



**HFEA ANNUAL REPORT  
2005/6**

**Presented to Parliament pursuant to  
section 7(3) of the Human  
Fertilisation and Embryology Act  
1990**

## CHIEF EXECUTIVE'S FOREWORD

One of the benefits of regulation is that it can secure and maintain consensus in a controversial area. In the UK we have developed a mature system of regulation of IVF, donor conception and embryo research which attracts praise from other countries and is, in many cases, being replicated into new regulatory frameworks elsewhere in the world.

In fulfilling one of our roles - to maintain public confidence in fertility treatment and embryo research - we work in close partnership with the fertility sector, patients, donor groups, researchers, the Department of Health and the general wider public. The rapid advances in the field require us to anticipate and adapt to many challenges. This means we have to ensure that regulation is flexible and able to evolve according to new circumstances. By working with other partners we can ensure safe, quality care for patients and offspring in a culture of continuous improvement.

The past year has demonstrated how the HFEA has adapted, anticipated and improved. There have been many demands placed on regulation. The following pages in this report outline some of the achievements during the year and demonstrate how we have continually updated and strengthened how we regulate.

We have continued to streamline regulation of treatment and research to ensure it is proportionate, targeted, effective and risk-based. A major highlight has been the 20 per cent efficiency saving in the type and number of information requests to centres as part of the inspection process. On research we have similarly improved processes including new inspection methods and extending the pool of peer reviewers. Our approach has been to work closely with clinics and a new initiative was the setting-up of the Licensed Centres' Panel which enables a range of staff in clinics to give us their views and raise issues for us to address.

A major strand of work has been undertaken in preparing for the requirements of the European Tissue and Cells Directive (EUTCD). We have developed guidance for existing centres as well as those not previously regulated, again working closely with the professional bodies. We have taken the lead in working with other regulators and practitioners through the new European Assisted Conception Consortium (EACC).

We have further progressed our major modernisation programme by completing the Historic Audit Project. Key data on offspring and donors will prove to be a real benefit for clinics and offspring. Our Electronic Data Interchange plan has been implemented to give clinics the capacity to transmit timely and accurate data electronically to HFEA. This will further reduce the burden of regulation.

Throughout the year we have worked hard to make sure that as an organisation we are as patient focussed as possible. Our aim is to ensure that we are making a practical difference to patients' experiences. We are using a variety of channels to hear patients' views, including routinely surveying patients' experiences as part of inspections and through our new online patients' panel, *Fertility Views*. We want to empower patients so they have greater knowledge and involvement in selecting the right clinics and treatments for them. Our 2005 Guide to Infertility with its online clinic search was developed following extensive research and involvement from patients and has been widely welcomed by patients.

Working with stakeholders and the public has been a feature of the policy work we have undertaken during the year. We launched a major dialogue with the public and stakeholders on PGD (Pre-implantation Genetic Diagnosis) for late onset, lower penetrance treatable conditions which has given us valuable feedback to support the development of a policy. We also launched a major review on the issue of multiple births and embryo transfer and convened a working group of clinicians, patients, PCTs, neonatologists and international experts to develop policy proposals for the Authority. These issues will subsequently be consulted upon.

We have actively collaborated with the newly established Human Tissue Authority over the year including setting up joint working and providing services to HTA where appropriate.

All this has been achieved by prudent resource management and within the monetary and headcount reductions required by the Department of Health Arms Length Body Review targets for budgetary savings.

HFEA staff and authority members have been at the heart of delivering this very demanding programme of work and we are very grateful to them for their dedication and hard work in helping the HFEA improve further in regulating fertility treatment and embryo research in the UK.

Sadly, Dame Suzi Leather left the HFEA in August 2006 after four years as Chair. Lord Richard Harries of Pentregarth is the Interim Chair pending the appointment of a new joint Chair for the HFEA and Human Tissue Authority.



**Angela McNab**  
**Chief Executive**

**November 2006**

## Who we are

The Human Fertilisation and Embryology Authority (HFEA) formally came into being on 7<sup>th</sup> November 1990 and began operating on 1<sup>st</sup> August 1991. The HFEA was created by the Human Fertilisation and Embryology Act 1990 to license and regulate human embryo research and specified forms of infertility treatment. The HFEA is an executive Non-Departmental Public Body sponsored by the Department of Health.

## What we do

The Human Fertilisation and Embryology Act 1990 (HFE Act) provides for the regulation of centres offering assisted conception involving the manipulation of sperm, eggs or embryos outside the human body (e.g. In Vitro Fertilisation –IVF, Donor Insemination - DI), the storage of sperm, eggs or embryos and research involving human embryos. The HFEA aims to safeguard the interests of patients, children, the wider public and future generations, and will:

- Provide efficient, effective, economic and fair regulation of centres to promote good practice and maintain the highest ethical standards of patient safety
- Provide centres with clear and comprehensive guidance to promote high standards in the services they offer
- Provide relevant information and advice to centres, people receiving treatment services, gamete and embryo donors and members of the public in an open and accessible way
- Assist centres to tackle and resolve any difficulties which may arise in relation to patient safety and care, and to ethical procedures
- Identify the ethical and social implications of developments in research and treatment and to develop policy accordingly

Our statutory responsibilities are to:

- License and monitor clinics carrying out IVF and DI
- Regulate storage of eggs, sperm and embryos
- Provide information and data about the services, treatments and techniques that clinics provide

- Keep a register of treatments to enable people born as a result of IVF or DI to obtain information about their origins
- License embryo research to ensure science can progress in a responsible way
- Advise government on all aspects of assisted reproductive technology
- Produce a Code of Practice to help clinics comply with the requirements of the HFE Act
- Publicise the services the HFEA provides

### **Performance during the year 2005/6**

The HFEA continues to operate in a fast moving, complex and ethically challenging area of science, with a very high level of public interest in its activities. The organisation is constantly in the media spotlight and is continually required to adapt to changes in the external environment.

The policies developed take into account the disparate and often conflicting view of the public. The organisation recognises the importance of engaging well with a range of stakeholders and with the fertility sector. Maintaining public confidence in fertility treatment and embryo research are paramount and ensuring safety for patients, embryos and children born as a result of Assisted Reproductive Technologies (ART).

The HFEA leads the establishment of the European Assisted Conception Consortium (EACC) to bring about closer international links between ART regulation and service providers in anticipation of and preparation for the EU Tissue and Cells Directive (EUTCD).

The Directive extends the HFEA's remit to include the regulation of all treatments involving the use of human gametes (sperm and eggs), such as Intra-Uterine Insemination (IUI), for example. It will reinforce the need to focus on a quality system approach for clinics.

During 2006, as the government conducts its review of the regulation of infertility treatment and embryo research, the need to ensure that the patient's voice is heard is more important than ever. The HFEA has a prominent role in this.

The organisation has demonstrated how well it has adapted to changing expectations over the years and is now taking a rigorous approach to the requirements of the Department of Health's Arms Length Body Review agenda, specifically more targeted, proportionate and risk-based regulation, is demonstrated in the implementation of the new inspection process.

#### **Ministerial Performance Targets for 2005/06**

- A continued rigorous approach to inspection and regulation, including the development and implementation of a risk-based inspection process
- Completion of the Register Project, including the Historic Audit (verifying HFEA register data against information held in clinic records) by 31 March 2006
- Preparation for the implementation of the requirements of the EUTCD
- The development of arrangements with the Human Tissue Authority (HTA), including the provision of back office functions and systems that can be easily integrated on the establishment of the Regulatory Authority for Tissues and Embryos (RATE)

#### **Some highlights of 2005/6**

- Held two Licensed Centres Panel to engage and consult the sector
- Recruited 750 patients to the Fertility Views on-line panel, an increase of 150 from 2004/05
- Processed 175 import / export directions
- Answered 16,000 patient enquiries by telephone / email an increase of 1,500 from 2004/05
- Handled 50 patient complaints
- Audited 84,000 treatment outcome cycles
- Handled 97 incidents
- Issued 3 alerts

## Meeting Key Challenges

The HFEA delivered on all its 2005/06 business plan activities. Below are selected achievements in each of our major functions up until August 2006.

:

### **Improving Regulation**

**Our aim is to continue to modernise, to provide more proportionate, cost-effective, efficient, targeted and streamlined regulation.**

#### **Actions in 2005/6**

- Fully implemented a risk-based approach to licensing, inspection and incident management, which will ensure that centres performing well against the Code of Practice receive less intervention
- Engaged with the fertility sector by setting up a consultative Licensed Centres Panel, composed of staff from clinics, which met twice during the year
- Carried out a fundamental review to streamline the inspection process, incorporating all changes suggested by the Licensed Centres Panel which resulted in a 20% efficiency saving in the type and number of information requests to centres as part of the inspection process
- Improved information and training for Persons Responsible for licensed clinics and introduced more rigorous assessment of applicants
- Strengthened the independence, accountability and consistency of inspection by recruiting and training a team of full-time inspectors to develop greater in-house expertise
- Produced thematic reports on centres' performance and developed pre-inspection analysis to ensure more focused inspections
- Analysed 1,500 patient questionnaires and produced profiles of patient views on each centre licensed for treatment

#### **Progress towards meeting 2006/7 Business Plan Objectives**

- The new streamlined inspection process has been rolled out from April and the new Self Assessment Questionnaires issued to centres in June

- All Inspectors received training on the new inspection process in April
- The revised inspection report has patient feedback incorporated
- New consent forms were issued to centres in June
- The risk matrix is applied to all portfolio centres on a six monthly basis
- External adviser training is in place for implementation of policy decisions on Sperm Egg and Embryo Donation (SEED) and the Welfare of the Child
- Pilot EUTCD inspections have been carried out and findings analysed
- Two joint inspections have taken place with the Healthcare Commission (HCC) to look for areas of duplication/overlap
- Person Responsible (PR) training package has been prepared and was well received by the Licensed Centres Panel
- Incident investigations have taken place within 30 days of notification
- All enquiries from centres have been responded to within three working days

### **Implementing the EU Tissue and Cells Directive (EUTCD)**

**Our aim is to move forward with the implementation of the EU Tissue and Cells Directive and to provide detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies**

#### **Actions in 2005/6**

- Prepared for the implementation of the Directive for currently licensed centres by April 2007 by working with professional bodies and clinics to explain requirements by use of the standards
- Worked with other European networks, regulators and practitioners to achieve consistency in implementation alongside sharing best practice approaches to improve safety (European Assisted Conception Consortium (EACC))
- Supported the Department of Health in negotiations on the Directives to make requirements relevant and appropriate for ART

- Engaged with centres providing Intra-Uterine Insemination (IUI) and Gamete Intra-Fallopian Transfer (GIFT) treatment by carrying out a scoping exercise to identify the likely numbers of centres new to regulation and issues from the sector's perspective
- Compiled a detailed implementation plan and developed costing proposals to support a strategy for fees that need to be charged to clinics
- Ensured planned approach to regulation under the Directive is consistent and cost-effective by working in collaboration with other organisations

### **Progress towards meeting 2006/7 Business Plan Objectives**

- Developed licensing and inspection procedures and a fee strategy to implement the Directive
- Commenced public consultation on the fee strategy
- Continued close working with the professional bodies around the Service Standards/possible changes to Service Standards based on outcome of the consultation on the Code of Practice
- Carried out preparatory work for the issue of new licenses and regional workshops for the sector have been planned
- Ensured preparation has continued for the implementation of the Directive by working with professional bodies and clinics to explain requirements by use of the Standards

### **Improving our data systems and the HFEA Register**

**Our aim is to progress the modernisation of the data systems and Register.**

#### **Actions in 2005/6**

- Completed the Historic Audit Project (HAP), with a comprehensive audit of all key data on offspring and donors. This has been a significant achievement with a total of 95.2% of all available records audited and 96% of relevant centres. The remaining percentage relates to records at centres which have been closed and where records cannot be located. The HAP has made a major contribution towards ensuring the consistency between centres and HFEA data

- Continued to roll out the Electronic Data Interchange, ensuring all clinics have the capacity to transmit timely and accurate data electronically to HFEA. This will improve the smooth exchange of information between centres and over time reduce the burden of regulation (at year end 60% of centres have systems installed)
- Modernised the Register, developed a new centres database and implemented an electronic records management system
- Created validation rules to evaluate the accuracy of data going into the Register

### **Progress towards meeting 2006/7 Business Plan Objectives**

- Continued to roll out the Electronic Data Interchange (EDI) to all clinics wishing to adopt the HFEA standalone version. The timescale for the full roll out of the EDI and automated billing process is 21 December. A recent Authority Directive will ensure that all documentation is submitted electronically from clinics to the HFEA from January 2007. This will improve the smooth exchange of information, ensure greater accuracy of data and in the medium term reduce the burden and cost of regulation. Feedback from the early users of EDI has been very positive.
- Register Project – The review of the validation rules and process is taking longer than anticipated and consuming additional resources. However, it is vital to get this process completed correctly to reduce/eliminate errors entering the Register in future. Over time, less resources will be required for error correction and Patients Guide to Infertility data verification
- Merged the HAP cleansed data back into the Register – again the cleansing data activity has taken longer than originally anticipated but the HAP data is now about to be merged into the Register
- Ensured centres have the ability to apply on-line for licenses – the functionality has been developed on behalf of the HTA and will benefit both organisations
- Implemented a new Content Management System (CMS) in June
- Developed a new Customer Relationship Management System (CRM) that stores all related contact information on a centre or individual in one place.

## **Improving patient information and choice**

**Our aim is to help patients improve their choice, knowledge and involvement.**

### **Actions in 2005/6**

- Delivered an on-line version of the 2005 Guide to Infertility, and raised awareness of the Guide with patients through targeted communication, marketing and advertising with audiences
- Implemented a Patient Communication Programme including setting up a new on-line Patient Consultative Panel (Fertility Views) to seek views and feedback from prospective, current and past patients
- Improved the HFEA website and electronic communication for patients, including more tailored information, such as fact sheets and published inspection reports
- Produced patient leaflets on key issues, such as travelling abroad for treatment
- Developed the 2006 Guide to Infertility and new format, building on patient feedback
- Produced a Parliamentary Briefing to inform Parliamentarians about HFEA's role and work
- Developed new contacts with GPs and Primary Care Trusts to publicise the HFEA's role in providing regulation and information
- Held an annual conference bringing together clinic staff, counsellors, patients, MPs and other stakeholders to address key issues affecting the regulation of the sector

### **Progress towards meeting 2006/7 Business Plan Objectives**

- Finalised Licence Committee reports are now published on the website within 10 working days (target is 15 working days)
- Presented the findings of a thematic review of the sector to the Authority (publication of inspection reports and the thematic review is being planned for the Autumn aimed at patients)

- Carried out launch and marketing activity for the HFEA Guide to Infertility
- Launched the new HFEA website geared at meeting needs of patients, donors and stakeholders
- Carried out Fertility Views (HFEA online patients' panel) survey

**Collaborate with Human Tissue Authority (HTA) in the move towards the creation of the Regulatory Authority for Tissue and Embryo (RATE)**

**Our aim is to develop close working relationships with the HTA to create joint working wherever possible in transition to RATE.**

**Actions in 2005/6**

- Provided a central HR service to the HTA covering recruitment, employment, employee relations, guidance and support
- Provided the HFEA's corporate governance policies and documents to ensure consistent policies and terms and conditions were applied in each organisation
- Held joint workshops on preparation requirements for the EUTCD to share knowledge and promote joint working where possible
- Provided corporate expertise by seconding staff to the HTA
- Provided a tailored legal service and expertise to the HTA

**Progress towards meeting 2006/7 Business Plan Objectives**

- The sharing of human resources and legal functions is now soundly established
- The HFEA has provided a finance function for the HTA from the beginning of July
- Significant work has taken place in respect of looking at integration of back office systems
- Strong commitment has been given to the Department of Health RATE Steering Group by offering capacity and expertise to identified project workstreams

## **Implement the changes in the removal of donor anonymity**

**Our aim is to provide reliable information and advice to donor conceived adults, donors and parents of donor-conceived offspring.**

### **Actions in 2005/6**

- Implemented safe, accessible processes to allow donor-conceived offspring to make applications for information on data held by the HFEA and handle such requests promptly and sensitively
- Conducted major policy reviews including public consultation on SEED
- Worked with professional bodies, patient groups and others to identify people's needs and awareness of ancillary services (counselling, mediation etc.). Also assessing the capacity and expertise in the provision of services
- Developed procedures and information resources for donors, donor-conceived adults and parents of donor-conceived offspring to facilitate understanding of their rights

### **Progress towards meeting 2006/7 Business Plan Objectives**

- Produced revised guidance given in the HFEA Code of Practice on SEED

## **Research Regulation**

**Our aim is to help improve public confidence in research, assisted conception and stem cell research**

### **Actions in 2005/6**

- Publicised HFEA's role in licensing research, the improvements we are making in streamlining our processes and the benefits of a strong system of regulation
- Improved public understanding of research regulation through media briefings and holding the third annual research conference
- Communicated HFEA's licensing of individual research applications, including reports on the HFEA website on how decisions have been taken
- Made available lay summaries of research licence applications granted and included how and why decisions have been made

- Extended the pool of peer reviewers internationally to capture further expertise to handle the increasingly complex area of research applications
- Evaluated and, where appropriate, licensed complex, novel applications
- Carried out a fundamental review of inspection methods and developed new protocols and processes to ensure rigorous but proportionate regulation

### **Progress towards meeting 2006/7 Business Plan Objectives**

- New processes for research regulation implemented
- Research Person Responsible (PR) Assessment has now been developed and was reported to Regulation Committee in October
- Research centres are incorporated into the unannounced inspection programme
- The annual meeting of the expert panel reviewing the peer review and HFEA processes post the Korean research incident took place in June
- Relevant speeches by the Chair and Chief Executive of the HFEA at key conferences on research regulation have taken place

### **Develop our policies**

**Our aim is to develop clear, evidence-based policies in order to increase stakeholders' confidence in the HFEA.**

### **Actions in 2005/6**

- Developed a new process for horizon-scanning for new scientific developments including an international expert panel to be more fully prepared to address future licensing issues
- Launched the review of multiple births with an international multi-disciplinary group to assess the implications in the United Kingdom
- Developed a project to understand the variation in success rates at clinics and areas in which this could be improved
- Produced detailed recommendations to the Department of Health on the review of future legislative requirements to ensure the effective regulation of ART

- Carried out a review of HFEA consent forms and made revisions following consultation with the sector
- Launched the Choices and Boundaries Review on Pre-Implantation Genetic Diagnosis (PGD) and late onset cancer with a dialogue with stakeholders and the general public
- Concluded reviews and produced comprehensive new guidance on SEED and the Welfare of the Child
- Worked with Medical Research Council and other bodies to develop approaches to facilitating and utilising research in assisted reproduction
- Reviewed the safety and efficacy of electronic witnessing equipment in IVF procedures

### **Progress towards meeting 2006/7 Business Plan Objectives**

- The Draft standards were published by April
- The Code of Practice was launched in September
- Public consultation
- Publication and launch of Choices and Boundaries Report on PGD
- Launched consultation on egg donation and research
- Conducted policy review on import of sperm from overseas, leading to new guidance

### **Develop the organisation and staff**

#### **Our aim is to develop our staff to improve the efficiency of the HFEA**

#### **Actions in 2005/6**

- Created an organisational development strategy covering the support of change management, developing a learning organisation, developing leadership, team building and cross team working, aligned to the principles of Investors in People
- Promoted staff involvement by establishing a staff forum with cross-departmental representation and improving internal communications through the intranet

- Improved training and development through a programme based on performance reviews, desired competencies, corporate objectives and accessing a wide range of in and out of house provision
- Improved recruitment and retention through job evaluation, career opportunities, analysis of exit questionnaires
- Carried out the second staff survey and developed an action plan with the Staff Forum
- Provided a comprehensive exit strategy to support the HAP project which ensured retention of 90% of HAP staff until project completion (particularly significant as staff were on fixed term contracts) and supported staff into their next appointment
- Delivered a significant change management programme which culminated in an all-staff development and achievement event
- Turnover rates reduced by 6% from 2004/05
- Sickness absence remained low at under 2.5%

#### **Progress towards meeting 2006/7 Business Plan Objectives**

- The Management Accounts were produced in accordance with the specified timetable, issues of concern were scrutinised by the Organisation and Finance Committee
- The balanced score card for Department of Health to support the monitoring of business plan is in place
- The closure of the HAP audit process was a significant achievement. The HR policies and training packages put in place for staff ensured very low staff turnover at project completion (which was a very critical time) the HR support was well appreciated by staff who left and those that remained
- The new employment age legislation is in force and awareness training has taken place
- A core training needs programme has been agreed by the senior management team with the actions that are necessary to ensure the organisation achieves its objectives
- Continuing to provide a comprehensive HR service to the HTA which matches the agreed Service Level Agreement

- Finance training/awareness for budget holders was carried out by the finance team and was well received
- The full roll out of the EDI and automated billing process is 21 December. A recent Authority Directive will ensure that all documentation is submitted electronically from centres to the HFEA in January 2007
- There has been significant progress on the equality and diversity agenda led by the Director of Policy and Communications, which was targeted at all levels within the organisation. A training programme has been developed and rolled out to staff and Authority members
- A senior management team/heads of department workshop event took place the beginning of September to discuss ideas for developing an internal communications plan. The Staff Forum will now play a key role in taking this forward

### **Ensuring effective management**

**Our aim is to maintain robust financial management and corporate governance to increase efficiency and reduce costs**

#### **Actions in 2005/6**

- Developed and implemented a coherent plan to achieve savings required by the Arms Length Bodies (ALB) Review Team budgetary framework
- Management of working capital by ensuring prompt collection of fees due
- Proposed a framework for fees for EUTCD regulation of gametes and embryos, based on a pilot exercise to assess the scale of work involved
- Put clear plans in place to achieve the ALB headcount reduction by March 2007

#### **Progress towards meeting 2006/7 Business Plan Objectives**

- Developed and implemented a coherent plan to achieve savings required by the ALB Review Team budgetary framework
- Regular meetings have taken place with budget holders and the activity costing model is now an integral part of the business planning process
- A review of the 2005/06 Risk Register has been completed and communicated to Audit Committee and Heads of Service

- All audit recommendations from the internal auditors Kingston Smith LLP (05/06) have been prioritised and appropriate action taken
- The Annual Report and full set of accounts was produced by the end of June, certified by the end of July and laid before Parliament's summer recess
- Reports to ALB team are provided as requested and there has been strong engagement regarding the template and scrutiny over the figures
- The percentage of invoices paid is 90% at half year against a target of 95%. This reduction is primarily due to resources being diverted to EDI automated billing and other key finance workstreams, which should result in longer term benefits for the organisation
- The financial modelling for the EUTCD is complete and fees consultation exercise taking place
- Management of working capital by ensuring prompt collection of fees due
- Proposed a framework for fees for EUTCD regulation of gametes and embryos, based on a pilot exercise to assess the scale of work involved
- Put clear plans in place to achieve the ALB headcount reduction by March 2007

### **Longer term goals**

The following goals are contained within the Authority's Strategic Plan 2004-9. These are broad goals for the HFEA until RATE is set up:

- Strengthening our regulatory role
- Being an open organisation through excellent communication and working in partnership with stakeholders
- Working closely with other regulators and international agencies
- Strengthening the process of policy development
- Developing an information base, which meets the needs of the offspring, stakeholders and the wider regulation and public health functions, and supports the delivery of services to required standards

- Supporting the development of research in assisted conception and its application
- Developing an organisation that will fulfil these goals supported by strong corporate governance

**ANNEX 1**

**Performance Indicators – Achievements from April 05 to March 06, including 06 April to September 06**

<b>A. Inspection and Regulation</b>	<b>Target 2005/06</b>	<b>Achieved 2005/06</b>	<b>Target 2006/07</b>	<b>Achieved April-September</b>
No. of random unannounced inspections carried out in the year	4	7	4	2
Reports resulting from inspection of treatment centres available to centre within 20 working days of the inspection date (28 working days in 2006/7)	90%	73%*	90%	91.6%
Reports resulting from research inspections available to centre within 4 weeks	90%	90%	90%	100%
Alerts issued within 21 working days	90%	3 alerts issued	No longer a performance indicator in 06/07	
New licence applications processed within 4 months of receipt	90%	90%	90%	100%
Research licence applications processed within 3 months of receipt of complete application & peer review	90%	100%	10%	To be assessed at year end following roll out of inspection process
Reduction in items of information required from clinics during the inspection process	20%	Achieved		
<b>B. Communication and Information</b>				
Patient/public enquiries replied to within 3 working days	95%	90% **	95%	84.1%
Number of Authority meetings held in public during the year	3	3	3	2
Number of stakeholder events	7	8	7	4
Freedom of information requests dealt with 20 working days	100%	100%	100%	100%

<b>C. Corporate</b>				
Invoices paid within 30 days from receipt of invoice	95%	93%	95%	90%
Debts collected within 65 days from date of invoice	85%	83%	85%	88%
Monthly billings of clinics achieved in three weeks from the end of the month in which treatment forms are submitted	100%	100%	100%	100%
<b>D. ALB Targets</b>				
Reduce revenue costs to £8.4m	On target	On target	On target	On target
Reduce headcount to 79.1 (by March 07)		On target		On target
Assess shared services potential for back-office study of finance	N/A	Complete (HR function not viable for shared service) Finance & HR functions shared with the HTA.	N/A	Complete (HR function not viable for shared service) Finance & HR functions shared with the HTA

\* A fundamental review of regulatory practices was carried out during the year, and virtually an entirely new inspection team appointed. The out-turn figure of 73% against a target of 90% is understandable due to this, and is an improvement on the 2004/5 out-turn at 72%

\*\* Slight performance decline due to staff turnover and need to train new staff

### Business Plan Objectives for 2005/06

- To undertake within the HFEA's modernisation a strategic drive to more cost-effective, efficient, targeted and streamlined regulation. This will fulfil the requirements of the ALB review to reduce costs and will meet the principles of proportionality set out by the Better Regulation Taskforce. The use of risk indicators which have been under development will be a key element in this programme.
- To drive forward the implementation of the EUTCD, providing detailed guidance for centres, working with those centres not previously regulated by the Authority, and agreeing processes with the professional bodies.
- To further progress the major modernisation programme of its data system and register. As we enter the last 18 months of this project we will move from focusing on "data validation and accessibility" to information and knowledge management. This will ultimately underpin our regulation and policy work.
- To advance the HFEA's work with empowering patients facilitating choice, knowledge and inclusion
- The HFEA will work with the newly established HTA developing close and integrated working wherever appropriate. Both organisations will come together to establish the combined organisation, the Regulatory Authority for Fertility and Tissue ( RAFT) in three years time following the review of the HFE Act
- To implement the changes in legislation following removal of donor anonymity
- To fully implement the Freedom of Information Act
- To support and respond to the review of the HFE Act and the report of the House of Commons Select Committee on Science & Technology

### **Business Plan Objectives for 2006/07**

The key objectives for 2006/07 are:

- Provide proportionate more cost-effective, targeted and risk-based regulation to be seen as a model regulator
- Drive forward the implementation of the EUTCD and lead the European Committee in addressing this
- Provide reliable information and advice to donor-conceived adults and donors
- Empower patients and inform patients of future choices
- Strengthen relationships with key stakeholders by better engagement
- Develop public understanding and confidence in research on assisted conception and stem cell research
- Develop close working relationships with HTA to create integral working wherever possible in readiness for the transition to RATE
- Develop the 7<sup>th</sup> edition Code of Practice, incorporating professionally agreed standards to meet requirements of the EUTCD and Better Regulation Taskforce objectives
- Maintain robust financial and staff management and corporate governance to increase efficiency and reduce costs

All of these objectives will be underpinned by detailed operational plans. The challenge for the HFEA will continue to be delivering on an increasingly complex, demanding agenda against a backdrop of continuing financial constraint.

**List of Authority Members as at September 2006**

Lord Richard Harries of Pentregarth (**Interim Chair**)

Ms Sharmila Nebhrajani (**Deputy Chair**)

Mr Hossam Abdalla

Professor David Archard

Professor David Barlow

Professor Christopher Barratt

Mr Ivor Brecker

Ms Clare Brown

Professor Iain Cameron

Mrs Ruth Fasht OBE

Professor Neva Haites

Ms Jennifer Hunt

Professor Emily Jackson

Dr Maybeth Jamieson

Mrs Jane Jeffs

Sir Simon Jenkins

Mr Walter Merricks

Ms Sara Nathan

Dr Sue Price