

## Authority Paper

<b>Committee:</b>	Authority Meeting
<b>Meeting Date:</b>	2 July 2008
<b>Agenda Item:</b>	16
<b>Paper Number:</b>	[HFEA (02 /07/08) 455]
<b>Paper Title:</b>	Regulation Annual Report
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<b>For information or decision?</b>	For Information

### 1 Regulatory Activity Report – May 2008

1.1 This report sets out the activities and performance of the Regulation Department for the month ending May 2008.

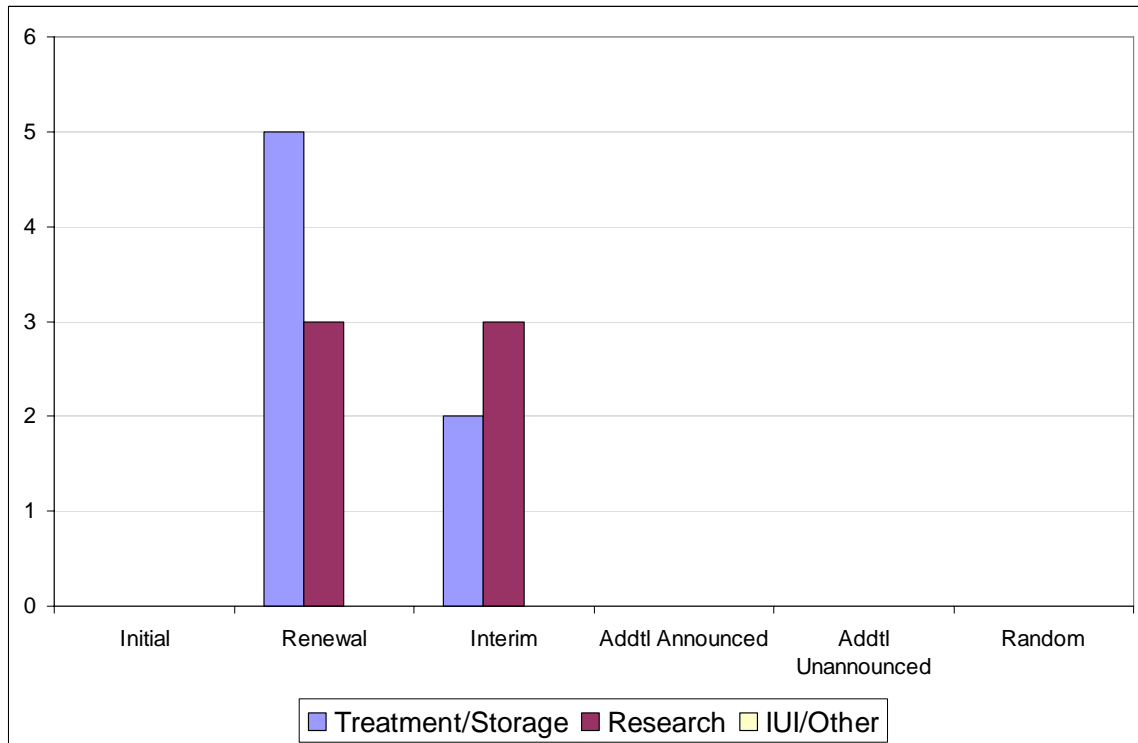
### 2 Inspection Programme and Reports Issued

2.1 The inspection team carried out 13 visits during May; five renewals to treatment and storage centres (**0037, 0052, 0115, 0148, 0149**) and three renewals to research centres (**0246** and **0017** where two research licences are due for renewal). Interim inspection visits were made to two centres with treatment and storage licences (**0017** and **0094**) and three centres with research licences (**0017, 0037, 0052**). No visits were made to Storage only or IUI centres in May.

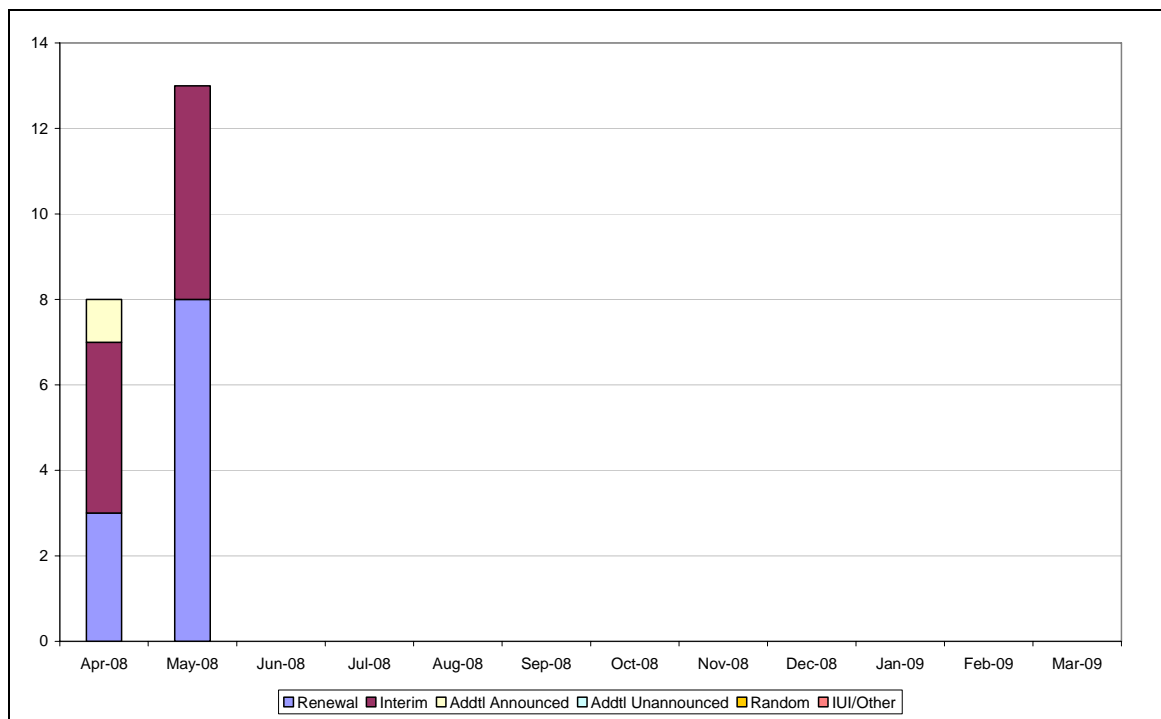
Licence Type/Visit	Inspection Type	Targeted	Inspection Breakdown	
		No. of Inspections	Completed May '08	Cumulative To Date
Treatment/Storage	Initial	25	5	7
	Renewal	35	2	5
	Interim	N/A		1
	Additional Announced	N/A		
	Additional Unannounced	4		
Research Only	Initial	10	3	4
	Renewal	23	3	4
	Interim	N/A		
	Additional Announced			
IUI (Other Treatments)	Additional Unannounced			
	Initial	16	0	0
	Renewal			
	Interim			
	Additional Announced			
	Random			
	Exemptions		--	--
<b>Total</b>		<b>113</b>	<b>13</b>	<b>21</b>

**Table 1 – Inspection Programme Breakdown for May 2008**

2.2 **Table 1** shows all relevant inspections for the period to date (starting April 2008) and **Figures 1** and **1b** provide representation of the number of inspections done by general type.



**Figure 1 – Completed Inspections for month ending – May 2008**



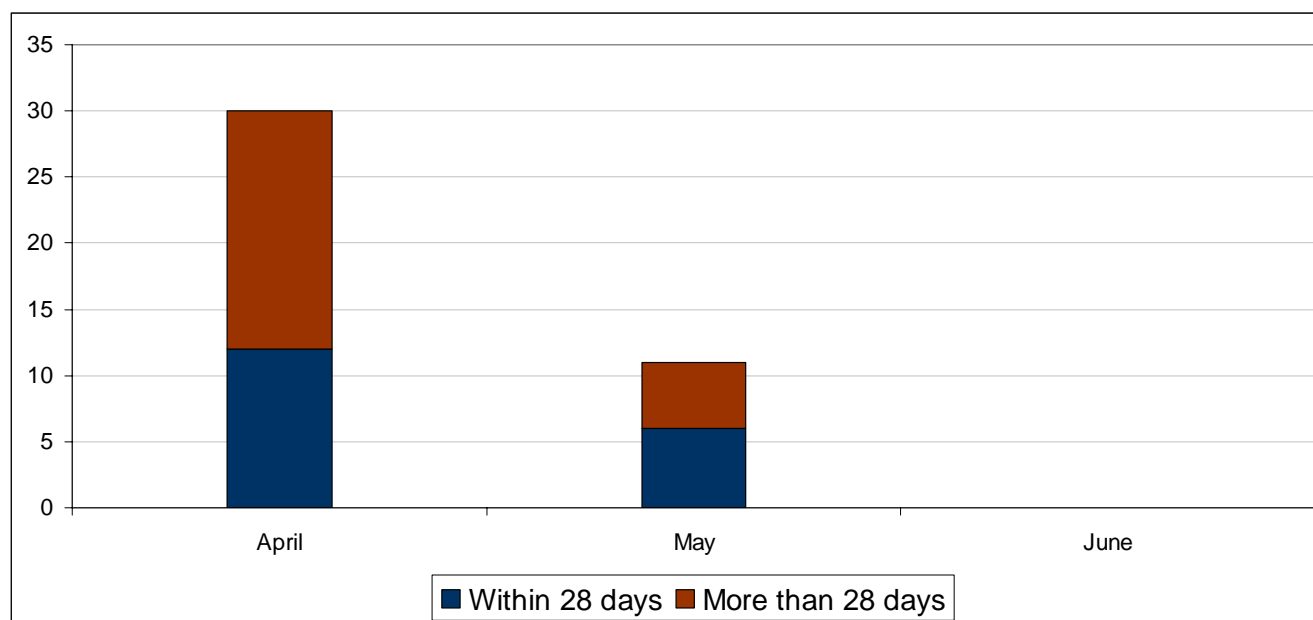
**Figure 1b – Total Monthly Inspections done by Type; April 2008 – March 2009**

### 3 Report Production

3.1 Eleven reports were due to be sent to centres in May 2008. Of the five that were not sent, three remain outstanding on 10 June 2008. One report was six days late: completion of the report was delayed because the lead inspector took annual leave. Three of the reports were delayed in part because the lead inspectors had had a higher than usual workload in the first quarter of 2008. One report was delayed because of long term staff illness.

Reports	Apr 2008	May 2008	Jun 2008	2008/09 Cumulative
Within 28 Days	12	6		<b>18</b>
More than 28 days	18	5		<b>23</b>
% Achievement	40	55		<b>44</b>

**Table 2 – Report Production within 28 days, May 2008**



**Figure 2 – Overall Report Production, within 28 days, April 2008 – June 2008**

#### 4 Import/Export Directions

4.1 In May 2008, the Regulation Department processed seven Import and Export Special Directions. Two applications were to import sperm from USA and one application to import embryos from Hong Kong. Two applications were to export sperm to USA and Switzerland and two export embryo applications to export embryos to Hong Kong and USA. These were all approved by Regulation Committee on May 1<sup>st</sup>, 2008. Eleven Import sperm notifications to import sperm from Denmark and USA, three notifications to export embryos to USA and five export sperm notifications to export sperm to Spain and USA were received by the Regulation Department in May

Type	Apr 2008		May 2008		Jun 2008	
	SD	Notifications	SD	Notifications	SD	Notifications
Import Sperm	0	9	2	0		
Export Sperm	0	9	2	3		
Import Embryos	0	0	1	11		
Export Embryos	0	0	2	5		
<b>Total</b>	<b>0</b>	<b>18</b>	<b>7</b>	<b>19</b>		

Table 3 – Import / Export Applications, April - Jun 2008

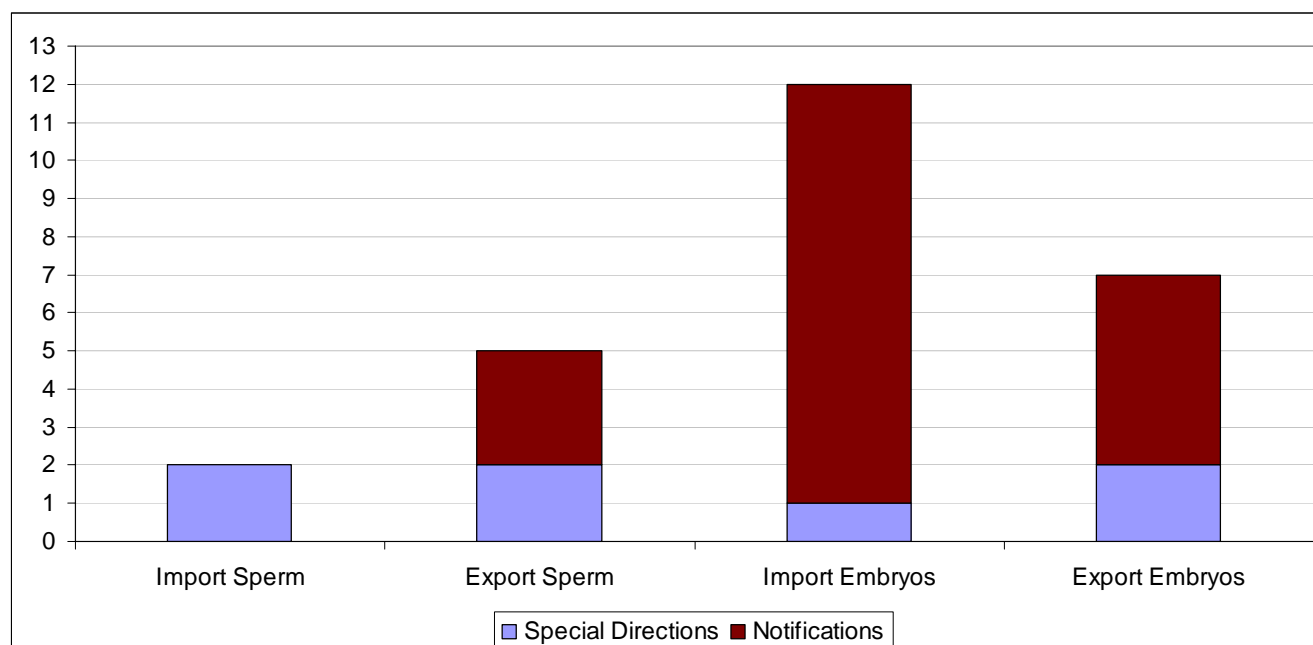


Figure 3a – Import / Export of Gametes Comparison – May 2008

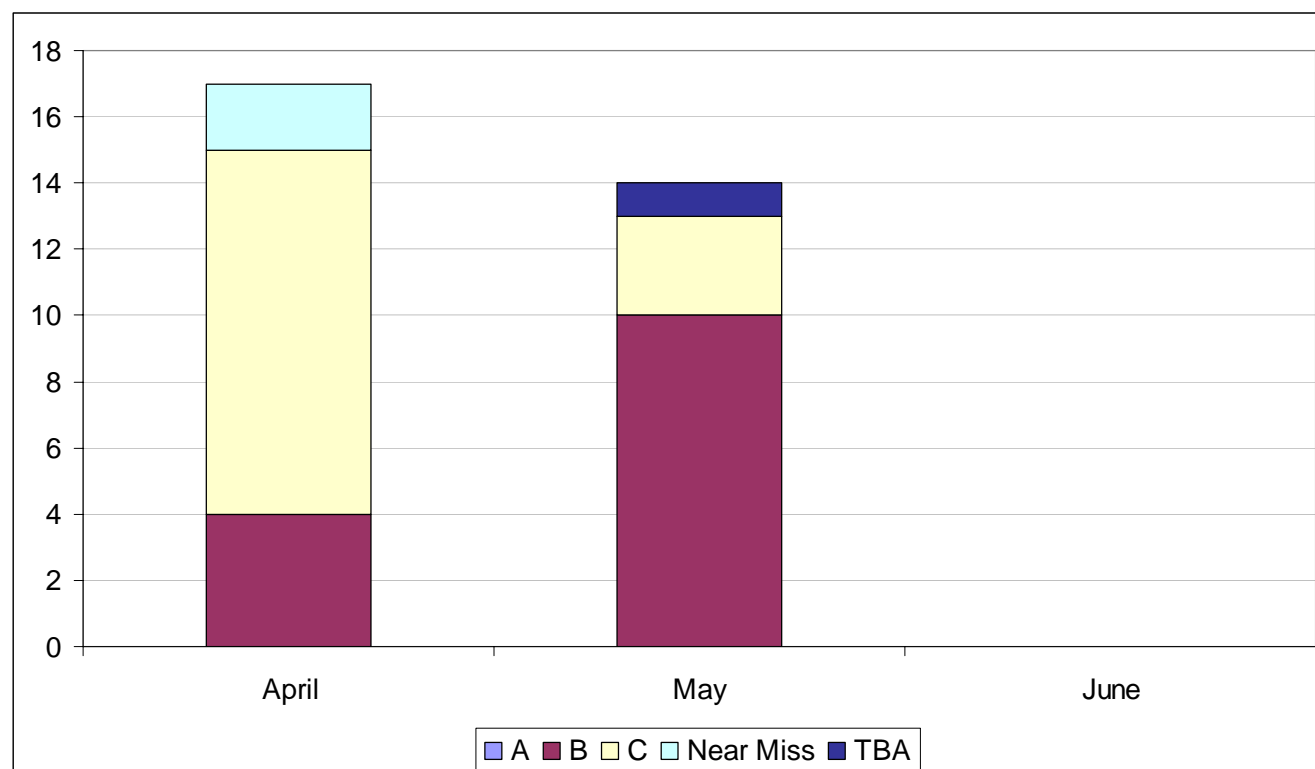
## 5 Incidents

Incidents	Apr 2008	May 2008	Jun 2008
Grade A	0	0	
Grade B	4	10	
Grade C	11	3	
Assessed as 'TBA'	0	1	
Near Miss	2	0	
<b>Total</b>	<b>17</b>	<b>14</b>	

**Table 4 – Incidents Reported by Category, April 2008 – Jun 2008**

5.1 There were 14 incidents reported in May, ten **Grade B**, three **Grade C** and one to be assigned a grade. Six of the ten **Grade B** incidents have been down graded from an initial **Grade A**. The Grade B incidents are being actively investigated by the Centres and the investigation reports will be reviewed by Clinical Governance.

5.2 6 Grade B incidents were from the same centre which is undertaking an audit of storage tanks; many of the samples have been in storage for many years and are unidentifiable or have been placed in the incorrect location. The audit is to be completed by June 30<sup>th</sup>, 2008.



**Figure 4a – Number of incidents reported per category, Apr 2008 – Jun 2008**

5.3 Conversely there were four incidents closed during this period (See **Table 4b** below).

Incidents	Apr 2008	May 2008	Jun 2008	Cumulative Year-to-date
Reported	17	14		31
Centres Visited	0	1		0
Closed	10	4		14

**Table 4b – Incidents Reported and Closed April 2008**

## 6 Alerts

6.1 HFEA Alert 24: Recruitment of Donors – Payments & Restrictions was issued on May 7<sup>th</sup> 2008. This alert reminded the centres of the obligations under Section 12(e) 1990 HFE Act regarding that 'no money or other benefits shall be given or received in respect of any supply of gametes unless authorised by Direction.'

## 7 Complaints about Centres

7.1 Six complaints were received in May the main themes were Financial, Communication and Patient Information. Five of six complaints were referred back to the Centre Complaints procedure and one is to be followed up. Four complaints were closed during May

## 8 Licensing Committee Activity

8.1 There were two Licence Committee meetings in May (on 12 and 21). These considered a total of 15 items of business, including 2 PGD applications and 2 PGD/HLA applications. The "other" item referred to in the graph was a briefing provided to the Licence Committee concerning an IUI licence which had been allowed to expire at the centre's request.

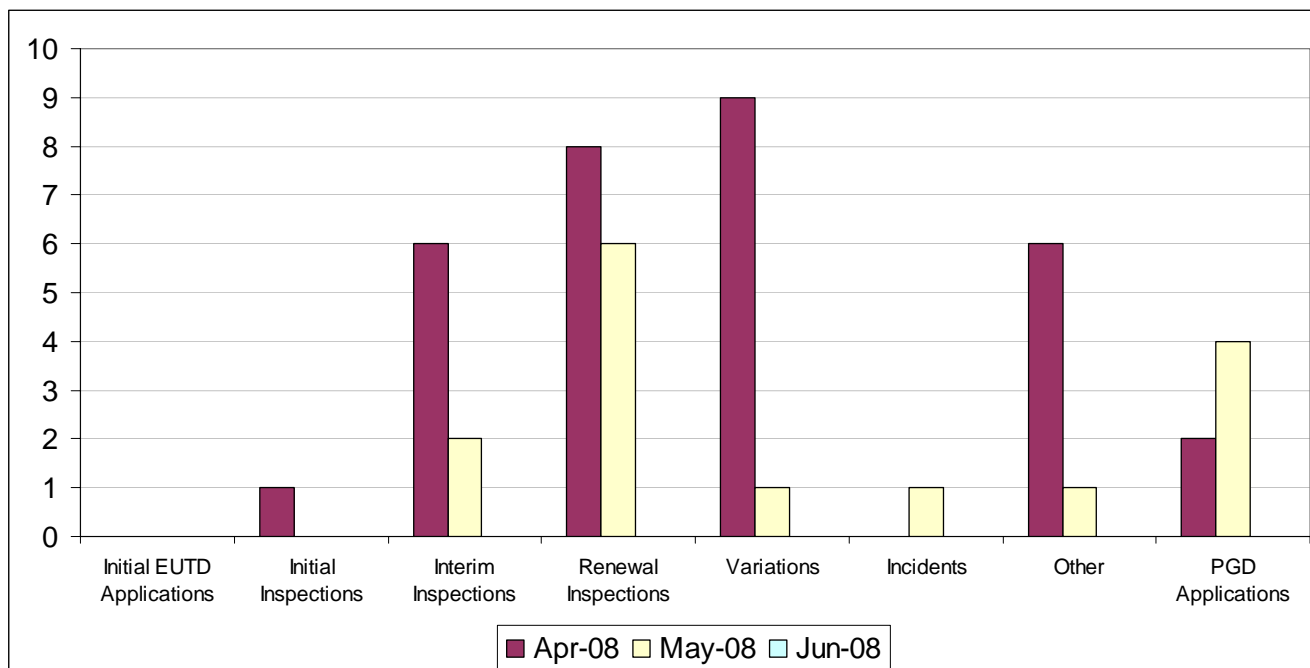


Figure 5 – Breakdown of LC Business items, April 2008 to June 2008

Research Licence Application	Date Received	Peer review	Licence Committee	KPI
Clinical Sciences Research Institute, University of Warwick (0305)	6 Feb 2008	Completed	18 June 2008 (withdrawn from April 2008 licence committee)	<input type="checkbox"/>
Treatment Licence Application	Received	Site Visit	Licence Committee	KPI
Fisher Bio Science (0300) – Storage only	October 2007	4 April 2008	24 July 2008	<input type="checkbox"/>
Bridge at Holly House (0304)	Jan 2008	TBA	Withdrawn	<input type="checkbox"/>
Create (0299) – Previously withdrawn 11 Jan 2008 (Re-submitted March 2008)	March 2008	3 June 2008	13 Aug 2008	<input type="checkbox"/>

<b>EUTD Treatment Licence Application</b>	<b>Received</b>	<b>Site Visit</b>	<b>Licence Committee</b>	<b>KPI</b>
<b>Variation (PGD) to Licence Application</b>	<b>Received</b>	<b>Licence Committee or Executive</b>		<b>KPI</b>
Centre 0070 – Von Hippel Lindeau	31 March 2008	16 Apr 2008 (Exec)		<input checked="" type="checkbox"/>
Centre 0070 – Congenital Adrenocortical Hyperplasia	31 March 2008	21 May 2008 (Exec)		<input checked="" type="checkbox"/>
Centre 0070 – Metachromatic Leukodystrophy	31 March 2008	25 Jun 2008 (Licence Committee)		<input type="checkbox"/>
Centre 0088 – Chromosomal Rearrangements	14 April 2008	12 May 2008		<input checked="" type="checkbox"/>
Centre 0037 – Burton Agammaglobulinemia Tyrosine Kinase	28 April 2008	7 July 2008		<input type="checkbox"/>
Centre 0044 – Beta Thalassaemia With HLA	14 April 2008	5 June 2008		<input type="checkbox"/>
Centre 0044 – Beta Thalassaemia With HLA	14 April 2008	5 June 2008		<input type="checkbox"/>
Centre 0044 – Beta Thalassaemia Major with HLA (Case 1)	14 April 2008	12 May 2008 (Licence Committee)		<input checked="" type="checkbox"/>
Centre 0044 – Beta Thalassaemia Major with HLA (Case 2)	14 April 2008	12 May 2008 (Licence Committee)		<input checked="" type="checkbox"/>
Centre 0101 – Torsion Dystonia	02 April 2008	12 May 2008 (Licence Committee)		<input checked="" type="checkbox"/>

**Table 5 – New Licensing Application Activity for P/E February 2008**

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