based on self-assessment);
- evidence of compliance against additional licence conditions;
- annual activity data for the human application sector (due to the requirements of the Q&S Regulations);
- Serious Adverse Events and Reactions (SAEARs) information for the human application sector; and
- forms requesting changes to licences (e.g. change of premises or activity).

All information is submitted to the HTA electronically.

The HTA has very recently reviewed its data requests as part of the Development of Regulatory Methodology (DRM) programme. This programme covered development of a re-licensing process for establishments with licences due to expire, and a review of the HTA’s risk methodologies. As a result of the DRM, data requests relating to self-assessment and compliance updates will

be further varied according to risk.

The HTA currently shares limited information with other regulators.

Examples of good regulatory practice:

**Self-assessment of establishments against HTA standards for licence applications**

Licence applicants can apply for between one and six licences in one process by providing one set of data. Applicants produce self-assessments, providing text against each standard and a score from 1 – 4 (1 being ‘not met’ and 4 being ‘fully met’). The format of licence applications for all the sectors is the same, although the human application form is more detailed due to the additional requirements under the Q&S Regulations. As a compromise for this prescriptive approach in the human application sector, establishments are only asked to provide text if they score ‘not met’ or ‘partially met’.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

In the post-mortem, research, anatomy and public display sectors, the HTA only collects information for the purpose of making licensing decisions – no further information is collected after a licensing decision has been taken unless conditions are imposed on a licence or the establishment wants to vary its licence. This low frequency of data-collection is complemented by the HTA’s risk-based approach: the volume of data collected from establishments in different sectors during the licence application process is varied according to the perceived-risk of non-compliance in that sector. The Review Team therefore concluded that the HTA has done well to minimise data-collection burdens in these four sectors.

The first batches of licences that the HTA issued are now up for renewal (the original licences were time-bound as the HTA had been due to be replaced by the new Regulatory Authority for Tissue and Embryos, but the plans for the new regulator were abandoned by the Government in October 2007). The HTA has therefore very recently designed a new licensing framework, in which regulated establishments are issued with open-ended licences rather than licences of fixed duration. This “continuous licensing” system removes the need for regulated establishments to submit data periodically for licence renewal, ensuring that the future administrative burden is minimised.

In the human application sector, establishments have to submit activity data to the HTA every year. This higher-

level of data collection is due to the very prescriptive requirements of the Q&S Regulations, and the HTA therefore can do little to reduce this burden. There is also a statutory requirement for establishments in the human application sector to report information on all Serious Adverse Events and Reactions (SAEARS). As part of the DRM, the HTA considered whether this requirement should be extended to the other sectors it regulates. The Review Team would urge the HTA to make any such reporting voluntary, in order to avoid imposing a new burden. In this way, regulated establishments could exercise judgment and report only those events it thinks would be useful to help others learn lessons.

Some stakeholders in the human application sector expressed concern that at present they do not know how the annual activity return data and SAEARs data is used by the HTA or the European Commission, to whom the data is ultimately provided. The HTA is holding ongoing discussions with stakeholders on how to make best use of this data. The Review Team would strongly encourage this dialogue.

Across all sectors, the HTA's licensing form asks how long it takes for the form to be completed. This is in line with Hampton's recommendations, but the Review Team considers that this data could be used more effectively by the HTA and fed back to stakeholders.

## INSPECTIONS

### *Hampton principle*

*No inspection should take place without a reason.*

Key findings on Inspections:

- The HTA plans its inspection programme on the basis of risk, using transparent risk assessment methodology. The HTA should continue to focus its resources on establishments with the highest risk scores.
- The HTA's inspectors are friendly, helpful and pragmatic, and they use inspections to impart large amounts of advice and guidance to establishments. The HTA's inspection process is transparent.
- The HTA may benefit from further collaborative inspection activity with other regulators, particularly those with technical expertise that may be relevant to the work of the HTA (this would help HTA inspectors to further develop their technical knowledge of these sectors).

Any relevant background information such as the number of inspections and the number of businesses inspected; the regulator's risk model etc

The HTA has a two-stage inspection process:

- A **Phase 1 inspection** is predominantly desk-based and involves a thorough analysis and evaluation of an establishment's licence application, often supplemented with additional verbal or written information. A Phase 1 inspection leads to a licensing decision. Given that there is no on-site component to a Phase 1 inspection, and it involves analysis of information provided on a form, the Review Team considered this process under the previous section on 'data requests';
- A **Phase 2 inspection** is a site visit to a licensed establishment. During a Phase 2 inspection, the HTA reviews an establishment's operational policies and procedures, inspects its premises and scrutinises its practices. This involves interviews with a range of staff at the premises. A Phase 2 inspection allows the HTA to evaluate progress against any licence conditions imposed at Phase 1 inspection and follow-up any areas of non-compliance. The HTA does not routinely ask for any documentation in advance of the Phase 2

inspection.

All establishments regulated by the HTA undergo Phase 1 inspections when they make their licence applications. In the human application sector, European law (transposed into UK law via the Q&S Regulations) requires the HTA to conduct Phase 2 inspections of establishments every two years. In the post-mortem, research, anatomy and public display sectors, there is no statutory inspection frequency and so Phase 2 inspections are planned according to risk (see review findings below).

<b>Sector</b>	<b>Total number of licensed premises (at March 08)</b>	<b>On-site inspections in reporting period*</b>	<b>Number of conditions issued in reporting period**</b>
Human application	212	51	127
Anatomy	45	4	16
Research	236	10	131
Post-mortem	298	49	98
Public display	13	2	2
<b>Total</b>	<b>804</b>	<b>116</b>	<b>374</b>

\* Data is taken from the HTA's sectoral 'Summary Inspection Reports' ([http://www.hta.gov.uk/about\\_hta/publications/summary\\_inspection\\_reports.cfm](http://www.hta.gov.uk/about_hta/publications/summary_inspection_reports.cfm)). For the Human Application and Post-mortem sectors (the highest risk sectors), the reporting period covered in the Summary Inspection Reports is 1 April 2007 – 31 March 2008. For the Research, Public Display and Anatomy sectors (lower risk) the reporting period is 1 September 2006 – 31 March 2008

+ This is the total number of conditions imposed following phase 1 and phase 2 inspections.

Across all sectors, unannounced inspections occasionally take place as a result of whistleblowers, complaints or serious adverse events.

Examples of good regulatory practice:

### **The HTA's transparent approach to inspection**

Stakeholders were very complimentary about the pragmatic approach taken by HTA on-site inspection teams. Visits were often described as informal and

friendly, with lots of advice and guidance issued by the inspectors to the regulated establishments. The HTA's inspection process is proportionate, open and transparent:

- Pre-inspection – the licensed establishment is contacted approximately eight weeks prior to an inspection to arrange a convenient date. The lead inspector explains the format of the day and arranges the timetable. A flexible approach is taken to ensure minimum disruption, and a guidance document is provided prior to the visit;
- Day of the inspection – the HTA inspection team (1-3 inspectors depending on the establishment's size and risk score) holds an introductory meeting with staff at the licensed establishment to tell them why they are being inspected and what the inspection will be focusing on. Feedback about areas for improvement is given throughout the inspection, and more formally at a meeting at the end of the day;
- Post inspection – the licensed establishment is provided with the draft inspection report within four weeks of the inspection and is asked to provide comments on factual accuracy within ten days. The final inspection report is then issued within 21 days.

Establishments are asked to submit feedback following a site visit inspection, in order to help the HTA continuously improve its process.

Review findings:

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

As it has only completed two full operational business years, the HTA is in its first round of Phase 2 inspections for four sectors: post-mortem, anatomy, research and public display. However, the HTA is conducting its second round of inspections in the human application sector where there is a statutory requirement to inspect every two years.

Site visit inspections are prioritised on the basis of risk – the HTA generates a risk score for each establishment during the Phase 1 inspection by considering both the potential impact caused by non-compliance and the likelihood of non-compliance. Establishments with the highest risk scores are seen first. The table above clearly shows that in those sectors where it has discretion over inspection frequency the HTA inspects only a small proportion of licensed establishments, in line with a risk-based approach. The HTA should continue to focus its resources on the establishments with highest risk.

The validity of Phase 1 risk scores is tested during the Phase 2 assessments. The HTA also tests the validity of its risk assessment methodologies by conducting random inspections of low risk premises, in keeping with model Hampton methodology. The HTA has recently reviewed its risk-assessment process and sought feedback from stakeholders in a series of workshops. The Review Team supports this transparent approach.

The HTA currently takes into account information from other relevant bodies when conducting inspections. For example, establishments with full accreditation from Clinical Pathology Accreditation UK Ltd (CPA) are currently exempt from certain HTA standards. The HTA has conducted one joint inspection with the Health and Safety Executive in order to reduce the burden on the regulated establishment under scrutiny. The HTA may benefit from further collaborative inspection activity with other regulators and organisations, particularly those with technical expertise that may be relevant to the work of the HTA (e.g. the Medicines and Healthcare products Regulatory Agency). Indeed, several stakeholders told the Review Team that HTA inspectors would benefit from greater technical knowledge, and joining-up would provide a means of gaining this further expertise.

## SANCTIONS

### ***Hampton & Macrory principles***

*The few businesses that persistently break regulations should be identified quickly and face proportionate and meaningful sanctions.*

*Regulators should be transparent in the way in which they apply and determine administrative penalties.*

*Regulators should avoid perverse incentives that might influence the choice of sanctioning response.*

*Regulators should follow up enforcement actions where appropriate.*

Key findings on Sanctions:

- The Review Team found that the HTA's approach to sanctioning is very flexible with respect to different levels of non-compliance.
- The HTA always tries to use advice and guidance to bring those found in breach of the legislation back into compliance. It is important the HTA continues with this approach as at present the majority of inspections lead to some form of regulatory action, implying that a large proportion of regulated establishments struggle to reach minimum standards.
- The HTA's sanctioning processes are transparent and regulated establishments understand why enforcement actions are taken.
- The fact that only four representations against sanctions have been made to date (and only one decision has been appealed) suggests that the HTA uses sanctions proportionately.

Background information such as a summary of sanctions available to the regulator and any data on sanctions imposed by the regulator:

The HTA's regulatory responses to non-compliance on the part of a regulated establishment may include increasing the establishment's risk score, carrying out an unannounced inspection, carrying out a scheduled reactive risk inspection or asking for regular progress reports against compliance. The HTA may ultimately revoke a licence, but where possible it will consider other proportionate sanctions available to it, including suspending a licence, varying a licence by adding additional conditions, issuing a short fixed term licence, or issuing Special Directions.

For licensing decisions, the licensed establishment is given a statutory 28 day period for stating its intention to make representations against a proposed decision made by the HTA. This does not apply to Special Directions, which take immediate effect and are not subject to representations against the licensing decision.

Examples of good regulatory practice:

### **Regulatory Action Panels (RAPs)**

Regulatory Action Panels are convened whenever significant regulatory action is considered. RAPs provide a robust framework for escalation of licensing decisions, ensuring a fair, proportionate, justifiable, evidence-based decision. In order to achieve this, RAPs can be suspended and the HTA may provide advice and guidance to the establishment(s) concerned, offering them the opportunity to respond with further information. The RAP is then re-convened and a final regulatory decision made.

Nine RAPs were convened between 1 April and 31 August 2008, five in the human application sector and four in the post-mortem sector.

Review findings:  
  
The extent to which the review team believes the regulator is acting in line with the Hampton principles and Macrory characteristics:

The Review Team found that the HTA's approach to sanctioning is very flexible with respect to different levels of non-compliance. The most common sanction imposed is addition of licence conditions, and the Review Team found this to be a proportionate tool that can be easily tailored to the particular circumstances of a regulated establishment.

In keeping with the Hampton principles, the HTA always tries to use advice and guidance to bring those found in breach of the legislation back into compliance (the HTA performed well in the 'Advice and Guidance' section of this review). However, the fact that the majority of inspections lead to some form of regulatory action (see table in 'inspections' section) suggests that a large proportion of regulated establishments struggle to reach minimum standards. This is to be expected in the early days of a new regulatory regime, but suggests that greater use could be made of 'soft' measures at this point in time. In practice, however, once a condition has been imposed, regulated establishments are given reasonable time and support to reach full compliance (the condition is kept under review). Given that very few licences have been revoked to date (3 licences were revoked in the post-mortem sector in 2008), the Review Team did not consider the HTA to be 'heavy-handed'.

The HTA's sanctioning processes are transparent (the HTA publishes its Regulation Enforcement Policy on its website) and regulated establishments understand why enforcement actions are taken. Due to the tailoring of licence conditions to individual premises, decisions to impose these are well-understood and rarely queried. Licensed establishments are informed when any RAPs are convened or any regulatory actions taken against them. The fact that only four establishments have made representations against HTA licensing decisions to date (and only one decision has been appealed) reinforces the Review Team's view that the HTA acts proportionately.

The HTA uses several methods to ensure consistency in its enforcement actions. There is a guidance document in place to help staff distinguish between conditions and advice and guidance, and all regulatory action is checked by a legal advisor. Also, induction and six-month training programmes are in place for Regulation Managers, and regular development seminars are organised to share learning between those taking licensing decisions.

## FOCUS ON OUTCOMES

### *Hampton principle*

*Regulators should measure outcomes and not just outputs.*

Key findings on Focus on Outcomes:

- In June 2007, the HTA published research commissioned from Ipsos MORI on the levels of public and professional confidence in the sectors it regulates. The HTA will commission similar surveys at regular intervals going forward, so that it may determine if its regulatory activity is having an impact on this key outcome measure.
- The HTA systematically measures the impact of its activity on the levels of compliance among those it regulates, and publishes this data.
- The HTA's strategic objectives are clearly understood by all staff throughout the organisation.

Background information such as the regulator's key objectives:

The HTA's strategic aim is to create a regulatory system for the removal, use and disposal of human tissue and organs that is clear, consistent and proportionate and in which professionals, patients, families and members of the public have confidence.

The HTA strategic plan sets out the organisation's high-level aims, remit, and objectives. It is supplemented by the HTA business plan, which sets out corporate priorities for the year ahead in more detail.

HTA's strategic objectives for 2008/09-2009/10 are as follows:

- review and refine systems to ensure the donation, removal, retention, use and disposal of human bodies, organs and tissue is legal, ethical and respectful, and conducted in accordance with the wishes of the individual;
- ensure that the regulatory system is understood and accepted by those affected by it;
- work in partnership with other regulators, public bodies and relevant organisations to avoid over-regulation, provide consistent advice and guidance, and streamline inspections;
- involve the professionals who work in the establishments to be regulated, as well as the

public, in reviewing and enhancing the regulatory system and providing advice and guidance;

- create an organisation that delivers on time and within budget whilst keeping costs to a minimum; and
- develop, refine and implement an education and training programme for staff to achieve their full potential and fulfil the HTA's corporate goals.

Examples of good regulatory practice:

### **Ensuring that regulatory objectives are well-understood by staff**

The Review Team was impressed that responsibility for achieving the HTA's outcomes is clearly cascaded within the organisation. The HTA organised a corporate awayday, attended by everybody working in the organisation, to discuss its objectives. The organisational objectives derived from the business plan are clearly aligned with the objectives of each directorate, which in turn are clearly aligned with the objectives of each individual member of staff.

The extent to which the review team believes the regulator is acting in line with the Hampton principle:

Given the HTA's strategic aim is to increase 'confidence' amongst its key stakeholders and the public, the Review Team felt that the key outcome measure for the HTA should be around public perception. In June 2007, the HTA published research commissioned from Ipsos MORI on the levels of public and professional confidence in the sectors it regulates. The Review Team felt that the data gathered in this exercise should provide a baseline, and the HTA should commission similar surveys at regular intervals going forward to determine whether its regulatory activity is achieving the desired outcome. The Review Team is therefore happy to note that the HTA plans to commission another survey of public perception in 2009/10 and repeat this measurement every two years.

Although the HTA have not yet repeated another large-scale perception survey, they do very regularly 'take the temperature' with stakeholders through feedback from events and consultations, annual review case study interviews, and inspection feedback. Once again, stakeholders gave very positive feedback about the HTA's willingness to engage with them by a wide variety of means.

The HTA systematically measures the impact of its activity on the levels of compliance among those it regulates. Two regulatory action reports are generated on a regular basis: a monthly report to the Director and Heads of Regulation,

and a quarterly report given to the Authority members. Comparing the levels of non-compliance over time gives an indication of whether of the HTA is achieving its strategic objectives. Summary inspection reports collate compliance data on an annual basis, and these are published on the HTA's website to ensure that the organisation's performance is transparent.

## **Appendix 1: Review team membership**

### **Gary Robson**

Gary Robson graduated from Middlesex University with a BA (Hons) in Politics and English studies, and has also completed his MBA at Henley Business school. Most of his career has revolved around customer management primarily in Contact Centre operations at senior management levels with organisations such as Littlewoods, Vodafone and The Carphone Warehouse.

More recently Gary has broadened his sector experience by working in quite varying areas such as the music industry for the Performing Right Society as Head of Operations managing an annual sales budget in excess of £100 million and in the regulatory field at The Pensions Regulator, where Gary also completed his MBA dissertation on "The growth of risk based regulation".

Gary now has the role of Head of Customer Experience with the East Thames group which is the largest housing association operating in east London and Essex managing more than 13,500 homes and is responsible for a number of key operational areas as well a group wide remit for customer contact strategy.

### **Amanda-Jane Balfour**

Amanda-Jane Balfour graduated from Aberdeen University with a BSC (Hons) in Biochemistry, before gaining an MSc in Forensic Science at Strathclyde University. Having pursued a career within scenes of crime with Greater Manchester Police for ten years, Amanda joined the Forensic Science Service and led on major national programmes of work such as the DNA expansion programme funded by the Government. This was a £34million programme of work enabling the taking of DNA samples for volume crime. Amanda then went on secondment to the Home Office and led on the National Prisoner DNA sampling programme.

On leaving the Forensic Science Service Amanda joined the regulatory field working in the Gambling Commission initially as Programme and Quality Manager. She now has the role of Head of Business Strategy at the Gambling Commission and is responsible for internal and external reviews, and leads on programmes of work such as the Co-Regulation Programme as well as developing and ensuring delivery of the Business Plan.

### **Tim Courtney**

Tim Courtney graduated from the University of Oxford with a MChem (Hons) in Chemistry in 2002. Having begun his civil service career in the Department for Transport, he joined the Regulatory Impact Unit in the Cabinet Office in early 2004 to work on bureaucracy reduction for front-line public services. Following the creation of the Better Regulation Executive (BRE) in 2005, Tim worked on the Administrative Burdens Measurement Exercise and the first round of government departments' Simplification Plans, which were published in December 2006. In his time in the BRE, Tim has also developed the Hampton Implementation Review framework and guidance, and worked on the

Regulators' Compliance Code.

Tim is now the Head of Strategic Support in the BRE.

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