Interim Inspection Report

South East Fertility Centre
0208

Date of Inspection: 20 November 2007
Date of Licence Committee: 13 February 2008

TRIM: 06/5619

CENTRE DETAILS

Centre Address	Amberley House 9 Queens Road Royal Tunbridge Wells Kent TN4 9LL
Telephone Number	01892-614110
Type of Inspection	Interim Inspection
Person Responsible	Mr. Michael Rimington
Nominal Licensee	Mr Mark Wilcox
Licence Number	L0208-6-a
Inspector(s)	Tony Knox Tahir Hussain
Fee Paid - date	Not due.
Licence expiry date	30th April 2009

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About the Inspection:
This inspection visit was carried out on 20th November 2007 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between January 2007 and 31st October 2007.

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 interim 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, recommendations 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.

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 .

Brief Description of the Centre and Person Responsible

Centre 0208 was originally located within the Nuffield Hospital in Tunbridge Wells. An application was received in 2006 to close the unit from within the Nuffield and move premises to its current location. A new centre number was allocated (Centre 0253) which was presented to Licence Committee. The application for the new premises was granted in November 2006 and a three year licence was awarded. Following the opening of the centre in January 2007, a decision was made within the HFEA that for Registration purposes primarily, the centre should revert back to its original centre number of 0208. As such, although the centre shows that it has been established since 2004, the unit has only been in existence since January 2007.

An application to vary the centre licence in preparation for the EU Tissue and Cells Directive was received at the HFEA and presented to licence Committee on 2nd April 2007. Variation of licence was granted.

Activities of the Centre

Licensed treatment cycles	IVF ICSI FET Egg Provider Egg Recipient	116 97 61 13 17
Donor Insemination		36
Unlicensed treatments	Ovulation Induction	
Research	No	
Storage	Yes	

Summary for Licence Committee

The centre appears well organised and is run by highly qualified and professional staff.

The inspector has highlighted a number of issues, which in his view, amount to the Breaches and non-compliance with the Code. The weight to be attached to these issues is a matter for the licence Committee to consider.

The inspectorate recommends the continuance of this centres licence with no additional conditions.

Risk Assessment

The centre risk score calculated for compliance with the EU Tissue and Cells Directive was calculated at 2%, which is low risk. As this centre has only been operating from its current location since January 2007, a previous general risk score had not been calculated. Following this inspection, the centre has been awarded with a general risk score of 5%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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 given 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
Validation of processes and procedures as required in S 7.8.3 of the Code of Practice have not been conducted. (See section five).	Recommendation is made to devise a plan of processes and practices and to prioritise the list according to impact on quality. Upon completion, a systematic approach to validation be adopted commencing with areas of greatest risk through to those of lower risk.	Six months.

Non-Compliance
In the opinion of the inspector, the following are areas of non-compliance: -

Area for improvement	Action required	Time scale
Air quality testing was last performed within the unit prior to the commencement of licensed treatments in January 2007.	It was recommended that processes be put in place to monitor the air quality within the unit on a regular basis (see G.9.4.7 of the Code of Practice), and that recordings are kept as evidence that air quality standards are being maintained.	Three months.

Recommendations	Time scale
It was noted that the three-embryo transfer log only contained the age of the woman as the reason. It was recommended that additional factors should also be included as evidence that age was not the only reason for three-embryo transfers being performed. (See section five of this report, "Laboratory and Clinical Practice"). (CH(04)01).	Immediate.
A formal documented contingency plan should be formalised and documented for any possibility that the whole unit be inaccessible. (See section one of this report, "Organisation"). (A.10.23)	Three months.
It was noted that although competencies have been documented for laboratory staff, these are still currently in development for other departments such as nursing. It was recommended that these be finalised and implemented for all departments. (See section five of this report, "Laboratory and Clinical Practice"). (A.10.9).	Six months.
Plant equipment used for the laboratory and treatment room is housed at the back of the unit. It was noted that this is unguarded and could therefore potentially be accessible to vandals. It is recommended that the centre risk assess the potential risks associated with the equipment being vandalised and its effect on the running of the business. (See section three of this report, "Premises and Equipment").	By next inspection.

Proposed licence variations

None

Changes/ improvements since last inspection

Recommendation	Action taken
None	

Additional licence conditions and actions taken by centre since last inspection

C	None
A	Complied Y/N

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 findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
• The centre was seen to be well organised with all staff interviewed being aware of their responsibilities. The PR has completed his PR Entry Programme and intends using some of the content from that programme in training exercises to be used for other staff within the unit. • The centre has a robust quality management system in place, has assigned a quality manager, is ISO 9001:2000 accredited (certificate on display and re-certified in October 2007), and holds regular meetings with staff at the centre to discuss quality issues and Clinical Governance. Evidence of these meetings was provided to inspectors in the form of minutes taken from the meetings. • An audit calendar for 2007 was provided to the inspectorate providing evidence of audits being performed in April and October 2007. The audits reviewed were performed by external auditors. Evidence was also provided of observations that had been made during the audits, corrective and preventative actions that had been taken as a result of the auditing processes. Evidence of internal audits was also provided including dewar, drugs and contractors. • Third party agreements are in place. The third party process for the centre also ensures that wherever possible ISO accredited suppliers are used. Contracts were seen to be in place for all services that are directly patient related, including the independent counsellor. Evidence was also provided of an approved supplier list in the form of a true quality management system. • There is a robust system in place for the reporting of incidents to the HFEA, which all staff interviewed were aware of. • There is a policy in place for all critical equipment including the power supply to the unit. Procedures are also in place for contingencies such as loss of utilities including gas and water. A locum service is available for nursing and laboratory staff, which can be accessed if required. • There are no reported problems from the HFEA Finance Department regarding late payment of treatment fees.

Areas for improvement
• Although policies and procedures were evidenced to show that contingencies have been considered for loss of power, utilities and staff, it was noted that a form documented contingency plan had not been documented should the whole unit be inaccessible. It was noted by the PR and the nominal licensee that in such an event, other units locally would be contacted verbally, however it was recommended that this be formalised.
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

2. Quality of service

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

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates
As the centre was granted a licence in November 2006 but only commenced licensed treatments in January 2007, it is currently too early to have any live birth data for analysis.
Areas of firm compliance
• The centre has a robust 'Welfare of the Child' policy, which meets with the requirements of the HFEA. Any potentially difficult cases are discussed in a multidisciplinary meeting where a general consensus to treat or refuse treatment would be established. Any patient refused treatment would be seen by the Pr to explain the reasons for refusal. • Patient records were seen to be held securely within the unit. All current patient notes are held within the nursing office on the ground floor. The notes are stored within a lockable storage unit and the door to the area is secured by keypad controlled access lock for which only authorised personnel are given the code. It was explained that all other patient notes are returned to this area at the end of the day if not in use. Other areas housing patient notes were also seen to be secured by keypad controlled access locks. The unit is alarmed and connected to the local police station. • Patients are provided with all treatment options available to them during initial consultation and in the provision of patient information prior to the consultation. This was confirmed during patient interviews on the day. • The centre has a patient suggestion box within the waiting room of the unit. Fifteen HFEA patient questionnaires had been returned to the HFEA since the opening of the centre in January. All questionnaires received included positive comments concerning the unit generally, the care received at the centre and the friendliness and professionalism of the staff. • The complaints register is held electronically (on a secure server), in addition to a file containing all paperwork received centrally. The complaints policy and procedure is robust and known to all staff interviewed. All complaints received are discussed during multidisciplinary team meetings (evidenced in the minutes of the meetings. The complaints file provided evidence that the complaints received are handled appropriately and included evidence of corrective and preventative actions to be taken/implemented.

- The counsellor is fully qualified, registered with an appropriate professional body, receives 50 minutes of supervision twice monthly, and stated that she felt included in the activities of the centre. The use of a consulting room within the centre can be made available for her for counselling sessions although she also noted that she can see some patients at her own home f this is preferred. The counsellor confirmed that all notes are kept in secure storage at her own home. The counsellor confirmed that counselling is provided free of charge to patients and that there is currently no waiting list. Wherever possible, the counsellor also attends the regular staff meetings. Where this is not possible, copies of the minutes from those meetings are made available to her.
- Sperm donors are recruited at the centre. A robust screening policy and procedure is in place and evidence was provided to show that all appropriate screening had been undertaken.

Areas for improvement
None

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Egg sharing and surrogacy Protection of children arrangements.

Evaluation
No improvement required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
• The premises were seen to well maintained with a high standard of general housekeeping. • The unit comprised of: - o Two consulting rooms (one containing a scanning machine and the other used also as the PR office). o The nominal licensee office o Pharmacy (secured by digilock access control). o Secretarial office o A staff changing area, toilet/shower facilities and lockers along with a kitchen for staff use on the first floor. o A spacious waiting room with drinks facilities o Reception area. Patient billing is conducted within the reception room, the door to which is closed when staff are discussing finances with patients. o A nursing office containing the current patient notes. o Patient toilets. o A producing room (equipped with an alarm and an internal telephone). It was noted that on producing their sample, the patient contacts the laboratory by using the internal telephone. A member of the laboratory staff then meet the patient by the producing room to collect the sample and to obtain a signature from the patient that the sample was produced by them. o A storage room o Three recovery rooms (one of which has been designed to allow for disabled access) o A treatment room containing the emergency crash trolley. It was evidenced that this is checked daily. o Laboratory area. Within the laboratory area is a designated room used for the processing of sperm samples and a separate room used as a cryostore (containing seven dewars). The cryostore has piped liquid nitrogen from a holding tank outside the unit. Gases used within the laboratory are also piped into the laboratory from a secure holding facility outside of the unit. o The basement of the building contains archived patient notes (securely) and the units' central computer servers. • The PR noted that no more than five egg collections would be performed in any one day, which was considered suitable by the inspectorate based on the numbers of staff employed at the unit and on the facilities available. • Evidence was seen that all portable electrical appliances had been tested around the unit. • A file was evidenced containing all monitoring sheets for critical equipment including

dewars and incubators. The file included recordings made of the cleaning and microbiological tests performed on the water from the incubators.

- A file was evidenced including daily and weekly monitoring conducted which included evidence of a six weekly cleaning of the incubators.
- The dewars within the cryostore were seen to be secure, fitted with low level liquid nitrogen probes, which in turn were connected to an auto dial facility. It was noted that recent changes had been made to the alarm system, which had generated a number of false alarms. The alarm system has since been altered to ensure false alarms are not activated however, it was noted that each false alarm was acted upon immediately and ensured that the procedures for responding out of hours is effective. This alarm system is routinely tested once per month. There is a low level oxygen monitor in situ which is tested weekly and a low level extraction system in cases of emergency.

Areas for improvement
• It was noted that the plant equipment used for the laboratory and treatment room is housed at the back of the unit. It was noted that this is unguarded and could therefore potentially be accessible to vandals. It is recommended that a risk assessment is conducted to assess the potential damage that unauthorised access to this equipment could allow and to take appropriate actions based upon the findings.

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

4. Information

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

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
An audit was conducted on five sets of patient notes. All notes audited were seen to be well maintained and structured to enable swift access to relevant information. One set of patient notes contained a 'Welfare of the Child' assessment form that had not been signed by the patient. This was brought to the attention of the PR who noted that this oversight would be rectified. All other relevant consent forms were evidenced as being within the notes. Two sets of notes were checked against the witnessing requirements. No discrepancies were noted.
Areas of firm compliance
• Regular minuted multidisciplinary meetings are held within the centre where issues such as counselling, individual patient cases, quality management, patient feedback and staff suggestions and review of incidents are discussed. Evidence was provided during the inspection of the minutes created. Evidence was also provided of minutes generated from the centres management (strategy) meetings. • All policies and procedures evidenced both pre and during inspection were seen to be version controlled, contained the authors name and the date for review in accordance with the centres quality management system requirements. • The centre have published a booklet which is provided to all patients and donors attending the centre containing all pertinent information including treatments available, counselling, screening requirements, an explanation of the laboratory processes and complaints procedure. • There were no reported problems of late reporting from the Registry Department of the HFEA. • A list of all policies and procedures is held electronically on the units secure computer system. Access to this system is password protected and given to authorised personnel only. General access to the policies and procedures is granted to all staff by means of clicking on a particular policy/procedure on the list, which is then hyperlinked to the actual policy or procedure. General access is granted read only rights, which ensures that policies and procedures may not be altered inadvertently. All changes made to policies and procedures are made by authorised members of staff only, and after approval, replace the existing policy on the system.

- A comprehensive system for traceability is in place. Evidence was provided during the inspection that wherever possible, CE marked equipment is purchased and used, a batch control folder was evidenced which listed all the media, consumables and laboratory essentials used and dates when new batches of media were replaced.
- All records requested on the day of the inspection were provided quickly indicating a robust record management system in operation.

Areas for improvement
No improvement required.

Executive recommendations for Licence Committee
None.

Areas not covered on this inspection
All areas covered.

Evaluation
Some improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	2
NMC registered nurses	3
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	8 - 6 staff in administrative roles, 1 independent counsellor and 1 healthcare assistant.

Summary of laboratory audit
The last audits of dewars performed were conducted prior to the move to the new unit in December 2006. Evidence was provided that both dewars containing sperm had no discrepancies noted. Of the remaining four dewars audited containing embryos, four administrative errors were recorded and amendments made to correct these.
Summary of spot check of stored material
A spot check was not conducted during this inspection.
Areas of firm compliance
• Human resources policies are in place and considered fit for purpose to ensure staff are recruited with appropriate qualifications, are registered with their professional bodies and that consideration is given to both equality and diversity and past criminal convictions prior to employment. • There is an appropriate induction policy and program in place for all new employees. Evidence was provided of a training and induction plan for the newest member of staff, including competencies that the staff member was working to. • Comprehensive training logs are held on the units secure server. Evidence was provided of a training log which contained all funded continuous professional development training attended along with evidence of mandatory training attended. • Evidence was provided to show that staff needs for continuing professional development

have been and continue to be addressed and provided for appropriately. This was confirmed during staff interviews.

- Emergency procedures were seen to have been documented for responding to damaged vessels within the laboratory and in the responding to emergencies within the unit.
- Evidence was provided to show that staff had received mandatory training.
- All staff interviewed stated that they are well supported in their continuing professional development needs, and are well supported by the management of the unit as well as fellow colleagues.
- The three-embryo transfer log provided evidence that no three embryo transfers had been conducted in women under the age of 40 years.
- An audit of two sets of patient notes provided evidence that all witnessing steps are being completed in accordance with the Code of Practice Version 7 and the Witnessing Directions.

Areas for improvement

- It was noted that although competencies have been documented for laboratory staff, these are still currently in development for other departments such as nursing. It was recommended that these be finalised and implemented for all departments.
- It was noted that the three-embryo transfer log only contained the age of the woman as the reason. It was recommended that additional factors should also be included as evidence that age was not the only reason for three-embryo transfers being performed.
- Although evidence was provided to show that the air quality within the unit had been tested and had achieved Grade A within the laboratory and Grade B in the Andrology laboratory and treatment room, it was noted that these tests had been last performed prior to licensed treatments being commenced within the unit. It was recommended that processes be put in place to monitor the air quality within the unit on a regular basis (see G.9.4.7 of the Code of Practice), and that recordings are kept as evidence that air quality standards are being maintained.
- Validation processes were discussed with the Acting Laboratory Manager. It was noted that although ongoing monitoring processes are in place for equipment used within the unit, the policies and procedures should be revised to ensured that files are maintained on all major pieces of equipment which should include information pertaining to their installation and suitability for the purposes the equipment was obtained for. Consideration is also required to ensure that an FMEA (Failure Mode Evaluation Analysis) is conducted for critical processes and equipment.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

PGD/PGS is not performed at this unit.

Evaluation

Some improvement required.

Report compiled by:

Name TONY KNOX

Designation Inspector.

Date 20th November 2007

Appendix A: Centre Staff interviewed

Mr. Michael Rimmington - Person Responsible.
Five other members of the unit staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 2nd April 2007
Approval given to vary the centre licence in accordance with the requirements of the EU Tissue and Cells Directive.

2006
Licence Committee 22nd November 2006
Approval provided for the opening of the South East Fertility Clinic for three years.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0208

Name of PR Michael Rimington

Date of Inspection 20th November 2007

Date of Response 28th January 2008

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

I would like to thank the inspectors for their time and support at the inspection. The advice and guidance was constructive and relevant. I would particularly like to acknowledge the professionalism and efforts of Tony Knox who oversaw the establishment of SEFC in his regulatory capacity. Sound advice, common sense and experience helped make for a seamless transfer of SEFC from an existing hospital to a stand alone setting.

Air quality testing was carried out in January 2008 and was satisfactory. A regular programme for testing will be devised by the embryologists. However it would be helpful if the HFEA could provide best practice guidelines to help all centres.

A local fertility clinic has been contacted seeking a formalised and hopefully reciprocal agreement to accept patients currently undergoing treatment in the event of the centre being inaccessible.

A 'cage' to safeguard the plant equipment has been designed and will be in place within a few months.

'Digilocks' have been fitted to the two doors which give access to the laboratory area.

We have advertised for and are seeking to employ another experienced fertility nurse and senior embryologist.

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

Signed……

Name……..

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

None

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

13 February 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

South East Fertility Centre (0208)
Interim Inspection

Members of the Committee:

Anna Carragher, Lay Member – Chair
Emily Jackson, Lay Member
Maybeth Jamieson, Consultant Embryologist, Glasgow Royal Infirmary
William Ledger, Professor of Obstetrics and Gynaecology, University of Sheffield

In Attendance:

Trish Davies, Director of Regulation / Deputy Chief Executive
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Graham Miles, Morgan Cole Solicitors

Observing:
Isabel Greenman and Lan Zhang from Deloitte & Touche LLP

Conflicts 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 (29 pages)
- no papers were tabled.

1. The papers for this item were presented by Parvez Qureshi, HFEA Inspector. Mr Qureshi informed the Committee that this centre has only been in its current premises since January 2007. Following the inspection the centre has a risk score of 5%, in the low range.

2. Mr Qureshi drew the attention of the Committee to the response to the inspection report by the Person Responsible, appended to the report at page 21. This response demonstrates that most of the concerns of the inspection team have now been addressed or are in the process of being addressed.

3. The Committee noted and endorsed most of the recommendations of the inspection team. However, they did not agree with the recommendation that

reasons should be recorded for all three embryo transfers to women over 40 years of age.

4. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed…… … Date……..
Anna Carragher (Chair)