

2010  
2011

# Business Plan

Human Fertilisation & Embryology Authority

# Contents

1.	HFEA Purpose, Principles and Statutory Functions .....	2
2.	Looking Back on 2009/10 .....	4
3.	Future Strategic Direction.....	10
4.	Looking Forward to 2010/11 .....	11
5.	Business Objectives for 2010/11 .....	12
6.	Corporate Enablers and Resources .....	26
7.	Financial Picture .....	29
8.	Performance Indicators .....	32

# HFEA Purpose, Principles and Statutory Functions

## Purpose

We are the UK's independent regulator of treatment using eggs and sperm, and of treatment and research involving human embryos. We set standards for, and issue licences to, centres. We provide authoritative information for the public, in particular for people seeking treatment, donor-conceived people and donors. We determine the policy framework for fertility issues, which are sometimes ethically and clinically complex.

## Principles

We treat people and their information with sensitivity, respect and confidentiality

We observe the highest standards of integrity and professionalism in putting into effect the law as it governs our sector<sup>1</sup>

We consult widely - listening to and learning from those with an interest in what we do

We keep abreast of scientific and clinical advances

We exercise our functions consistently, proportionately, openly and fairly.

## Functions

In November 2008, the Human Fertilisation and Embryology Bill received Royal Assent. The majority of the resulting Act subsequently came into force in October 2009.

The HFEA is required to have regard to two primary sets of legislation:

- The Human Fertilisation and Embryology Act 1990 (as amended) – in this business plan we refer to this as “the 1990 Act (as amended)”; and
- The Human Fertilisation and Embryology Act 2008 (“the 2008 Act”).

Primarily, the 2008 Act is amending legislation. It extensively amends the provisions of the 1990 Act, which continues to form the main framework governing the duties and responsibilities of the HFEA. However, the 2008 Act also contains new provisions which were not originally in, and have not been inserted into, the 1990 Act. In particular, these include provisions relating to legal parenthood.

The 1990 Act (as amended) gives the HFEA a number of statutory functions:

- To keep a formal register of information about donors, treatments and children born as a result of those treatments
- To license and inspect clinics carrying out in vitro fertilisation and donor insemination treatment
- To license and inspect establishments undertaking human embryo research

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<sup>1</sup> ‘The sector’ refers to the assisted reproduction/fertility sector and all the treatment clinics, storage centres and research establishments within it.

- To license and inspect the storage of gametes (eggs and sperm) and embryos
- To maintain a formal register of licences granted
- To produce and maintain a Code of Practice, providing guidance to clinics and research establishments about the proper conduct of licensed activities
- To maintain a register of certain serious adverse events or reactions (this relates to certain specific activities, which are set out in the amended Act)
- To investigate serious adverse events and serious adverse reactions and take appropriate control measures
- To respond to any request from a competent authority in another European Economic Area state to carry out an inspection relating to a serious adverse event or reaction, and to take any appropriate control measures
- To collaborate with the competent authorities of other European Economic Area states.

In addition to these specific statutory functions, the legislation also gave the HFEA some more general functions, including:

- Publicising the HFEA's role and providing relevant advice and information to the donor-conceived, donors, clinics, research establishments and patients
- Promoting compliance with the requirements of the 1990 Act (as amended), the 2008 Act and the Code of Practice
- Maintaining a statement of the general principles that should be followed by the HFEA when conducting its functions, and by others when carrying out licensed activities
- Observing the principles of best regulatory practice, including transparency, accountability, consistency, and targeting regulatory action where it is needed
- Carrying out its functions effectively, efficiently and economically
- Reviewing information about:
  - Human embryos and developments in research involving human embryos
  - The provision of treatment services and activities governed by the 1990 Act (as amended)
- Advising the Secretary of State for Health on developments in the above fields, upon request.

# Looking Back on 2009/10

## Meeting Key Challenges

### Better Regulation and Regulatory Compliance

#### *Addressing Legislative Changes*

In preparation for the changes to the 1990 Act, the HFEA had previously put in place a major change programme, Programme 2010. Through this programme, which continued into the 2009/10 business year, we were able to run a series of projects to put new systems and processes in place, ready for the implementation of the revised Act, alongside the delivery of our normal work.

#### *New Licensing and Appeals Processes*

In preparation for the legislative amendments, the HFEA developed new licensing and appeals processes, including new directions and licence conditions. An Executive Licensing Panel was established to handle all routine and uncontentious licensing decisions (an arrangement that will be reviewed by the Authority after a year), and an Appeals Committee consisting of external members was formally constituted.

#### *New Compliance Cycle and Quality Improvements*

We contributed as needed to the finalisation of Regulations governing HFEA regulation and compliance activities. We reviewed our inspection processes, and started to develop a full Quality Management System (QMS), initially for the Compliance Directorate, with clear Standard Operating Procedures (SOPs). This work is ongoing into the next business year. We developed a new risk tool to assist us in determining inspection priorities, and further developmental work on the risk tool will continue in the next business year. The Person Responsible Entry Programme (PREP) was also revised and aligned with the new requirements.

We reviewed aspects of research regulation and licensing, to ensure that we were prepared for newly licensable activities (research involving admixed embryos or alteration of the genetic structure of embryonic cells). A specific licensing process, with documentation and guidance, was also developed for centres where embryos may be used for training purposes.

Alongside all of these projects, we also delivered our normal annual inspection and licensing programme.

#### *Joint Working and Relationships with Other Agencies*

The HFEA continued to maintain good working relationships with regulators and other agencies to ensure that investigations and inspections could be carried out jointly when possible, in keeping with the Concordat (a voluntary agreement between organisations that regulate, audit, inspect or review elements of health and healthcare in England). We also continued to participate in the European Union Standards and Training in the Inspection of Tissue Establishments (EUSTITE) project to establish Europe-wide inspection standards.

## ***Hampton Review and Better Regulation***

The Hampton Review<sup>1</sup> report about regulation, inspection and enforcement at the HFEA was published in December 2009<sup>2</sup>. The Authority began to consider the recommendations in the report at its January 2010 meeting, and further work will follow from this. Recognising and implementing improvements will help to ensure the HFEA is eligible for increased powers under the Regulatory Enforcement and Sanctions Act 2008, if the Authority chooses to seek these at some time in the future.

Throughout the year, we also continued to meet the requirements of the Government's Better Regulation agenda, providing required information on regulatory impact and budgets, and contributing to Department of Health simplification plans as needed.

## **Information Provision and Usage**

### ***Choose a Fertility Clinic***

The HFEA publicly consulted on and then reviewed its publication of clinic information and performance data. As a result, more national data is available on the HFEA's website, and a revised version of 'Find a Clinic', now called 'Choose a Fertility Clinic' was published. This provides more performance information for the sector and for patients. In addition a one year national data analysis has been produced and quarterly updates of outcome data and early pregnancy rates are made available through Choose a Fertility Clinic.

### ***HFEA ID***

The HFEA ID is intended as a unique identifier applied to individuals whose data is held on the HFEA register. The HFEA ID enables us to track individuals across different licensed clinics, avoid duplicates and enhance the integrity of register data. During 2009/10, the HFEA ID was applied retrospectively to all donor information. Work is ongoing to apply the HFEA ID to patient information.

### ***Online Information***

Online access to HFEA forms and information for centres has been improved, with the introduction of an online portal for centres and online application forms for licences, preimplantation genetic diagnosis (PGD) and imports/exports. More online applications will follow, streamlining interaction between the HFEA and the centres it regulates.

### ***Access to Register Information***

A revised policy on opening up access to Register information to donors, donor-conceived people and their parents was put in place to address new information access rights created by the 1990 Act (as amended). A voluntary sibling contact register for donor-conceived people (known as Donor Sibling Link, DSL) has been developed, enabling individuals who have opted in to this facility to supply certain personal details which the HFEA may then disclose to genetic siblings on request.

We also addressed new statutory requirements to disclose Register data to researchers. The new Regulations were finalised through Parliament just before the end of the business

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<sup>1</sup> This was one of a series of reviews of regulatory bodies focusing on the assessment of regulatory performance against the Hampton principles and Macrory characteristics of effective inspection and enforcement. It was carried out by a review team drawn from the Better Regulation Executive, Companies House and Natural England, in April 2009. Further information about the reviews can be found at:

<http://www.bis.gov.uk/policies/better-regulation/improving-regulatory-delivery/assessing-our-regulatory-system>

<sup>2</sup> The HFEA's Hampton review report can be viewed online at:

<http://www.berr.gov.uk/files/file53852.pdf>

year, and we have in place a policy on the release of Register data for research purposes, with appropriate consent arrangements. The Authority will have an oversight role.

## **Policy Development and Implementation**

### ***Code of Practice 8<sup>th</sup> Edition***

A comprehensive review of the format, effectiveness and content of the Code of Practice was conducted, informed by feedback from a public consultation exercise in early 2009. The new 8th edition of the Code of Practice was published in July 2009 and came into effect in October, when the revised Act was implemented. The Code is accompanied by a guide to inspection and licensing for clinic staff, and revised consent forms reflecting the requirements of new legislation and HFEA policies. This new edition of the Code specifies which requirements of the sector are mandatory and which are best practice guidance, and gives greater clarity for the sector about what constitutes a breach of the Act, and how the HFEA will deal with such a breach. Guidance for centres on the provision to patients of written costed treatment plans has been included in the Code, to ensure that patients receive clearer information about expected treatment costs. Information workshops for clinics and for inspectors were held, to ensure understanding and awareness of the new requirements.

In developing new policies for the Code of Practice, diversity issues were considered and equality impact screening and assessments were undertaken where relevant.

Going forward, equality and diversity concerns will form a necessary part of developing new policies, for example as part of our review of donations policy.

### ***Multiple Births and Single Embryo Transfer***

The HFEA continued with its work to reduce the incidence of multiple births across all centres, monitoring and analysing multiple birth and pregnancy rates, and using information gained from inspections to help to evaluate the effectiveness to date of the policy. In January 2010, the Authority set a second year upper limit of 20% as the new maximum multiple birth rate target for centres in 2010/11.

### ***PGD Licensing***

Clear criteria and a licensing decision-making process were put in place for PGD decisions made by Licence Committees, to ensure such decisions are consistent. The licensing on a case-by-case basis of certain PGD decisions was also considered. In January 2010 the Authority decided to cease case-by-case decision making for lower penetrance conditions, but endorsed its continued use for PGD/Human Leukocyte Antigen (HLA) cases. New guidance was also adopted on non-disclosure testing<sup>1</sup>, in cases where patients wish not to find out their own genetic status.

### ***SEED and Donation Review***

The practical impacts for clinics, donors and patients of the sperm, egg and embryo donation (SEED) policies stemming from the 2005/06 SEED review were evaluated. As a result of this review, in December 2009 the Authority was able to choose a number of donation policies which need to be more fundamentally reviewed in light of possible new evidence or changed social attitudes. The resulting policy work, including a programme of consultation, will be delivered throughout 2010/11.

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<sup>1</sup> Further background information on these decisions and the scientific terminology can be found at <http://www.hfea.gov.uk/5602.html>

## ***Other Policy Development Work***

The Authority continues to consider scientific and ethical matters through its Scientific and Clinical Advances Advisory Committee (SCAAC) and Ethics and Law Advisory Committee (ELAC). An annual horizon scanning exercise, involving an external panel of experts, was carried out to help the HFEA to identify and anticipate emerging research and treatments. This work assists in planning for future policy development and licensing needs and supports evidence-based decision-making by the Authority. ELAC is considering operating a similar annual horizon scanning exercise on upcoming legal and ethical issues, and in February 2010 held its first horizon scanning conference to discuss fertility treatment abroad and to identify other future issues for consideration.

## ***Communication and Dialogue***

Joint working, dialogue and ongoing contact with key professional stakeholders and patient groups was maintained throughout the year. These include the British Fertility Society, the Infertility Network, the Donor Conception Network, the National Gamete Donation Trust, the RCN Fertility Nurses Group, the Human Genetics Commission, the British Infertility Counselling Association and the Project Group on Assisted Reproduction. The HFEA's own Licensed Centres Panel met three times during the year. The HFEA has continued to consult and engage widely with the public during the development and implementation of new policies, to increase public understanding of the HFEA's work and current issues in fertility treatment and research.

The HFEA did not carry out any patient surveys in the year, instead choosing to consult with patients in a number of public meetings, phone interviews and user testing.

## ***Parliamentary Questions***

The HFEA assisted Department of Health officials with 144 parliamentary questions (PQs) during the year. The themes of the questions varied, although broadly the focus was on the following: the derivation of stem cells from embryos; hybrid embryo research; the donation of eggs for research projects; witnessing guidance provided by the HFEA for licensed centres; and the Hampton review.

## ***Equipping the Organisation for the Delivery of Revised Legislation***

### ***Operational Infrastructure***

The Programme 2010 work has produced an operating model that equips the HFEA for the delivery of its future role. This year we have embedded programme and project management into the organisation as an effective way of managing cross-organisational projects.

We also began initial work towards the development of a new fee structure that will equip the HFEA financially to deliver its business. There will be further work on this in the coming business year.

### ***Processes to Deliver New Legislation***

Most of our internal procedures were reviewed as part of the change management process. HR policies, IT processes, workflow models, financial and accounting procedures and quality management have all been improved or introduced through the year. Further internal work will be initiated following on from our Hampton review, to ensure that the HFEA meets the requirements of the Regulators' Compliance Code.

### ***Developing the HFEA's Workforce***

The HFEA has provided training and induction for all staff and Authority Members, including an introduction to the revised licensing processes, training for inspectors in new methods and

tools, ongoing legal training, and the introduction of a formal system of appraisal for Members, to make better use of their skills. Appeals Committee members have also been trained to deliver their new role.

## **Improving Internal Procedures**

### ***Developing the HFEA as an Employer***

THE HFEA Staff Forum represents all employees and encourages their active participation in the affairs of the HFEA. We recognise the importance of employee input and feedback and the Staff Forum is used as a framework for discussion and consultation on matters affecting all employees.

Briefing meetings for all staff take place fortnightly and staff are encouraged to participate and contribute information for sharing. Building on the success of the previous year's work on new ways of working (an agreed list of the attitudes and qualities we value) and internal communications, the HFEA continued to make good use of its internal intranet for staff communications, and introduced an e-newsletter, the HFEA Insider, to keep staff up to date and informed.

The HFEA also led the introduction of a collaborative talent management programme across a group of arm's length bodies, to improve development opportunities for staff. An ongoing training plan has been developed for managers and other groups of staff.

A thorough review of all HR policies has been conducted, to improve their clarity and efficacy. This is ongoing and will be completed in the first quarter of 2010/11. In addition, the HFEA has conducted an internal survey to assess the organisation's readiness to apply for Investors in People status in the future.

### ***Information Governance and Document Management***

Information governance processes were reviewed and improved to ensure that Cabinet Office security requirements were adequately addressed. This included mandatory training for all staff, and particularly Information Asset Owners. Ongoing training in the HFEA's electronic document management system (TRIM) was established to ensure that all staff remain proficient in its use. A programme of training for all staff in Freedom of Information (FOI) requirements and request handling was also established, to ensure that FOI requests are dealt with appropriately and within time limits.

Work on improving our document management practices commenced, with a thorough stock-take of documents currently held in the building. Version control was put in place for relevant document types. There will be a larger project on records management in the coming business year.

Much of the project work delivered during the year involved the development of workflow processes to improve the ways in which internal administration and task management are accomplished.

### ***Knowledge and Information Management***

The HFEA continued to use and refine the Customer Relationship Management software introduced the previous year, in order to increase organisational intelligence about external contacts and communications. During the year, a knowledge and information management strategy has been developed, and will be implemented from the beginning of the next business year.

## Facts and Figures:

The following facts and figures give a wider picture of the type and volume of HFEA work.

	2008/09	2009/10
Total number of active clinics and research establishments	139	138
Clinics and research establishments inspected	95	83
Number of licences inspected	128	97
New licence applications processed and presented to a Licence Committee	7	6
Licence renewals processed and presented to a Licence Committee/Executive Licensing Panel	65	52
Applications for Preimplantation Genetic Diagnosis (PGD) with HLA processed and presented to a Licence Committee/Executive Licensing Panel	42	25
New PGD applications processed and presented to a Licence Committee	51	52
Number of incident reports from centres processed	- <sup>1</sup>	494 <sup>2</sup>
Number of alerts issued	3	2
Number of complaints about centres processed	63	45
Licensed Centres Panel meetings held	3	3
Meetings held with Patient Organisations	2	2
Public and stakeholder consultation meetings (of which 6 were organised by external bodies but where HFEA played an important part 2009/10)	47	30
Freedom of Information (FOI) requests dealt with	113	133
Environmental Information Regulations (EIR) requests dealt with	0	0
Opening the Register requests received	72	90
Opening the Register requests closed	74	91
Enquiries responded to under the Data Protection Act	6	4
Parliamentary Questions responded to	93	144
Number of Authority meetings held (including 3 open to the public)	8	7
Phone enquiries from patients and the general public	10,712	4781 <sup>3</sup>
Email enquiries from patients and the general public	10,026	6073 <sup>3</sup>
Number of visits to the HFEA website	503,991	558,780

<sup>1</sup> The collation of this information did not commence until 2009/10.

<sup>2</sup> Of the 494 incident reports received from centres, once processed, 21 of these did not fall with the definition of an HFEA incident.

<sup>3</sup> The decrease in both phone and email enquiries for 2009/10 was as a result of the updated website.

# Future Strategic Direction

The HFEA published a new 3 year corporate strategy in April 2010, setting out five broad strategic objectives which were identified through extensive Authority and staff discussions during the 2009/10 financial year. The HFEA's strategic objectives set out our key major aspirations for the medium term future. The discussions on this have been framed by consideration of a wide range of issues and drivers, such as:

- Techniques for treatment
- Advances in science and genetics
- Social views and social change
- The nature of those treated (and other stakeholder groups)
- The role of regulators generally, and the regulatory environment (e.g. with respect to quality and service improvement)
- Responding to the external environment

The HFEA's strategic objectives for the next 3 years are as follows:

**1. Role and boundaries**

To develop a clearly defined and mutual understanding of our role, and the boundaries between ourselves and other regulators, research-focused organisations, patient organisations and professional bodies in related fields.

**2. Meeting the needs of existing fertility service users and stakeholder groups**

To identify and address more fully the needs of fertility service users before, during and after treatment.

**3. Identifying and addressing the needs of new and emergent stakeholder groups**

To identify and start to address the needs of new or emergent stakeholder groups including donor-conceived people, fertile people seeking fertility treatment, and researchers.

**4. HFEA data used for research purposes**

To monitor and improve consent rates for using data for research purposes, and to give active consideration to the nature and outcomes of the research conducted.

**5. Improving organisational performance**

To enhance organisational performance and governance through operational efficiencies, improved regulatory effectiveness and better information management.

The HFEA's full corporate strategy for 2010-2013 can be found at <http://www.hfea.gov.uk/148.html>

# Looking Forward to 2010/11

In the business year 2010/11, there are significant extra pressures on public spending in the UK. It will therefore be important for the HFEA, in common with all public sector organisations, to be able to demonstrate real cost benefits and value for money in the outcomes it delivers and the resources it uses to deliver them.

This Business Plan has been updated prior to publication to address all the new public sector spending controls introduced by the Treasury and the Department of Health<sup>1</sup>. Like all public bodies, the HFEA has had its grant in aid funding cut by 3% at the beginning of the financial year, and needs to work within the new constraints imposed by central Government. This Business Plan shows how the HFEA is responsibly managing its resources within the new rules, and ensuring all the new requirements are met.

Within this overall economic context, the HFEA will need to continue to deliver its core regulatory business. In 2010/11, this will include the ongoing implementation, embedding, evaluation and continuous improvement of the new systems and processes that were introduced in 2009/10 in order to implement the HFE Act 1990 (as amended) and the HFE Act 2008. We will also need to continue to address new and emerging treatment and research developments which may have policy and regulatory implications for the sector.

The HFEA's business objectives for 2010/11 will be:

- 1. Embedding the new regulatory and licensing framework**  
To complete the introduction of the new regulatory and licensing framework, and to embed, refine and commence ongoing evaluation of the new processes.
- 2. Improving the HFEA's information provision to the public and patients**  
To improve the transparency, range and quality of information provided to the public and to others with an interest in data held or published by the HFEA.
- 3. Corporate efficiencies and improved governance**  
To review elements of the HFEA's governance and corporate enablers, so as to continuously improve the organisation's financial, workforce and governance framework and the capability of Members and staff to deliver high quality outcomes and results.
- 4. Leading-edge policy developments**  
To ensure that the policies the HFEA has in place successfully promote best current practice in treatment and research, leading to improved outcomes.

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<sup>1</sup> HM Treasury, letter dated 27 April 2010, *Review of Civil Service Expense Policies*; Department of Health, letter dated 28 May 2010, *HFEA revised budget 2010-11 and implementing efficiencies to support £6bn savings*; Department of Health, two letters dated 14 June 2010, *Efficiency measures in 2010-11* and *Implementing controls relating to the communications freeze*.

# Business Objectives for 2010/11

The objectives outlined above are a clear statement of the strategy the HFEA is following over the coming year, and beyond. In 2010/11 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.

## Objective 1: Embedding the new regulatory and licensing framework

**To complete the introduction of the new regulatory and licensing framework, and to embed, refine and commence ongoing evaluation of the new processes.**

### Regulatory framework

Following a year of legislative change and process development, the HFEA will implement a new compliance cycle and inspection approach on 1 April 2010. This will include a new risk tool and pre-inspection Self-Assessment Questionnaire (SAQ). Throughout the coming year, we will work to further develop, embed and ultimately evaluate the new tools and processes.

### Licensing framework

New licensing processes were introduced in October 2009, and these will continue to be monitored and evaluated, with an external evaluation planned for October 2010.

### Evaluation

We will also plan during the year to conduct a full evaluation of the first year of operation of the new compliance cycle, commencing in April 2011.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Regulatory framework	To ensure that the new compliance cycle and inspection and audit processes introduced in April 2010 are operating effectively.	Full implementation of the risk tool, Self-Assessment Questionnaire (SAQ) and new cohesive inspection and audit processes, with ongoing evaluation and refinements/ enhancements as needed. New post-inspection questionnaire developed. Development of new research SAQ.	New, improved tools and processes. Two year inspection cycle achieved; centres issued with licences for up to four years. Refinements to the risk tool and related processes (e.g. the inspectors' notebook) developed and implemented as needed. Risk tool validated by comparing outputs to inspection information.	April 2010 to March 2011
		Further development of the online applications system.	Further streamlining of the interaction between the HFEA and centres. More convenient processes.	By March 2011
		Training for operational audit staff in inspection methodology and for inspection staff in operational audit methodology (ongoing programme).	Inspections more focused and consistent in approach. Linked inspection and audit, improving the inspection experience for centres, and increased efficiency in use of resources for HFEA.	April 2010 to March 2011
	To develop specialist investigation expertise within the inspection team.	To establish a cohort of inspectors trained to Police and Criminal Evidence Act (PACE) standards with expertise in conducting incident investigations, including taking witness statements, storage of documents, obtaining evidence and dealing with issues of continuity.	Improved compliance and enforcement skillset.	By March 2011

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Regulatory framework	To review and improve data collection in the regulation of research projects.	Project to review how the HFEA collects data on the number of embryos collected and used in research, including consideration of how that data is verified.	Authority decision on future policy.	March 2011
	To improve the HFEA's internal database of centres' details.	Implementation of the outcomes of an options appraisal to be completed in May 2010.	Options appraisal completed. Project plan developed and commenced for chosen solution.	May 2010 July 2010
	To review the Enforcement Policy and adverse incident reporting.	A review of the Enforcement Policy and adverse incident reporting.	Updated and improved Enforcement Policy and adverse incident reporting.	March 2011
	To promote high standards and consistency of regulation of Tissues and Cells throughout Europe for the benefit of UK patients and centres.	Continued work with other European regulators to ensure that knowledge is shared on the regulation of Tissues and Cells. Ensure that inspectors are sufficiently trained and knowledgeable in the European Directives.  Licensing project.	Attendance at Competent Authorities' Meetings, Brussels.  EUSTITE successor projects (basic and advanced training for inspectors; project on serious adverse reactions and events (SAREs)). Delivery of basic and advanced training for inspectors.  Revised licences, revised Choose a Fertility Clinic.	Bi-Annual  2-3 year projects

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Licensing framework	To ensure that Executive Licensing Panel (ELP) and licensing processes introduced in October 2009 are operating effectively.	Embedding, evaluation and refinement of new ELP and Licence Committee arrangements. Production of guidelines and precedents.	Internal self-audit at 3, 6 and 12 months from October 2009 inception. ELP and Licence Committee operating successfully. Licensing processes running with greater efficiency. Regular reporting from the Chair of ELP to the Chair of the Licence Committee; regular reporting from the Chair of the Licence Committee to the Authority.	March 2011  Throughout year
		External review of consistency of decision-making and adherence to Regulations and protocols.	Authority receives review and makes a decision on the future operation of the system.	January 2011
	To review the list of licensable activities to ensure conformity with the HFEA Act 1990 (as amended) and the EUTCD.	Full revision of the list of licensed activities and corresponding updates to online forms, the Code of Practice, the HFEA's centres database, Choose a Fertility Clinic, and the Centres' Guide to Inspection and Licensing on the HFEA website.	Activities on licences will be in line with current legislation. All related HFEA systems will contain the same list of licensed activities. List of approved methods used to carry out a licensable activity. Clear policy on what is a licensable activity and clarity for centres on when they must apply to carry out a new methodology.	March 2011

Evaluation	To begin to review the first year's operation of the new regulatory framework.	To plan a review of the operation of the new tools and processes that make up the compliance cycle.	Review and evaluation plan in place to commence after first full year of operation.	March 2011 (review to commence April 2011)
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## Objective 2: Improving the HFEA's information provision to the public and patients

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**To improve the transparency, range and quality of information provided to the public and to others with an interest in data held or published by the HFEA.**

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### **Published information**

Following a year in which we have relaunched the HFEA website and the Choose a Fertility Clinic function, we will now seek to maintain and improve the ways in which the HFEA communicates online with its audiences. In addition to improved transparency and availability of information, we will improve the presentation and format of key reports.

### **Information access**

We will continue to fulfil the numerous requests made under various information access regimes. In addition, we will implement new Regulations on the disclosure of information for research purposes, including the establishment of an Oversight Committee and Register Research Panel.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Published information	To maintain and improve the ways in which the HFEA communicates with patients and clinics (while maintaining compliance with central Government rules on communications).	<p>Publication of key reports (e.g. Annual Report, annual Horizon Scanning report, revised Guide to Infertility). Ongoing maintenance of the HFEA website. Authority consideration of how and when best to incorporate patient feedback into the Choose a Fertility Clinic function. Consider producing more guidance for clinics on suitable practices, working in collaboration with professional bodies. Continue to publish Committee and Authority papers on the HFEA website.</p>	<p>Published information is accurate, timely and useful. Presentational and content improvements identified and implemented for annual publications. Improved transparency and ease of access to key information such as Committee papers and minutes. More efficient handling of some Freedom of Information requests, through signposting to the website.</p>	March 2011
		To ensure that the HFEA's website and publications are compliant with the Equality Act 2010.	Compliance with the Equality Act 2010.	March 2011 and ongoing

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Information access	To implement the new Regulations on disclosure of information for research purposes.	The Authority acts as the Oversight Committee and creates a decision-making panel (the Register Research Panel) that reports to it.	Information is provided to researchers in accordance with the new Regulations. Authority has ongoing oversight of requests and processes.	April 2010 onwards
	To facilitate access to information under various regimes.	'Opening the Register' requests continue to be met in a timely and sensitive manner and within required time limits.	20 working days, excluding time for counselling.	Throughout year
		To run and maintain the newly established voluntary contact sibling register for genetic siblings (Donor Sibling Link).	This will allow new donor conceived individuals to access this new service.	Throughout year
		Continuing information provision in response to Freedom of Information (FOI), Data Protection Act (DPA), Environmental Information Regulations (EIR) requests, and Parliamentary Questions.	FOI requests – 20 working days; DPA requests – 40 calendar days; EIR requests – 20 working days; Parliamentary Questions – varying deadlines, set by the Department of Health on a case-by-case basis.	Throughout year

## Objective 3: Corporate efficiencies and improved governance

**To review elements of the HFEA's governance and corporate enablers, so as to continuously improve the organisation's financial, workforce and governance framework and the capability of Members and staff to deliver high quality outcomes and results.**

### **Financial framework**

We intend to build on initial work done during 2009/10, with a view to a future review of the HFEA's fee structure. Phase one of this work will be to improve our ability to understand and quantify all of the costs associated with our regulatory activities. The fees review itself is likely to follow in the 2012/13 business year.

### **Governance framework**

We will review our Committee governance arrangements, following the establishment of a new structure in 2009/10. We will commence a major project to improve our records and information management and ensure good information governance, having made some preparatory steps already. We will also commission a formal external evaluation of the recent programme of change management (Programme 2010) that was put in place to deliver legislative and other changes.

### **Delivery framework**

We will also seek to improve overall organisational efficiency by establishing an organisation-wide Quality Management System (QMS), and exploring ways in which we can better manage and utilise the information and knowledge we hold.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Financial	To improve the HFEA's financial framework.	Improve the HFEA's understanding and quantification all of the unit costs associated with our regulatory activities. This will be phase one preparatory work for a future fees review.	Clear picture of regulatory costs.	March 2011
	Governance	To review and improve the HFEA's governance framework.	Review of all HFEA Committees.	Authority Committees reviewed. Recommendations developed.
Formal external evaluation of all outcomes from Programme 2010.			Recommendations for future consideration on programme management; quality assurance of efficacy of processes and delivery of benefits.	December 2010
To review and improve the HFEA's information governance.		Project on records management and reporting requirements to ensure that documents and other records are well-managed, accurately filed, accessible and not held in duplicate. Further increase in proportion of documents scanned and stored electronically. Processes (such as archiving, librarianship and bulk scanning) and workflows in place to deliver the Authority's Knowledge and Information Strategy.	Decrease in the volume of papers in hard storage. Greater search efficiency when documents are required. Ability to store and retrieve information held by the HFEA, and to avoid storing information unnecessarily. Records management element of Knowledge and Information Strategy begins to be delivered.	March 2011
	The HFEA achieves ongoing compliance with the Regulators' Compliance Code.	Incorporating actions agreed by the Authority in response to Hampton Review recommendations.	Authority working group established to consider actions and outcomes.	Not yet known

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Delivery	To improve organisational efficiency through a programme of work relating workforce considerations to operational requirements.	Ongoing consideration of workforce needs.	The organisation is resourced with the right workforce and therefore able to deliver all of its activities.	
		Continued coordination of the collaborative Talent Management Consortium for ALBs.	Improved development opportunities for HFEA staff. Assessment programme in place to evaluate progress.	Throughout year April 2010 onwards
	To build on previous work to update Standard Operating Procedures (SOPs) in keeping with the new compliance cycle, by designing an organisation-wide Quality Management System (QMS).	Project to develop organisation-wide QMS, including necessary workflows developed as part of this and other corporate projects.	QMS system established across whole HFEA. QMS element of Knowledge and Information Strategy begins to be delivered.	March 2011 and beyond
	Improving the ways in which the HFEA manages, utilises and disseminates the information and knowledge it holds.	Implementation of the Authority's 3 year Knowledge and Information Strategy.	Skilled and flexible workforce. Common goals, common practice in records management and information provision. Cost reduction for the HFEA.	March 2011 and beyond
		Customer service policy and approach developed.	Increased effectiveness and expertise in dealing with enquiries and complaints. HFEA reputation enhanced. Staff capacity used more efficiently.	March 2011

## Objective 4: Leading-edge policy developments

**To ensure that the policies the HFEA has in place successfully promote best current practice in treatment and research, leading to improved outcomes.**

### Policy reviews

We will undertake a review of donation policies, addressing a range of discrete issues surrounding embryo, egg and sperm donation. We will continue to monitor the progress and effectiveness of the Authority's policy to reduce the incidence of multiple births.

### Policy development

We will evaluate the impact of the Equality Act 2010 on HFEA guidance and the work of the sector. We will conduct and complete some smaller projects including the regulation of PGD (preimplantation genetic diagnosis) applications. We will extend the HFEA's unique identification system to all patients on the Register and start a review of the data that the HFEA collects from clinics. We will also carry out public attitudes polling during the summer of 2010.

### Evidence-based decision-making

We will continue to support evidence-based decision-making by the Authority through annual horizon scanning exercises, to anticipate and inform future policy development. Our formal horizon scanning will be extended to include more fully ethical, legal and social perspectives.

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Policy reviews	To continue to monitor the progress and effectiveness of the Authority's policy to reduce the incidence of multiple births.	Ongoing monitoring of outcomes following the setting of a year two upper limit for multiple births. Ongoing monitoring of related treatment developments.	Reduction in incidence of multiple births.	March 2011
	To ensure that the HFEA's policies on the donation of sperm, eggs and embryos are evidence based, workable and in line with wider social attitudes.	To review HFEA donation policies, taking into account clinical, patient, donor and wider social perspectives.	New Code of Practice guidance, new Directions, new patient and public information.	April 2010 – March 2011
Policy development	To extend the HFEA's unique identification system for data relating to donors (HFEA ID) to all patients and people born as a result of treatment.	HFEA ID system extended to all those on the Register.	Data about patients and offspring is correctly recorded and each individual can be uniquely identified, regardless of centres used. HFEA policies can be accurately monitored and enforced.	October 2010
	To develop a considered Authority response to the Equality Act 2010.	Review and discuss needed Authority actions.	Possibly an Authority decision.	Summer 2010 – March 2011
	To review how decisions are made by the HFEA about PGD licence applications in order to achieve safe, evidence based practice.	Compliance Committee discussion and decision.	Revised decision tree on PGD.	April – July 2010

Heading	Aim	Actions and Outputs	Measurables and Outcomes	Timescale
Policy development	To commence a register data set review of the information the HFEA collects from clinics.	To carry out scoping work in preparation for a review in the following business year, taking into consideration the burden of data provision for clinics and the disclosure of data to researchers.	A register data set review in 2011/12 to ensure that the size and scope of the HFEA dataset is based on sector consensus and balances burden with data usefulness.	March 2011
Evidence-based decision-making	To conduct a public attitudes survey.	Polling on public attitudes towards HFEA and various social and ethical issues, following on from 2005 poll.	Develop better understanding of public attitudes and trends over time.	June 2010 (completed)
	To support evidence-based decision-making by the Authority.	Scientific horizon-scanning exercise for 2011/12 through the Scientific and Clinical Advances Advisory Committee, involving external panel of experts. Collaborative working through ESHRE meeting in July.	Emerging research and treatments considered and anticipated. Future licensing and policy decisions informed by work.	Ongoing work
		Corresponding horizon-scanning exercise by the Ethics and Law Advisory Committee.	Ethical and legal issues considered and anticipated. Future policy decisions informed by work.	Ongoing work

# Corporate Enablers and Resources

## Delivery Framework

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

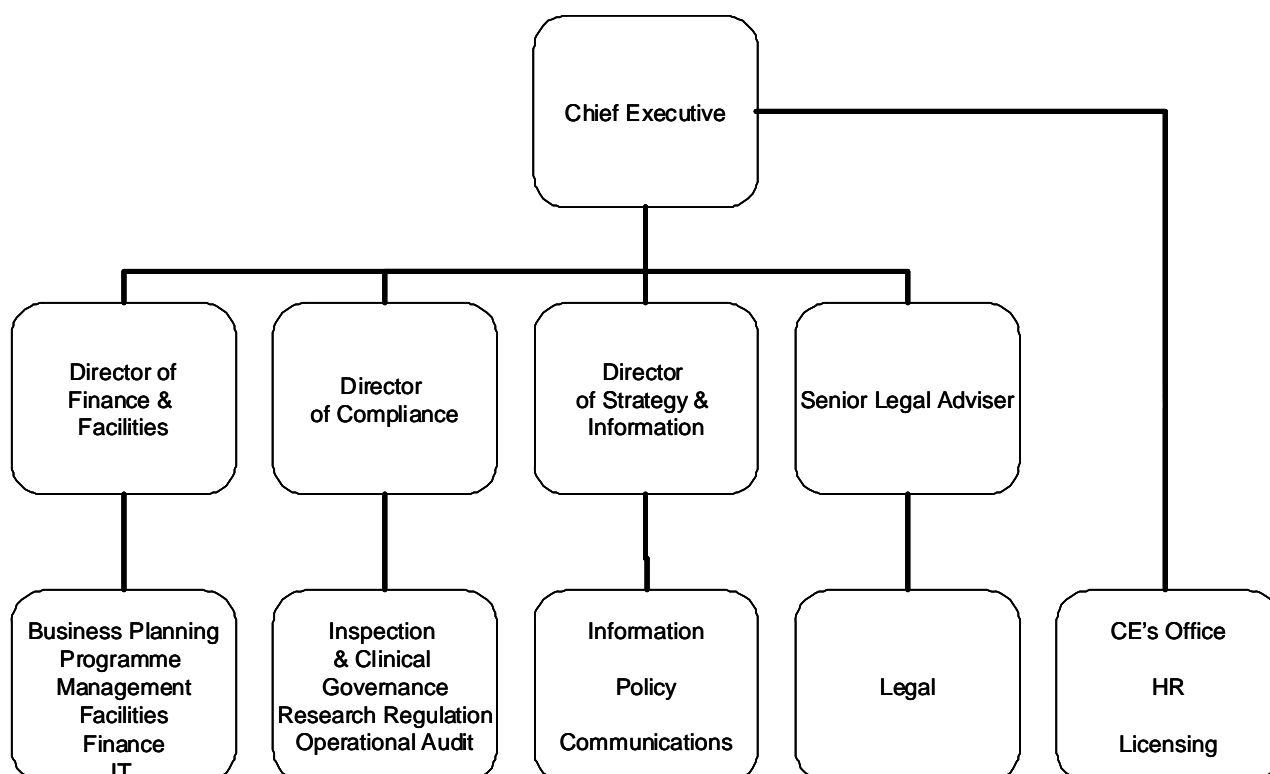
A sound delivery framework and a well-maintained organisational infrastructure are prerequisites for the delivery of the business plan. The HFEA has in place a number of corporate functions and strategies which underpin its day-to-day activities. These include a Knowledge and Information Management Strategy, a Sustainability Action Plan, a Human Resources Strategy and a Corporate Governance Framework.

## Organisational Development

Over the coming year, we will continue to instil best practice into our business processes and develop our people to support the changes that have come into effect. This will be underpinned by beginning to roll-out an organisation wide Quality Management System, enhancing the role of our internal Programme Board in managing projects and further developing our people, for example by collaboration with others in talent management.

In 2009/10, the HFEA completed a change management programme called Programme 2010. This led the organisation through the changes that were needed in order to establish the right structure and processes to deliver an effective regulatory system under the 1990 Act (as amended). The resulting changes, new processes and policies have become part of the organisation's infrastructure and ways of working.

The following diagram shows the HFEA's staffing structure under the new model:



## Financial Context

The HFEA will need to continue to develop and evaluate all of the new processes that were put in place in 2009/10. It will also need to continue to deliver its underlying regulatory business, and to remain responsive to economic and political drivers by increasing its organisational efficiency and cost-effectiveness.

The HFEA will continue to maintain sound financial governance and business planning processes. We will continue to drive out inefficiencies and introduce quality processes and, because of our size, to collaborate or co-operate with similar bodies to improve economies of scale. This should enable the HFEA to demonstrate better and effective use of resources.

## Human Resources (HR)

The HFEA will continue to maintain sound HR processes, including recruitment and retention practices to attract and retain a high quality workforce within agreed establishment and budgets. The HFEA's management training and key skills programmes will be continued, so as to equip staff with the core skills and competences they need in order to perform their roles effectively, as well as providing the organisation with greater flexibility in the deployment of staff.

Together with the other Arm's Length Bodies and the Department of Health, we have actively developed a Talent Management network to nurture and manage talent across the sector and provide personal development and career planning for managers and future leaders. We may continue to take this forward in 2010/11.

In 2009/10, significant progress has been made with a review of all HR policies, which will be completed in the first quarter of 2010/11. Management and reporting procedures will continue to be improved. HR database and payroll procedures were also updated. In 2010/11 we will continue to build on this work making more effective use of IT to support HR processes where feasible.

The HFEA undertook an audit in 2009/10 in preparation for seeking Investors in People status at some stage in the future.

All staff pay is determined in line with HM Treasury annual guidance.

## Information Technology (IT)

The HFEA has an IT project pipeline plan that underpins the developing Knowledge and Information Management Strategy and an Information Asset Register identifying our key IT systems and their owners. IT ensures the HFEA complies with the data management requirements of legislation, including the HFE Act 1990 (as amended) and supports the significant databases we hold.

## Business Continuity

The HFEA has a business continuity plan in place, and this is regularly updated. This includes consideration of arrangements for continuing to operate business critical functions in the event of an emergency or significant staff sickness and has undergone a significant overhaul to reflect the new organisation.

## Estates Strategy

The HFEA has an estates strategy in place, and has responded to a property data benchmarking exercise carried out by the Office of Government Commerce. The accommodation strategy for the coming year will include an options evaluation in preparation for a forthcoming potential lease break in 2012, in alignment with Office of Government and Commerce (OGC) Directives. The office improvement at the beginning of 2009/10 continues to work well and deliver a much improved working environment.

## Sustainable Development

In conjunction with our landlord, the Insolvency Service, the HFEA recycles paper, plastic and glass bottles, cans, drinks cups, batteries and toner cartridges. All capable printers are pre-set to print on both sides of the paper and in black-and-white. Several old and high-cost printers were removed and lower-cost multi-functional devices introduced to print and scan, as part of the office redesign. Our IT equipment is reused as far as possible, switched off when the offices are not in use and surplus equipment either sold or donated.

The building has water taps operated by motion detectors to prevent water wastage, and all plants in the building are planted in peat free material and in 100% recycled pots. Nevertheless, the DEC shows a rating of G, which poorly reflects the efforts made by building and HFEA staff to be more sustainable but does indicate some serious building infrastructure shortcomings. These include the uncertain performance of the large photovoltaic array on the atrium roof. The HFEA intends to work constructively with the landlord on BUG (Bloomsbury Users Group), which was initiated in 2009/10, to assess what can be done.

In the coming year, the HFEA will further increase the use of video-conferencing, avoiding unnecessary travel; further reduce its dependency on paper; and introduce improvements to existing scanning equipment.

## Assurance Framework

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

The HFEA has robust information security arrangements in place, in accordance with Cabinet Office Security Policy Framework requirements. These include a Security Policy for staff, secure and confidential storage of and limited access to Register information, and stringent data encryption standards. All staff completed mandatory training on information security in 2009/10.

The HFEA also operates a clear desk policy, and has on-site shredders and confidential material disposal arrangements in place.

## Establishment and Resources

The new legislation that came into effect in 2009/10 has brought with it increased duties for the HFEA. The organisation's workforce strategy needs to reflect this. The resource position is set out in the following financial section.

# Financial Picture

## Overview

The HFEA is not immune from the pressures on the public finances, notwithstanding being the regulator for a sector that appears to be seeing demand maintained in the face of adverse UK economic circumstances. The underlying financial resources reflect 2009/10 levels, providing the HFEA sufficient capacity to continue to embed the changes initiated in response to the new Act and its change management programme, some of which are in the final stages of delivery, or in further development, in 2010/11. The numbers of people permanently employed will not increase overall.

The HFEA expects to once again have a tight budget and constrained resources, meaning that spend will continue to need careful management. A series of non-recurring projects to deliver essential improvements are planned, with Department of Health agreement. Some of the funding needed for these projects will come from reserved 2009/10 fee income (£0.4m). The HFEA overall approach is to manage resources prudently and deliver within organisational capacity in any single year and ensure that this year's projects logically build on those already delivered.

## Income Assumptions

The current assumption is that fee income for 2010/11 will be stable and be similar to last year's forecast level. Broadly, the impact of HFEA policies, NHS availability and the economic situation combine to produce no material change in patient demand for services.

The HFEA has accepted the Department of Health grant in aid offered and allocated it to cover both revenue and recurring capital. It is recognised that the small real drop in grant in aid is a stimulus to deliver operational efficiencies.

## Authority and Committee Costs

There are some new obligations that arise or start to incur costs in 2010/11. The new Act requires the HFEA to run the Donor Sibling Link, the Appeals Committee and the Research Oversight Committee, for example. There will also be costs on working groups for projects such as the internal assessment of unit costs required this year as a prelude to the fees review and on internal projects such as records management. The HFEA now publishes Member and Senior Officer expenses and seeks to use travel costs as effectively as possible. However, essentially, the overall demand on Members' time and the need for the Executive to support the Authority will remain largely unchanged in 2010/11.

A significant amount of process and improvement work is intended in dealing with the Hampton Review implications and taking forward work to build an HFEA quality management system. Activities and the resources that go with them will be re-shaped or re-configured to improve delivery – and a particular focus will be on effective use of IT to teleconference and improve document collaboration so as to save time and travel costs.

## Cost changes incorporated in 2010/11

There are no significant recurring cost changes in 2010/11. A number of one-off projects totalling £0.8m have been identified to improve records management and our corporate centre database, to evaluate both Programme 2010 and the Executive Licensing Panel, to review donation policies and in early 2010/11 to complete the public attitudes polling started in 2009/10. Collaboration with other ALBs, in talent management and other possible joint procurement, is expected to develop further.

HFEA costs are directly related to our payroll and the need for a suitable London office to accommodate our work, with associated running costs. A minor proportion is contracted out – for example, legal advice and other professional services.

### **Capital Costs**

There are no major capital projects expected in 2010/11.

# Budget Summary

2010/11 Budget	
Item	£m
<b>Costs:</b>	
Salaries (88 posts)	4.7
Training and other staff costs	0.3
Travel and subsistence	0.2
Recruitment, maternity etc.	0.2
<b>Total staff costs:</b>	<b>5.4</b>
Printing and telephones	0.2
Offices	0.4
Service Charges	0.3
Publications, events, web and media	0.5
<b>Total Office costs:</b>	<b>1.4</b>
Legal Fees	0.3
Audit fees etc.	0.4
<b>Total non-staff legal and governance costs:</b>	<b>0.7</b>
Members	0.4
<b>Total Member costs:</b>	<b>0.4</b>
<b>Total revenue costs 'base'</b>	<b>7.9</b>
<b>Capital 'base':</b>	
IT hardware/software	0.1
Furniture/office	0.0
<b>Total capital:</b>	<b>0.1</b>
<b>Total costs:</b>	<b>8.0</b>
<b>Income:</b>	
Clinic fees	5.2
EUTCD fees	0.1
Licences	0.1
Grant in aid revenue	2.1
Grant in aid capital	0.1
Reserved 2009/10 fee income	0.4
<b>Total income:</b>	<b>8.0</b>

# Performance Indicators

Performance against last year's targets is shown in the table below:

Performance Results in 2009/10:	Target	Outcome
<b>A. Compliance</b>		
No. of random unannounced inspections carried out this year	4	3
Reports resulting from initial applications and renewals inspections of clinics and research establishments available to clinics within 28 working days of the inspection date.	90%	92%
New treatment and research licence applications processed within four months of receipt of all necessary documentation and confirmation that the premises are ready for use.	90%	100%
<b>B. Communication and Information</b>		
Respond to requests for contribution to Parliamentary Questions within the deadlines set by the Department of Health	100%	100%
Number of Authority meetings held in public during the year.	3	3
Written enquiries from patients and the public responded to within three working days	95%	100%
Increase in visits to the HFEA website compared to 2008/9	10% increase	10.9% increase
Increase in visits to Find a Fertility Clinic/Choose a Fertility Clinic function on the HFEA website compared to 2008/9	10% increase	42%
Publication of finalised Licence Committee/Executive Licence Panel decisions on the HFEA Website within 20 working days	90%	100%
Freedom of Information (FOI) requests dealt with within 20 working days	100%	90%
Opening the Register requests dealt with within 20 working days (excluding counseling time for the person making the request)	100%	100%
<b>C. Corporate</b>		
Invoices paid within 30 days	95%	96%
Debts collected within 60 days	85%	82%
Monthly billings of clinics achieved in three weeks	95%	100%
<b>D. Arm's Length Bodies (ALB) Targets</b>		
Achieve revenue cost targets	Achieve £2.4 million Grant-in-Aid	Achieved <sup>1</sup>
Maintain full-time equivalent staff numbers	86.1 wte	81.8 wte

<sup>1</sup> The revenue cost target of £2,397,000 was achieved with only £1,937,299 being drawn down from the Department of Health  
2010/05263

Performance targets for this year have been set as follows:

<b>Performance Indicators for 2010/11:</b>	<b>Outcome 2009/10</b>	<b>Target 2010/11</b>
<b>A. Compliance</b>		
No. of random unannounced inspections carried out this year	3	4
Reports resulting from initial applications and renewals inspections of clinics and research establishments available to clinics within 28 working days of the inspection date.	92%	90%
New treatment and research licence applications processed within four months of receipt of all necessary documentation and confirmation that the premises are ready for use.	100%	90%
<b>B. Communication and Information</b>		
Respond to requests for contribution to Parliamentary Questions within the deadlines set by the Department of Health	100%	100%
Number of Authority meetings held in public during the year.	3	3
Respond to written enquiries from patients and the public within 20 working days of receipt (all are acknowledged within 3 working days).	Revised indicator for 2010/11	95%
Respond to policy enquiries within 3 days of receipt by Policy team.	New indicator for 2010/11	90%
Increase in visits to the HFEA website compared to 2009/10	10.87% increase	10% increase
Increase in visits to Find a Fertility Clinic/Choose a Fertility Clinic function on the HFEA website compared to 2008/9	42% increase	10% increase
Publication of finalised Licence Committee/Executive Licence Panel decisions on the HFEA Website within 20 working days	100%	90%
Freedom of Information (FOI) requests dealt with within 20 working days	90%	100%
Opening the Register requests dealt with within 20 working days (excluding counseling time for the person making the request)	100%	100%
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