

Authority Meeting

Committee:	Authority
Meeting Date:	5 September 2007
Agenda Item:	6
Paper Number:	HFEA (05/09/07) 394
Paper Title:	Regulation, Finance and HR Report
Author:	Trish Davies, Rachael Henry and Fiona Daffern
For Information or Decision?	Decision
Resource Implications:	None
Recommendation to the Committee:	To Approve the Report

Regulatory Activity Report – July 2007

This report sets out the activities and performance of the Regulation Department for the month ending July 2007.

Inspection Programme and Reports Issued

For the month of July, a total of eight inspections were completed. Three inspections were carried out to treatment and storage centres; one interim (**0100**) and two additional inspections (**0019** and **0293**). Two interim inspections of research-licensed facilities were also done (for **0017** and **0100**). The remaining three inspections were done for IUI related centres recently licensed under the European Union Tissue Directive (EUTD); the relevant centres being **0255**, **0256**, **0279**.

Licence Type/Visit	Inspection Type	Targeted	Inspection Breakdown	
		No. of Inspections	Completed June '07	Cumulative To Date
Treatment/Storage	Renewal	25		7
	Interim	45	1	11
	Additional Announced	N/A	2	6
	Additional Unannounced	N/A		2
	Random	4		0
Research Only	Renewal	12		4
	Interim	21	2	6
	Additional Announced	N/A		2
IUI (Other Treatments)	Initial / Additional	TBA	3	3
	Exemptions	20	--	--
Total		107	8	41

Table 1 – Inspection Programme Breakdown for July 2007

Table 1 shows all relevant inspections for the period to date (started April 2007) and **Figure 1** provides representation of the number of inspections done by general type.

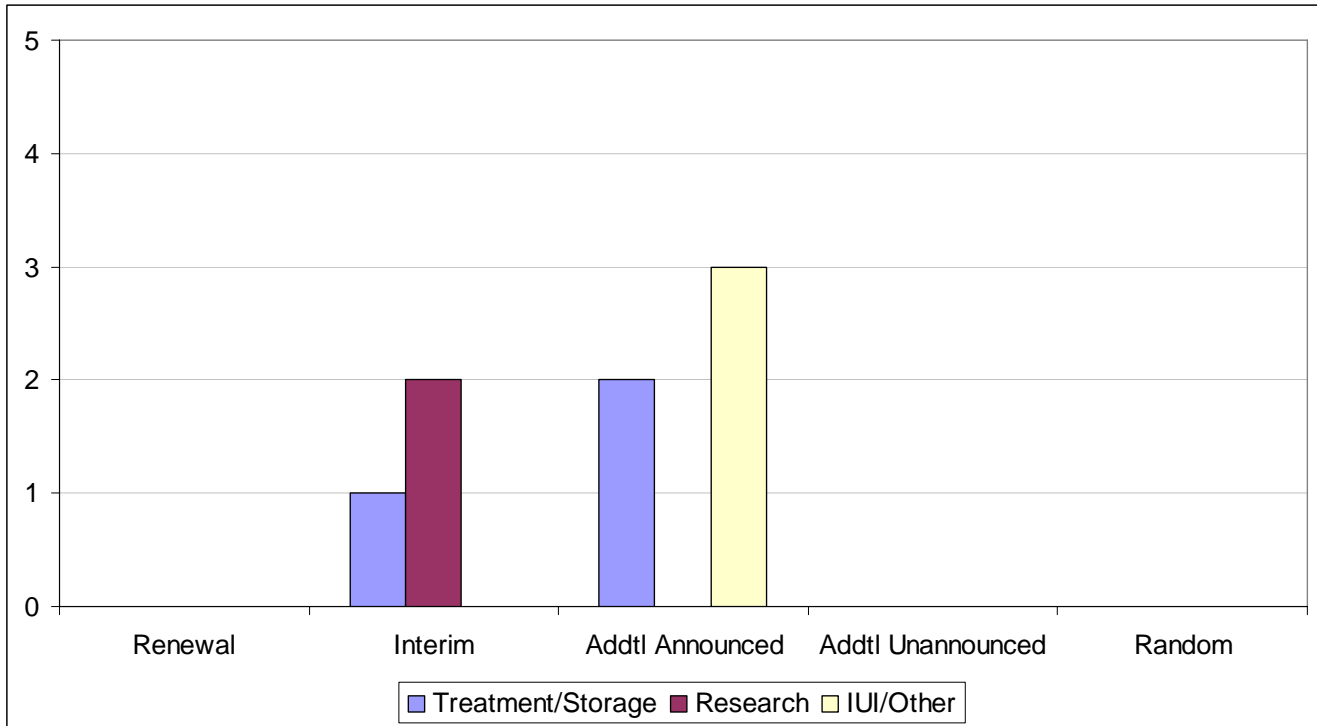


Figure 1 – Completed Inspections for month ending – July 2007

Report Production

Nine reports were sent out within 28 days of which five were within 20 days. Two reports were over 28 days due to IT problems with laptop(s).

Reports	May 2007	Jun 2007	Jul 2007	2007/08 Cumulative
Within 28 Days	6	12	9	35
More than 28 days	1	0	2	4
% Achievement	86	100	82	90

Table 2 – Report Production within 28 days, July 2007

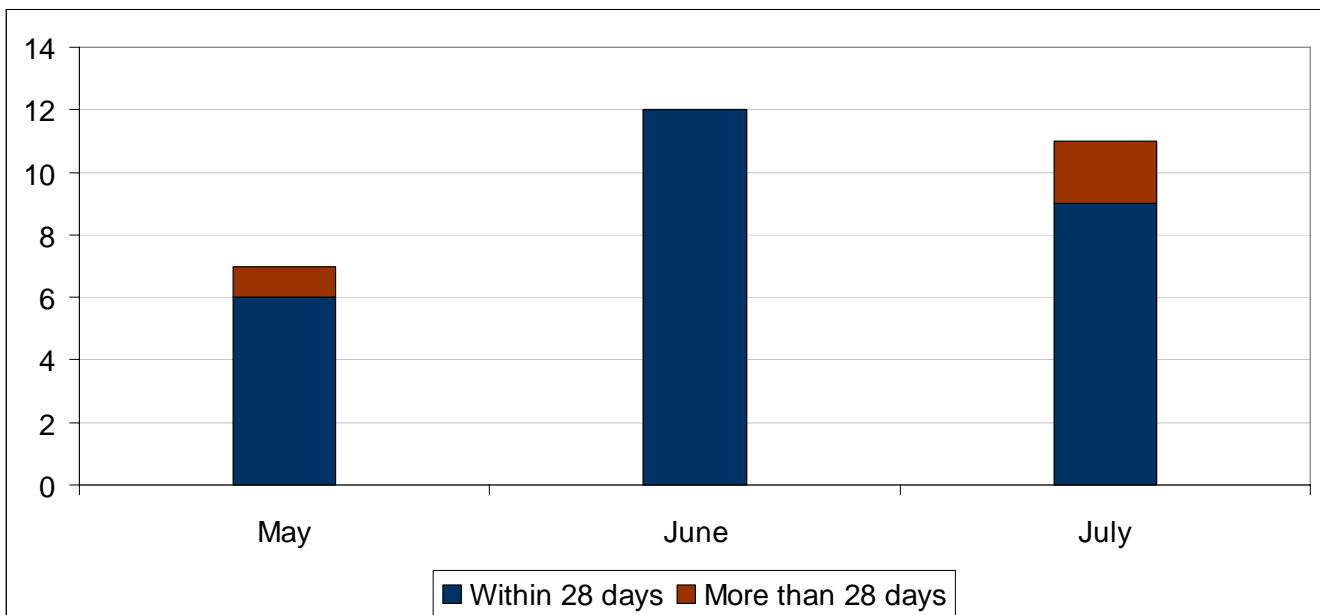


Figure 2 – Overall Report Production, within 28 days, May – July 2007

Import/Export Directions

This month the Regulation Department responded to nine import/export applications, for patients for individual use. A breakdown of the figures shows that 109 straws/vials of sperm were imported from Italy, USA and Denmark and 12 embryos were also imported from Canada. The Regulation Department responded to two applications to export embryos to Ireland and the USA. There were two exports of sperm notifications for sperm being exported to Australia and Italy. No applications went to Licence Committee in July 2007.

Type	Average '06-'07	May 2007	Jun 2007	Jul 2007
Import Sperm	27	1	3	6
Export Sperm	3	5 ¹	0	2
Import Embryos	2	1	1	1
Export Embryos	2	1	2	2
Total	34	8	6	6

Table 3 – Import / Export Directions & Notifications, 2006/2007 Average vs July 2007

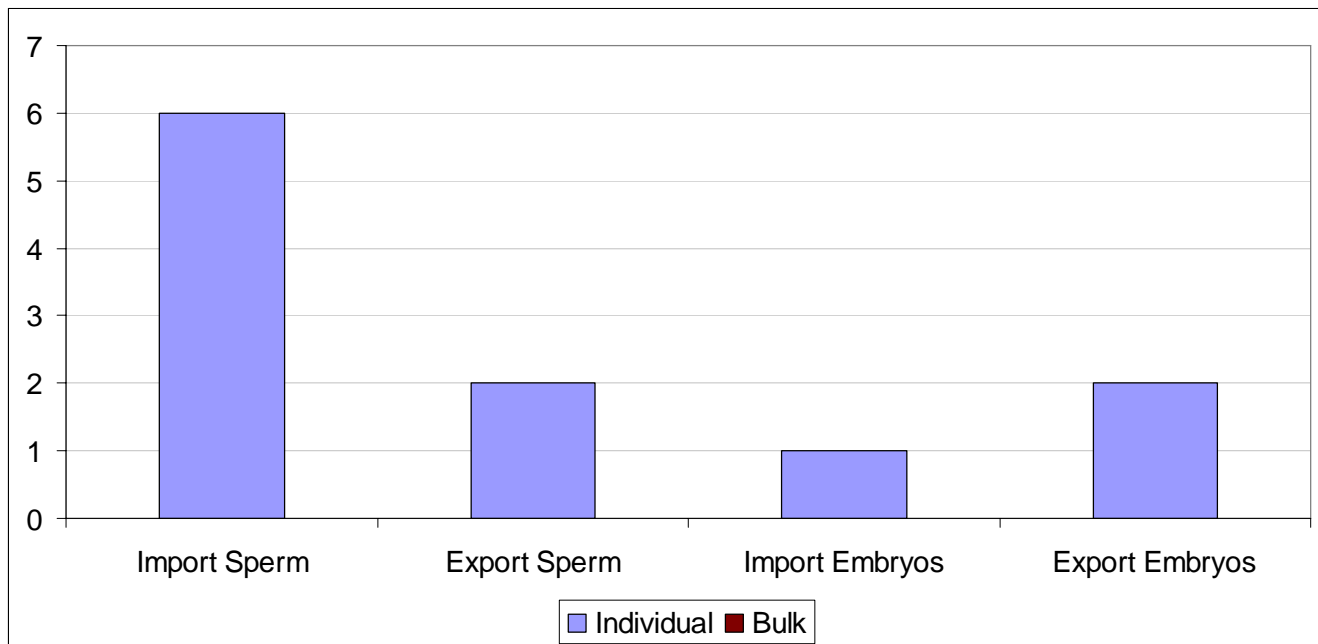


Figure 3a – Import / Export of Gametes Comparison – July 2007

¹ Notifications made to the HFEA regarding intention to export material is not to be equated with an export direction

Incidents

The incident standard operating procedure (SOP) is currently under annual review and will be re-published shortly. There were no **Grade A** incidents reported in July 2007.

Incidents	May 2007	June 2007	July 2007
Grade A	1	0	0
Grade B	3	8	7
Grade C	8	6	8
Assessed as 'TBA'	0	1	0
Near Miss	1	1	0
Total	13	16	15

Table 4 – Incidents Reported by Category, May – July 2007

Incidents reported for July 2007 were as follows: zero **Grade A**; seven **Grade B**; and eight **Grade C**, See **Table 4**. The numbers however are consistent with the past two months (**Figure 4a**).

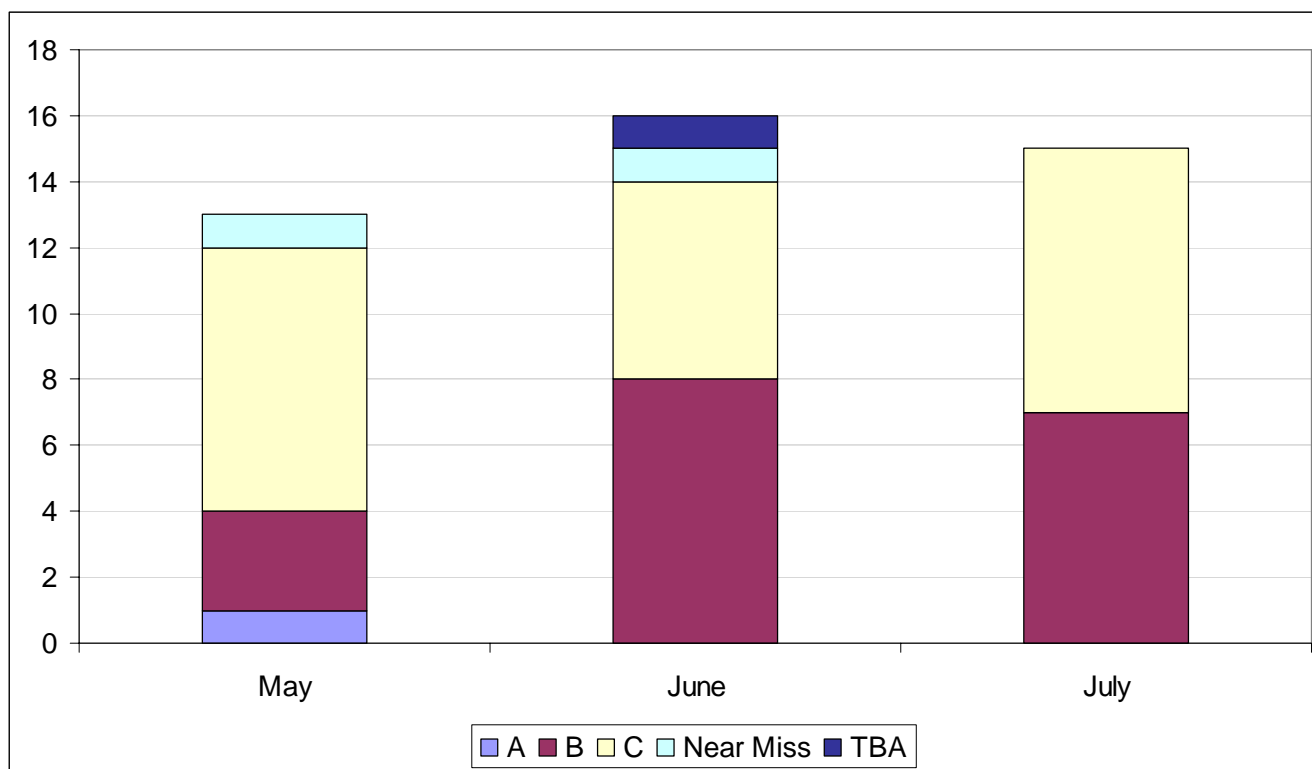


Figure 4a – Number of incidents reported per category, May – July 2007

A total of 56 incidents have been reported since the start of the year (2007/08). Fifteen incidents were reported and twenty-one closed for this month (Table 4b).

Incidents	May 2007	Jun 2007	Jul 2007	Cumulative Year-to-date	Cumulative ²
Reported	13	16	15	56	654
Centres Visited	0	0	0	1	24
Closed	5	16	25	51	589

Table 4b – Incidents Reported and Closed July 2007

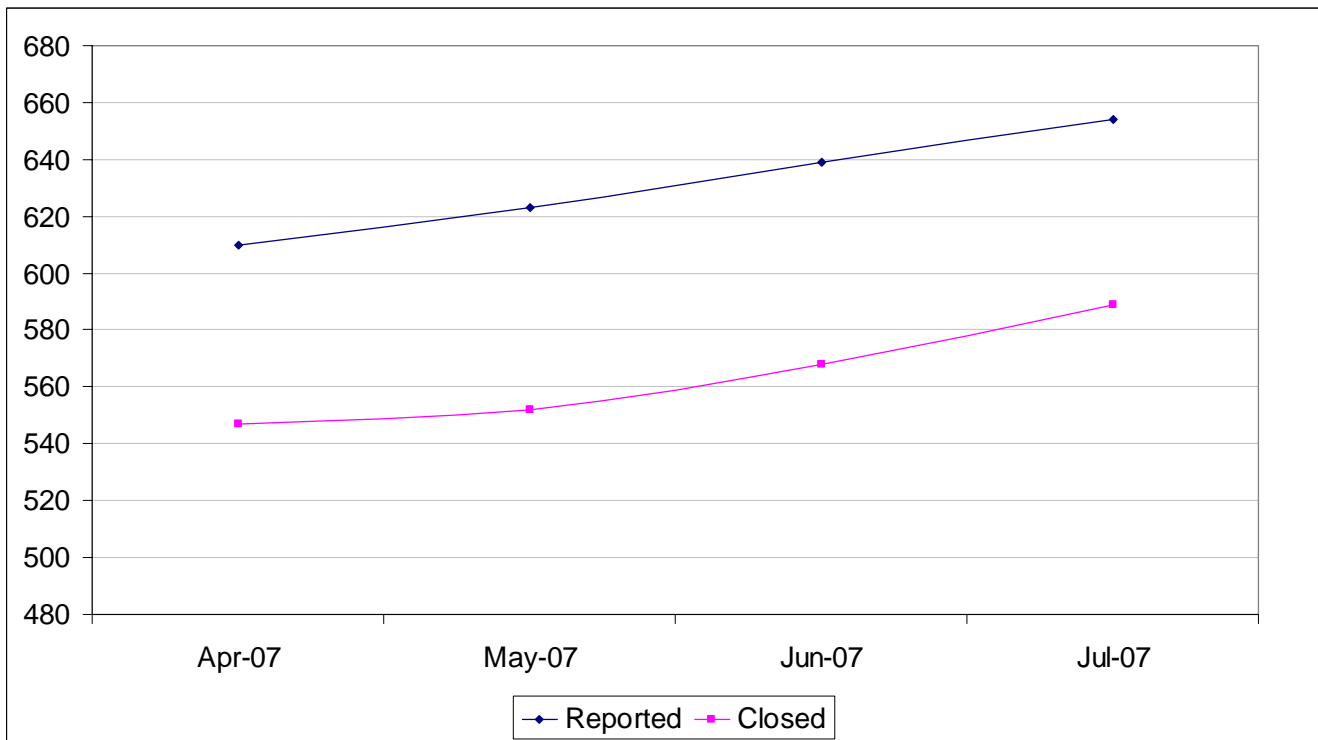


Figure 4b – Cumulative Incidents reported and closed, April – July 2007

² Aggregated total of all incidents since recording began.

Alerts

There were no Alerts published during the month of July 2007.

Complaints about Centres

For July, there were a total of six complaints recorded. Of this number, there were three clinical complaints involving patients disagreeing with the centre's decision-making, for example the number of embryos transplanted and whether different treatment options should have been offered. Other complaints involved the information given to the patient regarding egg sharing and required from the patient regarding their donor.

Licensing Committee Activity

Three Licence Committee meetings took place in July: two ordinary meetings and one Research Licence Committee meeting. A total of 20 items of business were considered with an unusually large volume of PGD applications. The Committees also considered two applications to revoke the licences of closed centres. Additionally there was a representations hearing held (relating to Centres **0157 & 0206**)

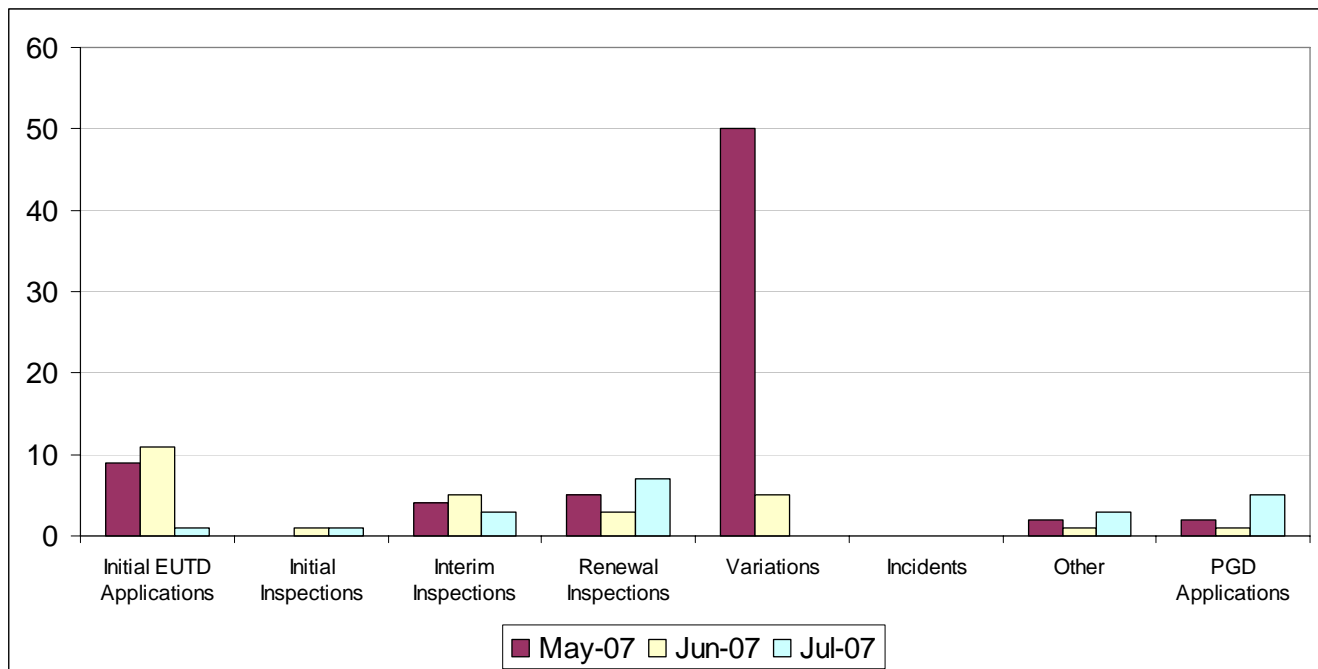


Figure 5 – Breakdown of LC Business items – May - July 2007

There were two new applications received in July; one PGD and the other a Treatment & Storage licence application (See **Table 5** below).

Research Licence Application	Date Received	Peer review	Licence Committee	KPI
Edinburgh Fertility & Reproductive Endocrine Centre Edinburgh Royal Infirmary Little France Edinburgh EH16 4SA	10 May 2007	8 Jun 2007	25 July 2007	<input checked="" type="checkbox"/>
Treatment Licence Application				
Treatment Licence Application	Received	Site Visit	Licence Committee	KPI
Andrology Solutions 55 Wimple Street London W1	4 May 2007	23 May 2007	20 Jun 2007	<input checked="" type="checkbox"/>
EUTD Treatment Licence Application				
EUTD Treatment Licence Application	Received	Site Visit	Licence Committee	KPI
Royal Bournemouth Hospital Castle Lane East Bournemouth Dorset, BH7 7DW	24 May 2007	26 Sep 2007	20 Jun 2007 Approved (although to be inspected within three months)	<input checked="" type="checkbox"/>
Crosshouse Hospital Crosshouse, Kilmarnock Ayrshire Scotland, KA2 0BE	24 May 2007			<input type="checkbox"/>
North Middlesex Hospital Sterling Way Edmonton London, N18 1QX	20 June 2007			<input type="checkbox"/>
University Hospitals of Morecambe Bay NHS Trust Gynaecology Department, Furness General Hospital, Dalton Lane Barrow-In-Furness Cumbria, LA14 4LF	June 2007	N/A IUI Centre	15 August 2007	<input checked="" type="checkbox"/>
Fertility Unit, Barking Havering and Redbridge Hospitals Trust Queens Hospital, Rom Valley Way Romford Essex, RM7 0AG	June 2007	N/A IUI Centre	15 August 2007	<input checked="" type="checkbox"/>
St Mary's NHS Hospital Trust Department of Obstetrics & Gynaecology, St Mary's Hospital, Praed Street London, W2 1NY	27 June 2007	N/A IUI Centre	26 July 2007	<input checked="" type="checkbox"/>

Variation (PGD) to Licence Application	Received	Licence Committee or Executive	KPI
0102 – Guys Hospital; Partial Lipodystrophy	Application in April 2007	Licence Committee 14 May 2007 Not Approved Licence Committee 09 May 2007 Approved	<input checked="" type="checkbox"/>
0102 – Guys Hospital; Osteopathia striata	Application in April 2007	Licence Committee 14 May 2007 Approved	<input checked="" type="checkbox"/>
Centre 0070 – Marfan Syndrome	8 May 2007	Licence Committee 9 July 2007 Approved	<input checked="" type="checkbox"/>
Centre 0070 – Beta Thalassaemia with HLA Matching	8 May 2007	Licence Committee 9 July 2007 Approved	<input checked="" type="checkbox"/>
Centre 0044 – BRAC 1	May 2007	Licence Committee 9 July 2007 Approved	<input checked="" type="checkbox"/>
Centre 0157 – Fragile X	2 May 2007	Executive approval 6 August 2007 (after LC agreed OK for executive to approve on 2 August 2007)	<input checked="" type="checkbox"/>
Centre 0101 – To combine screening for single gene defects with PGS in appropriate patients	Mid May	Licence Committee 30 May 2007 Approved	<input checked="" type="checkbox"/>
Centre 0101 – Alpers Syndrome	1 June 2007	Licence Committee 9 July 2007 Approved	<input checked="" type="checkbox"/>
Centre 0101 – Haemophilia	1 June 2007	Executive approved June 2007	<input checked="" type="checkbox"/>
Centre 0101 – Hypohidrotic Ectodermal Dysplasia	1 June 2007	Executive approved June 2007	<input checked="" type="checkbox"/>
Centre 0102 – Von Hippel Lindau Haemophilia B Fragile X	4 June 2007	Executive approved June 2007	<input checked="" type="checkbox"/>
Centre 0157 – OTC	20 June 2007	Reviewed but decision deferred until resolution of regulatory issues on 13 July 2007 – MT advised timescale; Executive approval 6 August 2007 (after LC agreed OK for executive to approve on 2 August 2007)	<input checked="" type="checkbox"/>
Centre 0101 –Treachers Collins Syndrome	18 July 2007	Licence Committee 15 Aug 2007 Approved	<input checked="" type="checkbox"/>

Table 5 – New Licensing Application Activity for period ending July 2007

Trish Davies,
Deputy Chief Executive/Director of Regulation

Finance Report

KEY ISSUES

1. This report presents the July 2007 management accounts. The accounts were reviewed by SMT at their meeting on 13th August 2007.
2. The forecast for income has been increased by £115k in respect of invoiced treatments detailed in paragraph 3 below. The forecast for legal fees has also been increased by £114k over budget and external audit fees increased by £1k, resulting in a net break-even position for the HFEA.

INCOME

Y-T-D Actual £2.6m, Budget £2.3m

Full Year Forecast £7m, Budget £6.8m

3. Licensing fee income remains above budget on the basis of forms recently provided to the HFEA by two clinics that have been the subject of recent regulatory action. The amount invoiced in July totalled £114k. As mentioned in the June finance report, it is too early in the financial year to establish whether the general trend is permanent. However forecast income for the year has been increased by £115k to reflect this amount of "catch up" income. Fee income will continue to be closely monitored, and month end calculations of treatments not yet reported will be reviewed in detail.
4. Other income includes a one off amount for IT development work undertaken on behalf of HTA. In addition, since April 2007 the HFEA has been providing the HTA with IT support services under a Service Level Agreement. IT salaries are anticipated to be in excess of budgeted amounts as staff numbers have been increased to support this additional workload.

COSTS

Chief Executive's Office

Y-T-D Actual £188k, Budget £173k

Full Year Forecast £517k, Budget £517k

5. The CEO's office costs reflect the resource requirements of the current regulatory action. This is likely to continue for the remainder of the year and therefore a virement into this budget head will be needed. However, at this stage of the financial year it is too early to predict the total amount accurately. Further information will be provided in future finance reports as and when costs can be estimated with more certainty.

Staff Costs – Other

Y-T-D Actual £106k, Budget £107k

Full Year Forecast £323k, Budget £323k

6. Staff costs for the year to date are slightly under budget, mainly resulting from lower costs than planned for central maternity and long term sickness. There are a number of members of staff who will be taking maternity leave later in 2007 and therefore no adjustments to this forecast are anticipated at this stage in the year.
7. Recruitment costs continue to be over budget, but it is too early in the financial year to establish whether this is a permanent trend. Data from exit interviews will provide information on any staff who have left as a result of the uncertainty generated by RATE. In these instances, we will look to the transitional funding budget to provide support for the related additional recruitment costs. Training costs are also over budget, however a training plan for the remainder of 2007/08 is currently being prepared following the PDP process earlier this year and the forecast will be reviewed once this is completed. It is anticipated that a virement into this budget head will be required to provide additional support for staff during the regulatory action and the lead up to RATE.

Authority/Committee Costs

Y-T-D Actual £77k, Budget £88k

Full Year Forecast £255k, Budget £255k

8. Members' fees reflect the payments made to those members contributing to committees via telephone conferences following an assessment of payment practice.

Regulation and Corporate Planning

Y-T-D Actual £456k, Budget £444k

Full Year Forecast £1.376m, Budget £1.357m

9. Regulation salaries are over budget for the month resulting from the need to engage temporary staff to provide information to the public following the Licence Committee outcome for a high profile clinic, and from a redundancy which took place in 2005 the costs for which were not invoiced until this year.
10. The work required in respect of the EUTD is currently anticipated to be more resource intensive than initially thought. Some newly licensed clinics may require two visits this year, which may require additional staff support. At this point in time it is not certain how much additional resource is required, and therefore the amount of additional funding needed for pay costs, however further information will be provided in future finance reports.

11. It is anticipated that the other variances within this budget relate to timing differences. All cost heads will however be kept under regular review for the rest of this financial year.

Communications and Policy

Y-T-D Actual £419k, Budget £460k

Full Year Forecast £1.31m, Budget £1.29m

12. Expenditure overall is under the forecast budget. There is a significant underspend on the salaries budget due to maternity leave and the pattern of recent recruitment.
13. The overall budget is however planned to be on target at the end of the year. Changes in the Policy department's priorities (hybrids and multiple births work) have led to a re-prioritisation of work which has impacted on the pattern of expenditure at this stage of the financial year.
14. Some budget headings are overspent to date – library and subscriptions; policy work (including hybrids consultation); media relations and development; and public meetings and external networking. It is anticipated that there will be virements into these cost heads once future costs can be calculated more accurately, and more information will be provided in further finance reports.
15. In the meantime, the budget will be closely monitored on a monthly basis.

Resources and Corporate Development

Y-T-D Actual £446k, Budget £473k

Full Year Forecast £1.4m, Budget £1.4m

16. The salary costs in the Resources directorate are in excess of budget as temporary staff were required in Finance to cover holiday absence. This cover was required to support the increased workload generated by the requirements of the SLA with the HTA. Temporary cover was also required in the Facilities team, where holiday absence coincided with the likelihood of increased enquiries relating to licensing decisions.
17. Other variances relate primarily to timing differences. All costs will however be kept under review for the rest of this financial year.

Information Management

Y-T-D Actual £387k, Budget £376k

Full Year Forecast £1.2m, Budget £1.2m

- 18.** Overall there is a net cumulative overspend of £11k in this department, however this relates primarily to the purchase of software and IT consumables earlier in the year than planned. It is anticipated that spend in these areas will lessen in the latter half of this year.
- 19.** Salaries are showing an underspend of £5k. This may however translate into an overspend as the year progresses, as new IT staff are recruited to replace leavers and to provide the necessary support to the new IT SLA agreement with HTA. This cost head will be kept under review, and a virement may be made later in the year if appropriate.
- 20.** No virements to this budget head are accordingly anticipated at the moment, although spend will be closely monitored for the rest of this year.

Legal Fees

Y-T-D Actual £113k, Budget £90k

Full Year Forecast £236.5k, Budget £123k

- 21.** Legal costs for July have been adjusted to take account of the up to date information provided by the HFEA's external firm of solicitors. Previous months' figures had included accruals based on estimated costs, which were proved to be over-prudent in light of the actual amounts invoiced.
- 22.** However it seems likely that the forecast for the year should remain forecast in excess of budget by £114k based on current best estimates as to how legal costs will arise for the rest of this financial year.
- 23.** This cost area will be kept under close review on a monthly basis, and consideration given as to how to meet any future forecast revisions in the most appropriate way.

Professional Fees

Y-T-D Actual £4k Budget £16k

Full Year Forecast £242k, Budget £241k

- 24.** The forecast for external audit fees has been increased by £1k to accommodate increased charges by NAO following the additional work undertaken prior to their sign off of in July of the 2006/2007 Annual Report and Accounts.

Capital Costs

Y-T-D Actual £14k, Budget £19k

Full Year Forecast £87k, Budget £87k

- 25.** Expenditure is slightly below budget. In general, proportionately more costs arise in this budget head in the latter half of the financial year, and accordingly no changes to forecast are planned at present.

Transitional Costs

Y-T-D Actual £1k, Budget £150k

Full Year Forecast £450k, Budget £450k

- 26.** Planning for transitional costs is currently underway. In the meantime, whilst some costs in relation to joint meetings with HTA have arisen, no material spend has as yet occurred. Detailed profiling will follow from current planning work and will be incorporated into this budget head in future reports.

HR REPORT: April – July 2007

1. HR STATISTICS

1.1 Establishment - Projected

Profile of HFEA Headcounts 2007-08 (ALB Return)

Month	Projection		
	Headcount	WTE	P/T headcount (WTE)
April	84	82.1	6 (4.1)
May	84	82.1	6 (4.1)
June	84	82.1	6 (4.1)
July	84	82.1	6 (4.1)
August	84	82.1	6 (4.1)
September	84	82.1	6 (4.1)
October	84	82.1	6 (4.1)
November	84	82.1	6 (4.1)
December	84	82.1	6 (4.1)
January	84	82.1	6 (4.1)
February	84	82.1	6 (4.1)
March	84	82.1	6 (4.1)
TOTAL	84	82.1	6 (4.1)

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								
Resources	10	10	9	11*								
CoPo	14	15	18	19*								
Regulation	24	24	24	24								
Information	22	22	20	23*								
Total	78	79	79	85*								

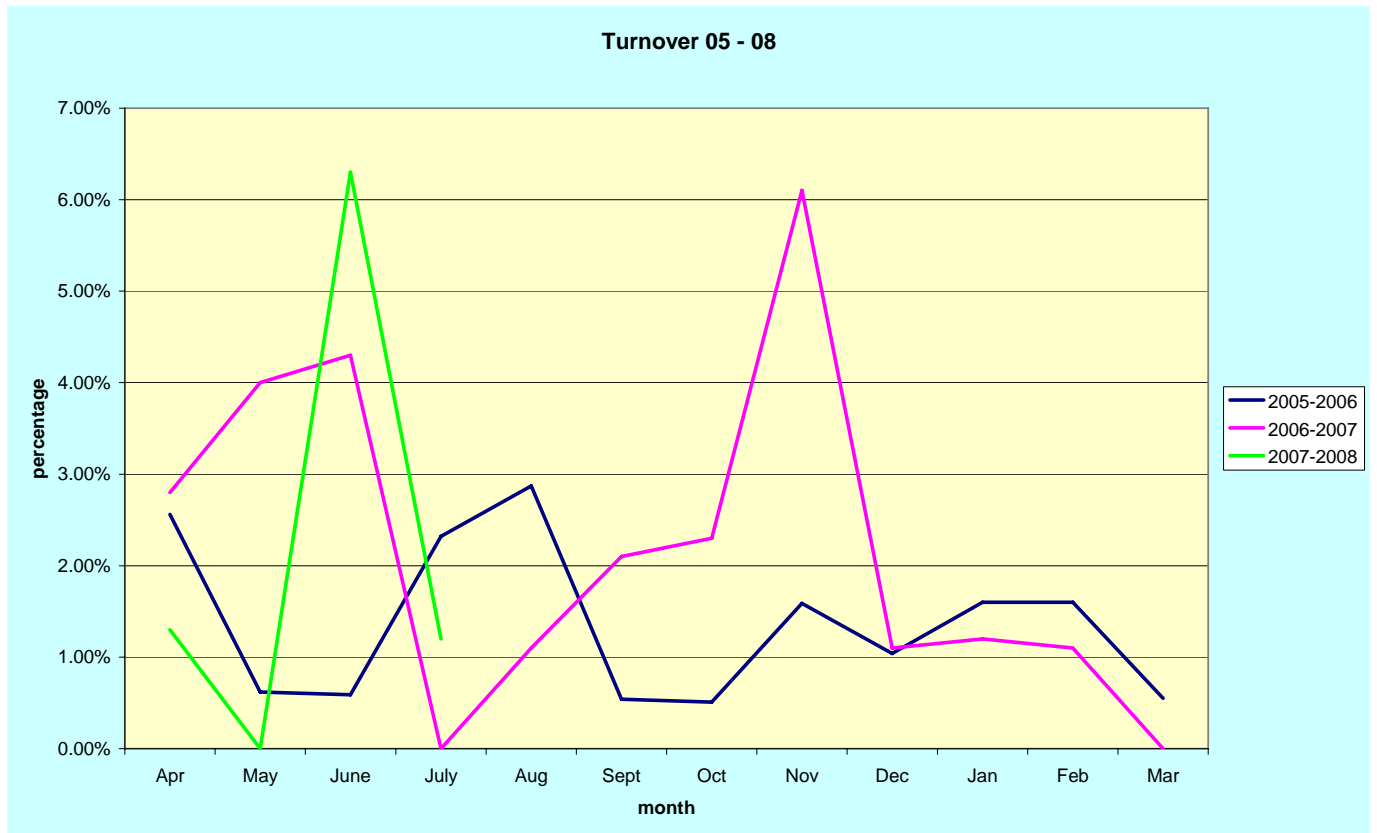
*Actual headcount includes 3 people on paid maternity leave, plus their cover (i.e. double counted for establishment purposes)

1.3 Staff Turnover

Month	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Monthly turnover %	1.3%	0%	6.3%	1.2%								

Annual Projection			
Actual annual turnover 06/07	26.1%	12 month rolling average annualised turnover 07/08	26.4%

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: Turnover rates of 20%

Comment: Turnover has dipped in July, following a significant peak in June, but will rise again in August and will not dip in the following couple of months at least.

1.4 Absence

Month	Apr	May	Jun	July	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar
Sickness absence rate %	1.6%	3.3%	2.8%	2.3%								
Actual Days	24	50	48	38								
Actual Staff Absent	11	10	13	10								

Annual Projection

Average sickness absence rate	2.50%
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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

The slightly high sickness rate in May was due to a pregnancy related sickness absence and surgery for another staff member.

2. CURRENT or ANTICIPATED RECRUITMENT

Information

Senior Network Analyst (6 month contract to support HTA)
Assistant Network Analyst (6 month contract to backfill acting up)
Information Officer
Director of Information

Policy & Communications

Communications Assistant (on hold)
Policy Manager

Regulation

Head of Inspection
Head of Clinical Governance and Patient Safety

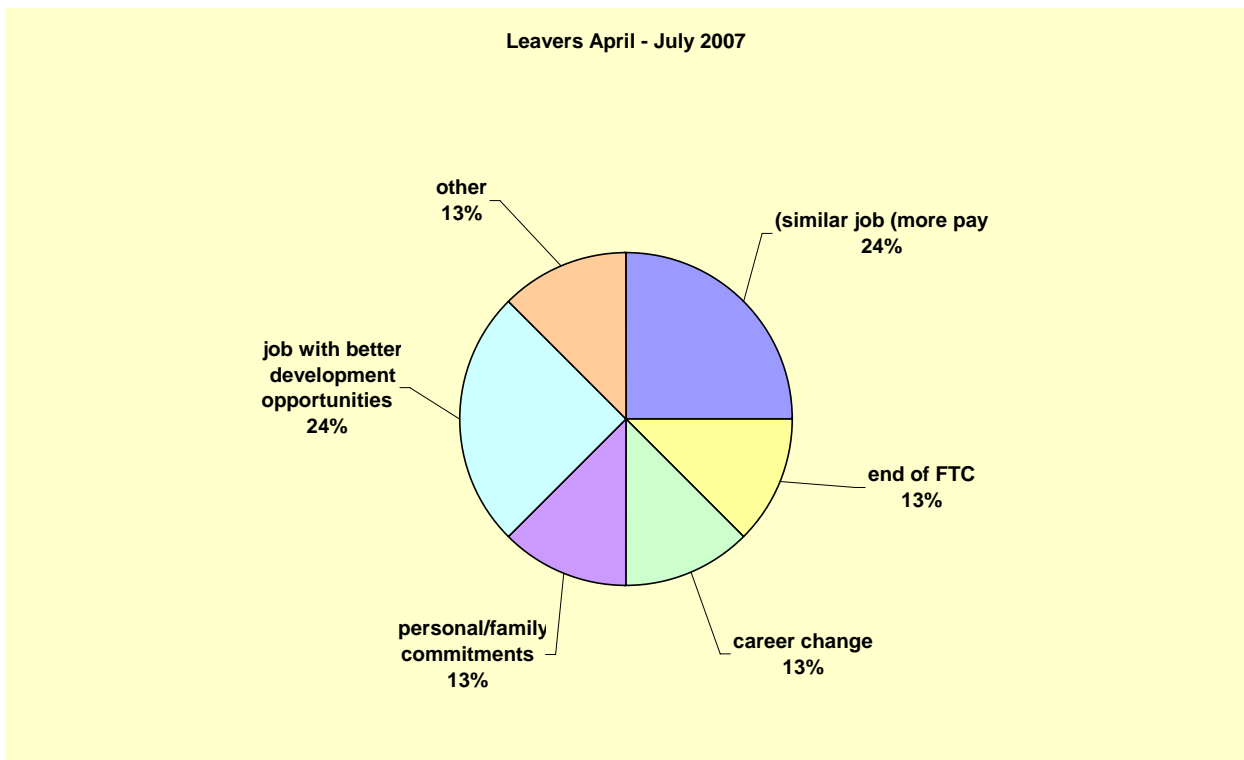
3. NEW EMPLOYEES FROM 1 JULY 2007 AND ACCEPTED OFFERS OF EMPLOYMENT

Directorate	Post	Date of Joining
Information	Assistant Network Analyst	2 July 2007
Policy	9 week placement – Policy Officer	4 July 2007
Information	Developer (6 months)	16 July 2007
Information	Developer	23 July 2007
Resources	Facilities Assistant (maternity cover)	30 July 2007
Policy	Policy Officer	7 August 2007
Legal	Interim Legal Adviser (6 months)	13 August 2007
CEO	PA to CEO	13 August 2007
Policy	Health Economist	21 August 2007
Resources	HR Officer (maternity cover)	10 September
Legal	Senior Legal Adviser	8 October 2007

ORGANISATIONAL CHANGES FROM 1 JULY 2007

Information	Acting Senior Network Analyst (6 months)	6 August 2007
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4. REASONS FOR LEAVING



key: 13% = 1 person

5. ACTIVITY AGAINST THE 07/08 HR WORK PLAN

5.1 PDP Process

The Resources Committee endorsed the recommendations for this year's pay award which will be implemented in August.

5.2 Training & Development

Organisational Training and development priorities have been agreed by SMT. The full plan for 07/08 is being finalised.

We have commissioned cross departmental training on conflict resolution/managing difficult conversations which will be delivered in September.

5.3 Diversity

We have met with the local Disability Employment Adviser (DEA) to progress our application to be awarded the ✓✓ 'Positive about Disabled People' national disability symbol award.

5.4 Recruitment

There has been continued high levels of recruitment activity, which will continue for a while.

5.5 HTA

Activity to support the HTA has lessened and is being managed within the normal SLA levels.

5.6 Staff Benefits.

The Cycle to Work Scheme, which facilitates the acquisition of reduced cost bikes and bike equipment for staff through a salary sacrifice scheme, has proved extremely popular with several people taking this up in the first month.

5.7 RATE

We have been working with DH ALB team and our counterparts at the HTA to progress various activities against the HR RATE workplan. This has included matters relating to pensions, initial screening for the Equality Impact Assessment on HR matters (this will continue to be reviewed and updated), further discussions on relocation packages for each organisation and communication flows.

Fiona Daffern

Assistant Director HR&OD