

Delivering better regulation

Human Tissue Authority

Annual Report and Accounts 2006/07

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Introduction by the Chair and Chief Executive

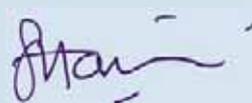
In the last year the Human Tissue Authority (HTA) has moved rapidly from set-up phase to delivery of modern, effective regulation. It has involved a lot of hard work – not just by the staff in the Executive, but by Authority Members and the large numbers of our stakeholders who have worked alongside us to help us develop our Codes of Practice and licensing standards. We would like to thank everyone for their contribution to putting the HTA so firmly on the regulatory map.

We have created an entirely new regulatory system for licensing more than 500 establishments across five diverse sectors, and for approving donations of organs and bone marrow from living people. Regulation of human tissue should be seen in a positive light: it raises standards and can play a part in improving both public health and confidence. We are pleased that the sectors share this view and that they have taken the opportunity of describing their experience of regulation by the HTA in this Annual Report.

The Hampton and Better Regulation Task Force reports of 2005 established five principles of better regulation, which have exercised a defining influence on our work. These principles are reflected in our aim to create a regulatory framework that is clear, consistent and proportionate and in which the public and professions have confidence. We have been commended by the many sectors we regulate for our inclusive, risk-based approach and we intend to continue in the same vein.

Pending legislation, the new Regulatory Authority for Tissue and Embryos (RATE) will combine the statutory functions that are currently the responsibilities of the HTA and the Human Fertilisation and Embryology Authority. We will continue to adopt these principles as we work towards bringing the best of the HTA to RATE.

The challenge for the year ahead lies in reviewing, refining and embedding the systems and policies that we have put in place. By continuing to drive up standards across the sectors that we regulate, we will ensure that consent and public safety remain at the heart of all the work we do.



Shirley Harrison
Chair



Adrian McNeil
Chief Executive



“There’s no doubt about it – the HTA has raised standards in areas where it was needed. I think the licensing of tissue banks has been an excellent aspect of the HTA’s work.”



Tissue for human application

Dr Mark Lowdell, Director of the Paul O’Gorman Laboratory of Cellular Therapeutics at the Royal Free Hospital, London

“There’s no doubt about it – the HTA has raised standards in areas where it was needed. Tissue banks have strived to meet standards, because licensing increases the quality and safety of tissue used for transplantation. Once the Human Tissue Act was passed, there had to be an Authority to get it to work on the ground. I think it is working, and everybody is teaching each other.

“ The HTA is not a faceless Authority. I think the licensing of tissue banks has been an excellent aspect of the HTA’s work. People like Sandy Mather, the Director of Regulation, have come to professional meetings, stood up, presented the case for the HTA, and explained how it is going to perform as a regulator.

“ From that perspective, the HTA has a face that people are familiar with, and I think the consultation process has worked well.”

The HTA and better regulation: our view

1 April 2006 saw establishments that store tissue for human application as the first sector to be licensed by the HTA. This was part of the UK’s requirement to comply with the EU Tissue and Cells Directive (EUTCD). We issued our first ever licence to the Bristol Eye and Heart Bank on 25 April 2006. 128 establishments storing tissue for human application are now licensed.

Our **accountability** has been demonstrated by working closely with establishments that store tissue for human application to develop clear licensing standards. The involvement of the sector has made a significant contribution to the effective implementation of regulation in the UK. Thanks to this collective effort, the HTA is now seen across Europe as leading the way in implementing the EUTCD.

Our licensing remit will be extended in summer 2007 when the Quality and Safety Regulations bring the EUTCD fully into force. This means that patients can be further assured about the safety, quality and effectiveness of human tissue that is used in their treatment, for example in skin grafts and bone marrow transplants.

Research

Dr Andrew Maines, Head of Research and Development at the University Hospital of South Manchester NHS Foundation Trust

"I think regulation is important. My core activity is research governance, so I understand where it comes from. In my talks and seminars, I point out that the Regulations come from the fact that the public want assurance that things are being done in the right way.

"Our job is to support research and allow it to develop. The HTA's Codes of Practice have been extremely useful. They've given us quality assurance standards; and our operating procedures are now based on what they set out. The guidance is there to be used, and we've been able to check our standards, asking ourselves 'can we do this?' and 'does this make sense?'.

"Regulation isn't holding back tissue-based research. We thought the HTA and compliance with the legislation would stop clinical research in its tracks. That's not happened. We have seen no effect on the level of activity, and there's been an increase in quality."

The HTA and better regulation: our view

The HTA began licensing establishments that store human tissue for research on 1 September 2006 when the Human Tissue Act 2004 (HT Act) came fully into force. Close partnership working and intensive publicity and communications made sure that all regulated sectors were aware of their duties under the new legislation.

One of our key aims is to ensure that tissue-based medical research continues to thrive in the UK. We believe that good regulation supports good science, which in turn leads to improved healthcare. Many establishments storing tissue for research have consolidated their stocks into central collections. This good governance will give researchers wider access to high quality tissue samples.

We have demonstrated our **transparency** by involving researchers and research-funding organisations in the development of our Codes of Practice and licensing standards. 146 establishments storing tissue for research are now licensed by the HTA.

**“Regulation isn’t holding back tissue-based research.
We have seen no effect on the level of activity,
and there’s been an increase in quality.”**



Pathology

David Spratt, Lead Scientist and Manager for the Department of Cellular Pathology at Epsom General Hospital

“This job doesn’t allow you to get bored. Anything can come at you from any direction at any time. There are lots of standards to meet. The Human Tissue Act has helped. It’s made me more aware. The Codes of Practice and guidance are like having a worksheet. You don’t have to store everything in your head.

“In a way, the Act has provided the tools to help me deliver a more effective service. There’s always been a lot of respect for the bereaved amongst mortuary staff, but the Act concentrates the mind.

“I know where I can go for the information I need. I can consult the website, or I can ask the HTA for advice. The guidance from the HTA helps me to advise people straight away on what to do. The staff at the HTA have always been helpful, well informed and supportive. I could not have learnt as much as I needed to, in the time available, without their support.”

The HTA and better regulation: our view

The overriding aim of the HTA is to implement the HT Act in a way that gives the public confidence that their wishes will be respected and professionals the confidence that they are working within a clear regulatory framework. Our Codes of Practice provide guidelines to ensure that sectors comply with the legislation and are aware of best practice.

Our licensing framework, which is based on the assessment of risk, amply demonstrates our **targeted** modern approach to regulation. This includes licence applications that require establishments to self-assess their compliance with our standards. This is followed by detailed desk-based evaluations to validate and verify that these criteria have been met, and to prioritise site visits on the basis of risk. 226 establishments are now licensed to carry

out autopsies. The same licences also allow the removal and storage of human tissue for purposes specified in the HT Act, such as research.

We launched an information-rich, user-focused website in July 2006. The website allows paperless licence applications and transplant approvals, as well as providing the public with information about body donation and other issues.



“The staff at the HTA have always been helpful, well informed and supportive. I could not have learnt as much as I needed to, in the time available, without their support.”

“The HTA’s been excellent. It’s tackled complex issues around organ donation without creating extra barriers or over-complicating things.”



Living-donor transplants

Dr Kesh Baboolal, Consultant Nephrologist and Transplant Physician at the University Hospital of Wales

“As a nephrologist, I form professional relationships with patients with kidney disease. You take them through many stages in their lives and help them face the challenges of kidney failure. As a transplant physician I help patients and their families explore the opportunities that kidney transplantation offers.

“Kidney transplantation enables patients to have a better quality of life and longer life, but it requires organ donors. The Human Tissue Act and the HTA help us to find the right balance between the needs of the patient with kidney failure and the needs of the organ donor. They give everyone confidence in the system: clinicians, organ donors, recipients and families. The HTA’s been excellent. It’s tackled complex issues around organ donation without creating extra barriers or over-complicating things. The system is better now that it was previously.

“The transplant community is always exploring new ways of making transplants happen. Thanks to the HTA, we are able to offer paired transplants, which can overcome some of the biological barriers to transplantation. In the past there has been an element of fear that has prevented this kind of innovative treatment, but as it is now regulated by the HTA, everyone can have confidence in the system.”

The HTA and better regulation: our view

On 1 September 2006, the HTA became responsible for approving donation of solid organs and bone marrow from living donors. We have trained 140 Independent Assessors and 55 Accredited Assessors to work on our behalf, and that of the donor, to assess applications for organ and bone marrow transplants.

The HTA has also allowed more flexibility in who can donate to whom, by allowing paired and non-directed altruistic transplants. This means that more people can now benefit from transplants.

Our **consistency** has been demonstrated by the even application of an ethical framework for making organ and bone marrow transplant decisions. In the past year the HTA has approved 430 organ donations and 64 bone marrow donations.

“The element of consent is vital. Donors often want to give something back to society. Now they can give with confidence.”



Anatomy

Louise Evans, Anatomy Donations Coordinator at the London Anatomy Office

“What I like about my job are the people I meet over the phone. I’m helping them to make sure the last wishes of their loved ones are met.

“I welcomed the Human Tissue Act 2004. It’s helped people understand that things are being done to remedy the mistakes of the past. Even though it’s increased my workload, making sure people have consent in writing has made it absolutely clear that they want to donate their bodies.

“Under the old Anatomy Act, two people could sign as witnesses to a verbal declaration, but this didn’t guarantee what the person wanted. Now, it’s absolutely clear. And the HTA have honoured any written declaration made prior to the introduction of the Human Tissue Act.

“The element of consent is vital. Donors often want to give something back to society. Now they can give with confidence. They’re giving a great gift to everybody; not just to future surgeons and medical students, but to the whole of society.”

The HTA and better regulation: our view

Informed consent, freely given, is the cornerstone of the HT Act and forms the basis for the HTA’s licensing and ethical decisions. All establishments carrying out anatomical examinations are now licensed by the HTA. This makes sure that they meet the consent standards relating to the taking, storing and use of human tissue.

In order to reduce the burden for the anatomy sector, we have developed an online system for registering body donations from the deceased. We also publish information on our website for people who want to find out how to donate their body to medical science.

We regularly respond to enquiries from the public on donation. Following media interest in March 2007 about body bequests, we received a huge volume of enquiries, which we directed on to anatomy schools.

Public display

Stella Mason, Keeper of the College Collections at the Royal College of Surgeons of England

“What has gone on in hospitals and universities, with the wholesale storage of human material for research without any planned end, and how it was acquired, was something that needed to be addressed. For this reason I’m broadly in support of licensing.”

“We have to subscribe to high ethical standards and we have a duty to educate and inform the public about medical history and practice. For new materials, it’s very important that we can obtain consent.

“I do have concerns about the cost of a licence, but the HTA may reduce it in future. We are a small part of the HTA’s remit, but overall we support what they are trying to do.”

The HTA and better regulation: our view

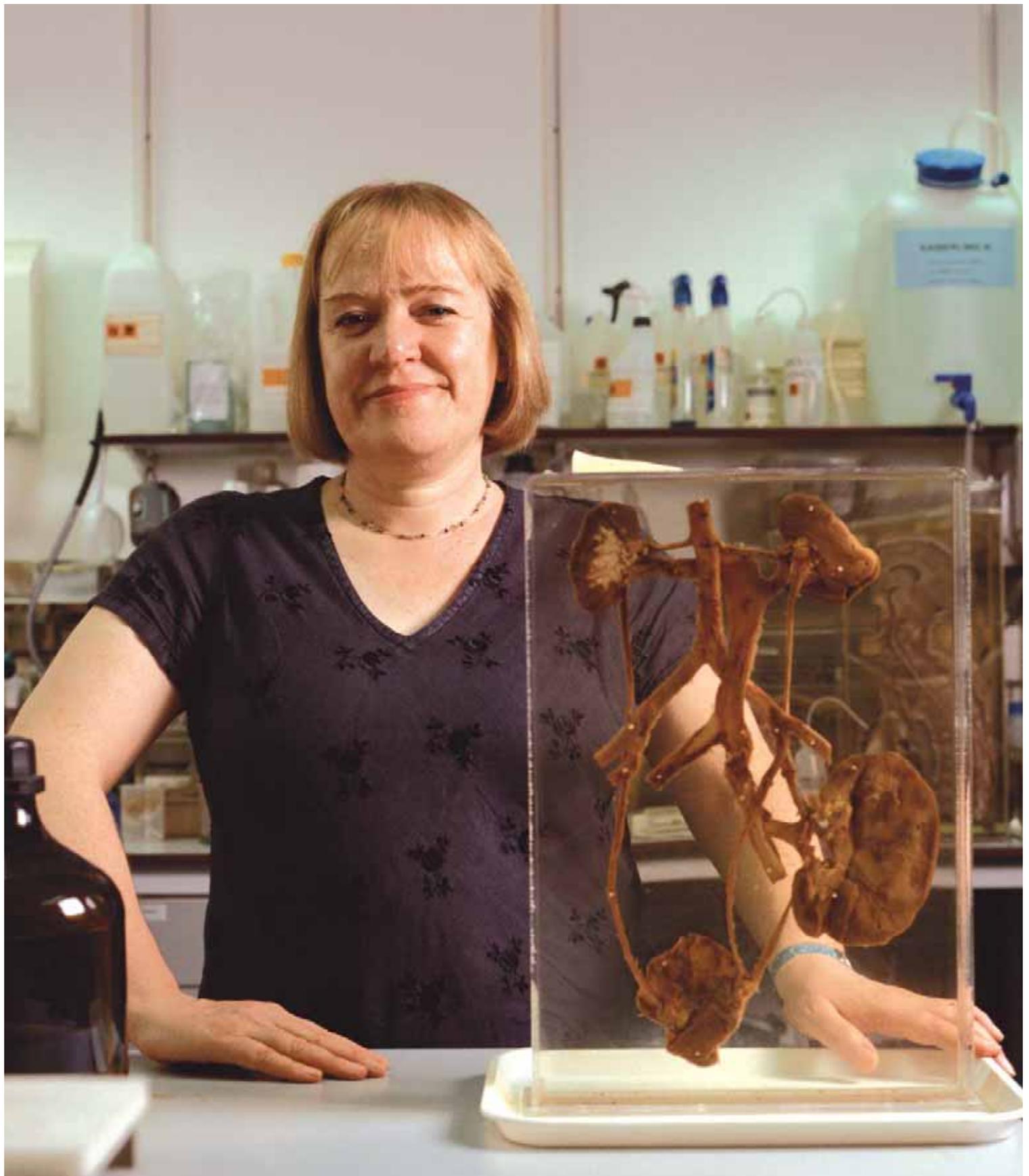
On 1 September 2006, the HTA became responsible for licensing museums and other sites that display human remains or tissue.

The transition from being unregulated to becoming regulated led to some initial concerns from the public display sector. In light of this, we published guidance on the public display of human bodies, body parts and tissue following an extensive consultation. The consultation included a lively and constructive workshop, which was well attended by members of the museum sector and broadcast media.

In February 2007 we ran a consultation on our proposed new licence fee structure. This was based on the key principle laid down by Government that the fee should reflect the actual, unsubsidised cost of regulation. The work needed to regulate public display is not as extensive as the other sectors – for example because we

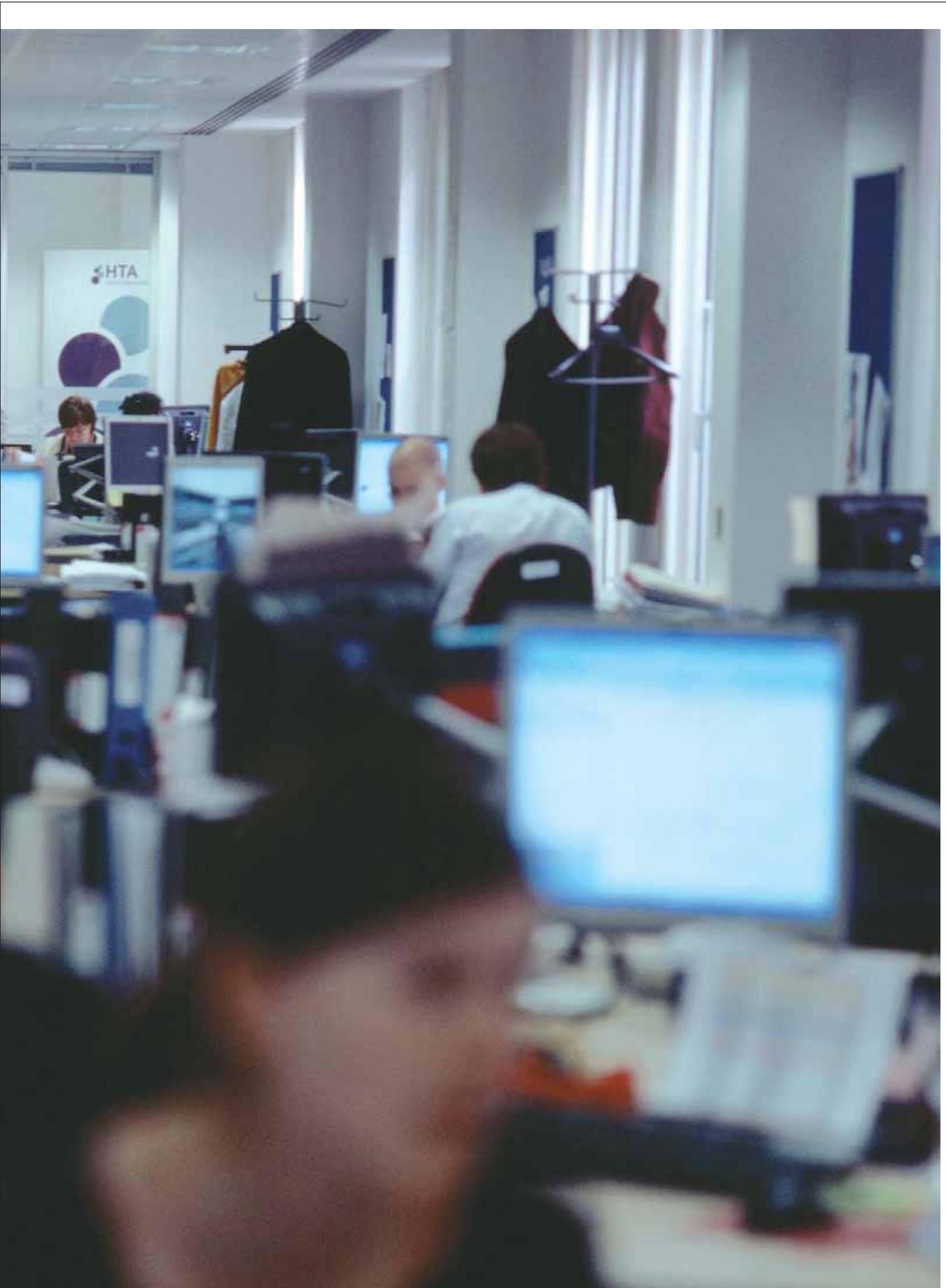
are likely to inspect these establishments much less frequently because of the low risk they present.

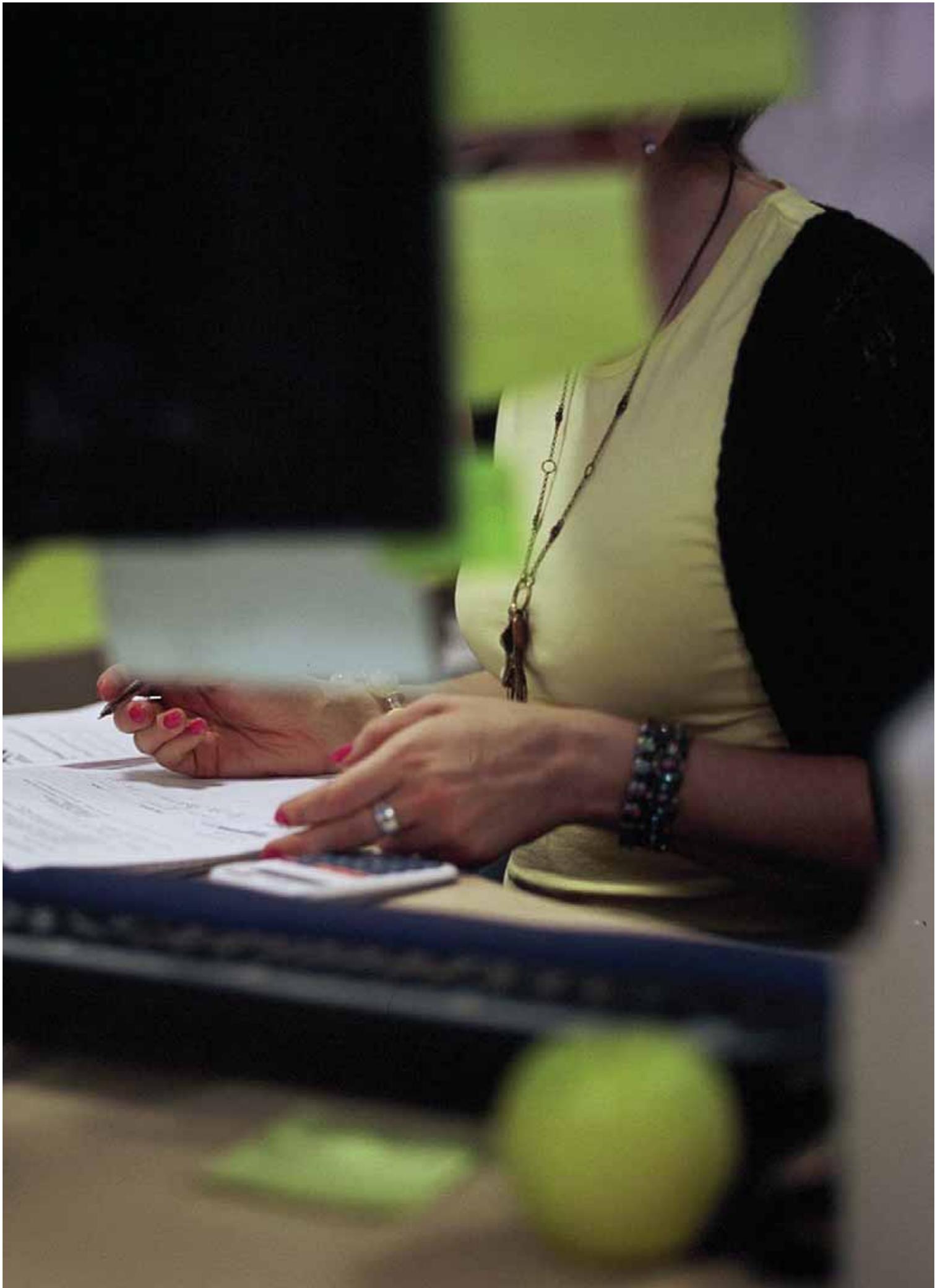
In keeping with our aim to be **proportionate**, we decided to charge a considerably lower fee for public display establishments that exhibit fewer than 20 items.



“We have a duty to educate and inform the public about medical history and practice. For new materials, it’s very important that we can obtain consent.”







An efficient, responsive, transparent regulator

Providing value for money

We started licensing on 1 April 2006 and 1 September 2006 with a staff of about 20. We were able to achieve this by outsourcing corporate support functions such as HR, IT support, facilities management, and finance. We also tried to outsource our site visit inspections, but could not; so we had no alternative but to seek the agreement of the Department of Health to increase our staffing complement to 42. This is the minimum number needed to sustain such a wide and complex regulatory remit. We will keep to this limit because we want to keep fees as low as possible. We have also kept fees to a minimum by adopting a risk-based approach to regulation, and by introducing streamlined systems and processes.

Being responsive

The HT Act is complex and wide-ranging. We are asked daily by phone and via our enquiries mailbox to provide interpretation and advice about an incredibly large range of issues. In the three months between January and March 2007, we received 146 written enquiries seeking clarification and advice, and we responded to 78% of these within our target of 10 working days.

Being transparent

In 2006/07 we held two of our Authority meetings in public – in London and Birmingham. This gave members of the public and key stakeholders the opportunity to observe the decision-making process of the Authority. Our commitment to openness and transparency is further demonstrated by the fact that we publish all minutes and papers from Authority meetings on our website. As part of our requirement to comply with the Freedom of Information Act, our Publications Scheme is available online.

PART 2 – Annual accounts 2006/07

Chief Executive's report

Remit and functions

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

The HTA has two principal statutory functions. The first is to provide advice and guidance on all matters within our statutory remit. We have put considerable emphasis on providing advice and guidance to our stakeholders as this is more likely to lead to better compliance and is consistent with the Authority's strategic decision to be a proportionate, risk-based regulator. Our advice and guidance takes several forms, namely:

1. the publication of Codes of Practice on:

- consent
- donation of solid organs, tissue and cells for transplantation
- post mortem examination
- anatomical examination
- removal, storage and disposal of human organs and tissue
- donation of allogenic bone marrow, peripheral blood stem cells and donor lymphocytes for transplantation
- import and export of human bodies, body parts and tissue;

2. the publication of

- licensing standards
- guidance on public display
- policy guidance, e.g. on relevant material
- guidance for Independent Assessors and transplant teams
- guidance for people wishing to donate bodies for anatomical examination
- a bimonthly e-newsletter
- leaflets on organ and bone marrow transplants;

3. through training events and workshops, e.g. for Designated Individuals

4. correspondence via the HTA's enquiries mailbox.

The second of our principal statutory remits is to regulate the:

- storage of human bodies for anatomical examination;
- carrying out of post mortem examinations;
- 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 human application and research;
- donation of organs or part organs by living donors; and
- donation of bone marrow by certain donors.

The DH's review of its Arms' Length Bodies in 2003 concluded that the functions of the HTA and the HFEA should be combined under a new Authority, the Regulatory Authority for Tissues and Embryos (RATE), which will also regulate the taking and storage of blood (which is at present the responsibility of the MHRA). The HTA has begun to work with the DH, the HFEA and the MHRA to prepare the legislative and operational basis for the establishment of RATE.

Principles and values

The HTA continues to adopt the following core values in achieving our strategic aims and objectives:

- behaving with integrity
- being open and transparent
- engaging stakeholders
- working collaboratively (with other regulators)
- being responsive

In striving to be a model, modern, risk based regulator the HTA has, from the outset, applied the principles espoused in the reports in 2005 by Philip Hampton and the Better Regulation Task Force. These are that a regulatory system should be:

- proportionate
- accountable
- consistent
- transparent
- targeted

Resources

As an Executive non-Departmental Public Body, the HTA receives a proportion of its income through grant-in-aid from central government (Department of Health). Our total annual expenditure is in the region of £2.9 million. About 80% of this will be met by fees. The HTA is not a profit-making organisation.

To facilitate the transition to RATE, all HTA staff are employed either by the HFEA or the DH and seconded to the HTA. Secondment agreements, mostly for staff at SMT level, are fixed to 30 June 2009.

Secondment agreements for all other staff are until 30 June 2009 or the creation of RATE, whichever is the later.

We are committed to maintaining a small core group of staff and to outsource wherever possible. Not only is this our preferred organisational model, but it is also compliant with wider Government policy. In our first year of delivery, the small core staff have achieved a level of service that is acknowledged to be of high-quality and broadly meets the needs of our stakeholders. We tried, this year, to outsource site visit inspections for all our licensed sectors except for public display. This proved to be unsuccessful mainly because of capacity and potential conflicts in priorities in the bidder organisations. Nevertheless, we buy in many of our back-office services, including:

- human resources – provided by the HFEA on a service level agreement that covers a significant part of our HR requirements
- legal advice and services – once again provided through a service level agreement that provides HTA with the services of a senior and junior legal adviser, both of whom are employed directly by the HFEA
- financial services – provided by the HFEA on a service level agreement that covers all financial processing
- facilities management – provided through an agreement with our landlord, the Government Actuaries Department (GAD), which includes building, security and cleaning services
- IT services – provided by GAD on a service level agreement that includes provision of equipment, infrastructure and support

All future services we may require will, in the first instance, be considered for contracting out.

Governance

The Authority has met nine times during the year, with two of those meetings being open to the public. The Authority focuses on setting the strategic vision and goals of the HTA and takes decisions on all the key high level issues and policies. The Authority is also accountable to the Secretary of State for Health for the delivery of its strategic and business plans. Responsibility for all operational issues falls to the Executive.

Audit Committee

The Audit Committee is chaired by Sharmila Nebhrajani, a non-executive member of the HTA, who is a member of the Institute of Chartered Accountants of England and Wales. Other non-executive members are Michael Banner, Shirley Harrison (resigned 30 September 2006), Ruth Musson, David Sharpe, James Underwood and Michaela Willis. The Chief Executive, Director of Resources, Internal and External Auditors, Department of Health representatives and the HTA's Business Manager are invited to attend. The Committee's terms of reference outline the support this body provides to the Accounting Officer throughout the year, in particular in providing evidence to justify signing the Statement of Internal Control. The Committee has met four times in the year.

Register of interests

The HTA maintains a register of interests which details company directorships and other significant interests held by Authority members which may conflict with their HTA responsibilities. Anyone who wishes to view the Register should apply in writing to the Director of Resources.

Equal opportunities and diversity

The HTA is committed to providing equal opportunities for all staff. Our aim is to ensure that all staff are aware that any form of discrimination against people because of their gender, marital status, race, age, sexual orientation, religion, disability, part time or fixed term working, is prohibited within the HTA and to ensure that the Authority abides by the statutory regulations regarding discrimination.

Information for staff and communications policy

The HTA regularly keeps all members of staff informed about organisational, management and policy issues. We operate a system of monthly staff meetings, chaired in rotation by a member of staff and circulate a monthly Chief Executive's Report.

Training and development

The Authority actively promotes the development of staff through personal training plans and a corporate development programme.

Payment of suppliers

The HTA complies with the Better Payment Practice Code. The policy is that all bills should be paid in accordance with credit terms, or where no such terms exist, within 30 days of the receipt of goods or services, or upon the presentation of a valid invoice, whichever is the later. The outstanding creditor days was 18 days at the end of the financial year. No interest payments were made to suppliers under the Late Payment of Commercial Debts (Interest) Act 1998.

Auditor

The Comptroller and Auditor General is the external auditor for HTA's accounts. The external auditor's remuneration in 2006/07 was set at £22,000. No fees were incurred for non-audit work.

To the extent of my knowledge, as Accounting Officer for the HTA, I am confident that:

- a) There is no relevant audit information of which the HTA's auditors are unaware and;
- b) I have taken all possible steps to make myself aware of any information of relevance to the HTA's auditors and to make them aware of it.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date: 29 June 2007

The Authority

The Authority currently consists of 15 members who have been appointed by the Secretary of State for Health. They come from a variety of medical, scientific, legal, administrative and political backgrounds. By law, at least half must be lay members.

Shirley Harrison, Chair from 1 January 2007

(interim Chair from 1 October 2006 to 31 December 2006) (lay member)

Shirley Harrison is also Chair of the Human Fertilisation and Embryology Authority. Her professional career has been in marketing and public relations, both as a practitioner and an academic. Her community activities have encompassed the fields of education, criminal justice and health. She has served as a JP since 1998. Her health-related activities include patient representation on a number of local, regional and national bodies, largely concerned with cancer research and education. She is a Fellow of the Royal Society of Arts, and a Member of the Chartered Institute of Public Relations, the Society of Authors and the Magistrates Association.

The Rt Hon Baroness Hayman, Resigned as Chair on 30 September 2006

(lay member)

Helene Hayman has worked in the voluntary sector and the National Health Service in a variety of roles for over thirty years. She entered the House of Lords in 1996 and was a member of the Government from 1997 to 2001, serving at the Department of Environment, Transport and the Regions, Department of Health, and as Minister of State at the Ministry of Agriculture, Fisheries and Food. Helene is now the Speaker of the House of Lords.

Professor Michael Banner

(lay member)

Michael Banner is a Fellow of Trinity College, Cambridge. Amongst previous committee experience, he chaired a Committee of Enquiry for MAFF from 1993–1995, the CJD Incidents Panel at the Department of Health, and the Home Office's Animal Procedures Committee from 1998–2006.

Dr D Ceri Davies

(professional member)

Ceri Davies has been a Licensed Teacher of Anatomy for more than twenty years and is a member of the Council of the Anatomical Society of Great Britain and Ireland. Ceri is currently Reader in Neuroscience at St George's University of London.

Professor James Ironside, Deputy Chair

(professional member)

James Ironside is Professor of Clinical Neuropathology in the University of Edinburgh, and an Honorary Consultant Neuropathologist in the Lothian Health

University Hospital and Tayside Health University Hospital, Scotland. He has been using human tissues in diagnosis, education and research for 30 years, and was formerly Deputy Chair of the Spongiform Encephalopathy Advisory Committee.

Jane Jeffs

(lay member)

Jane Jeffs is a lay member who has had personal experience of bereavement and the debate around post mortem examinations and organ retention and disposal. She was Chief Officer of a Community Health Council before her retirement and in that role carried out research into public opinion regarding post mortems. She was a member of the Welsh Organ Retention Advisory Group and is the member of the Authority appointed by the Welsh Assembly Government.

Professor El-Nasir Lalani

(professional member)

El-Nasir Lalani is the Robert Leith Professor of Pathology and Academic Head, Department of Pathology in the Division of Cancer Studies at the University of Birmingham. He is also an Honorary Consultant Histopathologist at the University Hospital Birmingham NHS Foundation Trust. He was codirector and founder of the Human Biomaterials Resource Centre at Imperial College / Hammersmith Hospitals Trust and codirector of the Medical Research Council Fetal Tissue Bank. He served on the joint Department of Health and Royal College of Obstetricians and Gynaecologists Polkinghorne guidelines review committee. He is the Chairman of the Tissue Banking Committee on the International Network for Cancer Treatment and Research. His main research interests are in urological cancers with a focus on prostate cancer, epithelial / stem cell and MUC1 functional biology.

Dame Suzi Leather, Resigned on 31 August 2006

(lay member)

Suzi Leather chaired the Human Fertilisation and Embryology Authority from 2002 to 2006 and is now the Chair of the Charity Commission. Her particular interests and experience include regulation and public health. Suzi was founder Deputy Chair of the Food Standards Agency and has chaired an NHS Trust, as well as being founder Chair of the UK's first combined Healthy Living Centre and UK online centre. Suzi's academic background is in political science.

Ruth Musson

(professional member)

Ruth Musson started her career in public service administration, before qualifying as a Registered General Nurse, later gaining experience in a number of fields, including medicine, terminal care and

research. She now leads a small team of nurses and a midwife who work with families, clinical teams, coroners and researchers addressing all issues relating to consent, retention and return of tissues from post mortem examinations. She joined the HTA's Audit Committee on 16 January 2007.

Sharmila Nebhrajani (lay member)

Sharmila Nebhrajani is BBC Future Media and Technology's Chief Operating Officer where she is responsible for the operational management, financial and business strategy, editorial compliance, business development and commissioning relationships with the independent production sector across bbc.co.uk and the BBC's interactive television services. She is Deputy Chair of the Human Fertilisation and Embryology Authority and a member of the Olympic Lottery Distributor. She is also Chair of the HTA Audit Committee.

Dr Andrew Reid (professional member)

Andrew Scott Reid was appointed in November 2002 as the full-time coroner for the jurisdiction of the Inner Northern District of Greater London, consisting of the London boroughs of Camden, Hackney, Islington and Tower Hamlets. Andrew deals with Inquests at Poplar and St Pancras Coroner's Courts.

Mr Keith Rigg (professional member)

Keith Rigg is Consultant Surgeon, Director of Transplantation and Clinical Director for General Surgery at Nottingham University Hospitals NHS Trust. He is currently Vice-President of the British Transplantation Society.

Dr Kate Robson-Brown (lay member)

Kate Robson-Brown is Senior Lecturer in Biological Anthropology and Graduate Dean of Arts at the University of Bristol. She is Director of the University archaeological skeletal collections and the Bristol Osteoarchaeological Research Group. Her research interests include human evolutionary anatomy and forensic anthropology.

Dr David Sharpe (lay member)

David Sharpe is a Barrister practising law primarily in Belfast but also in London, where he is a member of Chambers at 12 King's Bench Walk. He has experience of acting for both patients and doctors (and other healthcare professionals) in medical litigation and inquests. David is the member of the Authority appointed by the Northern Ireland Department of Health, Social Services and Public Safety.

Helen Shaw (lay member)

Since 1994 Helen Shaw has been codirector of INQUEST, an organisation with a national reputation for excellence and a proven track record in providing advice and support about the inquest system to bereaved families and their lawyers. She was a member of the Retained Organs Commission from 2001–2004. Helen is also vice-chair of the National Bereavement Partnership.

Professor Sir James Underwood

(professional member)

Prior to his retirement, James Underwood was Professor of Pathology at the University of Sheffield and Consultant Histopathologist to the Sheffield Teaching Hospitals NHS Foundation Trust. Sir James was an observer on the Retained Organs Commission and President of the Royal College of Pathologists from 2002–2005. Sir James is currently Chairman of the National Bereavement Partnership.

Michaela Willis (lay member)

Michaela Willis is the Chief Executive of the National Bereavement Partnership, a registered charity offering a unique service by providing information, advice and support to people who have experienced bereavement, and to professionals working with bereaved people, particularly where a post mortem is requested or required. Michaela is a senior lecturer at Stafford University on Death, Bereavement and Human Tissue studies and was a former member of the Retained Organs Commission.

Attendance at Authority meetings

A total of nine Authority meetings were held throughout 2006/07; member attendance is listed below. As with the previous year, the business of attending Authority meetings represents only a part of the work carried out by Authority members. All are involved in a mix of Authority activity. This includes membership of the Audit Committee; chairing and participating in conferences and workshops for stakeholders; participating in working groups and members' groups covering the work of the Directorates; representing the HTA in the media and at conferences and providing advice to the Executive.

Name	Authority meetings attended
Michael Banner	9
Ceri Davies	8
Shirley Harrison, Chair	9
Helene Hayman (resigned 30 September 2006)	5
James Ironside	8
Jane Jeffs	8
El-Nasir Lalani	7
Suzi Leather (resigned 31 August 2006)	3
Ruth Musson	9
Sharmila Nebhrajani	6
Andrew Reid	8
Keith Rigg	8
Kate Robson-Brown	8
David Sharpe	5
Helen Shaw	7
James Underwood	8
Michaela Willis	7

Attendance at Audit Committee meetings

There were four Audit Committee meetings held in 2006/07.

Name	Audit Committee meetings attended
Michael Banner	4
Shirley Harrison (resigned 30 September 2006)	3
Sharmila Nebhrajani, Chair	4
Ruth Musson (joined 16 January 2007)	1
David Sharpe	2
James Underwood	2
Michaela Willis	3

The Executive

The Executive implements the policy and strategic goals set by the Authority. It is led by a Chief Executive and consists of a core team that is split into four directorates.

- Adrian McNeil, Chief Executive
- Leslie Boodram, Director of Resources
- Dr Shaun Griffin, Director of Communications
- Peter Lemmey, Director of Policy
- Dr Sandy Mather, Director of Regulation



FTE = Full Time Equivalent

Management commentary

Financial position

2006/07 has been the HTA's first year of implementation of its role as the statutory regulator of the removal, retention, use and storage of human tissue in England, Wales and Northern Ireland. Expenditure this year has been directed at building the necessary business and regulatory systems to operate as an efficient and effective risk-based regulator. One of the key financial objectives in our first year of delivery was to ensure that we generated sufficient funds from licence fees to meet those operating costs not covered by grant-in-aid from the DH.

Total expenditure was over £2.8 million. Salaries and related expenditure represent 52% of total expenditure, whilst expenditure relating to office premises such as rent, utilities and facilities management constitutes 10% of overall costs. Other costs have been managed to ensure best value is achieved partly by outsourcing services such as finance, IT support, HR and payroll.

Staff costs will increase in 2007/08 as significant numbers of staff were recruited in the last quarter of 2006/07, primarily to provide in-house site visit inspection. Other costs have increased in 2006/07 because of the planned growth in our regulatory, policy and communications activities.

The summary table below includes data taken from our accounting schedules and notes contained in these annual accounts:

Table 1 – Income and expenditure for the year ended 31 March 2007

	2006/07 £'000's	2005/06 £'000's Restated
Income		
Income from devolved administration	100	-
Licence fee	2,929	-
Total income	3,029	-
Expenditure		
Staff costs	1,510	540
General administrative costs	1,331	661
Total expenditure	2,841	1,201
Net income / (expenditure) for the financial year	188	(1,201)

See note 9 on page 47 and accounting policy 1.2 on page 43 for further explanation of the restatement of the 2005/06 results and movement in reserves.

Key Performance Indicators 2006/07

Each year, we agree a Business Plan with the Department of Health that includes performance targets covering delivery of our statutory remit and public accountability. Working towards the establishment of RATE will be a target in each of our annual plans.

The HTA agreed with the DH, the following key targets for 2006/07:

- Develop and implement licensing systems to regulate those establishments that fall within the HTA remit
- Publish and promote the statutory Codes of Practice approved by Parliament
- Develop financial and administration systems in accordance with better regulation and governance procedures
- Develop a fees structure that meets HTA financial requirements
- Where appropriate, develop systems with the Human Fertilisation and Embryology Authority that represent best value for money and can be easily integrated on to the establishment of the RATE
- Maintain robust, in year, financial management to ensure that operating costs are kept within budget and requests for grant in aid do not exceed allocations
- Keep the number of whole time equivalent core staff to a minimum

Progress against our key targets was monitored throughout the year by the Senior Management Team and progress against these and the Business Plan reported to the DH at quarterly accountability meetings. All targets were met.

Risks and uncertainties as at May 2007

The HTA operates within a fast-changing, dynamic environment which inevitably increases its exposure to risk as it is a small, tightly-focused organisation. A number of its staff are highly skilled and specialised. This creates a challenge both in terms of recruitment and retention. There is limited flexibility to move staff within the organisation which makes it increasingly difficult to reprioritise tasks during the life of the Business Plan. The main risks and uncertainties for the coming business year (2007/08) are summarised in the table below:

Risk	Mitigating factors and actions
Staff not adequately trained to perform HTA activities	HR strategy will ensure effective corporate training is provided to ensure key organisational objectives are met.
Staff attrition due to uncertainty about RATE	All staff employed with the full knowledge of plans for RATE. Additional resource sought from DH for HR and internal communications support.
Resources not sufficient to meet Business Plan activities	The HTA's governance structures identify corporate priorities and anticipate pressures. Thus the HTA is able to reappraise and reassign resources if priorities and pressures so require.
Lack of HTA business continuity plan	An effective business continuity plan is on track for completion early in 2007/08.
Business priorities may change during the year	The HTA will proactively work collaboratively with key stakeholders to identify any potential changes to the plan.

Social, community and environmental issues

Our environmental action plan includes recycling for paper and toner cartridges. We also have plumbed-in water.

2006/07 Accounts

The Annual Accounts have been prepared and issued by the HTA, under directions given by the Secretary of State with the approval of HM Treasury in accordance with Schedule 2 (section 16) of the Human Tissue Act 2004. The Accounts demonstrate the resources that have been used by the HTA to deliver its objectives. These Annual Accounts have been prepared in accordance with the guidance set out in the Government Financial Reporting Manual (FRM) for 2006/07.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date: 29 June 2007

Remuneration report

Salary and pension entitlements of Authority members

Members of the Authority receive an annual salary that is agreed by the Secretary of State for Health. This remuneration does not include any pension entitlements. Any increase or change to the remuneration is notified to the HTA by its sponsor department, the Department of Health. In the financial year 2006/07 these payments were as follows:

Chair (x1)	£25-30,000 per annum
Member (x16)	£5-10,000 per annum

Remuneration policy

Staff salaries, comprising a combination of cost of living increase and performance related pay, were reviewed in parallel with the HFEA. The Authority has now established a Remuneration Committee to determine increases in pay from 2007/08 onwards.

Salary and pension entitlements

The following sections provide details of the remuneration and pension interests of the Authority members and senior management. These details are shown in accordance with the Government Financial Reporting Manual (FRM). 'Salary' includes gross salary; performance pay or bonuses; overtime; reserved rights to London weighting or London allowances; recruitment and retention allowances; private office allowances and any other allowance to the extent that it is subject to UK taxation.

Senior manager remuneration

Name and post	Dates	Pro rata salary 2006/07	Salary range 2006/07	Salary range 2005/06
Adrian McNeil Chief Executive	Appointed 1 July 2005		£85-90,000	£75-80,000
Peter Lemmey Director of Policy	Appointed 18 July 2005		£65-70,000	£65-70,000
Sandy Mather Director of Regulation	Appointed 15 August 2005		£60-65,000	£55-60,000
Shaun Griffin Director of Communications	Appointed 15 August 2005		£55-60,000	£50-55,000
Colin Pavelin Director of Resources	Resigned 15 July 2006	£10-15,000		£40-45,000
Leslie Boodram Director of Resources	Appointed 22 September 2006	£30-35,000	£55-60,000	

Remuneration report (senior staff salaries)

Name of Officer	Total salary including performance pay (ii)	Real increase in pension at age 60 (iii)	Real increase in pension at age 60 (iv)	Pension at 31/03/07 (v)	Lump sum at 31/03/07 (vi)	CETV at 31/03/07 (vii)	CETV at 31/03/07 (viii)	Employee contributions and transfers-in (ix)	Real increase in CETV as funded by employer (x)
	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000	£'000
Adrian McNeil Chief Executive	85–90	0–2.5	5–7.5	35– 37.5	115– 117.5	804	886	1	43
Shaun Griffin Director of Communications	55–60	0–2.5	0	0–2.5	0	6	16	2	8
Peter Lemmey Director of Policy	70–75	0–2.5	0	32.5– 35	97.5– 100	703	728	1	–1
Sandy Mather Director of Regulation	60–65	0–2.5	0	17.5– 20	0	191	216	2	20
Colin Pavelin Director of Resources (to 15/07/06)	10–15	0–2.5	0–2.5	7.5– 10	25 27.5	119	131	1	10
Leslie Boodram Director of Resources (from 22/09/06)	30–35	0–2.5	0	0–2.5	0	0	7	1	6

The above disclosures in the remuneration report have been audited.

Benefits in kind

The monetary value of benefits in kind covers any benefits provided by the employer and treated by the HMRC as a taxable emolument. The HTA is currently agreeing a settlement and PSA with HMRC in relation to taxable emoluments of HTA staff and Authority members.

Cash equivalent transfer value

Columns (vii) and (viii) of the above table show the staff member's cash equivalent transfer value accrued at the beginning and end of the reporting period. Column (x) reflects the increase in cash equivalent transfer value effectively funded by the employer. It takes account of the increase in accrued pension due to inflation, contributions paid by the employee (including the value of any benefits transferred from another pension scheme or arrangement) and uses common market valuation factors for the start and end of the period.

A cash equivalent transfer value is the actuarially assessed capitalised value of the pension scheme benefits accrued by a member at a particular point in time. The benefits valued are the member's accrued benefits and any contingent spouse's pension payable from the scheme. A cash equivalent transfer value is a payment made by a pension scheme or arrangement to secure pension benefits in another pension scheme or arrangement when the member leaves a scheme and chooses to transfer the benefits accrued in their former scheme. The pension figures shown relate to the benefits that the individual has accrued as a consequence of their total membership of the

pension scheme, not just their service in a senior capacity to which disclosure applies. The cash equivalent transfer value figures, and from 2003/04 the other pension details, include the value of any pension benefit in another scheme or arrangement which the individual has transferred to the Principal Civil Service Pension Scheme arrangements and for which the Civil Superannuation Vote has received a transfer payment commensurate to the additional pension liabilities being assumed. They also include any additional pension benefit accrued to the member as a result of their purchasing additional years of pension service in the scheme at their own cost.

Cash equivalent transfer values are calculated within the guidelines and framework prescribed by the Institute and Faculty of Actuaries, as advised by the actuary to the Principal Civil Service Pension Scheme.

The real increase in the value of the CETV

This takes account of the increase in accrued pension due to inflation and contributions paid by the officer, and is calculated using common market valuation factors for the start and end of the period.

Civil Service pensions

Pension benefits are provided through the Civil Service pension arrangements. The PSCPS is an unfunded multi-employer defined benefit scheme but HTA is unable to define its share of the underlying assets and liabilities. A full actuarial valuation was carried out as at 31 March 2003 by the Scheme Actuary, Hewitt Bacon Woodrow. Details can be found in the resource accounts of the Cabinet Office at www.civilservice-pensions.gov.uk

From 1 October 2002, civil servants may be in one of three statutory based 'final salary' defined benefit schemes (classic, premium, and classic plus). New entrants after 1 October 2002 must join premium.

Classic scheme

Benefits accrue at the rate of 1/80th of pensionable salary for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. Members pay contributions of 1.5 per cent of pensionable earnings. On death, pensions are payable to the surviving spouse at a rate of half the member's pension. On death in service, the scheme pays a lump sum benefit of twice pensionable pay and also provides a service enhancement on computing the spouse's pension. The enhancement depends on length of service and cannot exceed 10 years. Medical retirement is possible in the event of serious ill health. In this case, pensions are brought into payment immediately without actuarial reduction and with service enhanced as for widow(er) pensions.

Premium

Benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum, but members may commute some of their pension to provide a lump sum up to a maximum of 3/80ths of final pensionable earnings for each year of service or 2.25 times pension if greater (the commutation rate is £12 of lump sum for each £1 of pension given up). For the purposes of pension disclosure the tables assume maximum commutation. Members pay contributions of 3.5 per cent of pensionable earnings. On death, pensions are payable to the surviving spouse or eligible partner at a rate of 3/8ths the member's pension (before any commutation). On death in service, the scheme pays a lump sum benefit of three times pensionable earnings and also provides a service enhancement on computing the spouse's pension. The enhancement depends on length of service and cannot exceed 10 years. Medical retirement is possible in the event of serious ill health. In this case, pensions are brought into payment immediately without actuarial reduction. Where the members' ill health is such that it permanently prevents them undertaking any gainful employment, service is enhanced to what they would have accrued at age 60.

Classic plus scheme

This is essentially a variation of premium, but with benefits in respect of service before 1 October 2002 calculated broadly as per classic.

Pensions payable under classic, premium, and classic plus are increased in line with the Retail Prices Index.

The schemes are unfunded with the cost of benefits met by monies voted by Parliament each year. Pensions payable under classic, premium, and classic plus are increased annually in line with changes in the Retail Prices Index. New entrants after 1 October 2002 may choose between membership of premium or joining a good quality 'money purchase' stakeholder arrangement with a significant employer contribution (partnership pension account).

Employee contributions are set at the rate of 1.5% of pensionable earnings for classic and 3.5% for premium and classic plus. Benefits in classic accrue at the rate of 1/80th of pensionable salary for each year of service. In addition, a lump sum equivalent to three years' pension is payable on retirement. For premium, benefits accrue at the rate of 1/60th of final pensionable earnings for each year of service. Unlike classic, there is no automatic lump sum (but members may give up (commute) some of their pension to provide a lump sum). Classic plus is essentially a variation of premium, but with benefits in respect of service before 1 October 2002 calculated broadly as per classic.

The partnership pension account is a stakeholder pension arrangement. The employer makes a basic contribution of between 3% and 12.5% (depending on the age of the member) into a stakeholder pension product chosen by the employee. The employee does not have to contribute but where they do make contributions, the employer will match these up to a limit of 3% of pensionable salary (in addition to the employer's basic contribution). Employers also contribute a further 0.8% of pensionable salary to cover the cost of centrally-provided risk benefit cover (death in service and ill health retirement).

Further details of HTA pension costs are disclosed in note 3 on page 45 and the accounting policy is disclosed in note 1.10 on page 44.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date: 29 June 2007

Statement of the Authority's and Chief Executive's responsibilities

Under the HT Act 2004, the HTA is required to prepare annual accounts for each financial year, in conformity with a Secretary of State's direction Schedule 2 (section 16), detailing the resources acquired, held or disposed of during the year and the use of resources by the HTA during the year. The Annual Accounts are prepared on an accruals basis and must give a true and fair view of the state of affairs of the HTA, the net resource outturn, resources applied to objectives, recognised gains and losses and cash flows for the financial year.

The Department of Health has appointed the Chief Executive as Accounting Officer of the Authority with responsibility for preparing the HTA's accounts and for transmitting them to the Comptroller and Auditor General.

In preparing the accounts, the Accounting Officer is required to comply with the Government Financial Reporting Manual prepared by HM Treasury, and in particular to:

- a) observe the relevant accounting and disclosure requirements, and apply suitable accounting policies on a consistent basis;
- b) make judgements and estimates on a reasonable basis;
- c) state whether applicable accounting standards, as set out in the Government Financial Reporting Manual, have been followed, and disclose and explain any material departures in the accounts;
- d) prepare the accounts on a going concern basis.

The responsibilities of an Accounting Officer, including responsibility for the propriety and regularity of the public finances for which an Accounting Officer is answerable, for keeping proper records and safeguarding the Authority's assets, are set out in the Accounting Officers' Memorandum, issued by the Department of Health, and published in Government Accounting.

Statement on Internal Control

Scope of responsibility

1. As Accounting Officer, I have responsibility for maintaining a sound system of internal control that supports the achievement of the Human Tissue Authority's policies, aims and objectives, whilst safeguarding the public funds and departmental assets for which I am personally responsible, in accordance with the responsibilities assigned to me in Government Accounting.
2. The Assurance and accountability frameworks for reporting to the Department of Health are agreed and require:
 - a) The Department of Health's approval of the HTA's Strategic and Business Plans.
 - b) The HTA to submit budget profile and headcount reports and quarterly performance reports to the timetable outlined by the Department of Health.
 - c) Quarterly Accountability reviews to be held between the HTA's Senior Management Team, the senior department sponsor and the Arm's Length Body Business Change Manager.
 - d) Annual accountability review meetings with the public Health Minister.
3. Department of Health officials attend Authority meetings, Audit Committee meetings and other HTA committees or working groups at the invitation of HTA officials, as observers. Officials from the National Audit Office (NAO) and our internal auditors also attend Audit Committee meetings as observers.
4. The HTA has maintained close links with the Department of Health since it was established and has held regular meetings with representatives from the departmental sponsor branch.

The purpose of the system of Internal Control

5. The system of Internal Control is designed to manage risk to a reasonable level rather than to eliminate all risk of failure to achieve policies, aims and objectives; it can therefore only provide reasonable and not absolute assurance of effectiveness. The system of Internal Control is based on an ongoing process designed to identify and prioritise the risks to the achievement of departmental policies, aims and objectives, to evaluate the likelihood of those risks being realised and the impact should they be realised, and to manage them efficiently, effectively and economically. The system of Internal Control, which accords with Treasury guidance, has been developed over the past year and will continue to develop as the HTA introduces new procedures to meet objectives.
6. Throughout the year, the Authority and its Senior Management Team have monitored HTA expenditure through a monthly reporting system. In addition, systems of internal control have been developed and embedded throughout the year in order to ensure the safe custody of the assets and finances of the HTA. These systems will continue to be enhanced in order to ensure the HTA meets best practice for an established public body. The HTA will build on advice from our External and Internal Auditors as well as other professional sources to ensure we are fit for purpose to meet the changing nature of our business as we move towards the establishment of RATE.

Capacity to handle risk

7. The HTA understands the importance of risk management and internal control. All members of the Authority and the Executive have responsibility for risk management.
8. The Authority is ultimately responsible for overseeing management of the HTA's strategic risks. I am responsible for providing leadership for management of risk within the organisation and all members of the senior management team (SMT) are responsible for managing the strategic or operational risks that may impact the delivery of policies and objectives in their areas of work.
9. In order to strengthen its internal controls and provide assurance, the HTA has appointed internal auditors. The HTA is also subject to external audit by the office of the Comptroller and Auditor General.

The risk and control framework

10. The HTA has spent much of the last year establishing and refining appropriate systems and processes to enable it to meet the requirements of a risk based regulator. These include more frequent Audit Committee meetings, development of an Internal Audit Strategy, an enhanced licensing IT system and an enhanced risk register which has been managed monthly by the Senior Management Team. Where appropriate, risk was also indirectly assessed by the Authority at its regular meetings. The regulation directorate has also maintained a risk register for activities related to licensing and inspection and this is regularly reviewed.
11. The HTA recognises the need to ensure that its risk management and Internal Control arrangements are fit for purpose and applied throughout the organisation as it develops its functions and works towards achieving its objectives. It also recognises the role of the Audit Committee as vital in ensuring that all elements of our risk and internal controls framework are scrutinised and reviewed on a regular basis. The Audit Committee is charged by the Authority to carry out this work and report back its findings to the Authority on a regular basis.
12. The HTA has agreed its corporate risk management strategy. A key part of the strategy was the establishment of a formal risk registers for strategic and operational risks.
13. The strategy sets out:
 - how the HTA will proactively identify, evaluate and manage risks to the delivery of its policies, aims and objectives;
 - roles and responsibilities in relation to risk management and how these will be communicated;
 - how the HTA will involve its stakeholders in identifying and managing risk;
 - how the HTA will determine the levels of risk it is willing to tolerate (risk appetite);
 - how the risk management process itself will be reviewed and continually improved; and
 - how business continuity will be addressed through the production of a Business Continuity Plan.

Review of effectiveness

As Accounting Officer, I have responsibility for reviewing the effectiveness of the system of Internal Control. My review of the effectiveness of the system of Internal Control is informed by the work of the internal auditors and the executive directors within the department who have responsibility for the development and maintenance of the Internal Control framework, and comments made by the external auditors in their management letter and other reports. I have been advised on the implications of the result of the reviews of the effectiveness of the system of internal control by the Authority, the Audit Committee and plans to address weaknesses and ensure continuous improvement of the system are in place.

The Director of Resources and I have kept the current system of internal control under review during 2006/07, and significant improvements have been introduced.

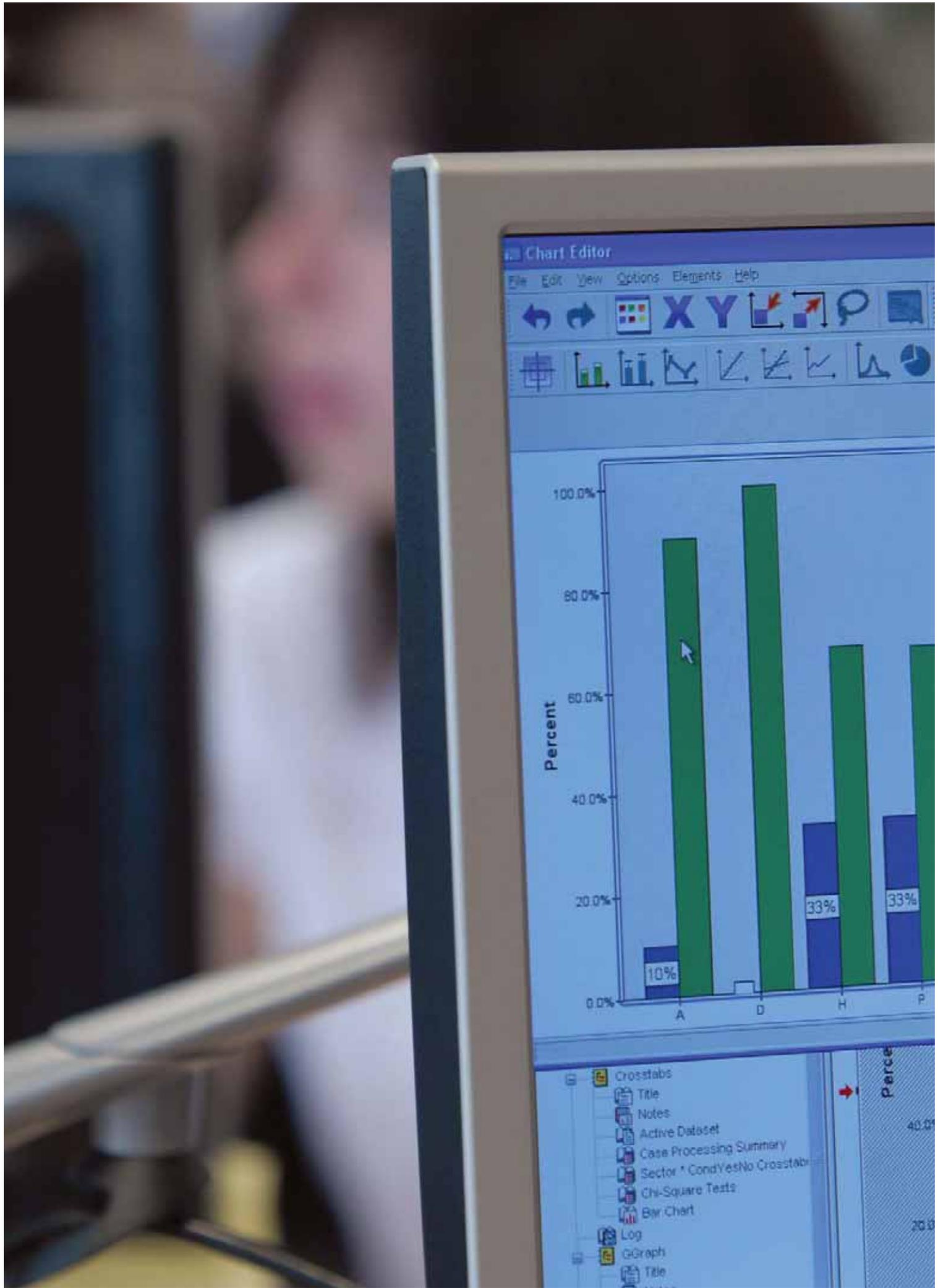
The Audit Committee have reviewed the management of risk across the HTA during 2006/07.

During the year the HTA engaged internal auditors to investigate nine key operational systems. Overall we have received substantial assurances from the internal auditors and are actively introducing measures to cover areas of weakness that have been identified.



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date: 29 June 2007



The Certificate and Report of the Comptroller and Auditor General to the Houses of Parliament

I certify that I have audited the financial statements of Human Tissue Authority (the Authority) for the year ended 31 March 2007 under the Human Tissue Act 2004. These comprise the Income and Expenditure Account, the Balance Sheet, the Cashflow Statement and Statement of Total Recognised Gains and Losses and the related notes. These financial statements have been prepared under the accounting policies set out within them. I have also audited the information in the Remuneration Report that is described in that report as having been audited.

Respective responsibilities of the Authority, Chief Executive and auditor

The Authority and Chief Executive are responsible for preparing the Annual Report, the remuneration report and the financial statements in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury and for ensuring the regularity of financial transactions. These responsibilities are set out in the Statement of the Authority's and Chief Executive's Responsibilities.

My responsibility is to audit the financial statements and the part of the remuneration report to be audited in accordance with relevant legal and regulatory requirements, and with International Standards on Auditing (UK and Ireland).

I report to you my opinion as to whether the financial statements give a true and fair view and whether the financial statements and the part of the remuneration report to be audited have been properly prepared in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury. I report to you whether, in my opinion, certain information given in the Annual Report, which comprises sections titled 'The Chief Executive's Report', 'The Authority', 'The Executive', Management Commentary and the unaudited part of the remuneration report, is consistent with the financial statements. I also report whether in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

In addition, I report to you if the Authority has not kept proper accounting records, if I have not received all the information and explanations I require for my audit, or if information specified by HM Treasury regarding remuneration and other transactions is not disclosed.

I review whether the Statement on Internal control reflects the Authority's compliance with HM Treasury's guidance, and I report if it does not. I am not required to consider whether this statement covers all risks and controls, or form an opinion on the effectiveness of the Authority's corporate governance procedures or its risk and control procedures.

I read the other information contained in the Annual Report and consider whether it is consistent with the audited financial statements. I consider the implications for my report if I become aware of any apparent misstatements or material inconsistencies with the financial statements. My responsibilities do not extend to any other information.

Basis of audit opinion

I conducted my audit in accordance with International Standards on Auditing (UK and Ireland) issued by the Auditing Practices Board. My audit includes examination, on a test basis, of evidence relevant to the amounts, disclosures and regularity of financial transactions included in the financial statements and the part of the Remuneration Report to be audited. It also includes an assessment of the significant estimates and judgments made by the Authority and Chief Executive in the preparation of the financial statements, and of whether the accounting policies are most appropriate to the Authority's circumstances, consistently applied and adequately disclosed.

I planned and performed my audit so as to obtain all the information and explanations which I considered necessary in order to provide me with sufficient evidence to give reasonable assurance that the financial statements and the part of the remuneration report to be audited are free from material misstatement, whether caused by fraud or error, and that in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them. In forming my opinion I also evaluated the overall adequacy of the presentation of information in the financial statements and the part of the remuneration report to be audited.

Opinions

Audit opinion

In my opinion:

- the financial statements give a true and fair view, in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury, of the state of the Human Tissue Authority's affairs as at 31 March 2007 and of its net income for the year then ended;
- the financial statements and the part of the remuneration report to be audited have been properly prepared in accordance with the Human Tissue Act 2004 and directions made thereunder by the Secretary of State with the approval of Treasury; and
- information given within the Annual Report, which comprises sections titled 'The Chief Executive's Report', 'The Authority', 'The Executive', Management Commentary and the unaudited part of the remuneration report, is consistent with the financial statements.

Audit opinion on regularity

In my opinion, in all material respects the expenditure and income have been applied to the purposes intended by Parliament and the financial transactions conform to the authorities which govern them.

Report

I have no observations to make on these financial statements.

John Bourn

Comptroller and Auditor General
National Audit Office
157-197 Buckingham Palace Road
Victoria
London
SW1W 9SP

Date: 2 July 2007

The maintenance and integrity of the Human Tissue Authority's website is the responsibility of the Accounting Officer; the work carried out by the auditors does not involve consideration of these matters and accordingly the auditors accept no responsibility for any changes that may have occurred to the financial statements since they were initially presented on the website.

Financial accounts 2006/07

Presented pursuant to the Human Tissue Act 2004 Section 36 and Schedule 2 (Section 16)

The Human Tissue Authority

Financial accounts 2006/07
(For the year ended 31 March 2007)

3 July 2007

Income and expenditure account

For the year ended 31 March 2007

	Note	2006/07 £	2005/06 Re-stated £
Income	2	3,029,436	-
Administration costs			
Staff costs	3	1,509,559	540,060
Other administration costs	4	1,331,240	660,581
Total expenditure		2,840,799	1,200,641
Net operating income / (expenditure)		188,637	(1,200,641)
Notional interest	1.9	(12,630)	(1,133)
Income / (expenditure) on ordinary activities		176,007	(1,201,774)
Write back of notional interest		12,630	1,133
Net income / (expenditure) for the financial year		188,637	(1,200,641)

Statement of recognised gains and losses

For the year ended 31 March 2007

	Notes	2006/07	2005/06 Re-stated
Income / (expenditure) for the financial year		188,637	(1,200,641)
Total recognised gains / (losses) for the year		188,637	(1,200,641)

Balance sheet

As at 31 March 2007

	Note	31 March 2007		31 March 2006	
		£	£	£	£
Tangible and intangible fixed assets					
Intangible fixed assets	5a	17,647		-	
Tangible fixed assets	5b	254,823		-	
			272,470		-
Current assets					
Debtors	6	306,102		29,315	
Cash at bank and in hand	15	602,441		88,070	
			908,543		117,385
Creditors					
(Amounts falling due within one year)	7	(386,017)		(94,070)	
Total current assets less current liabilities			522,526		23,315
			794,996		23,315
Financed by					
Income and expenditure reserve	9		794,996		23,315
			794,996		23,315



Adrian McNeil
Chief Executive
Human Tissue Authority
Accounting Officer

Date: 29 June 2007

The notes on pages 43–51 form part of these accounts.

Cash flow statement

For the year ended 31 March 2007

	Note	2006/07 £	2005/06 Re-stated £
Net cash inflow / (outflow) from operating activities	16	225,074	(1,135,886)
Capital expenditure and financial investments			
Payments to acquire intangible assets		(20,563)	-
Payments to acquire tangible assets		(273,184)	-
Financing	16	583,044	1,223,956
Increase in cash in the period		514,371	88,070

Fixed assets accruals at 31 March 2007 were £25,361.

The notes on pages 43–51 form part of these accounts.

Notes to the accounts

1.1 Statement of accounting policies

The financial statements have been prepared pursuant to the Human Tissue Act 2004, Schedule 2, Section 16 and in accordance with the Government Finance Reporting Manual (FReM) 2006/07 issued by HM Treasury. The accounting policies contained in the FReM follow UK generally accepted accounting practice for companies (UK GAAP) and the Companies Act requirements to the extent that it is meaningful and appropriate to the public sector. The particular accounting policies adopted by the Human Tissue Authority are described below. They have been applied consistently in dealing with items considered material in relation to the accounts. The financial statements are prepared under the modified historical cost convention by the inclusion of fixed assets at their value to the business by reference to current costs.

1.2 Change of accounting policies

With effect from the 2006/07 reporting period the FReM requires non-departmental public bodies to account from grants and grants-in-aid received for revenue purposes as financing because they are regarded as contributions from a controlling party which gives rise to a financial interest in the residual interest in NDPBs. This is a change in accounting policy from earlier periods when such items were recorded as income. The effect of this change on the certified 2005/06 accounts and the impact of the change on the results of the current year is shown below. Note there is no impact on the net liability position of the HTA as a result of this change in policy:

	At 31 March 2006 (as previously stated) £	Impact of adopting the new policy £	At 31 March 2006 Restated) £
Net Expenditure for 2005/06	23,315	(1,223,956)	(1,200,641)

1.3 Fixed assets

Fixed assets include tangible and intangible assets and the cost of acquiring or creating computer systems or software. Only items, or groups of related items, costing £1,000 or more are capitalised. Those costing less are treated as revenue expenditure. The assets have not been valued at the modified historical cost accounting as they have all been purchased at the end of the year and the historical cost basis has been used as a revaluation would be immaterial.

1.4 Foreign currency transactions

There were no transactions in foreign currency in 2006/07.

1.5 Depreciation and amortisation

Depreciation is provided on all tangible assets on a monthly basis from the date of deemed economic benefit at rates calculated to write off the cost of each asset evenly over its expected useful life. Expected useful lives are as follows:

Computer equipment	3 years
IT equipment	3 years

Depreciation is provided on constructed software on a monthly basis at a rate calculated to write off the cost of each asset over its expected useful life. The expected useful life of this constructed software is to 31 March 2009.

Amortisation is provided on intangible assets (which comprise software licences) on a monthly basis at a rate calculated to write off the cost of each asset over its expected useful life. The expected useful life of this software development is to 31 March 2009.

1.6 Leases

The Authority has no finance leases. The Authority has operating leases with the Government Actuary's Department with regards to the rent and hire of premises plus the lease of computer equipment. The Authority also has an operating lease with DANKA in respect of photocopying equipment. Commitments under operating leases are detailed in note 11.

1.7 Income

In 2006/07 income takes the form of fees for licences from bodies which have human tissue on their premises. Licence fee income will be recognised at invoice date.

1.8 Administration expenditure

Administration costs reflect the costs of running the HTA.

1.9 Notional charge

In accordance with Treasury Guidance, notional interest at 3.5 per cent of the average capital employed, excluding balances held in cash and in hand, has been credited in the Income and Expenditure Account amounting to 2006/07 £12,630 (2005/06 £1,133).

1.10 Pensions

Past and present employees are covered by the provisions of the Principal Civil Service Pension Scheme (PCSPS.) The defined benefit elements of the schemes are unfunded and are non-contributory except in respect of dependents' benefits. The HTA recognises the expected cost of these elements on a systematic and rational basis over the period during which it benefits from employees' services by payment to the PCSPS of amounts calculated on an accruing basis. Liability for payment of future benefits is a charge on the PCSPS. In respect of the defined contribution elements of the schemes, the HTA recognises the contributions payable for the year. Further details of pension details and commitments are included in the remuneration report.

1.11 Value Added Tax

The Authority was not registered for VAT during the financial year 2006/07.

1.12 Debtors

The Authority provides for bad debts. The provision consists of two elements: three percent of all outstanding debts less than six months old; and a further 50 per cent for debts over six months old.

2. Total income

In 2006/07 the Authority charged fees for licences.

	2006/07	2005/06
	£	Restated £
Administration income		
Income from devolved administrations	100,301	-
Other income	35	-
Licence fee income	2,929,100	-
Total	3,029,436	-

3. Staff numbers and related costs

a) Staff costs comprise:

	2006/07 £	2005/06 £
Wages and salaries – HTA staff	1,007,211	428,518
Social Security costs	86,002	34,409
Pension costs – HTA staff	166,389	66,556
Agency / temporary staff	249,957	10,577
Total	1,509,559	540,060
<i>Of which members emoluments</i>	<i>110,945</i>	<i>110,155</i>

More details on the remuneration policy can be found in the remuneration report.

For 2006/07, contributions of £162,949 (2005/06 £66,556) were paid to the PCSPS at rates prescribed by the Treasury. These rates were in the range of 17.1 – 25.5 per cent of pensionable pay, according to salary level.

b) Average number of persons employed

All staff are seconded through other Government bodies, these include Department of Health and Human Fertilisation and Embryology Authority. As of 31 March 2007 the HTA employed 36 staff (36 FTE). The average number of whole-time equivalent persons employed (including senior management), during the year was as follows:

	2006/07	2005/06
Seconded management staff	5	3
Seconded administrative staff	20	4
Total	25	7

4. Other administration costs

	2006/07 £	2005/06 £
Accommodation	305,890	248,141
Project costs	25,090	136,473
Travel, subsistence and hospitality	72,832	49,168
Recruitment	109,148	24,400
Training	145,815	26,946
Consultancy	76,009	17,715
Stationery and publications	49,819	7,082
Photocopier leasing costs	-	659
Shared services (IT support, finance, payroll, legal)	214,486	95,364
Operating lease on computer equipment	28,395	17,411
Computer running costs	28,370	3,540
Telecommunications	13,486	4,803
Legal fees	34,505	-
Other costs	73,257	16,379
Bad debt	80,000	-
Auditor's remuneration	27,500	12,500
Depreciation and amortisation	46,638	-
Total	1,331,240	660,581

5a. Intangible fixed assets

	Software	Totals
Cost as at 1 April 2006	-	-
Additions	20,563	20,563
As at 31 March 2007	20,563	20,563
Depreciation as at 1 April 2006	-	-
Charge for the year	2,916	2,916
As at 31 March 2007	2,916	2,916
Net Book Value (NBV)		
At 31 March 2007	17,647	17,647
At 1 April 2006	-	-
Increase in NBV	17,647	17,647

5b. Tangible fixed assets

	IT Equipment	Furniture & Fittings	Constructed Software	Totals
Cost as at 1 April 2006	-	-	-	-
Additions	15,400	96,872	186,273	298,545
As at 31 March 2007	15,400	96,872	186,273	298,545
Depreciation as at 1 April 2006	-	-	-	-
Charge for the year	2,223	7,516	33,983	43,722
As at 31 March 2007	2,223	7,516	33,983	43,722
Net Book Value (NBV)				
At 31 March 2007	13,177	89,356	152,290	254,823
At 1 April 2006	-	-	-	-
Increase in NBV	13,177	89,356	152,290	254,823

6. Debtors

	2006/07 £	2005/06 £
Licence fee debtors	373,839	-
Bad debt provision	(80,000)	-
Prepayments	9,062	29,315
Other debtors	3,201	-
Total	306,102	29,315

Debtors – intra government balances

	2006/07 £	2005/06 £
Balance with central government bodies	39,098	20,522
Balance with bodies external to government	22,404	8,793
Balance with local authorities	6,000	-
Balance with NHS trusts	238,600	-
Total	306,102	29,315

7. Creditors

	2006/07 £	2005/06 £
Amounts falling due within one year		
Trade creditors	70,407	851
Accruals	315,610	93,219
Total	386,017	94,070

There are no creditors falling due after one year.

Creditors – intra government balances

	2006/07 £	2005/06 £
Balance with central government bodies	110,133	80,030
Balance with bodies external to government	275,884	14,040
Total	386,017	94,070

8. Post-balance sheet events

There were no post balance sheet events to report. These accounts are authorised to be issued on 18 July 2007.

9. Income and expenditure reserve

The income and expenditure reserve represents the total net assets less liabilities of the HTA, to the extent that the total is not represented by other reserves.

	2006/07 £	2005/06 Restated £
Balance at 1 April 2006	23,315	-
Income / (expenditure) for the year	188,637	(1,200,641)
Grant-in-aid received towards resource expenditure	263,936	1,223,956
Grant-in-aid received towards capital expenditure	319,108	-
Income and expenditure reserve at 31 March 2007	794,996	23,315

10. Capital commitments

There were £123,536 capital commitments as at 31 March 2007.

11. Commitments under operating leases

	2006/07 £	2005/06 £
Land and buildings		
Expiring within one year	140,725	140,725
Other		
Expiring within one year	27,029	22,338

12. Contingent liabilities

There were no contingent liabilities as at 31 March 2007.

13. Related party transactions

The Department of Health is regarded as a related party and had various material transactions with the Authority during the year. This mainly related to the provision of the grant-in-aid.

The HTA lets a floor of a building paying its rent to GAD. During the year the rent payable amounted to £140,725. HTA GAD also provides services to HTA in respect of Finance, Facilities Management, Utilities, Members Payroll and IT services. A breakdown of services provided by GAD is shown below:

	2006/07 £	2005/06 £
Rent and hire of premises	163,073	117,271
Facilities management	136,489	120,160
Utilities	11,899	10,244
IT support	180,332	24,818
Lease of computer equipment	28,230	17,411
Finance services	16,169	24,050
Members payroll	-	1,954
Internal audit	3,746	141
Other costs	3,300	-
Total	543,238	316,049

Three staff were on secondment from the Department of Health during the year. All remaining staff were on secondment from the HFEA.

Baroness Hayman, the Chair of the Authority until 30 September 2006 was also a member of the HFEA until that same date. Dame Suzi Leather, an Authority member until 31 August 2006 was also Chair of the HFEA until that same date. Sharmila Nebhrajani, Chair of the Audit Committee, is also Deputy Chair of the HFEA.

Shirley Harrison was appointed as the Chair of HTA and HFEA as from 1 January 2007. Her salary and expenses are jointly met by the two organisations. At the year end the HTA was owed £1,723 by the HFEA in respect of its contribution towards the Chair's expenses.

The HFEA provide legal, payroll and HR services under a service level agreements totalling £124,580. At the year end the HTA had accrued payments owing to the HFEA totalling £28,277 in respect of the services provided.

The Authority paid £176.25 in respect of a meeting at the University of Birmingham. Professor El-Nasir Lalani, an Authority member, is the Head of Pathology at the University of Birmingham. The Authority paid £300 in respect of a meeting at the University of Bristol. Dr Kate Robson-Brown, an Authority member, is Senior Lecturer, Biological Anthropology, University of Bristol. The Authority paid £500 in respect of two separate conference fees to the National Bereavement Partnership. Michaela Willis, an Authority member, is the Chief Executive of the National Bereavement Partnership.

The Authority also received licence fee income from the following establishments in which the Authority members had an interest:

Ceri Davies	St Georges Hospital, University of London
James Ironside	Lothian and Tayside Hospitals
James Ironside	University of Edinburgh
El-Nasir Lalani	University of Birmingham
El-Nasir Lalani	University Hospital Birmingham NHS Trust
Ruth Musson	Queens, Medical Centre, Nottingham
Ruth Musson	University of Nottingham
Keith Rigg	Nottingham University Hospitals NHS Trust
Kate Robson-Brown	University of Bristol

None of the remaining Authority members, key managerial staff or other related parties has undertaken any material transactions with HTA during the year.

14. Performance against key financial targets

During 2006/07 the Authority managed to stay within an acceptable level of its allotted budget.

At the year end the creditors days was 18 and throughout the year creditors were paid promptly. It is hoped that through implementing a more rigorous procurement process, this figure will further improve next year and enable the Authority to continue fulfilling the criteria of the Better Payment Practice Code.

15. Cash at bank and in hand

	2006/07 £	2005/06 £
Balance at 1 April	88,070	-
Net change inflow	514,371	88,070
Balance at 31 March 2007	602,441	88,070
The following balances at 31 March 2007 are held at:	2006/07	2005/06
Office of HM Paymaster General, Barclays Bank plus cash in hand	602,441	88,070
	602,441	88,070

The Office of HM Paymaster General and Barclays bank provide a current account banking service. During the year, the Authority held a small amount of cash in hand – at year end this was £270. The balance of funds held in the HM Paymaster General and Barclays bank account on 31 March 2007 was £234,338 and £368,103 respectively.

16. Notes to the Cash Flow Statement

Note (i) reconciliation of operating net expenditure

	2006/07 £	2005/06 Restated £
Net inflow from operating activities		
Net income / (expenditure) for the financial year	188,637	(1,200,641)
Adjustment for depreciation	46,638	-
(Increase) in debtors	(276,787)	(29,315)
Increase in creditors	266,586	94,070
Net cash inflow / (outflow) from operating activities	225,074	(1,135,886)

Note (ii) Analysis of financing

	2006/07	2005/06
	£	Restated £
Grant in-aid and revenue Grant received from Department of Health	263,936	1,223,956
Grant in-aid and capital Grant received from Department of Health	319,108	-
Total grant-in-aid applied towards revenue expenditure	583,044	1,223,956

Note (iii) Analysis of changes in net funds

	At 31/3/07	Cash flow	At 31/3/06
	£	£	£
Cash at bank and in hand	602,441	514,371	88,070

17. Financial instruments

FRS13, Derivatives and Other Financial Instruments, requires disclosure of the role which financial instruments have had during the period in creating or changing the risks an entity faces in undertaking its activities. Because of the nature of its activities and its means of funding the HTA is not exposed to the degree of financial risk faced by business entities. Moreover, financial instruments play a much more limited role in creating or changing risk than would be typical of the listed companies to which FRS 13 mainly applies. The HTA has very limited powers to borrow or invest surplus funds and financial assets and liabilities are generated by day-to-day operational activities and are not held to change the risks facing the HTA in undertaking its activities.

As permitted by FRS13, debtors and creditors which mature or become payable within 12 months from the balance sheet date have been omitted from the currency profile.

Liquidity risk

The Authority's net revenue resource requirements are financed by a Grant from the Department of Health and a robust debt recovery and payment process. The HTA is not therefore exposed to significant liquidity risks.

Interest rate risk

The HTA's financial assets and liabilities are not exposed to interest rate risks.

Interest rate profile

The following table shows the interest rate and currency profiles of the HTA's financial assets.

Table 2 – Financial assets

	Total	Fixed-rate financial assets		Non-interest bearing financial assets (i)	Fixed-rate financial assets		Non-interest bearing financial assets
		Floating rate financial assets	Fixed-rate financial assets		Weighted-average interest rate	Weighted-average period for which rate is fixed	
	£	£	£	£	%	Years	Years
At 31 March 2007:							
Sterling	602,441	-	-	602,441	-	-	Note (i)
Other	-	-	-	-	-	-	-
Gross financial assets	602,441	-	-	602,441	-	-	-

(i) The HTA's non-interest bearing financial assets comprises cash at bank and in hand of £602,441.

Foreign currency risk

There was no foreign currency expenditure in 2006/07. Foreign currency expenditure in 2007/08 is expected to be minor.

Fair values

Set out below is a comparison by category of book values and fair values of the HTA's financial assets and liabilities as at 31 March 2007.

Table 3 – Fair values

	Book value £'000	Fair value (i) £'000	Basis of fair valuation
At 31 March 2007			
Primary financial instruments:			
Financial assets:			
Cash at bank	602,441	602,441	Note (i)
Financial liabilities:			
None Held	-	-	Note (i)

(i) Fair value is not significantly different from book value since, in the calculation of book value, the expected cash flows have been discounted by the Treasury discount rate of 2.2% a year in real terms.

18. Losses and special payments

There were no losses or special payments during the financial year.

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