

## Authority Paper

<b>Committee:</b>	Authority Meeting
<b>Meeting Date:</b>	18 February 2004
<b>Agenda Item:</b>	11
<b>Paper Number:</b>	HFEA (18/02/04) 138
<b>Paper Title:</b>	<b>REGULATORY ACTIVITY REPORT</b>
<b>Author:</b>	Trevor Clarke, Business Process Manager
<b>For Information or Decision?</b>	Information
<b>Resource Implications:</b>	N/A
<b>Recommendation to the Committee:</b>	Members are asked to <b>note</b> the report.

**Paper:**

**HFEA Regulatory Activity Report (February 2003 – January 2004)**

**Figure 1. Inspections**

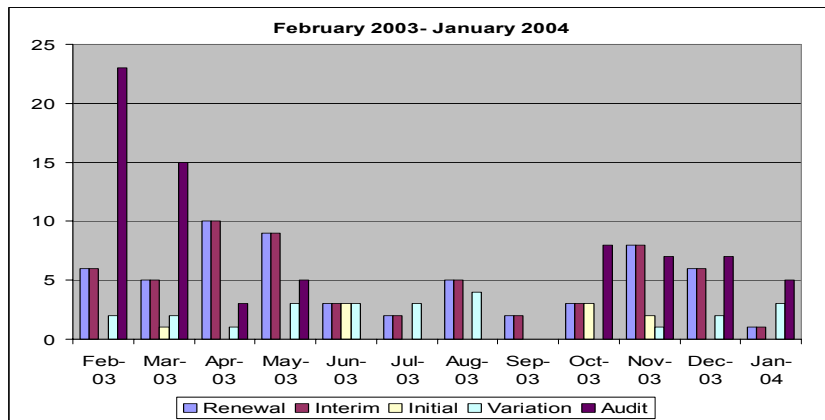


Figure 1 shows inspection visits for a rolling 12 month period from February 2003 to January 2004. The key points to note are

- the target of 5 inspections for January 2004 was achieved
- there was one joint inspection and audit visit
- the variation inspections included 2 practitioner visits and a change of premises visit
- Only 5 (45%) of 11 inspection reports were available to centres within four weeks. This delay was caused by bank holidays during the Christmas and new year period. We will factor this into our future scheduling.

**Figure 2. Incidents**

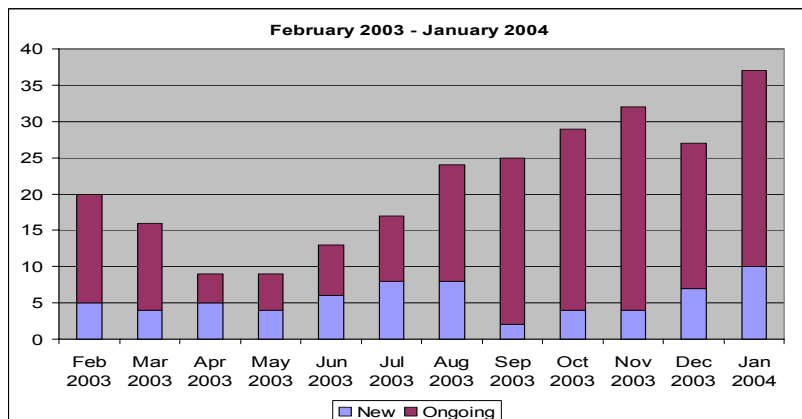


Figure 2 shows the incident cases (both new and ongoing cases) for a rolling 12 month period from February 2003 to January 2004. The key points to note are:

- 10 new incidents were reported in January 2004. They fell into the following categories:
  - technical – 4;
  - embryo handling – 3;
  - gamete handling – 2; and
  - reviewing/handling patient information - 1
- the number of active ongoing incidents continues to rise. This could be due to an actual increase in the incident rate but is more likely to reflect an increased rate of incident reporting.
- 2 incident related inspections took place

**HFEA Regulatory Activity Report (February 2003 – January 2004)**

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<b><u>Annual Inspections</u></b>	<b>FEB</b>	<b>MAR</b>	<b>APR</b>	<b>MAY</b>	<b>JUN</b>	<b>JUL</b>	<b>AUG</b>	<b>SEP</b>	<b>OCT</b>	<b>NOV</b>	<b>DEC</b>	<b>JAN</b>
Interims	5	6	4	3	10	10	3	7	0	4	5	4
Renewals	6	5	10	9	3	2	5	2	3	8	6	1
Initial	0	1	0	0	3	0	0	0	3	2	0	0
Audit Programme	23	15	3	5	0	0	0	0	8	7	7	0
<b>Total</b>	<b>34</b>	<b>27</b>	<b>17</b>	<b>17</b>	<b>16</b>	<b>12</b>	<b>8</b>	<b>9</b>	<b>14</b>	<b>21</b>	<b>18</b>	<b>5</b>

<b><u>Field Visits</u></b>	<b>FEB</b>	<b>MAR</b>	<b>APR</b>	<b>MAY</b>	<b>JUN</b>	<b>JUL</b>	<b>AUG</b>	<b>SEP</b>	<b>OCT</b>	<b>NOV</b>	<b>DEC</b>	<b>JAN</b>
Licence Variations	1	0	0	2	1	0	0	0	0	0	1	1
Practitioners	1	2	1	1	2	3	4	0	0	1	1	2
Advisory	0	0	0	10	3	2	0	0	4	1	0	0
Incident	1	1	0	0	0	5	4	2	3	3	0	2
Unannounced	n/a	n/a	n/a	n/a	n/a	n/a	n/a	2	0	0	1	0
New Centres	0	0	0	0	0	0	0	0	0	0	1	0
<b>Total</b>	<b>3</b>	<b>3</b>	<b>1</b>	<b>13</b>	<b>6</b>	<b>10</b>	<b>8</b>	<b>4</b>	<b>7</b>	<b>5</b>	<b>4</b>	<b>5</b>

<b><u>Incidents</u></b>	<b>FEB</b>	<b>MAR</b>	<b>APR</b>	<b>MAY</b>	<b>JUN*</b>	<b>JUL*</b>	<b>AUG</b>	<b>SEP</b>	<b>OCT</b>	<b>NOV</b>	<b>DEC</b>	<b>JAN</b>
Active at start of period	20	20	16	9	9	13	17	24	25	29	32	27
Reported	5	4	5	4	6	8	8	2	4	4	7	10
Resolved (Closed)	5	8	12	4	2	4	1	1	0	1	12	0
Active at end of period	<b>20</b>	<b>16</b>	<b>9</b>	<b>9</b>	<b>13</b>	<b>17</b>	<b>24</b>	<b>25</b>	<b>29</b>	<b>32</b>	<b>27</b>	<b>37</b>
Carried Forward Total	<b>87</b>	<b>91</b>	<b>96</b>	<b>100</b>	<b>106</b>	<b>114</b>	<b>126</b>	<b>128</b>	<b>132</b>	<b>136</b>	<b>143</b>	<b>153</b>

<b><u>Patient Complaints</u></b>	<b>FEB</b>	<b>MAR</b>	<b>APR</b>	<b>MAY</b>	<b>JUN</b>	<b>JUL</b>	<b>AUG</b>	<b>SEP</b>	<b>OCT</b>	<b>NOV</b>	<b>DEC</b>	<b>JAN</b>
Complaints Received	4	6	3	0	4	13	7	6	8	12	5	3

<b><u>Licence Committees</u></b>	<b>FEB</b>	<b>MAR</b>	<b>APR</b>	<b>MAY</b>	<b>JUN</b>	<b>JUL</b>	<b>AUG</b>	<b>SEP</b>	<b>OCT</b>	<b>NOV</b>	<b>DEC</b>	<b>JAN</b>	<b>Total</b>
Special	2	0	0	0	0	0	0	2	0	2	1	1	0
Standing	2	2	2	2	2	2	1	3	2	2	2	2	0
Research	n/a	n/a	n/a	n/a	1	1	1	1	1	2	1	1	0
Items Considered	<b>23</b>	<b>18</b>	<b>19</b>	<b>22</b>	<b>21</b>	<b>25</b>	<b>18</b>	<b>39</b>	<b>15</b>	<b>25</b>	<b>31</b>	<b>25</b>	<b>0</b>

Author: Trevor Clarke – Business Process Manager (Regulation)

Revisions SJ Mather – 9 February 2003