



## **Renewal Inspection Report**

**Ninewells Hospital  
0004**

**Date of Inspection: 13 May 2009  
Date of Licence Committee: 12 August 2009**

## Centre Details

Person Responsible	Dr Vanessa Kay
Nominal Licensee	Mr Gerry Marr
Centre name	Ninewells Hospital
Centre number	0004
Centre address	Assisted Conception Unit Ward 35 Ninewells Hospital Dundee DD1 9SY
Type of inspection	Renewal
Inspector(s)	Vicki Lamb
	Neelam Sood
	Paul Knaggs
Fee paid	12 March 2009
Licence expiry date	30 September 2009
NHS/ Private/ Both	Both

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## About the Inspection:

This inspection visit was carried out on 13 May 2009 and lasted for 7 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:

How well the centre is organised

The quality of the service for patients and donors

The premises and equipment

Information provided to patients and to the HFEA

The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre: No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.

Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.

Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website [www.hfea.gov.uk](http://www.hfea.gov.uk) .

### **Brief Description of the Centre and Person Responsible**

The Assisted Conception Unit at Ninewells Hospital has been licensed to provide NHS and self funded fertility treatments to patients from a wide geographical area since 1992. The unit is open from 8:00 to 17:00 on Monday to Friday and from 8:00 to 12:00 on Saturdays.

There are plans to expand the centre within the next year, to provide improved facilities to both patients and staff.

The PR has changed since the last inspection and this change has been approved by a Licence Committee. The PR has also completed the PR Entry Programme to the satisfaction of the HFEA Executive.

### **Activities of the Centre<sup>1</sup> for the time period from 1 January 2008 – 31 December 2008**

In vitro fertilisation (IVF)	347
Intracytoplasmic sperm injection (ICSI)	131
Frozen embryo transfer (FET)	115
Research	No
Storage gametes/embryos	Yes

### **Summary for Licence Committee**

Improvements are required in areas of organisation, quality of service and laboratory and clinical processes and are summarised below:

- Average payment times exceed the 28 day limit
- Some documents had not been reviewed in the last 12 months
- Competence assessments for all staff have not been performed
- Not all equipment has been validated
- Not all processes have been validated

The centre have made considerable progress with meeting the requirements of the HFEA since the last inspection and the executive recommend renewal of the licence for a period of four years.

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<sup>1</sup> This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

### Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service		X	
3. Premises and Equipment	X		
4. Information	X		
5. Laboratory and clinical processes		X	

### Breaches of the Act, Standard Licence Conditions or Code of Practice:

The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
The average payment time for treatment fees is 30 days. The HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3	By the next inspection
Some documents seen by the inspection team had not been reviewed in the last 12 months. The quality manager was aware of this and has plans to ensure that all documents are reviewed every 12 months. This is a breach of S.5.2.5.	The PR should ensure that all documents are reviewed at least every 12 months in compliance with S.5.2.5.	By the next inspection

Competence assessments for all staff have not been performed, although staff reported that a system for assessing competencies is being established. This is a breach of S.6.2.2(c) and S.6.2.7(a).	Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a).	By the next inspection
Validation is being performed for new equipment but existing equipment has not been validated. This is a breach of A.10.13.	Validation of all equipment should be performed to ensure compliance with A.10.13.	By the next inspection
Not all processes have been validated. This is a breach of S.7.8.3.	Validation of all processes should be performed to ensure compliance with S.7.8.3.	By the next inspection

### Non-Compliance

Area for improvement	Action required	Time scale
None		

### Recommendations

Area for improvement	Action required	Time scale
None		

### Changes/ improvements since last inspection

Recommendations	Action Taken
Laboratory staff to be trained for transportation of gametes according to HFEA Alert 21 and S.7.7.14, S.7.7.15	Training took place after the last HFEA inspection and again in March 2009.
Validations, service and maintenance history of transportation vessels to be logged (S.3.1.30)	Validation has been performed and a service history is available.
Records shall be kept of the complaints and their investigation together with the corrective action (S.9.2.2.)	This is now being done and was seen on the day of inspection.
The laboratory meetings to be	This is now done.

documented.(S.3.1.6, S.6.2.12, S.6.2.13)	
Some of the SOPs provided in the list pre-inspection require revision date (S.5.2.5)	All SOPs have revision dates and this was seen on the day of the inspection.
Forms for witnessing need to have signatures and time of procedure recorded at each stage (G.13.1, G 13.1.2)	This has been done and was seen on the day of the inspection.
There is no back-up support for the counsellor (G.7.1.2)	There is now a back-up arrangement in place and this was confirmed with the counsellor on the day of the inspection.
At the time of inspection, it was noted that the low-oxygen alarm was lying outside the laboratory; it needs to be in place in the laboratory, although 14 dewars are located there. (G.9.4.1, G.9.4.3, A,10.19)	Two low oxygen alarms are now in place in the laboratory.
The PR in conjunction with the principal embryologist should conduct a work force analysis.	Embryology staffing and work load from August 2007 to February 2008 was sent to the HFEA after the last inspection, and the inspectorate considered that the issue was resolved. Changes to work patterns have been implemented enable regular breaks to be taken and staff to finish work on time.
The centre needs to assess and document competencies regularly (S.6.2.9, G.1.5.3, G.1.5.6)	Competence assessments for all staff are not in place.
The centre needs to ensure that air quality is regularly monitored (G.9.4.1, G.9.4.3, A 10.19)	Air quality is monitored every three months.

### **Additional licence conditions and actions taken by centre since last inspection**

The licence was issued with no additional conditions.



## Report of inspection findings

### 1. Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

#### Areas of firm compliance

The PR at the centre has changed since the last inspection. The current PR has completed the PR entry programme satisfactorily and has been approved by a Licence Committee.

An organisation chart for the centre was provided to the inspection team. This showed clear lines of accountability.

There is an SOP for resource management and this was made available to the inspection team.

The centre has a clinical risk group which meets regularly to review all clinical incidents. If corrective action is required this is reported to staff at a multidisciplinary team meeting.

Staff were aware of the most recent alerts to be issued by HFEA.

In discussions with staff it became clear that they are aware of the complaints procedure. A complaints notice was on display in the patient area. The complaints log was provided to the inspection team. It contained action taken as a result of the complaint and records of correspondence with the complainant. Of the ten complaints received at the centre since the last inspection, eight had been resolved and two were ongoing. In discussion with the PR and quality manager, they informed the lead inspector that complaints are reviewed and discussed with staff as appropriate.

A business continuity plan is in place and is reviewed annually. Contingency arrangements are in place with centres 0019 and 0201 for transfer of gametes/embryos/documents in the event of closure of the centre.

The latest health and safety report was seen by the inspection team.

<p>An annual fire risk assessment is performed.</p> <p>The third party agreements for the supply of services and consumables were seen to be in place.</p> <p>Multidisciplinary team meetings are held monthly and minutes of these meetings were seen. In addition, individual departments have weekly meetings.</p> <p>Staff interviewed confirmed that if procedures change then all relevant staff are notified by email.</p>
<p><b>Areas for improvement</b></p>
<p>The average payment time for treatment fees is 30 days. HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.</p>
<p><b>Areas for consideration</b></p>
<p>None</p>
<p><b>Executive recommendations for Licence Committee</b></p>
<p>The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3.</p>
<p><b>Evaluation</b></p>
<p>Some improvement required</p>
<p><b>Areas not covered on this inspection</b></p>
<p>None</p>

## 2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

<b>Live birth rates<sup>1</sup></b>
In the time period from the 1 January 2005 to 31 December 2007 the centre's outcomes for all treatments and all ages of patients were in line with the national average.
<b>Areas of firm compliance</b>
The quality manual was provided to the inspection team. Quality and environmental policies with signatures were seen to be in place.  SOPs appropriate for the treatments offered at the centre were seen to be in place.  When changes are made to documents in the quality management system, the quality manager emails all staff with the updates.  Quality objectives are in place and the list of these was provided to the inspection team. These are reviewed on a regular basis  The centre has a programme of internal audits to identify any areas of non-conformance and action required. Audits have been performed since the last inspection and the list of monthly audits was provided to the inspection team.  The centre management conduct a regular review of the quality management system. The last review was held on 16 July 2008.  Evidence of the document control system was seen by the inspection team and considered to be appropriate.  ISO certification was obtained in March 2007. A surveillance audit was carried out by the certification body in June 2008 and a further inspection is due in July/August 2009.  Staff have the opportunity to make suggestions to improve the service. One example of how this has been put into practice is by the outpatient clinic waiting list being reduced by starting nurse-led clinics.  The most recent doctor to join the centre was interviewed and was positive about her

<p>experiences at the centre and the opportunities for learning.</p> <p>The centre has its own patient questionnaire and patient questionnaires received at the HFEA indicate that patients are satisfied with the service they receive. All questions on the questionnaire received positive responses from at least 80% of respondents. 92.9% of respondents considered that there was enough privacy. This has been an issue previously at this centre.</p> <p>The patient interviewed on the day of the inspection was very satisfied with the treatment and information she had been provided with. She was aware of the counselling service and had found it useful.</p>
<p><b>Areas for improvement</b></p>
<p>Some documents seen by the inspection team had not been reviewed in the last 12 months. The quality manager was aware of this and has plans to ensure that all documents are reviewed every 12 months.</p>
<p><b>Areas for consideration</b></p>
<p>None</p>
<p><b>Executive recommendations for Licence Committee</b></p>
<p>The PR should ensure that all documents are reviewed at least every 12 months in compliance with S.5.2.5.</p>
<p><b>Evaluation</b></p>
<p>Some improvement required</p>
<p><b>Areas not covered on this inspection</b></p>
<p>None</p>

### 3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

#### Areas of firm compliance

The HFEA licence was seen on display in the main corridor.

The recovery bay has facilities for four patients to recover at one time and the centre rarely perform more than four egg collections per day. The nurses' station is adjacent to the recovery bay.

Alterations were carried out in 2008 to improve patient privacy by enabling scans and examinations to be carried out in single rooms.

The emergency trolley log was checked on the day of the inspection and the checks conducted were found to be up to date and in line the SOP.

Fridge temperatures in the clinical areas were seen to be recorded on a daily basis.

Counselling is provided at the centre and the room for this was shown to the inspection team and considered to be appropriate. Counselling notes are kept in lockable cabinets to which only the counsellor has access.

The storage dewars were seen to be locked. Low level nitrogen alarms were seen to be in place and were linked to an autodialler system.

Calibrated probes are used to check the temperature of incubators and heated surfaces. The log of checks was made available to the inspection team.

The cleaning log for the laboratory was seen by the scientific inspector. The log demonstrated that cleaning was undertaken on a regular basis.

There is an on-call rota in the laboratory for emergencies. This is staffed by the state-registered embryologists.

Where available, consumables used are CE marked.

Air quality was seen to meet the requirements of the Code of Practice. The air quality is assessed every three months. Air quality is assessed by particle counts, settle plates and contact plates.
New equipment has been purchased since the last inspection. This has been funded by the Trust.
Patient records were seen to be kept in lockable cabinets in a lockable office.
In discussions staff and patients expressed satisfaction with the facilities at the centre.
Staff lockers and changing areas were available and were shown to the inspection team.
<b>Areas for improvement</b>
None
<b>Areas for consideration</b>
The liquid nitrogen tank used for filling the storage tanks is kept in the main corridor. Centre staff acknowledged that this is not ideal and this practice will not continue when the extended premises are finished. The inspection team were informed that the hospital health and safety assessor is aware of this situation and has agreed that there is no alternative position for the tank.
<b>Executive recommendations for Licence Committee</b>
None
<b>Evaluation</b>
No improvements required
<b>Areas not covered on this inspection</b>
None

#### 4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Provision of information to the HFEA register

<b>Audit of records</b>
Five patient records were checked for consents and welfare of the child assessments. No discrepancies were noted.  Three sets of patient records were checked for witnessing documentation. No discrepancies were noted. The inspection team were also informed that a list of staff signatures is held at the centre.  Three sperm donor records were checked to ensure that expenses payments were in line with directions. In all three cases evidence of the expenses incurred was present and expense payments matched the expenses incurred.
<b>Areas of firm compliance</b>
Patient information provided to the inspection team complied with the requirements of the Code of Practice.  There is a checklist in place to ensure that all information is given to patients.  Confidentiality of information stored on computers is maintained by password protection. All staff interviewed about this confirmed that this is the case.  Photographic identification is used to confirm the identity of patients. When consents are taken from patients who have previously consented, the signatures are checked to ensure that they match the originals.  One of the administration staff confirmed to the inspection team that they must check consents to disclosure and addresses before letters are sent out. This procedure was implemented in response to an incident.  The centre have cleared their error reports within the required timescales.
<b>Areas for improvement</b>
None
<b>Areas for consideration</b>
None
<b>Executive recommendations for Licence Committee</b>

None
Evaluation
No improvements required
Areas not covered on this inspection
Access to health records



## 5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

### Full time equivalent staff

GMC registered doctors	1.5
NMC registered nurses	5.83
Non NMC registered clinical staff	0.53
HPC registered scientists	2.0
Scientists working towards registration	2.0
Support staff (receptionists, record managers, quality and risk managers etc)	5.7
Counsellors	0.3

### Summary of laboratory audit

28 discrepancies were identified during the last stored sample audit. These were all documentation errors and have now been resolved.

### Summary of spot check of stored material

This was not performed as none of the errors on the laboratory audit indicated that samples had been stored in the incorrect location and no discrepancies were noted in the spot check at the last inspection.

### Areas of firm compliance

Nurses are undertaking accreditation in scanning. Two nurses have already gained accreditation and four more are in training.

Nursing staff have a programme of peer-based competency assessments covering all aspects of their work.

A review of scanning competencies is carried out annually for all practitioners.

A key performance indicator is in place to analyse success rates per embryo transfer for each

practitioner.

Laboratory staff participate in the NEQAS scheme for sperm assessment. The records of this were provided to the scientific inspector. The inspection team were also informed that the laboratory staff are also participating in the pilot scheme for embryo assessment.

Training and CPD logs were seen for a selection of staff and the inspection team considered them to demonstrate appropriate training.

All medical, nursing and laboratory staff attend annual resuscitation refresher courses. The last course was in December 2008.

All donors are screened in line with Code of Practice requirements including screening for gonorrhoea.

No three embryo transfers have been carried out in women under the age of 40 since the last inspection. Three embryo transfers have been carried out in three women over the age of 40 in the same time period.

The list of patients who should have had single embryo transfer (SET) according to the centre's multiple births minimisation strategy but did not was provided to the inspection team. There was only one case where a patient who met the criteria for SET had more than one embryo transferred. This was due to the patient's request.

An anaesthetist is always present for egg collections.

Compliance with witnessing is audited.

A risk assessment of the witnessing system has been performed and documented.

The protocol for transportation of samples was audited on the inspection and was found to be compliant with the Code of Practice.

Semen analyses are performed by a CPA accredited laboratory.

New laboratory equipment is validated before use.

The counsellor is a member of BICA and an accredited member of BACP.

Counselling is available for no charge

A back-up counsellor is available and a signed agreement is in place for this.

The counsellor has performed her own patient satisfaction questionnaire. The results of this were provided to the inspection team. Most patients were satisfied or very satisfied with the service.

#### Areas for improvement

Competence assessments for all staff have not been performed, although staff reported that a

<p>system for assessing competencies is being established. This is a breach of S.6.2.2(c) and S.6.2.7(a).</p> <p>Validation is being performed for new equipment but existing equipment has not been validated. This is a breach of A.10.13.</p> <p>Not all processes have been validated. This is a breach of S.7.8.3.</p>
<p><b>Areas for consideration</b></p>
<p>None</p>
<p><b>Executive recommendations for Licence Committee</b></p>
<p>Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a).</p> <p>Validation of all equipment should be performed to ensure compliance with A.10.13.</p> <p>Validation of all processes should be performed to ensure compliance with S.7.8.3.</p>
<p><b>Evaluation</b></p>
<p>Some improvement required</p>
<p><b>Areas not covered on this inspection</b></p>
<p>None</p>

**Report compiled by:**

Name.....Vicki Lamb.....

Designation.....Inspector.....

Date.....5 June 2009.....

**Appendix A: Centre staff interviewed**

The PR and seven members of staff were interviewed

**Appendix B: Licence history for previous 3 years**

<b>Licence</b>	<b>Status</b>	<b>Type</b>	<b>Active From</b>	<b>Expiry Date</b>
L0004/14/c	Active	Treatment with Storage	28/03/2009	30/09/2009
L0004/14/b	Replaced by new version	Treatment with Storage	01/02/2009	30/09/2009
L0004/14/a	Replaced by new version	Treatment with Storage	05/07/2007	30/09/2009
L0004/13/a	Replaced by new version	Treatment with Storage	01/10/2006	30/09/2009

**Appendix C: Response of Person Responsible to the inspection report**

Centre Number..... 0004.....

Name of PR..... Dr Vanessa Kay.....

Date of Inspection.....13<sup>th</sup> May 2009.....

Date of Response..... 26<sup>th</sup> June 2009.....

I have read the inspection report and agree to meet the requirements of the report.

Signed.....Vanessa Kay.....

Name..... VANESSA KAY.....

Date.....26<sup>th</sup> June 2009.....

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

- 1. Page 10. Organisation . Areas of firm compliance – ‘Staff interviewed confirmed that if procedures change then all relevant staff are notified by email’ should be changed to ‘Staff interviewed confirmed that if procedures change then this is discussed at a Unit meeting, and notified to all staff in the Minute, by email’
- 2. Page 15, regarding consents to disclosure and addresses. While it is correct that the procedure of checking addresses before sending out letters was implemented in response to an incident, it has always been Unit policy not to send out letters until the consent to disclosure is signed.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

3. Please state any actions you have taken or are planning to take following the inspection with time scales

- Payment times – this has been discussed with the Finance Department. The procedure has been amended so that invoices are sent directly from the ACU to the accounts payable department, bypassing the Hospital finance department. Process to be audited monthly.

- Document control - all documents have now been updated.
- Competence assessments:
  - a) Laboratory – competences assessed as part of training programme, then repeated annually.
  - b) Nursing – competences have been completed and recorded for each member of staff – to be repeated annually.
  - c) Medical – competency assessment included in induction pack and to be assessed annually for all medical staff.  
Three –monthly KPIs to include number of oocytes obtained versus estimated number of mature follicles on scan (theatre procedure record amended)
- Validation of processes and existing equipment – in quality plan for 2009/10.

# HFEA Licence Committee Meeting

## 12 August 2009

21 Bloomsbury Street London WC1B 3HF

### Minutes – Item 1

#### Ninewells Hospital (0004) - Renewal

Members of the Committee:	Committee Secretary:
Anna Carragher (lay) -- Chair	Kristen Veblen
Rebekah Dundas (lay) – by videolink	Legal Adviser:
Richard Harries (lay)	Stephen Hocking, Beachcroft LLP
Emily Jackson (lay)	
Apologies:	
William Ledger (clinician)	

Declarations of Interest: members of the Committee declared that they had no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for licence committee (48 pages)
- no tabled papers.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.

1. The Committee noted that the Centre had been licensed to provide NHS and self funded fertility treatments to patients from a wide geographic area since 1992.

2. The Committee considered the papers, which included the renewal inspection report, the renewal application form, communication and audit trail regarding invoices and previous Licence Committee minutes from 20 June 2007, 26 April 2007, 24 April 2008, 26 March 2009 and 22 January 2009.
3. The Committee noted that the renewal inspection had taken place on 13 May 2009 and that improvement had been required in the following areas:
  - Average payment times exceeded the 28 day limit
  - Some documents had not been reviewed in the last 12 months
  - Competence assessments for all staff had not been performed
  - Not all equipment had been validated
  - Not all processes had been validated.
4. The Committee agreed that the response of the Person Responsible (PR) including Appendix C in the report dated 26 June 2009 and correspondence regarding invoices had been complete and had addressed the areas for improvement. The Committee agreed that it was satisfied with the response and that the breaches listed in the report had been addressed and where necessary would be monitored at the next inspection.
5. Additionally, the Committee noted that the improvements required in the previous inspection report had been addressed, with the exception of the revision of documents to comply with 7<sup>th</sup> Code of Practice S.5.2.5, however, the response of the PR explained that this had now been rectified.

#### The Committee's Decision

6. The Committee noted that there were no issues regarding the character, qualifications or experience of the PR or her ability to perform her duties under section 17 of the HFE Act 1990 (as amended). The Committee agreed that the PR had discharged her responsibilities satisfactorily and the Committee was satisfied that she continued to be a suitable PR.
7. On the basis of the information provided by the report, which demonstrated that the Centre's premises met the statutory requirements and had been shown to be fit for purpose, the Committee was satisfied as to the suitability of these premises.
8. The Committee agreed that it was satisfied that the breaches in relation to the Centre's practices had been corrected, explained in the response of the PR,



and on that basis agreed that it was satisfied as to the suitability of the practices at the Centre.

9. The Committee noted that it was in receipt of a signed application form and that the relevant fee had been paid.
10. The Committee noted the recommendation of the Executive to renew the licence for 4 years. The Committee decided to renew the licence for 4 years with no additional conditions.

Signed Anna Carragher Date 25.8.2009  
Anna Carragher (Chair)