

Authority Paper

Committee:	Authority Paper
Meeting Date:	9 May 2007
Agenda Item:	6
Paper Number:	HFEA (09/05/07) 371
Paper Title:	a) Regulation b) Finance c) HR
Author:	Trish Davies, Rachael Henry, Fiona Daffern
For Information or Decision?	Decision
Resource Implications:	None
Recommendation to the Committee:	To Approve the Report

a) Regulatory Activity Report – March 2007

This report sets out the activity and performance of the Regulation Department for the month ending March 2007 (Mar '07). This is done alongside comparative data from the start of the financial year in respect of inspections, licensing and incidents and/or the previous year's averages.

Inspection Programme and Reports Issued

The programme has currently exceeded targets for proposed inspections of the 2006/2007 year. **Table 1** shows all inspections done against their targets and **Figure 1** shows the last three months' activity.

Licence Type/Visit	Inspection Type	Target 06/07	Inspection Breakdown	
		No. of Inspections	Completed	Cumulative
			Feb '07	To Date
Treatment/Storage	Renewal	22	1	24
	Interim	20	6	23
Treatment & Storage of Research related centre	Renewal	11	1	11
	Interim	13	1	13
Research Licences of T/S related centre	Renewal	24	1	22
	Interim	6	0	6
Research Only	Renewal	2	0	2
	Interim	1	0	1
Additional	Announced	n/a	0	31
Targeted	Unannounced	n/a	1	6
Random	Unannounced	4	0	4
Exempt	Interim	25	n/a	n/a
Total		103	11	143

Table 1 – Inspection Programme Breakdown for Mar '07

March 2007 completed the inspection year. All centres have been inspected during the year unless they had been subject to an inspection exemption agreed by Licence Committee in 2006. Two centres were given one year licences so more renewal inspections were carried out than projected at the beginning of the year. Two research licences discontinued which is why two fewer research inspections were conducted.

In March 2007, the remaining six treatment and storage centres (0200, 0105, 0186/0187, 0008, 0032, and 0185) were inspected on an interim basis, the one remaining treatment and storage centre (0032) had a renewal inspection and one unannounced inspection was carried out to follow up concerns at the previous inspection (0077). One centre did not have a renewal inspection (0157). Centre 0004 had a renewal research inspection and an interim treatment and storage inspection.

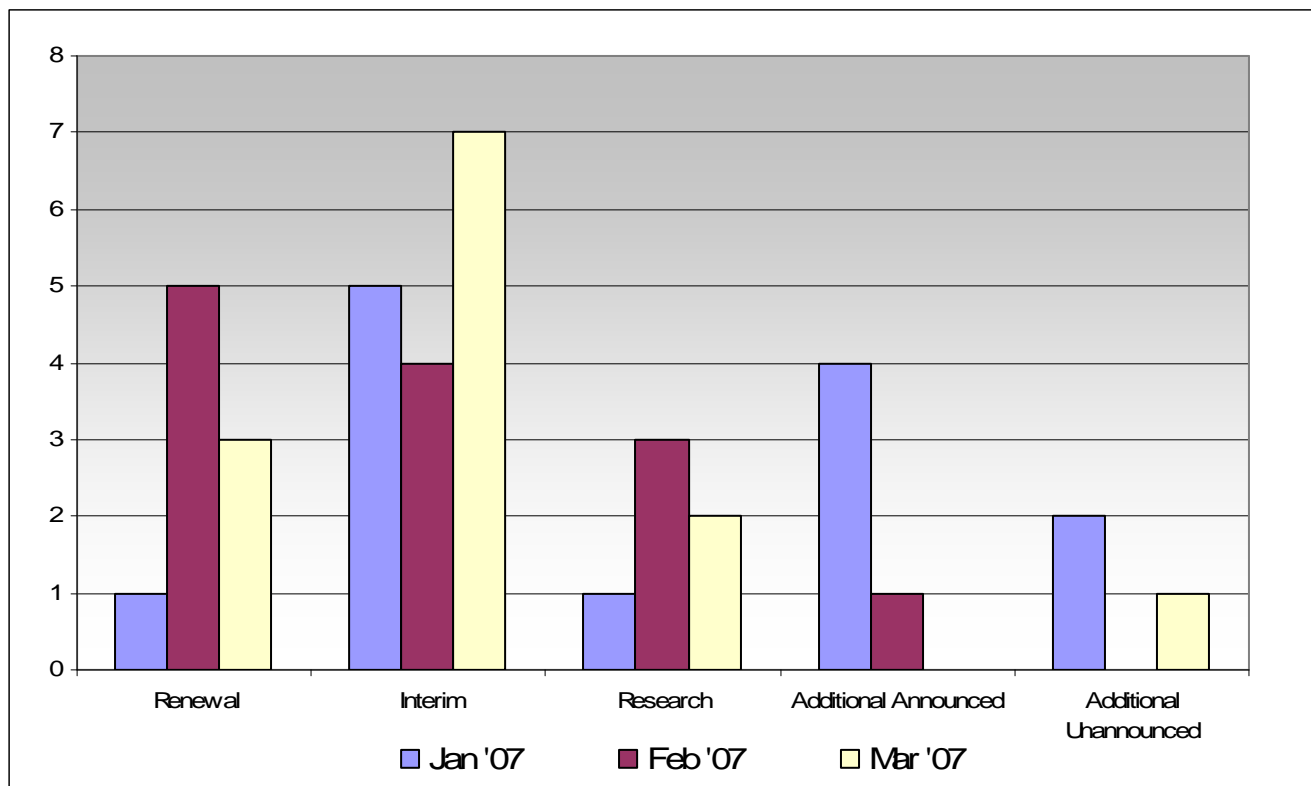


Figure 1 – Completed Inspections to date, Jan '07 – Mar '07

Report Production

Ten reports were distributed to centres within 28 days; eight of these were within 20 days. One report was sent to the centre outside the target time due to competing priorities. **Figures 2a and 2b** highlight the production of reports by the Regulation Department since the start of the year.

Reports	Average '05/'06	Jan '07	Feb '07	Mar '07	Average '06/'07
Within 28 Days	5	9	9	10	9
More than 28 days	2	1	2	1	1
% Achievement*	73	90	82	91	90

Table 2 – Report Production within 28 days, March 2007 vs '05/'06 Average

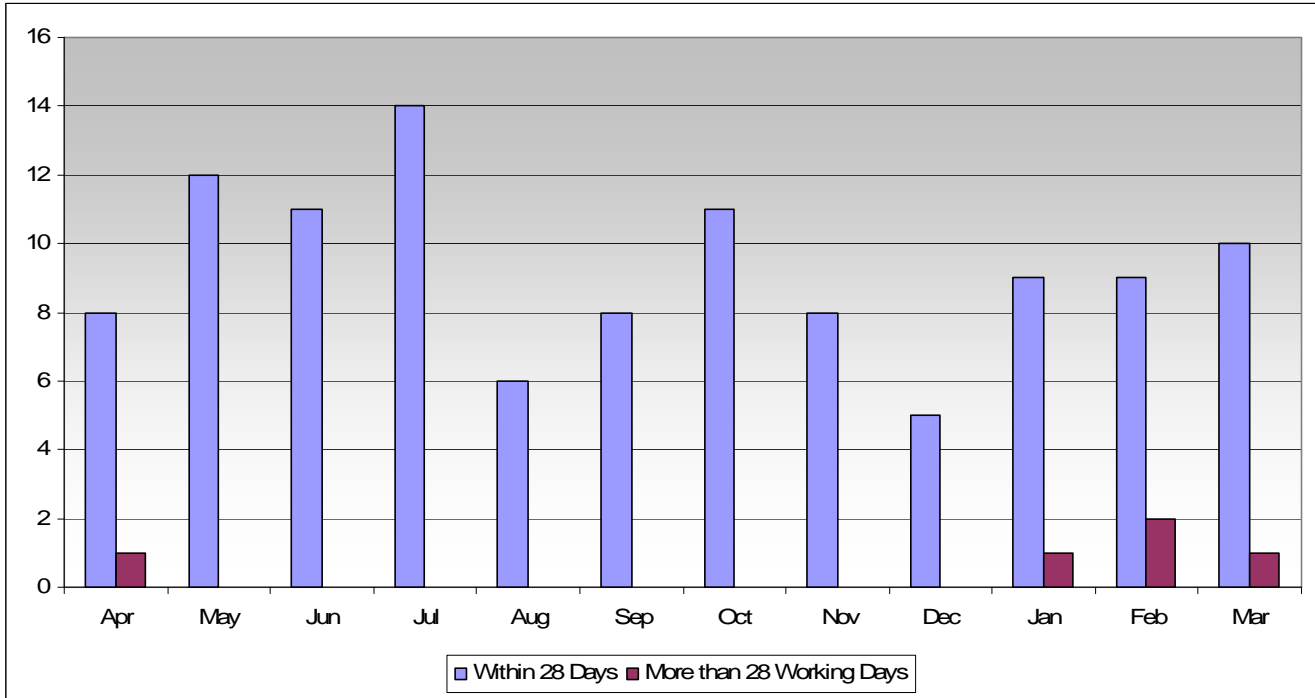


Figure 2a – Continued Overall Report Production within 28 days, Apr '06 - Mar '07

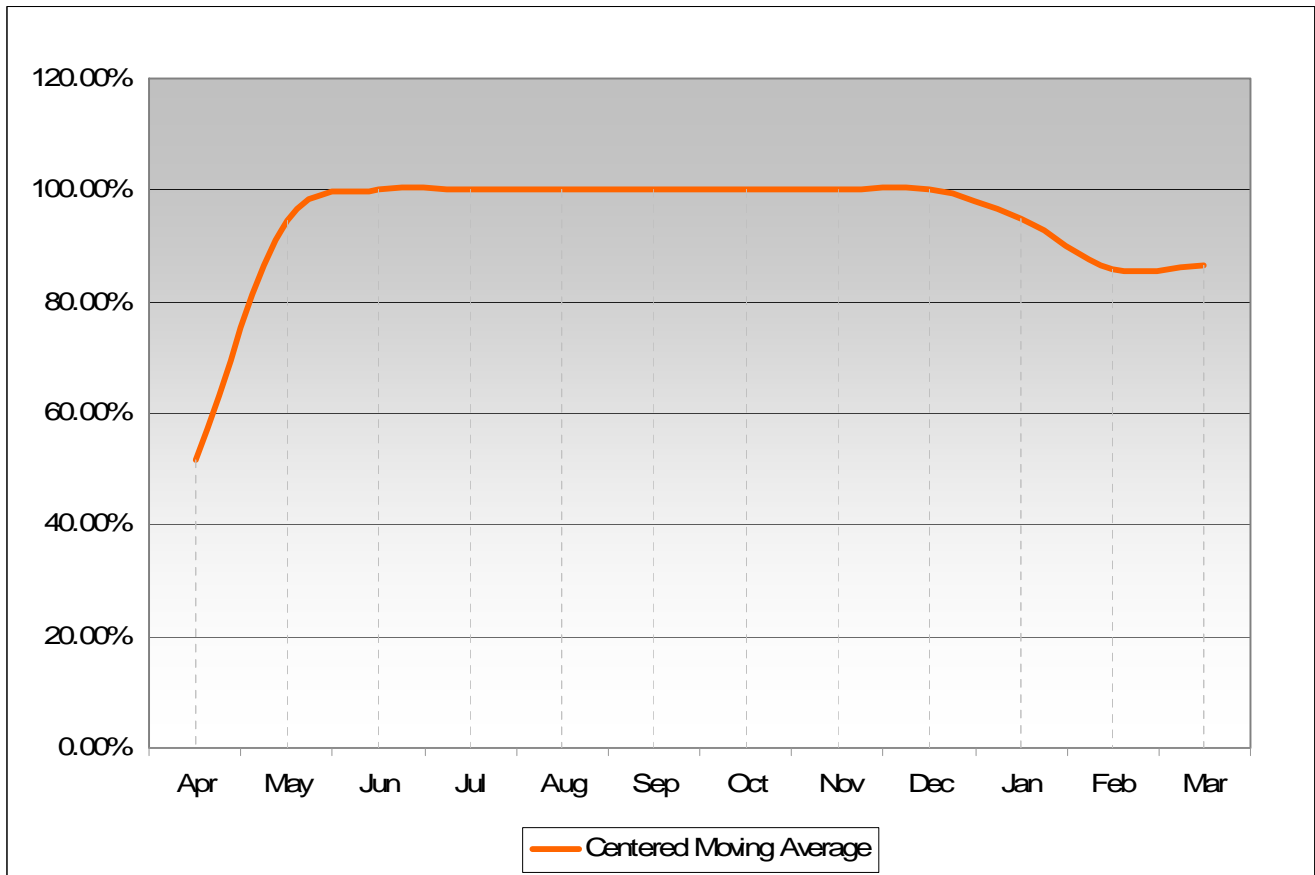


Figure 2b – Achievement % of reports completed within 28 days, Apr '06 – Mar '07

Import/Export Directions

This month the Regulation Department responded to 14 import/export applications, all for individual use. A breakdown of the figures shows that 123 ampoules were imported from the USA, Denmark and Republic of Ireland. The Regulation Department responded to two applications to import embryos from Germany and Belgium. Eight notifications for the export of sperm to Cyprus were received in March 2007. Two applications went to the Licence Committee this month, one for the export of sperm to Denmark as the storage period had been reached and the other for the export of embryos to the USA for a surrogacy arrangement.

Type	Average '05-'06	Jan '07	Feb '07	Mar '07	Average '06/'07
Import Sperm	8.3	75	86	12	27
Export Sperm	0.9	11	2	8	2.8
Import Embryos	0.9	4	2	2	1.8
Export Embryos	2.8	4	0	0	1.6
Total	12.9	94	90	22	33.2

Table 3 – Import / Export Directions, '05/'06 Average vs Mar '07

Import sperm applications were reduced this month but overall increased substantially during the 2006/7, making this year the largest for imports since recording began (**Figures 3a and 3b**).

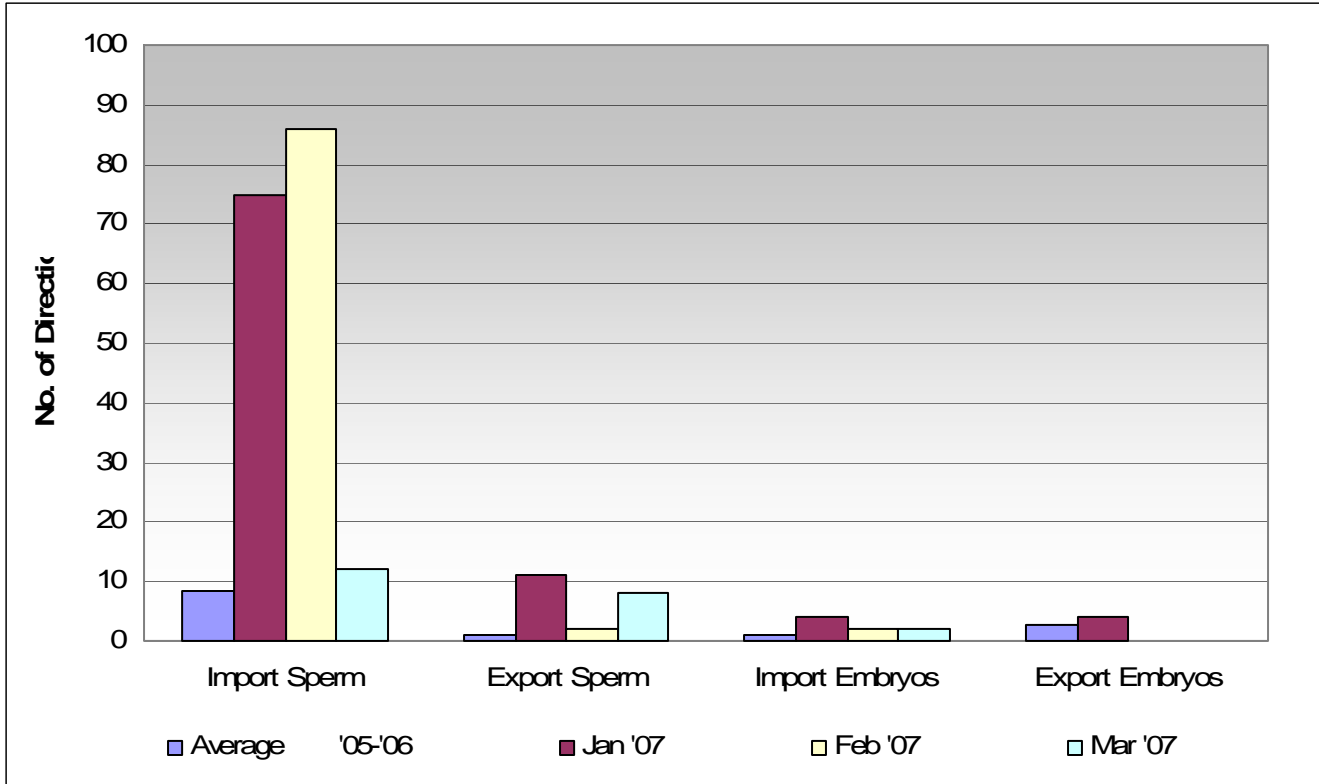


Figure 3a – Import / Export of Gametes Comparison – '05/'06 Average vs. Mar '07

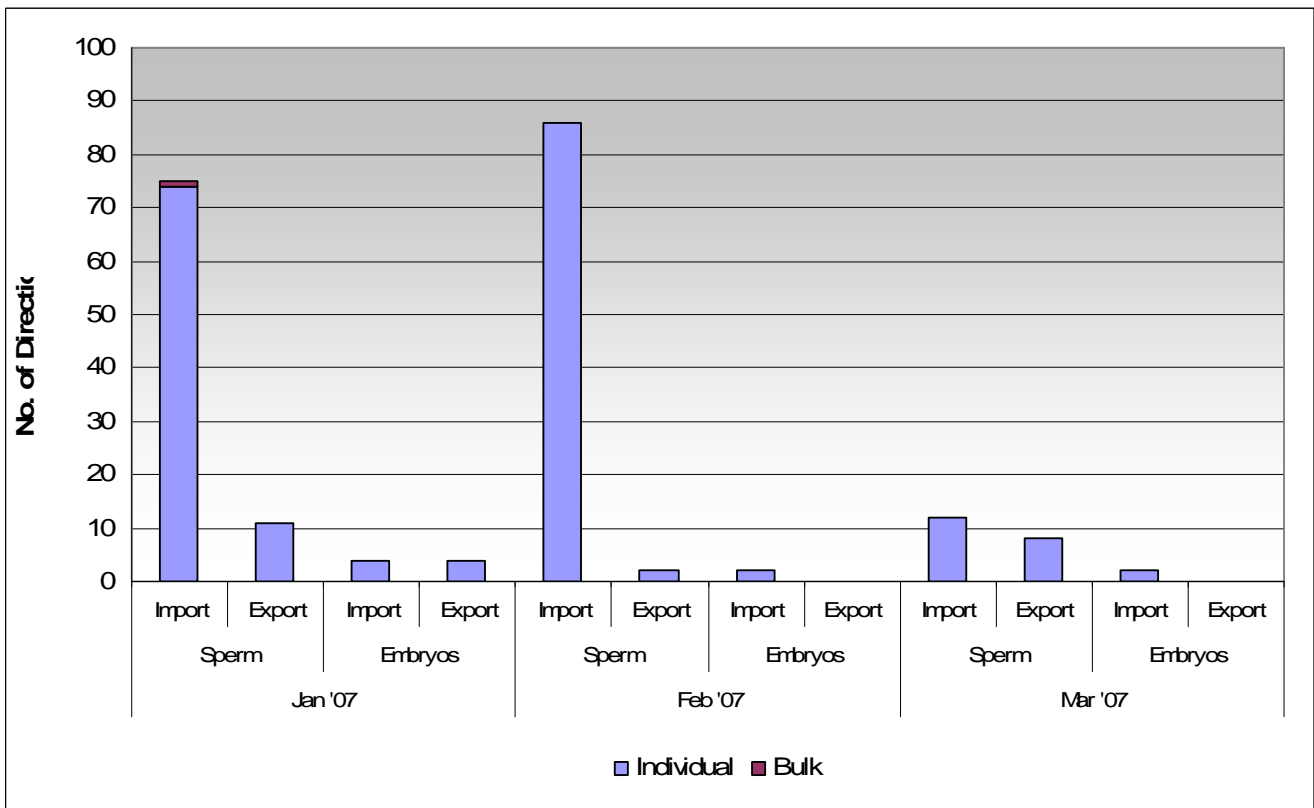


Figure 3b – Breakdown of Individual vs Bulk Gamete Usage, Nov '06 to Mar '07

Incidents

Some incidents have been moved to 'monitor' status and should be ready for closure in April 2007; very few were prepared for closure in March 2007 due to work-load priority of HFEA Helpline and back-log of work following staff absence in the Governance team during Qtr 1 of this year. The increasing number of witnessing-related incidents was prioritised and resulted in an onsite investigation, a licence committee (LC) report and the publication of Alert 22. Incidents reported for March 2007 were categorised as follows: two **Grade A**; two **Grade B**; six **Grade C**; 11 'to be assessed' (**TBA**); and one 'near miss'; See **Table 4**. To maintain consistency with the previous matrix used during the year, the categorised occurrence of these incidents is represented graphically (**Figure 4a**).

Incidents	Mar '07
Grade A	2
Grade B	2
Grade C	6
Assessed as 'TBA'	11
Near Miss	1
Total	22

Table 4 – Incidents Reported by Category, March 2007

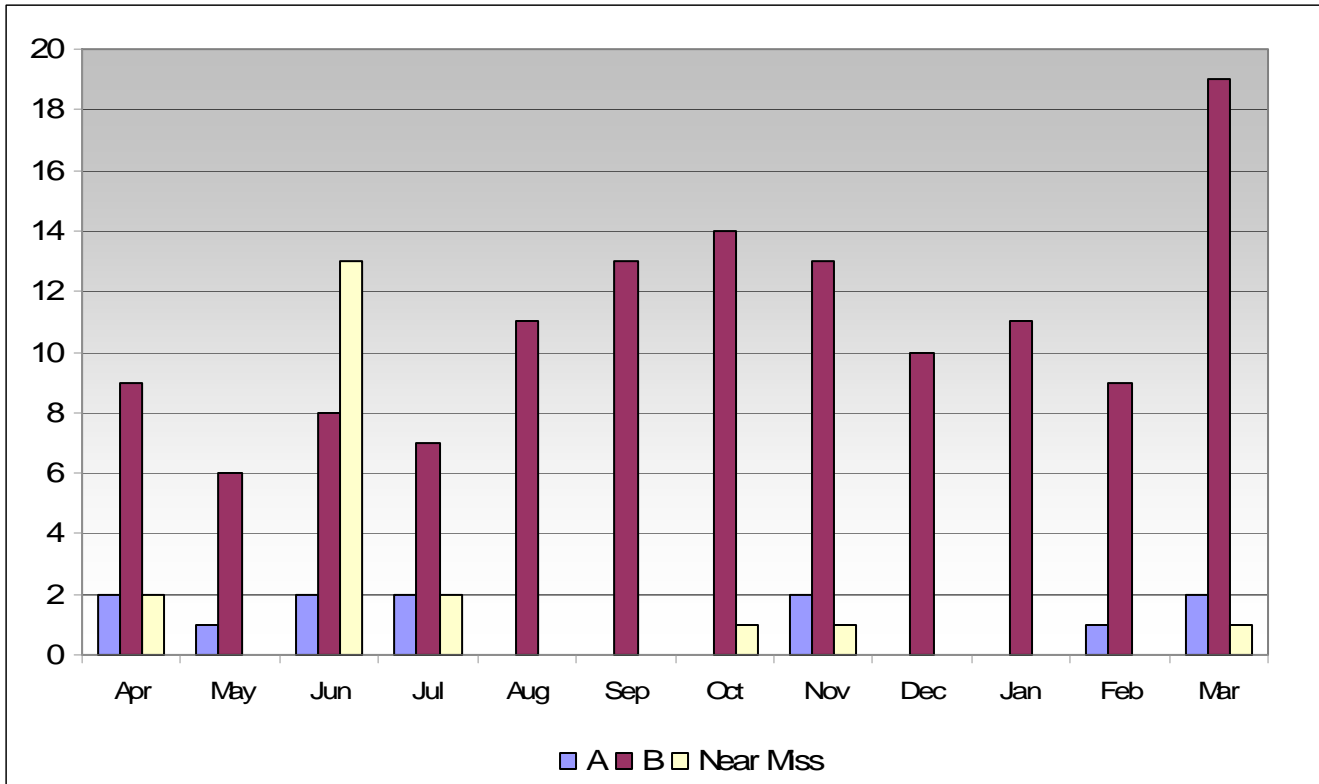


Figure 4a – Number of incidents reported per category, Mar '07

A total of 598 incidents have been reported since recording began. Three incidents were closed in this month with one centre being visited (**Table 4b**). **Figure 4b** shows the change in reported incidents and the gap between the numbers reported vs. those closed.

Incidents	Jan '06	Feb '07	Mar '07	Cumulative (to Mar '07)
Reported	11	10	22	598
Centres Visited	0	0	1	23
Closed	0	11	3	538

Table 4b – Incidents Reported and Closed March 2007 vs. Cumulative to date

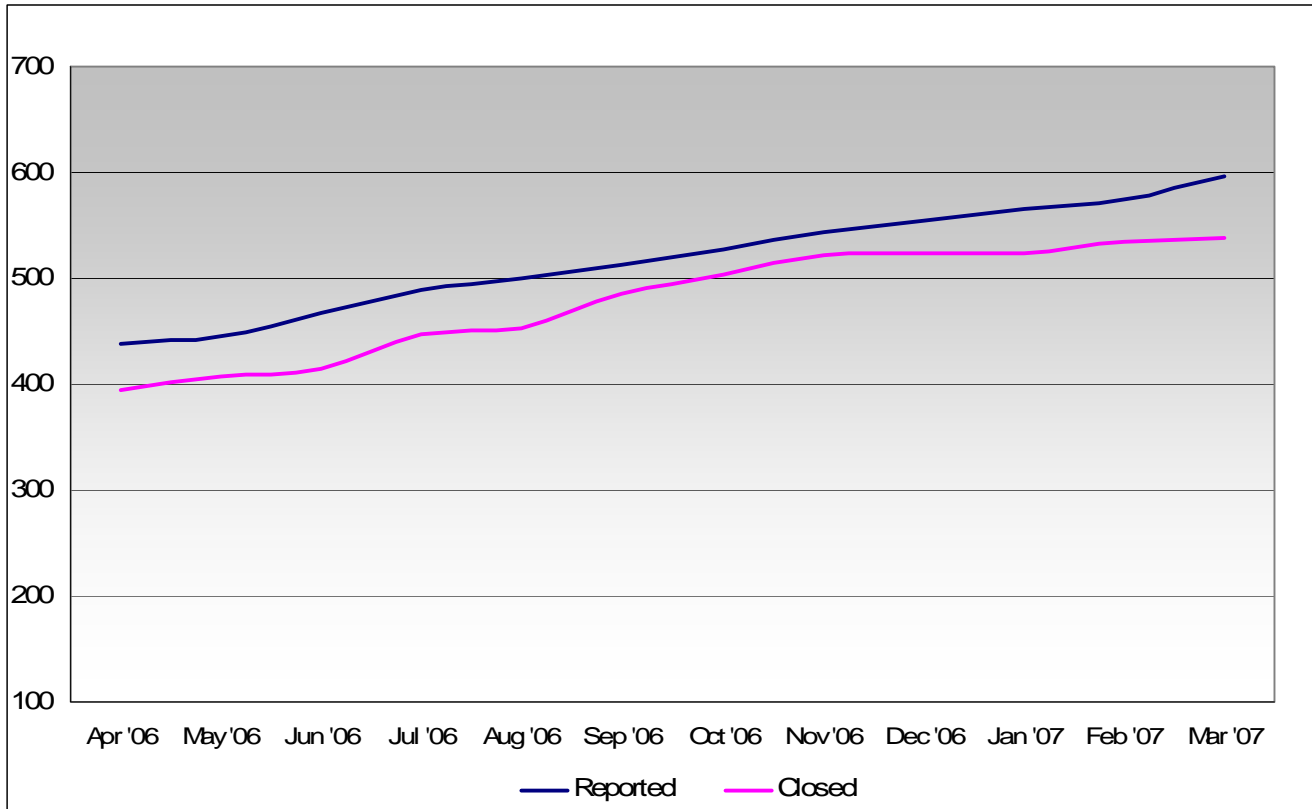


Figure 4b – Cumulative Incidents Reported and Closed, Mar '07

Alerts

One alert went out for the month of March. Alert 22 – witnessing of protocols involving Gametes and Embryos. This was a second Alert sent out recently around witnessing. Accompanying this alert was a paper on Human Error and the Swiss Cheese Tool.

Complaints

There were seven complaints during March. They varied between clinical and attitude, laboratory process and insufficient information. There was also one complaint about financial issues. A considerable amount of work is still underway with respect to complaints received previously about one centre.

Licensing Activity

Three Licence Committee meetings took place this month including one research licence committee meeting. There were 13 items of business in total. The items included under "other" in the graph (**Figure 5**) refer to one application to export embryos whose storage period had expired and one application to export sperm whose storage period had expired. The most notable trend this month were applications to vary the licence to add egg freezing; three applications of this sort were considered by the licence committees and all were approved, though with some suggestions for changes in the wording of patient information.

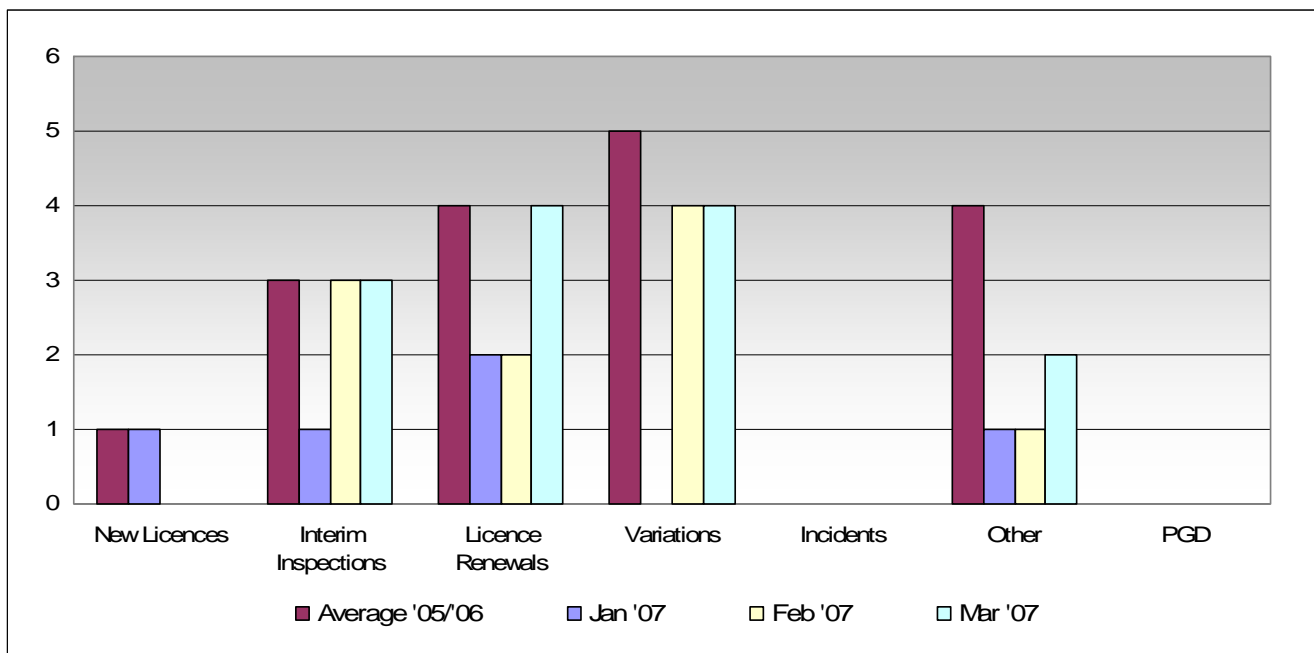


Figure 5 – Breakdown of Business – '05/'06 Average vs. Mar '07

There was one new PGD application received this month. These additional new applications for licensing are detailed in **Table 5** (below).

Research Licence Application	Date Received	Peer review	Licence Committee or Executive	KPI
Treatment Licence Application	Received	Site Visit	Licence Committee	KPI
Brighton Centre – Agora	30-10-2006	Initial New Premises/Centre visit 14 th Dec. 2006	18-01-2007 – Licence for one year granted	<input checked="" type="checkbox"/>
0208 – South East Fertility Unit	Nov. 2006	Visit – 9 th Nov, 2006 F/U visit carried out 19 th Jan 2007	Licence Committee 22-11-2006	<input checked="" type="checkbox"/>
Variation (PGD) to Licence Application	Received		Licence Committee	KPI
0101 – CARE Nottingham; X-linked cardiac valvular dysplasia	Application signed 11-10-2006		22-11-2006 Approved	<input checked="" type="checkbox"/>
0101 – CARE Nottingham; Chromosome 15	February 2007		Executive Approved 08-02-2007	<input checked="" type="checkbox"/>

Table 5 – New Licensing Application Activity for March 2007

Trish Davies,
Deputy Chief Executive/Director of Regulation

b) Finance Report

KEY ISSUES

1. This report presents the February 2007 management accounts together with income/cost and treatments reported by date graphs.
2. With increased proximity to the financial year end, all income and cost forecasts have been reviewed for the month and a number of virements have been calculated.
3. Overall, a forecast surplus of £61.5k for the year has been calculated. Hitherto, a break even position had been forecast. Discussions have been and are continuing to be held with the Department to enable the Authority to utilise the year end surplus to meet committed costs as at 31 March 2007. Approval has been given in principle on submission of details of these committed costs to the Department.
4. The two key areas of uncertainty which have the potential to make a material impact on the final outturn for the year however remain : fee income and the costs associated with current regulatory action.
5. An update on the final outturn to 31 March will be provided at this meeting.

INCOME

Y-T-D Actual £6.33m, Budget 5.78m

Full Year Forecast £6.7m, Budget £6.348m

6. Overall, there has been a net increase in forecast income of £91k.
7. On the basis that reported monthly fee income has remained buoyant, forecast license fee income for the year has been increased by a further £89k. This follows the increase in forecast fee income in January's management accounts of £130k.
8. The delay in the implementation of EDI resulted in the late receipt of comprehensive information to facilitate the forecast of income to the end of the financial year. Following the completion of the EDI rollout, this information will be more readily available for 2007/08.

9. Further progress was made in the month with the final stages of the EDI rollout. All clinics with the exception of two very small units are now on EDI. The reconciliations between manual and EDI data were completed during March and where material underbilling was confirmed, the clinics have been invoiced.
10. Work is in the course of completion to ensure that the calculation of year end accruals and deferred income are correct. The review of potential cumulative duplicate cycles since 2002 is still in progress, together with the review of potential unreported treatments by clinics. The overall aim of the foregoing work is to ensure that the fee income reported for March and the year overall is accurate.
11. In addition to the foregoing, forecast other income has been increased by £2k.

COSTS

Chief Executive's Office

Y-T-D Actual £466k, Budget £413k

Full Year Forecast £512k, Budget £451k

12. Overall, there has been an increase of £10k in the total forecast for the year. £5k has been vired into both pay costs and into non-pay costs to cover the costs of the interim legal adviser and the Chief Executive's travel to the Growing Globally (stem cell) Conference in San Francisco.

Staff Costs – Other

Y-T-D Actual £170k, Budget £296k

Full Year Forecast £226k, Budget £323k

13. Overall, there has been a virement of £5k into the total forecast for the year, relating to the purchase of training materials that will provide a resource to staff over subsequent periods.

Authority/Committee Costs

Y-T-D Actual £202k, Budget £229k

Full Year Forecast £236k, Budget £251k

14. No revisions to forecasts have been calculated in respect of these costs.

Regulation and Corporate Planning

Y-T-D Actual £1.23m, Budget £1.2m

Full Year Forecast £1.364m, Budget £1.316m

15. No revisions to forecasts have been calculated in respect of this department.

Communications and Policy

Y-T-D Actual £982k, Budget £975k

Full Year Forecast £1.19m, Budget £1.064m

16. Overall, there has been a virement of £10k into this department's budget, relating to an increase in forecast pay costs for the year. This has arisen primarily from recent changes to the staffing structures within the communications and press teams.

Resources and Corporate Development

Y-T-D Actual £1.216m, Budget £1.232m

Full Year Forecast £1.38m, Budget £1.345m

17. Overall, there has been a reduction of £16k in the forecast outturn for this department.
18. Following a review of all costs and revisions to calculations where appropriate, forecast pay costs have been reduced by £10k, stationery, courier and postage costs by £8k, and other costs by £2k. There has been an increase in forecast equipment hire costs of £4k.

Information Management

Y-T-D Actual £1.3m, Budget £1.2m

Full Year Forecast £1.435m, Budget £1.3m

19. Overall, there has been a virement of £10k into this department's forecast outturn, relating to a forecast increase in low value assets and consumables costs for the year.

Legal Fees

Y-T-D Actual £83k, Budget £61k

Full Year Forecast £132k, Budget £67k

20. As anticipated in earlier reports, forecast legal fees have been increased by £10.5k to cover the costs relating to current regulatory action. This increase is based on best estimates of Morgan Cole and counsel fees.

Professional Fees

Y-T-D Actual £35k, Budget £30k

Full Year Forecast £85k, Budget £145k

21. No revisions to forecast have been calculated in respect of these costs.

Capital Costs

Y-T-D Actual £61k, Budget £78k

Full Year Forecast £85k, Budget £85k

22. No revisions to forecast have been calculated in respect of these costs.

c) HR Report

1. HR STATISTICS

1.1 Establishment - Projected

Profile of HFEA Headcounts 2006-07 (ALB Return)

Month	Projection		
	Headcount	WTE	P/T headcount (WTE)
April	108	105.38	8 (5.38)
May	102	99.38	8 (5.38)
June	95	92.76	7 (4.76)
July	95	92.76	7 (4.76)
August	95	92.76	7 (4.76)
September	98*	95.76	7 (4.76)
October	83*	81.2	6 (4.2)
November	83*	81.2	6 (4.2)
December	83*	81.2	6 (4.2)
January	83*	81.2	6 (4.2)
February	83*	81.2	6 (4.2)
March	83*	81.2	6 (4.2)
TOTAL	83*	81.2	6 (4.2)

* Three posts added from original ALB return to cover EUTCD requirements

1.2 Establishment – Actual headcount

Department	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
CE's Office	8	8	8	8	8	8	8	7	7	7	7	7
Resources	10	9	9	9	10	10	9	9	10	10	10	10
CoPo	19	20	18	17	16	18	18	18	19	18	18	17
Regulation	26	25	23	23	23	25	25	23	26	26	26	25
Information	35	33	30	30	28	28	27	24	23	22	23	22
HAP	8	5	5	5	4	2	0	0	0	0	0	0
Total	106	100	93	92	89	91	87	81	85	83	84	81

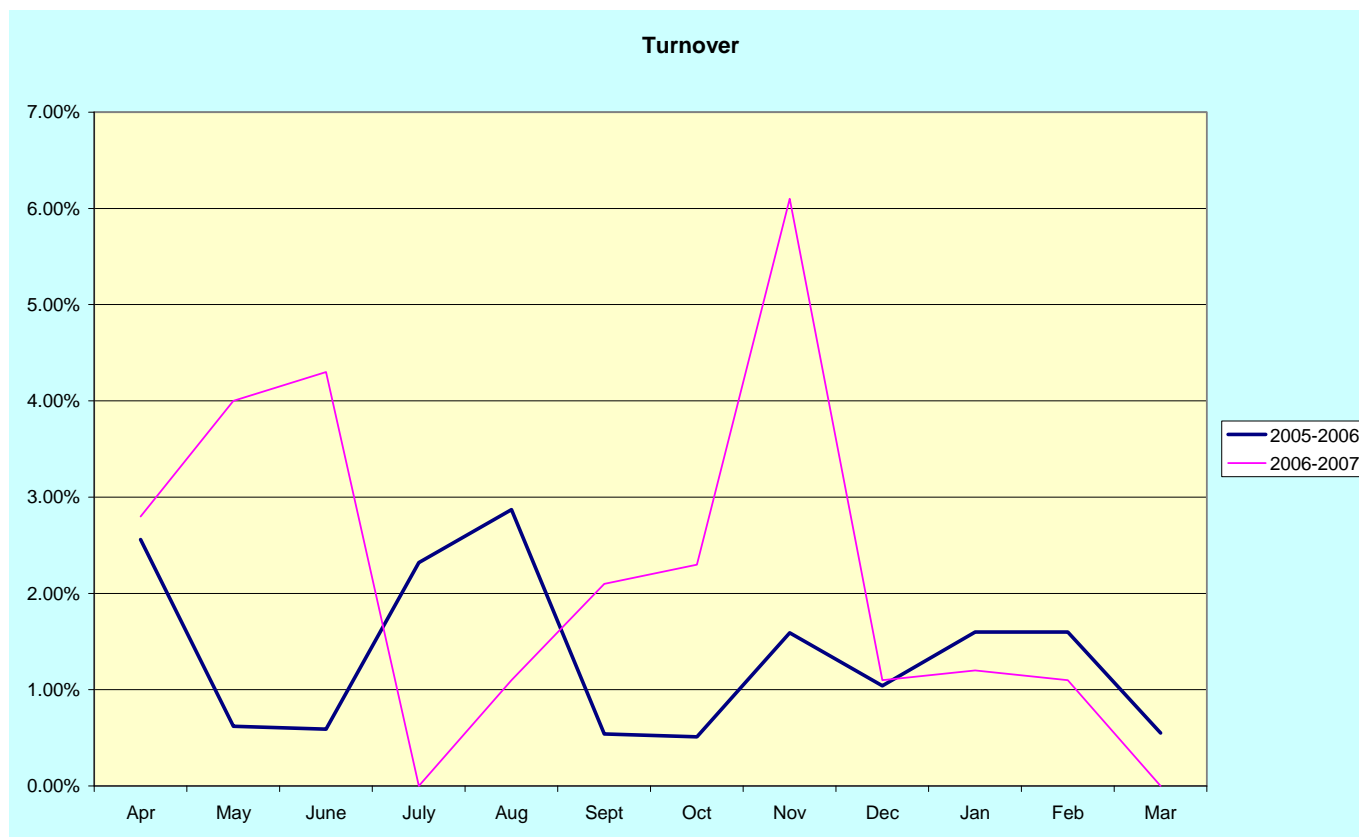
1.3 Staff Turnover

Month	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Monthly turnover %	2.8%	4%	4.3%	0%	1.1%	2.1%	2.3%	6.1%	1.1%	1.2%	1.1%	0%

Annual Projection

Actual annual turnover 05/06	14.9%	12 month rolling average annualised turnover 06/07	26.1%
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Turnover figures include all staff working for the HFEA, including fixed term staff. However staff who have left the Authority as a result of their contracts ending have not been included. Turnover rate calculated as: $\frac{\text{Number of leavers (headcount)}}{\text{Average headcount during period}} \times 100$



Target: Reduce turnover rates to 12%

Comment: Turnover rates have stabilised since December.

1.4 Absence

Month	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Sickness absence rate %	1.5%	0.78%	1.75%	0.98%	1.22%	2.35%	1.93%	3.64%	2.96%	1.69%	1.66%	1.23%
Actual Days	17	14	35	16	25	47	37	81	53	31	28	22
Actual Staff Absent	6	11	18	12	11	22	15	21	13	12	18	12

Annual Projection

Average sickness absence rate	1.80%
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Sickness absence rate is calculated as: $\frac{\text{no of working days lost} \times 100}{\text{Total staff time available (total no of working days)}}$

Target: Sickness rates at 3% or below

Average annual levels remain very low. Actual days off averages at 4.5 per person per annum. In comparison in 2005 (last data available) an average of 9.8 working days were lost per staff year to sickness absence across the whole Civil service.

2. CURRENT RECRUITMENT

Communications & Policy

Policy Officer
 Policy Manager (maternity cover)
 Press Officer / Media Relations Manager (1 post)
 Stakeholder Relations Manager

Regulation

Inspector

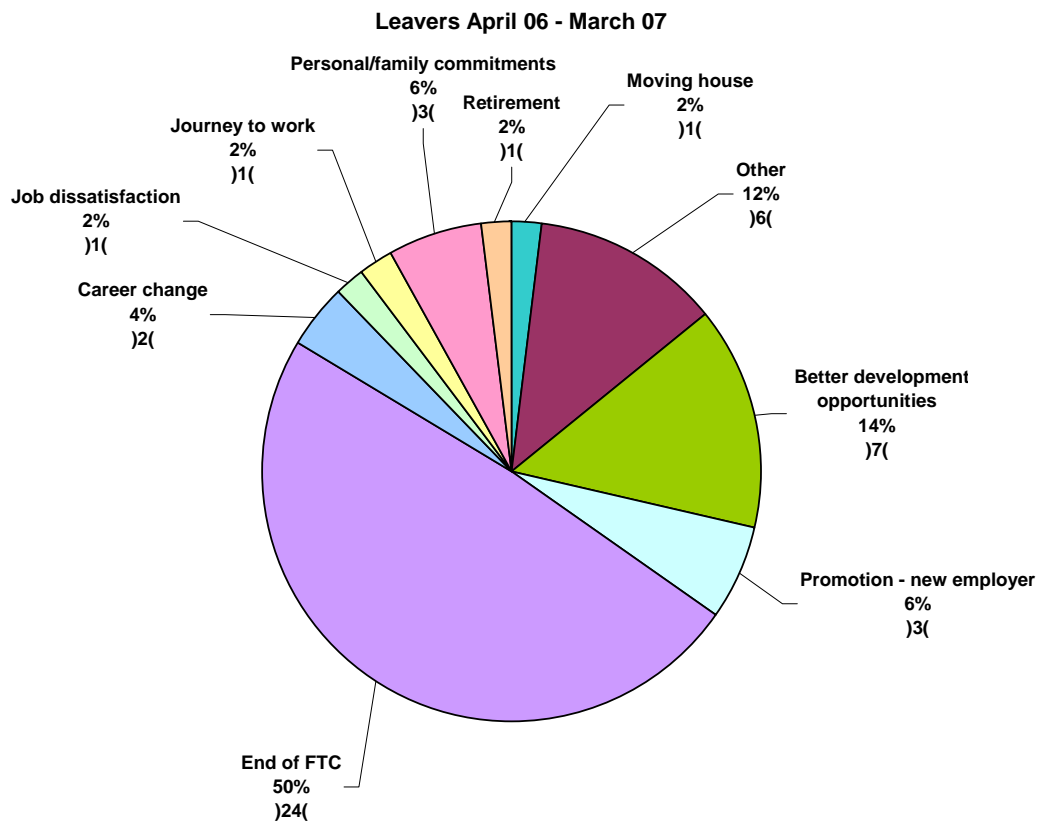
Annual recruitment:

- Undertaken 25 recruitment exercises for the HFEA (including 1 repeat exercise)
- 27 successful appointments (3 exercises resulted in 2 appointments)

3. NEW EMPLOYEES FROM 1 MARCH 2007 AND ACCEPTED OFFERS OF EMPLOYMENT

Directorate	Post	Date of Joining
Information	Assistant Network Analyst (HTA support)	02/04/07
CEO	PA to the Chair & Head of Business Planning	02/04/07
Information	Assistant Network Analyst	30/04/07
COPO	Policy Manager (secondment cover)	08/05/07
COPO	Policy Manager (secondment cover)	10/04/07
Regulation	Inspector (Scientific)	08/05/07

4. REASONS FOR LEAVING



Note: One leaver = 2 % (percentages above have been rounded). The numbers below are the actual numbers involved. 'Other' includes staff that have left for reasons which do not relate to matters that can be affected by actions within the workplace, for example, staff who have gone travelling, or staff who have ticked the 'other' box but not given a specific reason.

5. YEAR END REVIEW - 06/07 HR WORK PLAN

All HR objectives were materially met over the year. In addition to the range of operation work undertaken from payroll and pensions processing to job evaluation, the highlighted achievements for this year include:

5.1 Objective: Support managers to deliver PDP process

- Training delivered for staff and managers
- Definitions for ratings revised and introduced
- Heads level moderation introduced for consistency and transparency
- Process for awarding box markings for staff on maternity leave clarified
- PDPs completed for all staff
- Work group set up to develop guidelines of improving feedback and system being piloted

5.2 Objective: Identify core training needs for 06/07 and develop/commission/deliver annual programme of events

- Corporate training needs were identified and delivered on:
 - Equality and diversity (including Authority members) – all staff
 - Workshops to support implementation of the competencies framework – all staff
 - Handling public enquiries – communications, policy, regulation, PAs and QA staff
 - Continuing to develop leadership and management skills – individuals
 - TRIM – all staff
 - Implementing the new Inspection regime – Regulation
 - Preparedness for EUT&CD – Regulation
 - Developing the Staff Forum - Staff forum members
- Deferred pending decisions on introduction of CRM system
 - Customer relationship management
- Individual training needs were identified via the PDP process and priorities agreed with managers.

5.3 Objective: Develop behavioural competency framework for the HFEA and HTA and link to PDP and recruitment process

- Competency framework developed and implemented for the HFEA
- Competency based recruitment introduced for all new posts from 1 October 2006
- Competencies identified for staff at 6 month PDP review

5.4 Objective: Support and promote staff involvement in business and organisational issues through active engagement with Staff Forum

- Development day facilitated by the Work Foundation Oct 06
- Review of work programme undertaken and forward planning for 07/08 agreed
- Topics discussed throughout the year include:

- Equality and diversity strategy
- HR policy reviews
- Competencies framework
- Changes to the PDP process
- Internal communications, and
- Environmental issues

5.5 Objective: Promote good internal communication systems

- Contributed to development of Internal Communications Strategy
- Chaired cross departmental working groups on developing competencies; feedback for PDP; lone working; bullying and harassment
- Participated in Diversity strategy working group
- Delivered roadshows through team meetings on the competencies framework
- Use Intranet for delivering messages and updates
- Delivered training
- Consultations with all staff on HR policy development

5.6 Objective: Provide advice and support to managers and staff to maintain good employee relations

- There were three formal matters raised and satisfactorily concluded
 - 1 performance issue at probation
 - 1 disciplinary
 - 1 grievance

These have been analysed in terms of discrimination issues. There are no express concerns relating to either subject matter of the concerns or make up of the individuals involved.

5.7 Objective: Develop and start embedding equality & diversity issues within the organisation

- Provided advice and guidance to, and participation in, the working group set up to develop the HFEA Diversity Strategy
- Developed the HR strands of the Diversity Strategy, equality schemes and action plan
- Provided training for managers on the implications of the new Age discrimination legislation
- Undertaken an age audit of terms and conditions, and amended in line with legislation and introduced a Retirement policy
- Reviewed and updated all HR policies to ensure compliance with the range of current discrimination and diversity related legislation
- Commissioned a training programme for the organisation on diversity awareness
- Working group set up to make recommendations for action and guidance on harassment & bullying and lone working

5.8 Objective: To work with the HTA Executive to develop and deliver a comprehensive HR service in line with the SLA

- Regular meetings held to discuss strategic issues and concerns
- Acknowledgement and agreement reached on various matters of commonality and difference between the organisations

a. HR Ratio to staff

ALB target = 1:129

04 - 05 (HFEA only)	1:71
06 - 07 (inc HTA staffing)	1: 86
07 - 08 (inc HTA staffing)	1: 94

b. Cost of HR services

ALB average = £745

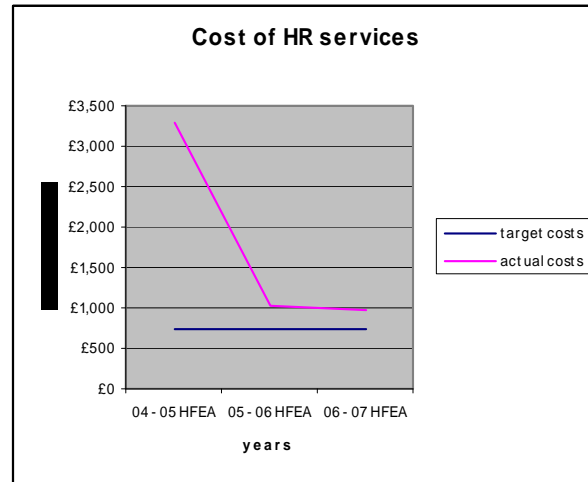
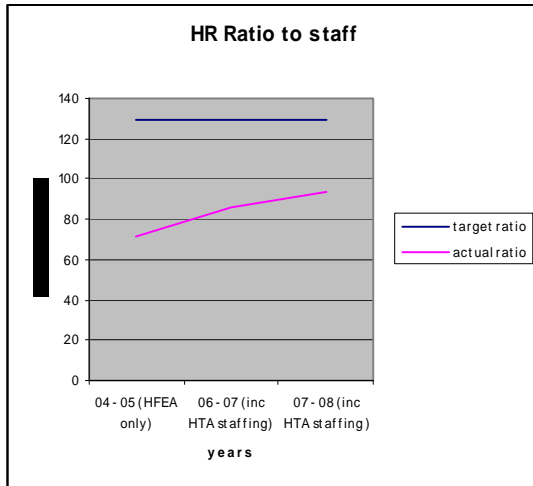
04 - 05 HFEA	£3,293*
05 - 06 HFEA	£1,023
06 - 07 HFEA	£980

* exceptional recruitment costs were incurred in staffing the Historic Audit Project

- Providing a development programme for an HTA staff member to train up as HR link between the organisations
- Undertaken 13 job evaluations for the HTA
- Undertaken 24 recruitment exercises for the HFEA (including 4 repeat exercises)
- 32 successful appointments
- Increased hours worked on the SLA between Sept – March.

5.9 Objective: Continue to review areas for efficiency savings, including shared services options, in line with the Gershon recommendations

Year on year efficiency savings have been made on HR staffing ratios and costs, as follows:



- Annual recruitment costs £47,169 (£84,831 under budget)

5.10 Objective: Working towards RATE

- Attending meetings of the OFHR sub group
- Drawn up project plan for the HR strand
- Developed in draft form, processes to be followed for staff transferring or appointed to RATE
- Undertaken research on relocation packages
- Developed, in draft form, template for staff survey to monitor how well the changes are managed and communicated with staff

Fiona Daffern
Assistant Director HR&OD