



# Business Plan 2008-2009

Human Fertilisation and Embryology Authority

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## Foreword

Our Business Plan describes what we achieved in 2007-2008, what we intend to achieve in 2008-2009, and how all of our work links together.

2007-2008 was a year of challenge. We issued the 7<sup>th</sup> edition of the Code of Practice whilst reducing the burden of regulation. We put into effect the European Union Tissue and Cells Directive whilst reducing our staff. We extended our policy guidance on complex and highly-charged areas firmly in the public eye, whilst retaining broad support for our work as a regulator. We maintained our level of activity and performance whilst experiencing several senior personnel moves.

2008-2009 will be a year of change. Change arising from the new Human Fertilisation and Embryology (HFE) Bill. Change growing out of Programme 2010 which is designed to make the HFEA fit for purpose as a world leading regulator in healthcare.

We can be proud of what our successes were in 2007-2008. The quality of our staff and the breadth of our achievements give me every confidence that we will deliver the change that is needed in 2008-2009.



Alan Doran CB  
Interim Chief Executive



## Purpose and Role of HFEA

The Human Fertilisation and Embryology Authority is the UK's independent regulator overseeing the use of gametes and embryos in fertility treatment and research. The HFEA licenses clinics and research establishments carrying out In Vitro Fertilisation (IVF), other assisted conception procedures and human embryo research, and provides a range of detailed information for patients, professionals, the public and Government.

The HFEA's aim is to be a leading healthcare regulator exercising its functions fairly and proportionately, supplying good quality, relevant and accessible information to all its stakeholders.

## Statutory Functions

The HFEA has a number of statutory functions. They are based on two specific roles: firstly the licensing and regulation of clinics and research establishments providing treatment, storage and research; and secondly, the maintenance and publication of information about donor treatment and assisted conception.

Parliament is currently considering the Human Fertilisation and Embryology (HFE) Bill. Therefore, the HFEA's functions may be subject to change in light of this forthcoming legislation. At present, the statutory functions are:

- To license and monitor clinics carrying out in vitro fertilisation and donor insemination.
- To license and monitor establishments undertaking human embryo research.
- To regulate the storage of gametes (eggs and sperm) and embryos.
- To implement the requirements of the European Union Tissue and Cells Directive (EUTCD) to relicense In Vitro Fertilisation (IVF) clinics and to license Intrauterine Insemination (IUI), Gamete Intrafallopian Transfer (GIFT) and other services new to regulation (in 2007).
- To produce and maintain a Code of Practice, providing guidelines to clinics and research establishments about the proper conduct of licensed activities.
- To maintain a formal register of information about donors, treatments and children born as a result of those treatments.
- To publicise the HFEA's role and provide relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients, including servicing the statutory right of access to register information.
- To review information about:
  - Human embryos and developments in research involving human embryos
  - The provision of treatment services and activities governed by the Human Fertilisation and Embryology (HFE) Act 1990 (or a revised Act, if and when this comes into force).
- Where appropriate, to advise the Secretary of State for Health on developments in the above fields.

## Looking Back

During the past year, the HFEA has worked hard to deliver its 2007-2008 business plan, and to drive improvements. The HFEA has continued to work with other regulators, including joint working with the Healthcare Commission and participation in the EU project on regulation known as EUSTITE (European Union Standards and Training in the Inspection of Tissue Establishments). Some of the main achievements are outlined in this section.

### Risk-Based Inspection

A revised risk assessment tool was produced, and Person Responsible (PR) assessments were carried out and feedback obtained from PRs after inspections. A new PR assessment procedure was also implemented for research establishments.

### European Union Tissue and Cells Directive (EUTCD)

Clinics that were newly regulated under the EUTCD were successfully integrated into regulatory activity.

### Hybrids

The HFEA undertook widespread public dialogue on the use of hybrid embryos in research, with support from Sciencewise, a government programme funded by the Department of Innovation, Universities and Skills. A public report on this was then produced. This work led to a policy decision on how the HFEA should approach the licensing of interspecies embryos for research.

### Multiple Births

An HFEA policy was also developed on reducing multiple births in assisted reproduction, in partnership with the sector.

### Code of Practice

The 7th edition of the Code of Practice was issued for licensed clinics and research establishments, and a web-based interactive edition was published, so as to increase accessibility.

The HFEA continues to operate across a wide range of areas. Some further achievements from the 2007-2008 business plan include:

- Incident Reporting
  - Implementation of electronic incident reporting by licensed clinics and a review of the findings of research inspections.
- Horizon Scanning
  - Identified priority areas of scientific embryology research and practice. Provided support and advice to the European Assisted Conception Consortium (EACC).
- Better Regulation
  - Developed a model process for conducting impact assessments and costing the implications of simplification plans.

- Electronic Data Interchange
  - Provided training and support to licensed clinics in the use of Electronic Data Interchange (EDI) to improve the accuracy of data submitted.
- Freedom of Information and Opening the Register Requests
  - Continued to manage the increasing number of requests made under the Freedom of Information Act 2000.
  - Continued to respond to Opening the Register and other requests.
  - Finalised a number of outstanding legal actions.

A major part of the HFEA's role is communications. In 2007-2008, the HFEA:

- Published a range of communications materials, in print and on the web.
- Introduced a Diversity Update for the sector.
- Completed and published a review of the HFEA's policy on the use of eggs in research.
- Published a report on horizon scanning issues considered in 2005 and 2006.

In addition the HFEA provided support to the Human Tissue Authority (HTA) for Human Resources, Finance, IT and Legal Services.

### Facts and Figures:

Clinics and research establishments inspected	119
New licence applications processed	43
Licence renewals processed	49
Applications for Preimplantation Genetic Diagnosis (PGD) processed	17
Services new to regulation integrated into regulatory activity under the European Union Tissue and Cells Directive (EUTCD)	35
Clinics relicensed under the EUTCD	116
Research inspection reports published on the HFEA website	11
Licensed Centres Panel meetings held	3
Meetings held with Patient Organisations	3
Fertility Views Panel surveys conducted	1
Public and stakeholder consultation meetings on multiple births and single embryo transfer	5
Freedom of Information requests dealt with	150
Opening the Register requests dealt with	65
Enquiries responded to under the Data Protection Act	16
Enquiries responded to under the Environmental Information Regulations	1
Number of Authority meetings held (including 3 open to the public)	9
Phone and email enquiries dealt with from patients and the general public	18,118
Phone and email enquiries from clinics and research establishments dealt with by inspectors	4,482
Number of visits to the HFEA website	449,048

## Corporate Goals 2004 - 2009

The current 5 year corporate strategy (published as the HFEA's Corporate Plan for 2004-2009), has been regularly reviewed and updated to take into account new legislation and other events with a key impact on the HFEA's role.

The current corporate goals, set out below, were revised in 2006 to reflect the intention to create a Regulatory Authority for Tissue and Embryos (RATE), in or before 2009. However, in response to the Report from the Joint Committee on the Human Tissue and Embryos (draft) Bill, the Government withdrew the proposal to create RATE. The HFEA intends to develop a new medium to long term strategy during the 2008-2009 business year. This will set out fresh corporate strategic goals for the future, and will be informed by the legislative changes going through Parliament, and the HFEA's Programme 2010 organisational development work programme.

### **Current corporate goals (2004-2009):**

1. Reducing the cost and burden of regulation and ensuring that it is proportionate, targeted and risk-based.
2. Preparing the organisation for transition to the Regulatory Authority for Tissue and Embryos (RATE), and for regulating against the changing demands of new legislation. *(The first half of this corporate strategic aim is no longer applicable, but regulating against changing demands is one of the main themes for 2008-2009).*
3. Being an open organisation, through excellent communications and working in partnership with stakeholders.
4. Working closely with other regulators and with international agencies.
5. Strengthening the process of policy development.
6. Developing an information base which meets the needs of offspring, stakeholders, and the wider regulation and public health functions.
7. Supporting the development of research in assisted conception, and its application.
8. Developing an organisation, which will fulfil these goals, supported by strong corporate governance.

## Looking Forward

The HFEA starts the 2008-2009 business year with a clear sense of looking to the future. The plan for a new regulator for tissues and embryos, the Regulatory Authority for Tissue and Embryos (RATE), is no longer to be included in the planned new Human Fertilisation and Embryology (HFE) Act. However many aspects of the new HFE Act being proposed by the Government will change the functions of the HFEA in other ways, and so 2008-2009 will be a time of change.

The HFEA will now continue as an independent, stand-alone regulator, whose future direction will be established by the new HFE Act, if and when it comes into force.

The main challenges for the HFEA over the next twelve months and beyond will be to perform its statutory functions whilst managing the work arising from the HFE Bill. In addition, there is other important work to be done about improving access to HFEA Register data, and to improve the information the HFEA provides about fertility treatments. These challenges are addressed in the four strategic objectives set out below.

In 2008-2009, the HFEA will aim to:

- A. Continuously improve the effectiveness of regulation, information to support patient choice, and the policy framework.
- B. Be ready to put the new HFE Act into effect in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating processes and procedures.
- C. Raise the quality of the information the HFEA makes available to each of its stakeholders, including patients, the public, clinics, donors and donor-conceived individuals.
- D. Ensure that the HFEA is able to offer the best guidance on existing and new fertility treatments through evidence based decision making, monitoring existing research, and horizon scanning for scientific developments.

# Objectives for 2008-2009

The objectives outlined above are a clear statement of the strategy the HFEA is following over the coming year and beyond. In 2008-09 there are specific and tangible outcomes expected. To ensure that these are met, the HFEA has agreed the following activities and deliverables under each objective.

**Please note:** The timescales originally published for 2008/09 have been revised following a delay to the HFE Bill. It was originally anticipated that the new HFE Act would gain Royal Assent in July 2008. The parliamentary timetable for the Bill subsequently changed, and so timelines for delivering related work were amended accordingly, in November 2008.

## Objective A

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**Continuously improve the effectiveness of regulation, information to support patient choice, and the policy framework.**

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### Regulation

The HFEA will further streamline information requirements and develop a wider range of performance measures. The HFEA will also ensure that European Union Tissue and Cells Directive (EUTCD) requirements are met by all applicable licensed services, and target breaches of requirements proportionately according to risks to patients, gametes and embryos.

### Patient Information

The HFEA is aiming for continuous improvement in information for patients and donors, in particular a requirement for licensed clinics to provide each patient with a costed treatment plan, ahead of treatment. The introduction of this requirement is a high priority for patients. The HFEA will be planning this initiative in conjunction with stakeholders in 2008-2009, with implementation in 2009-2010. This is part of a

longer term piece of work to review information provided through the website and through other means for patients, donors, the donor-conceived and other audiences.

### Policy Framework

The Regulatory Enforcement and Sanctions (RES) Bill will greatly affect the policy framework and regulatory requirements placed on licensed clinics and research establishments. The RES Bill will need to be reviewed and the better regulation agenda placed at the forefront of the drive to continuously improve the policy framework. Furthermore, the policy framework will need to reflect the multiple births decision and ensure strong ties and cooperation with the sector.

Objective	Activity	Deliverables and outcomes	Timescale
<b>Regulation</b>	Managing the increased inspection volume resulting from the addition of newly regulated clinics and services, following the introduction of the European Union Tissue and Cells Directive (EUTCD).	Appropriate management and control of the inspection workload.	Throughout year
		114 inspections <sup>1</sup> of licensed clinics and research establishments (53 renewal inspections and 61 interim inspections).	End of March 2009
		Newly regulated clinics and services gain a better understanding and experience of the inspection process, and start to improve towards the standard of the rest of the sector <sup>2</sup> .	End of March 2009
	Developing standard competencies for the inspection process.	The HFEA's inspectors are able to work towards achieving standard competencies in inspection processes (this work comprises part of a wider review of inspection).	Commenced July 2008; ongoing to October 2009 (2009/10 Business Plan)

<sup>1</sup> Some clinics and research establishments were subsequently granted an inspection holiday – final statistics are: 52 renewals, 57 interim inspections and 4 random unannounced inspections, totalling 113.

<sup>2</sup> The newly regulated services should show the same profile of medium to high risk as for other clinics by April 2010.

Objective	Activity	Deliverables and outcomes	Timescale
		Continual improvement of quality and consistency of inspections.	From April 2009 onwards (2009/10 Business Plan)
	Maintaining joint working and dialogue with key professional stakeholders from the sector and patient organisations.	Effective communication with key stakeholders and organisations.	Throughout year
		Surveys of patients through online Fertility Views Panel.	2 surveys during year
		Licensed Centres Panel meetings.	3 times during year
		Continuing to survey the Persons Responsible (PRs) of licensed clinics and research establishments, as a matter of routine, to measure satisfaction with: inspection process; the level of information received from the HFEA; and the HFEA's communications with clinics.  Increased patient and sector confidence in the effectiveness and proportionality of regulation, as indicated by the above surveys.	End of March 2009
	Joint working with other regulators, including joint inspections in accordance with the Concordat.	Effective work with other agencies to encourage safe and continually improving treatments.	Throughout year

Objective	Activity	Deliverables and outcomes	Timescale
	<p>Participation in the European Union Standards and Training in the Inspection of Tissue Establishments (EUSTITE) project, and implementation of its outcomes.</p>	<p>Outcomes of EUSTITE: EUSTITE inspection tool piloted, ready for next stage of work.</p> <p>Internationally accessible register of HFEA licensed clinics and research establishments.</p> <p>Plan for European-wide guidance and training on undertaking inspections under the EUTCD. Development of European-wide standards and a tool for reporting certain adverse incidents to the European Commission.</p>	<p>Ongoing to November 2009 (2009/10 Business Plan)</p> <p>Addressed June 2008 through the European Registry for Organs, Tissues and Cells – the Eurocet Register of centres</p> <p>End of March 2009 and beyond <sup>1</sup></p>
<b>Patient Information</b>	<p>Responding to requests for information from the Register of treatments and outcomes (including information about patients, donors and donor-conceived individuals), in a timely and sensitive manner and ensuring that data held is accurate.</p>	<p>‘Opening the Register’ requests continue to be met within the required time limits (20 working days, excluding time for counselling).</p> <p>Training and support for frontline staff.</p>	<p>Throughout year</p>
	<p>Information provision in response to Freedom of Information (FOI) requests.</p>	<p>FOI requests continue to be met within the required time limits (20 working days).</p>	<p>Throughout year</p>

<sup>1</sup> The EUSTITE work will continue until January 2010.

Objective	Activity	Deliverables and outcomes	Timescale
	Provision of a national picture of sector performance.	Revised version of the Find a Clinic function developed through a consultation process with patient groups and licensed clinics.	Consultation from July 2008 Implementation October 2009 (2009/10 Business Plan)
	Establishing a clear requirement in the Code of Practice for licensed clinics to provide patients with written costed treatment plans.	Clarity for patients about the prospective costs of treatment. New section in Code of Practice.	Developed July 2008 – June 2009; published July 2009; implementation October 2009 (2009/10 Business Plan)
		Patient views gathered (in the course of developing the new Code of Practice) by February 2009; compliance with the new requirement by October 2009.	February 2009 and October 2009 (2009/10 Business Plan)
	Review information provided through the website for donors, patients and other audiences.	Improved information for patients and others.	July 2008 – end of March 2009
<b>Policy Framework</b>	Continued development and updating of the current edition of the Code of Practice (and see objective B below for the review of the Code of Practice necessitated by the HFE Bill).	A Code of Practice which continues to reflect current policies and regulatory requirements, including those associated with the Better Regulation initiative.	Ongoing work
	Improved processes for policy development including transparency, assessment of impact, implementation and evaluation.	Policies which are more robust, and which are fully assessed.	End of March 2009

Objective	Activity	Deliverables and outcomes	Timescale
	Responding to the Regulators' Compliance Code and new legal duties.	Achievement of compliance with new statutory duties under the Regulators' Compliance Code.	Hampton Review February 2009
	Ongoing implementation and co-ordination of new ways of working in response to the Better Regulation agenda and the Regulatory Enforcement and Sanctions (RES) Bill.	Implementation of a process for conducting impact assessments. The HFEA is able to contribute to Department of Health simplification plans and three year regulatory budget.	December 2008
		Self-regulation against DH External Gateway principles <sup>1</sup> for all national NHS communications to prevent imposing excessive burdens on front-line services and ensure consistent and deliverable policy is promulgated.	April 2008 onwards (ongoing)
		The HFEA is in a state of readiness to apply for new regulatory enforcement powers.	December 2008 through to Hampton Review in February 2009 (and beyond)

<sup>1</sup> Gateway criteria cover, inter alia, processes which ensure that policies and guidance are impact assessed (equality and economic cost impacts), affordable, outcome focussed, consistent with wider government policy (e.g. the current priorities and the performance frameworks), clear in terms of purpose, and that they are communicated in a targeted and succinct manner. An audit trail of gateway decisions will be kept to inform Balance Scorecard performance monitoring from April 2008.

Objective	Activity	Deliverables and outcomes	Timescale
	Planning for any increased powers and additional sanctions (which will apply in England and Wales).	<p>Any additional powers and sanctions applied for by the HFEA.</p> <p>Agreed list of Authority decisions about the tariff of enforcement sanctions.</p> <p>The HFEA has in place an implementation plan to enable it to exercise any additional powers applied for under the RES Bill, making regulation of the sector more effective, targeted and proportionate.</p>	<p>End of January 2009</p> <p>April 2009</p> <p>November 2009 (2009/10 Business Plan). It is anticipated that powers would be awarded no earlier than April 2010.</p>
	Improving processes for licensing, regulation and appeals (including usage of the independent appeals panel to be proposed by the HFE Bill).	Advice to Department of Health on draft set of appeals regulations.	July 2008
		Up to date, appropriate and effective processes.	End of March 2009
	To respond to new requirements relating to European coding and traceability for gametes.	New standards and guidance for clinics on coding and traceability. (Please note: This outcome will be dependent on European Commission decisions which are expected during the 2008/09 business year.)	Not yet known (external dependency)

## Objective B

**Be ready to put the new HFE Act into effect in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating processes and procedures.**

### **Reviewing and Updating the Code of Practice**

The new HFE Act proposes specific changes in policy areas covered by the HFEA and the guidance within the Code of Practice. A key action therefore, will be to work with the sector to identify the changes needed to the Code of Practice and implement these as soon as is reasonably possible. This must build on the successes of the 7<sup>th</sup> Edition, particularly the internet based application.

### **Redesigning the Functions of the HFEA**

Now that the HFE Bill has removed the proposal to create the Regulatory Authority for Tissue and Embryos (RATE), amendments to the activities currently covered by the HFE Act 1990 will be realised by the HFEA. Under the proposed new HFE Act, the HFEA will take on additional responsibilities; for example, decision making powers on activities such as licensing are expected to be delegated to the Executive. The HFEA will need to undertake an extensive organisational development programme to ensure the extended functions are carried out effectively and efficiently.

### **Updating Processes and Procedures**

One of the main outcomes of the end of planning for RATE is that the HFEA can begin to develop as a regulator fit for the challenges of the 21<sup>st</sup> Century. Updating processes and procedures are central to this objective, with immediate action being taken to begin a review of the fee structure. Gradually all practices will be reviewed to be compliant with the new Act and the vision of a leading regulator.

Objective	Activity	Deliverables and outcomes	Timescale
<p><b>Reviewing and updating the Code of Practice</b></p>	<p>Working in conjunction with the sector to revise the Code of Practice in line with the new HFE Act, including a review of format and effectiveness.</p>	<p>8<sup>th</sup> Edition of Code of Practice, streamlining the information load for the sector. Slimmer and clearer Code of Practice.</p>	<p>Development throughout 2008/09. Publication July 2009; implementation October 2009 (2009/10 Business Plan)</p>
	<p>Ensuring there is clarity with regard to enforcement of the Code, so that stakeholders are clear what constitutes a breach, and how breaches will be dealt with by the HFEA.</p>	<p>Better compliance and greater consistency of enforcement.</p>	<p>Ongoing to October 2009 (2009/10 Business Plan)</p>
	<p>Improving the distinction between standards and guidance.</p>	<p>Standards and guidance that reflect the HFE Act 1990 (as amended) and give clarity to the sector.</p>	<p>Publication July 2009</p>
<p><b>Redesigning the functions of the HFEA</b></p>	<p>Advising the Department of Health on proposed changes during the passage of the HFE Bill.</p>	<p>Influencing the development of the HFE Bill so that it is effective, proportionate, workable and gives a clear framework for the HFEA's ongoing effectiveness as a regulator.</p>	<p>November 2008</p>
	<p>Planning for and implementing changes in HFEA regulatory practices arising from the new HFE Act and subsequent regulations.</p>	<p>HFEA functions are equipped and ready to take on additional responsibilities relating to the new HFE Act. New policies developed and put in place to deliver the new HFE Act. Authority members and the organisation are equipped and prepared to implement the additional responsibilities related to the new HFE Act.</p>	<p>Ongoing to October 2009 (2009/10 Business Plan)</p>

Objective	Activity	Deliverables and outcomes	Timescale
	A major review of information issues raised by the new HFE Act, including a revised policy on opening up access to Register information.	Clear policies and procedures to address the range of new information issues. Preparedness for the implementation of the new HFE Act and the widening of access to the Register of treatment and outcome information.	Ongoing to October 2009 (2009/10 Business Plan)
	Project to address a range of issues about consent, raised by the HFE Bill, incorporating feedback from clinic staff and inspectors on current consent forms.	Revised consent forms and accompanying guidance, which reflect the requirements of the new HFE Act and HFEA policy.	Development throughout 2008/09. Publication July 2009; implementation October 2009 (2009/10 Business Plan)
<b>Updating HFEA processes and procedures</b>	Reassess the overarching fee strategy of the HFEA to ensure adherence to modern requirements of regulation and fee setting, taking into account the views of all interested parties.	Improved transparency and clarity about fees within the sector <sup>1</sup> . Updated fee structure to reflect new powers in the HFE Bill (for example, charges to researchers for provision of Register information).	Initial work to establish approach by end of March 2009; further work during 2009/10 business year

<sup>1</sup> Ultimately, (in the 2009-2010 business year) the aim will be to create a fee structure that will support the HFEA's work, and will be compliant, consistent, efficient, and developed with appropriate consultation with the sector.

Objective	Activity	Deliverables and outcomes	Timescale
	Updating processes and procedures in line with the new HFE Act, through a programme of organisational development and change management.	Successful development and implementation of new ways of working to meet the requirements of the new HFE Act. Workforce trained and equipped for delivery under the new legislation (including new European legislation). Improved efficiency in HFEA processes.	End of March 2009, and beyond
	Clarifying licensing mechanisms.	Establishing new processes and developing a new regulatory framework.	End of March 2009, and further work during 2009/10 business year

## Objective C

**Raise the quality of the information the HFEA makes available to each of its stakeholders, including patients, the public, clinics, donors and donor-conceived individuals.**

### **Patients**

The HFEA will provide up to date and clear information in response to patients' information needs. 2007-2008 saw the publication of Find a Clinic data for 2005 and first half-year figures for 2007 as a result of Electronic Data Interchange (EDI). Further improvement in data quality for patients will be driven by speedier publication of 2006 Find a Clinic data, and the publication of full year figures for 2007. Further, by using EDI, the HFEA will aim to move towards a more regular publication of in-year early pregnancy data through 2008 and beyond.

### **Public**

The HFEA will continue to answer FOI requests in line with statutory obligations. The organisation will be reviewing its obligations in light of the requirements of the HFE Bill. The HFEA will also continue to monitor and incorporate the public's views on fertility treatment and embryo research issues, so that the information provided to them addresses their interests and concerns. The HFEA will work to improve the way enquiries from the public are responded to, and the ways in which policy decisions and information about new developments in the sector are communicated through the HFEA's website and publications.

### **Clinics**

The use of EDI by clinics will drive improvements in data quality. Controls within EDI will reduce the number of errors received by the HFEA. The use of new reporting tools will allow the HFEA to make better use of the information contained in the Register, supporting more holistic reporting and balanced scorecard initiatives.

### **Donors and the Donor-Conceived**

Opening the Register processes will be reviewed and updated to take into account the wider information provisions contained in the HFE Bill. This will relate to donors, the donor-conceived, offspring and siblings.

Objective	Activities	Deliverables and outcomes	Timescale
<b>Patients</b>	Continuing to consult on current fertility services and new developments, and to gather views from key audiences and stakeholders.	More responsive information produced and provided.	Throughout year
	Improving patients' access to good information through new web-based briefings, the interactive guide to licensed clinics, inspection reports, the Patient's Guide, and increased publicising of the HFEA's role.	Clear, effective and timely information is provided to patients. Key communications materials are accurate, relevant, well presented, accessible and produced on schedule.	End of March 2009
	Completing the Review of Information, encompassing the collection, analysis and publication of performance data about licensed clinics, Find a Clinic and thematic reviews.	Find a Clinic (or its successor) is developed to be more user friendly for patients, and contains more timely and relevant information.	Consultation and development work from September 2008  Implementation October 2009 (2009/10 Business Plan)
		Thematic review.	End of March 2009, and ongoing
<b>Public</b>	Putting in place new protocols to address the widening in groups of people who can access the Register.	The HFEA is able to respond to the widening of access to the Register (within 20 days, excluding time for counselling).	Throughout 2008/09 business year; disclosure policies in place October 2009 (2009/10 Business Plan)

Objective	Activities	Deliverables and outcomes	Timescale
Clinics	A Review of Information, including performance measurement and the reporting of outcome data and success rates for publication, and the development of a holistic approach to clinic success.	<p>Roll out of a holistic view of performance for all licensed clinics.</p> <p>Information that drives improvements in sector performance and raises clinics' self-awareness of their own relative performance (e.g. enhanced performance reporting in inspection reports).</p> <p>Greater usability of HFEA assessment results for the sector, and for patients.</p>	Ongoing to October 2009 (2009/10 Business Plan)
	Consideration of the HFEA's role in relation to releasing Register data to researchers, and related consent issues.	<p>A clear policy position on the provision of information to researchers.</p> <p>Processes to enable data to be released in accordance with policy.</p>	<p>March 2009</p> <p>October 2009</p>
	Development of greater standardisation, consolidation, simplification, and automation in HFEA information systems, and continuing work to maximise the potential of Electronic Data Interchange (EDI).	<p>Upgraded version of EDI rolled out to licensed clinics, incorporating improved functionality, leading to more accurate data.</p> <p>Improved reporting, accuracy and communications with clinics.</p>	<p>December 2008</p> <p>End of March 2009</p>
	Development of greater efficiency in managing internal information, leading to better coordinated contact management with all the HFEA's stakeholders.	<p>Implementation of a Customer Relationship Management (CRM) system.</p> <p>Improved methods for capturing internal knowledge.</p>	<p>December 2008</p> <p>End of March 2009; and further work in 2009/10 business year</p>

Objective	Activities	Deliverables and outcomes	Timescale
<b>Donors and the Donor-Conceived</b>	Publicity and awareness-raising about the widening of access to the Register of treatment and outcome information, and the information the donor-conceived can obtain.	Public are aware of their rights with respect to accessing register information. The HFEA is able sensitively to fulfil its statutory obligations to provide data to the donor-conceived.	Ongoing to October 2009 (2009/10 Business Plan)

## Objective D

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**Ensure that the HFEA is able to offer the best guidance on existing and new fertility treatments through evidence based decision making, monitoring existing research, and horizon scanning for scientific developments.**

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### **Evidence-based decision making**

To improve the HFEA's policy making through public consultation, dialogue with professional bodies, utilising evidence and expertise in order to ensure the best guidance is supplied. Areas for the coming year include multiple births, preimplantation genetic screening (PGS), consent issues, and other issues arising from the HFE Bill.

### **Monitoring existing research**

To provide the best guidance on existing and new fertility treatments, the HFEA will continue to monitor the progress reports submitted by research establishments. Outcomes of research will be used to inform the decision-making process regarding existing and new fertility treatments.

### **Horizon scanning**

In order to provide the best possible advice and guidance on research, and on new and existing fertility treatments, the HFEA will keep – through stakeholders, the sector and the public – a watching brief over scientific priorities and emerging techniques, such as cloning, and public dialogue on new developments in embryo research.

Objective	Activities	Deliverables and outcomes	Timescale
<b>Evidence-based decision making</b>	Continued work through the Scientific and Clinical Advances Group to support evidence based decision making by the Authority. (Process includes gathering and assessing evidence via literature reviews, seeking views from professional bodies, examining success rates, and evidence from scientific journals).	Decisions based on scientific evidence and informed expert views.	Throughout the year.
	Improving the HFEA's dialogue with the public.	Policies developed on a sound evidence-base including input from the public.  Clear, proportionate policies which incorporate due consideration to diversity issues, are effectively communicated and are capable of being implemented.	Throughout the year.
	Coordinating in conjunction with professional and patient bodies a national strategy for the reduction of multiple births, and a major communications campaign for patients and clinic staff.	Improved awareness of the multiple births policy, its rationale and its implications among patients, stakeholders and the public.	April 2008, and ongoing
		Policy on multiple births implemented in the sector.	January 2009
<b>Monitoring existing research</b>	Monitoring of research licences through progress reports and the research inspection process.	Research continues to be carried out legally.	Throughout the year
	Continue to monitor patient information on new and existing fertility treatments to ensure it is up to date and accurate, and review how research regulation and research policy information are published and communicated.	Up to date and accurate guidance for the public.  Increased public knowledge and understanding of research regulation and policy issues.	Throughout the year

Objective	Activities	Deliverables and outcomes	Timescale
	Review of HFEA research regulation.	The HFEA ensures the intentions of Parliament are met. Public confidence is maintained.	Review of research regulation complete by end of February 2009
<b>Horizon scanning</b>	Identification of scientific horizon scanning priorities for 2009-2010.	The HFEA remains responsive to new developments and is able to plan future policy work effectively.	November 2008
	Maintaining a watching brief and engaging in early public consultation and dialogue so that the decision-making process takes in a wide range of views about new developments in embryo research from an early stage.	Early communication with relevant stakeholders about emerging new issues.	Throughout the year

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The above high level objectives show the direction of the HFEA throughout and beyond the 2008-09 Business Plan. The risks attaching to delivery of this plan are set out below. There are also specific organisational outcomes and enablers that provide an infrastructure and a framework for all these activities over the coming twelve months. These are described below.

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# Risks

## Objective A

**Continuously improve the effectiveness of regulation, information to support patient choice, and the policy framework.**

Description of the risk	Controls in place to mitigate the risk
That resources are insufficient to deliver improved regulatory effectiveness in addition to existing work.	<p>This risk is being addressed through advanced planning to assess resource needs, and through managing the timing and relative priority of the different workstreams.</p> <p>Formal project management processes are in place to manage and control work throughout the year.</p> <p>External inspectors are being used to assist with the increased volume of inspections resulting from newly regulated services under the European Union Tissues and Cells Directive (EUTCD).</p>
That clinics new to regulation give rise to an increased number of incidents and alerts, stretching resources.	<p>A clinical governance process is in place to handle incident reporting and the production of alerts. The HFEA's system of audit and risk-based inspections helps to focus resources appropriately.</p> <p>There has been considerable engagement with the sector, including the newly regulated clinics.</p>
That the HFEA fails to meet the minimum requirements for applying for new statutory powers available as a result of the RES Bill, or that the HFEA has insufficient resources to bring itself up to the required standard, or to operate any new powers applied for.	<p>Thorough consideration of the RES Bill is being undertaken, with a view to deciding which powers the HFEA should apply for, and to scope out the implications (including resource implications), necessary actions and the timescales for implementation.</p> <p>Communications with the sector about the changes will be vital in raising awareness and ensuring good levels of compliance.</p>

Description of the risk	Controls in place to mitigate the risk
<p>That the HFEA has insufficient resources to operate different systems in England/Wales and Scotland/Northern Ireland (because the RES Bill applies only to England and Wales).</p>	<p>The detailed work on the RES Bill, mentioned above, will inform which powers the HFEA applies for. The implications (including resourcing needs occasioned by different legislation applying in the different UK countries), will be considered in full as part of this.</p>
<p>That the HFEA experiences difficulties in balancing its approach to Better Regulation (which aims to decrease the burden of regulation for licensed clinics and research establishments) with its duties as a regulator.</p>	<p>Initiatives to (for example) decrease the amount of information licensed clinics and research establishments are required to provide to patients will form part of planned work to take a more principles-based approach to the Code of Practice when revising it.</p> <p>Good communications with licensed clinics and research establishments will be maintained so as to give clear guidance on regulatory requirements as well as on the ways in which the regulatory burden is being reduced.</p>

## Objective B

**Be ready to put the new HFE Act into effect in keeping with the Government's intentions by: reviewing and updating the Code of Practice; redesigning the functions of the HFEA; and updating processes and procedures.**

Description of the risk	Controls in place to mitigate the risk
<p>That the additional workload associated with implementing the HFE Bill is not properly resourced, and that it is subject to expansion, overloading the business plan and jeopardising other work.</p>	<p>Detailed early planning has been taking place to allow full scoping of the work that will be involved in developing and implementing redesigned functions, processes and procedures.</p> <p>A thorough business case has been produced detailing all associated resourcing needs, and there has been ongoing dialogue with the Department of Health to agree additional resourcing for this work.</p>
<p>That the new HFE Act does not equip the HFEA with an effective regulatory framework, or is not as anticipated.</p>	<p>The HFEA has provided detailed advice and information as the HFE Bill has taken shape. The Authority and its Committees have closely followed the development of the HFE Bill.</p>
<p>In the development of a new fee strategy, that differing requirements of stakeholders cannot be reconciled, resulting in slippage of timescales and expanding workloads.</p>	<p>Project management will include close attention to timescales, and flexibility will be built into the schedule. Proposals will be worked up with input from key involved parties.</p>
<p>Amendments made to the HFE Bill during its passage could force previous policy decisions to be revisited.</p>	<p>If necessary, the HFEA will reprioritise other work, or else discuss resourcing options with the Department of Health.</p>

## Objective C

**Raise the quality of the information the HFEA makes available to each of its stakeholders, including patients, the public, clinics, donors and donor-conceived individuals.**

Description of the risk	Controls in place to mitigate the risk
<p>That the introduction of new regulatory processes and powers leads to inconsistencies in statistics, leading to challenges and lack of comparability year on year.</p>	<p>Quality assurance measures are in place to ensure that statistical information remains robust.</p> <p>Data collection considerations will be built into all projects dealing with the introduction of new regulatory processes.</p> <p>Outcome reporting will be carefully considered to ensure that the data published is as useful as possible to its intended audiences.</p>
<p>That the HFEA is under-resourced for the requirement to release certain types of information to researchers, potentially leading to legal challenges and other pressures.</p>	<p>Planned project work will ensure the HFEA is prepared for this new requirement. In addition to a specific piece of work to develop a clear policy position on information for researchers, a further project will examine a range of consent issues.</p>
<p>That an increase in Freedom of Information, Opening the Register and other requests leads to resourcing difficulties.</p>	<p>Resource needs are being carefully assessed. Technology upgrades included in the business plan will assist with information provision, and funding for these is being sought.</p>

## Objective D

Ensure that the HFEA is able to offer the best guidance on existing and new fertility treatments through evidence based decision making, monitoring existing research, and horizon scanning for scientific developments.

Description of the risk	Controls in place to mitigate the risk
That the HFEA policy on multiple births is not properly understood or is not adopted in practice by one or more key audiences.	Work with licensed clinics and partner bodies (professional and patient organisations) on the national strategy for multiple births.  A communications campaign is planned for 2008-2009.
Horizon scanning could miss major developments which emerge quickly.	Evaluation of the effectiveness of the horizon scanning programme.
Adverse public criticisms of embryo research, leading to a loss of public confidence.	Communicating regulatory research, and working with others to ensure key decisions are adequately informed and communicated.
Adverse criticism of the HFEA's role in research regulation, leading to a loss of confidence in the HFEA.	Transparency in both decision-making and communication of research regulation decisions and issues.

# Corporate Risks

## Risks that are relevant to the organisation and business plan as a whole.

Description of the risk	Controls in place to mitigate the risk
<p>Because of the high pressure, high change context in which the HFEA is working, that staff turnover increases and corporate knowledge is lost, with a knock-on effect on staff morale.</p>	<p>The HFEA has in place good corporate governance arrangements, and is working to ensure all procedures and processes are well documented so that existing corporate knowledge is captured.</p> <p>The HFEA aims to retain staff through offering excellent employer practices including induction, annual staff appraisals, and training and development opportunities, as well as an appropriate working environment and conditions of service.</p> <p>In the context of change management during the next year, work is planned on communications and organisational development.</p>
<p>That the internal change management work (Programme 2010) leads to an increase in turnover and a loss of existing working knowledge and practices, absorbs disproportionate resources, and diverts attention away from delivery of business.</p>	<p>There is a continued focus on internal communications, including active staff engagement.</p> <p>Staff involvement is integral to the change management work.</p> <p>External expertise and resources have been brought in to avoid overloading staff and preventing them from delivering their core business.</p>
<p>That recent changes in Authority membership and the position of Chair, coupled with the end of six Members' terms of office later in the business year, result in a lack of top-level continuity, and loss of key corporate knowledge.</p>	<p>Induction and acclimatisation arrangements in place.</p> <p>Organisational development work is being undertaken to improve decision-making and governance.</p>

Description of the risk	Controls in place to mitigate the risk
<p>That legal challenges, which may arise whenever the Authority is required to exercise discretion in its decision-making, or to act in a quasi-judicial capacity (as Licence Committees are required to do), result in resource pressures and reputational damage.</p>	<p>A tendering exercise has been completed for provision of legal advice to the HFEA. A panel of firms were appointed, with specific litigation and public law expertise.</p> <p>A programme of legal training has been planned for Authority Members on public law and human rights.</p> <p>It is envisaged that ongoing legal training will be provided at periodic intervals for Authority Members.</p> <p>The HFEA's resources are managed so as to handle the potentially high costs of legal/defensive actions, in dialogue with the Department of Health.</p>

# Corporate Strategies and Enablers

## Delivery Framework

In addition to the four main strategic objectives set out earlier, it is important to acknowledge the underlying core strategies, activities and functions that will enable the HFEA to deliver its business plan.

A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the delivery of the four strategic objectives. In addition the HFEA has in place a number of broader corporate frameworks and strategies which underpin its day-to-day activities, such as an Information Management and Technology Strategy, Sustainability Action Plan, Workforce Strategy and Corporate Governance Framework.

## Organisational Development

This year, the HFEA will also need to carry out effective organisational development to allow the organisation to manage anticipated legislative changes successfully and proactively. The HFEA has already commenced a change management programme called Programme 2010, designed to lead the organisation through the changes that will be needed to ensure the right structure and processes are in place to deliver an effective ongoing regulatory system under the new HFE Act, which is expected to receive Royal Assent during 2008.

## Finance

In addition to this change management programme and the other specific workstreams highlighted in the strategic objectives, the HFEA will also need to continue to deliver its underlying regulatory business, and to remain responsive to the key Arm's Length Body themes of organisational efficiency and cost-effectiveness. The HFEA will maintain sound financial and business planning processes, including budgetary controls, improved cost awareness and workforce planning, and a value for money exercise.

## Human Resources

The HFEA needs to maintain sound Human Resources processes, including recruitment and retention practices to retain a high quality workforce within agreed establishment and efficiency benchmarks. The HFEA aims to achieve the highest standards in human resources processes, and intends to sign up to the Skills Pledge in 2008-2009, a public commitment to support all employees to develop their basic skills. The HFEA is also broadly compliant with the NHS Very Senior Managers pay framework.

## Assurance

The HFEA will continue to improve its assurance framework and organisational infrastructure, through sound planning, resource and risk management, and the maintenance of appropriate premises and IT infrastructure.

## **Establishment and Resources**

The Government's response to the Scrutiny Committee and the developments associated with new legislation and accompanying organisational change are likely to place significantly increased workload on the HFEA. Although the HFEA plans to undertake organisational development work to rationalise the processes of the HFEA and take advantage of new technologies and ways of working, the organisational footprint of the HFEA could increase in 2008-2009 and beyond.

It is therefore prudent to examine the HFEA's establishment and the resources it receives from within the Arm's Length Bodies (ALB) sector. For 2008-2009 budgeting purposes, this has been discussed in detail with the Department of Health, and the resulting financial picture is set out in the section that follows.

# Financial Picture

## HFEA Budget 2008-2009 - Commentary

### 1. Overview

2008-2009 is a year of change, with the HFE Bill likely to redefine the HFEA's functions and the way in which it operates. The organisational development work of Programme 2010 will be a significant element of the planned work for the HFEA during the financial year. It is anticipated that ringfenced resources will be received from the Department of Health to facilitate the process of renewal within the HFEA, and indicative amounts have been included in the following financial summary. These resources will be subject to the approval of detailed business cases. The detailed impact of this programme on the 2008-2009 budget has not yet been fully quantified. However the organisation is committed to a break even position.

### 2. Income Assumptions

The Grant-in-Aid for baseline activities has remained broadly constant at £2m for 2008-2009. This amount has been increased by £100k carried over from 2007-2008 that has been agreed by the Department of Health to enable the HFEA to undertake a communications programme around the effect of multiple pregnancies. A detailed analysis of DH funding is included on page 37. This would form part of the National Strategy which will be developed with the professional bodies, the Department of Health and other interested stakeholders.

Income from licensed clinics and research establishments has been estimated at £5m based on current levels of reported treatments per annum, with an estimate of sector growth of 3%, based on historical levels of growth.

### 3. Authority and Committee Costs

The Authority and Committee costs are based on the current system of payment to Members.

Members' pay, travel and subsistence have been extrapolated from current levels. Any changes in payment levels or to the number of members would impact on these costs.

### 4. Regulation and Corporate Planning

The additional regulatory requirements brought about by the introduction of the European Union Tissue and Cells Directive (EUTCD), together with the addition of more clinics, have placed a further strain on the Regulation Directorate budget. While the newly regulated clinics are currently paying an annual fee, the work that the HFEA has had to undertake in the early period of regulation, to assist clinics in achieving the necessary standards, has been significantly more resource intensive. However, as the sector adjusts its practice to the European standards, the process of regulation should become less resource intensive over the next two years.

## **5. Policy and Communications**

Significant workstreams within this Directorate will be the work generated by the HFE Bill and the work for the National Strategy for Multiple Births, which commenced in 2007-2008 and continues into the 2008-2009 financial year.

## **6. Resources and Corporate Development**

The scheduled rent increase effective from November 2007 has increased the cost base for accommodation. However, these additional costs have been in part offset by reduced salary costs and general office costs, which will be the subject of a “value for money” exercise during 2008-2009.

## **7. Information Management**

Costs within the Information Management Directorate are forecast to remain broadly constant. Work on opening the Register continues and Electronic Data Interchange (EDI) continues to enable greater access to data.

## **8. Legal Fees**

Gross legal fees for 2008-2009 are budgeted on the basis of the amount included within the budget is the amount required in the absence of any significant legal challenges. Any funding needed to contest significant challenges has in the past been requested from the Department on a case by case basis.

## **9. Capital Costs**

The capital costs budget includes the rolling renewal programme for both information technology and office equipment and furnishings of £100k per annum plus a further one off programme of £200k for server virtualisation. This will bring greater resilience to the HFEA systems and bring them up to current best practice standards. It will enable users to achieve optimal server utilisation in hardware independent virtual machines and give the HFEA's systems the flexibility to allow the organisation to prepare for the requirements of the HFE Bill.

## **10. Change Costs**

Change costs relate to significant workstreams that the HFEA will need to undertake in order to meet the requirements of the HFE Bill. The programme of work is being carried out using recognised project management methodology and is underpinned by detailed project plans. Current estimates of the work on the HFE Bill may require a temporary increase in headcount. Further detailed business cases will be generated as the project work progresses, in support of any requests for payment of Grant-in-Aid.

## **11. Business Year 2009-2010**

The indicative budget for 2009-2010 has been generated on the basis that the recurrent organisational resourcing requirements will remain broadly constant. The new HFE Act, however, could require changes to be made to this.

## Budget Summary

	2007-08 Budget £'000	2007-08 Forecast £'000	2008-09 Budget £'000	2009-10 Budget £'000
<b>Summary HFEA</b>	<b>(restated)</b>	<b>(Month 7 return)</b>		<b>(Indicative budget)</b>
Operational Activity				
Income	6,806	7,198	7,056	6,880
REVENUE COSTS				
Chief Executive's Office	517	545	542	560
Staff Costs - Other	323	343	323	323
Authority / Committee Costs	255	255	278	286
Regulation & Corporate Planning	1,357	1,391	1,387	1,431
Communications & Policy	1,298	1,311	1,292	1,222
Resources & Corporate Development	1,404	1,405	1,422	1,447
Information Management	1,201	1,232	1,183	1,210
Legal Fees	123	411	143	126
Professional Fees	241	218	186	185
<b>Total Revenue Costs</b>	<b><u>6,719</u></b>	<b><u>7,111</u></b>	<b><u>6,756</u></b>	<b><u>6,790</u></b>
"Change" Costs *	450	250	750	-
<b>Total costs including "Change" costs *</b>	<b>7,169</b>	<b>7,361</b>	<b>7,506</b>	<b>6,790</b>
Less "Change" Funding Requested *	450	250	750	-
<b>Net Revenue &amp; "Change" Costs *</b>	<b>6,719</b>	<b>7,111</b>	<b>6,756</b>	<b>6,790</b>
CAPITAL COSTS	87	87	300	90
<b>Total Costs</b>	<b>6,806</b>	<b>7,198</b>	<b>7,056</b>	<b>6,880</b>
NET Operational Activities	-	-	-	-

\* Budgeted change costs are subject to Department of Health agreement of a business case.

## Workforce Planning

	07-08 WTE	08-09 WTE
Communications & Policy	17.6	18
Information Management (including IT and Audit)	21.5	21.5
Resources Directorate (inc. Finance, Facilities and HR)	10.0	10.0
Regulation (including Business Planning)	26.5	25.1
Chief Executive / Chair Office	4.7	4.7
Legal Office	1.8	2.8
Programme 2010 (temporary staffing to support change management programme, including HFE Bill work)	0.2 <sup>*</sup>	3.6 <sup>*</sup>
<b>Total (for ongoing business plus Programme 2010)</b>	<b>82.3</b>	<b>85.7</b>
<b>Total without Programme 2010</b>	<b>82.1</b>	<b>82.1</b>

\* One member of staff commenced January 2008, others in April 2008. Any additional resource needs for Programme 2010 in 2008-2009 will require a business case to be considered by the Department of Health.

## 3 Year Indicative Plan: ALBs Funding Targets 2008-2009 to 2010-2011

	REVENUE FUNDING 2008-2009	Indicative 2008-2009 £000	Indicative 2009-2010 £000	Indicative 2010-2011 £000
<b>Revenue Grant-in-Aid:</b>				
1	Baseline Allocation	1955	2405	2405
2	Brokerage required from 2007/08	100	0	0
	<b>Cash requirements – payment of provision</b>	450	-	-
3	<b>Total Revenue Grant-in-Aid and Cash</b>	2505	2405	2405
<b>Non-Cash:</b>				
	Depreciation	305	350	204
	Cost of Capital	46	46	46
4	<b>Capital Charges</b>	351	396	250
5	<b>Movement in Working Capital – payment of provision</b>	(450)		
6	<b>Total DH Target Funding</b>	2406	2801	2655
7	<b>“Change” Cost Requirements</b>	750	not yet known	not yet known
<b>CAPITAL FUNDING 2008-2009:</b>				
8	<b>Total Capital Grant-in-Aid and Cash (Baseline Allocation)</b>	300	90	92
<b>SAVINGS (Cumulative):</b>				
9	Total Cash releasing Savings/target	2726	2726	2726
		<b>wte posts</b>	<b>wte posts</b>	<b>wte posts</b>
10	<b>Headcount Savings Targets at 31 March</b>	82 + 3.6 re: change programme and HFE Bill implementation	82	82
<b>Notes:</b>				
1	The starting point for the baseline allocation is the business plans provided by ALBs in January 2006. These figures may have changed following ALB Programme Team review.			
2	This is the brokerage requested from 2007-2008.			
3	Revenue Cash Limit.			
4	Capital Charges are non-cash items but are part of the overall ALB sector for target purposes.			
5	Deduction of provision.			
6	The total resource provided by the Department of Health against which savings will be targeted.			
7	Change cost requirements associated with the programmes outlined in the commentary. The Grant-in-Aid funding and necessary headcount to carry out the change programme is subject to Department of Health approval of a detailed business case.			
8	The starting point for the baseline allocation is the business plans provided by ALBs in January 2006.			
9	Total cumulative Cash Savings made against 2005-2006 funding levels.			
10	These are the headcount savings/targets based on ALB business plans adjusted for the ALB Programme Targets.			

## Performance Indicators

Performance against 2007-2008 indicators:	Achieved 2006-2007	Target 2007-2008	Achieved 2007-2008
<b>A. Regulation</b>			
No. of random unannounced inspections carried out in the year	7	4	4
Reports resulting from inspection of clinics available to clinic within 28 working days of the inspection date	96%	90%	75.9% <sup>1</sup>
Reports resulting from research inspections available to research establishment within 28 working days	96%	90%	76.15% <sup>2</sup>
New licence applications processed within 4 months of receipt	100%	90%	90.75%
Research licence applications processed within 3 months of receipt of complete application & peer review	100%	100%	100%
Reduction in items of information required from clinics	10% reduction achieved	Further 10% reduction	Achieved
<b>B. Communication and Information</b>			
Patient/public enquiries replied to within 3 working days	92.22%	95%	67% <sup>3</sup>
Number of 'page views' of 'For Patients' section of website	-	5% increase	49% increase <sup>4</sup>
Number of 'page views' of Find a Clinic function on website	-	5% increase	15% increase
Number of Authority meetings held in public during the year	3	3	3
Number of stakeholder events	8	8	30 <sup>5</sup>
Freedom of information (FOI) requests dealt with within 20 working days	98.67%	100%	99.4%
Publication of finalised Licence Committee decisions on the website	90.6% within 14 working days	90% within 20 working days	77.5% <sup>6</sup>
<b>C. Corporate</b>			
Invoices paid within 30 days	93%	95%	97.25%
Debts collected within 60 days	83%	85%	82.5% <sup>7</sup>
Monthly billings of clinics achieved in three weeks	98%	95%	98.5%
<b>D. Diversity</b>			
Initial EIA screening completed for all major new policies or projects	-	95%	100%
Full EIA completed for all major policies or projects identified as requiring additional assessment	-	95%	(None required)
Develop self assessment and pre-inspection questionnaires, and provide guidance to clinic staff in their use	-	75% (of clinics)	100%
<b>E. Arm's Length Bodies (ALB) Targets</b>			
Reduce revenue costs	£1.93m Grant-in-Aid achieved	£2.109m Grant-in-Aid	Achieved
Reduce full-time equivalents to 82.1 by March 2007 and then maintain this reduction	82.1	82.1	82.15
Assess shared services potential for back-office study of finance	Finance function shared with HTA	-	-

<sup>1</sup> There were various additional work pressures in the year, notably the implementation of the EUTCD and a very high number of inspections in the final quarter. These affected several performance targets.

<sup>2</sup> See footnote 1 above.

<sup>3</sup> Better information on the HFEA's website means that staff now receive only the more complex enquiries, which in turn means response times are necessarily longer. In addition, staff vacancies during the year have meant there were fewer staff available to deal with these enquiries. These vacancies have now been filled.

<sup>4</sup> This higher than expected increase reflects improvements to the website.

<sup>5</sup> There were various additional stakeholder consultation events in connection with policy development work on the use of hybrids and chimera in research, and on multiple births.

<sup>6</sup> See footnote 1 above. In the final two quarters of the year, however, delivery had returned to 100% for this target.

<sup>7</sup> By the final quarter, this indicator was on target. Earlier there were some teething issues with newly regulated clinics, which were subsequently resolved.

Performance indicators 2008-2009:	Target 2008-2009
<b>A. Regulation</b>	
No. of random unannounced inspections carried out in the year.	4
Reports resulting from initial application and renewal inspections of clinics and research establishments available to clinic within 28 working days of the inspection date.	90%
New treatment and research licence applications processed within 4 months of receipt of all necessary documentation and confirmation that the premises are ready for use.	90%
<b>B. Communication and Information</b>	
Respond to requests for contributions to Parliamentary Questions within the deadlines set by the Department of Health.	100%
Number of Authority meetings held in public during the year.	3
Written enquiries from patients and the public responded to within 3 working days.	95%
Increase in visits to the HFEA website compared to the 2007-2008 year.	10% increase
Increase in visits to the Find a Clinic function on the HFEA website compared to the 2007-2008 year.	10% increase
Publication of finalised Licence Committee decisions on the HFEA website within 20 working days.	90%
Freedom of information (FOI) requests dealt with within 20 working days.	100%
Opening the Register requests dealt with in 20 working days (excluding counselling time for the person making the request).	100%
<b>C. Corporate</b>	
Invoices paid within 30 days.	95%
Debts collected within 60 days.	85%
Monthly billings of clinics achieved in 3 weeks.	95%
<b>D. Arm's Length Bodies (ALB) Targets</b>	
Achieve revenue cost targets.	Achieve £2m Grant-in-Aid
Maintain full-time equivalent staff numbers.	82.1 wte

**Note:** Qualitative service reviews are also carried out to assess the effectiveness of inspection, and user satisfaction with the website. These will continue in 2008-2009.

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