New Premises Site Visit Report

Name of Applicant	Mrs Geeta Nargund
Address of Proposed Premises	CREATE 3-5 Pepys Road West Wimbledon London SW20 8NJ
Has the applicant been licensed before	NO
If yes: Centre Number and Address of previous premises	---
Inspector(s)	Parvez Qureshi Andrew Leonard Janet Kirkland
Date of visit	3 June 2008
Date of any previous visits to these premises	----

About the Site Visit

The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

Brief Description of the Centre

Currently CREATE is operating as a satellite centre for the London Fertility Centre (0086). An application has been received from the proposed Person Responsible for a Treatment and Storage licence.

The premises consist of two sites which are located opposite each other on the same road. The main site will house the laboratory facilities, reception, waiting room, treatment and recovery rooms, office space and male production room. The second site will mainly be used for administrative purposes and consists of reception, waiting area, consultation rooms, nursing facilities and a designated area for storage of notes. There is controlled access to both sites.

There are proposals to conduct around 600 natural and mild stimulation treatment cycles per year. The centre's management are anticipating applying for NHS contracts.

The centre will be open for business seven days a week.

The Person Responsible (PR) has completed the PR Entry Programme.

Summary of findings for Licence Committee
(If final visit before Application considered by LC)

The centres proposed organisational structures were considered compliant with requirements although the further development of risk management procedures is recommended.

Proposed procedures for quality management appeared well developed: it is recommended that the centre implements systems for evaluation and continual improvement as appropriate

- The risk management structure needs to be fully developed to ensure risk assessments are conducted for key processes and procedures, the activity level and for the work areas.
- Third party agreements should be finalised.
- A procedure for conducting regular audits of practice must be developed.
- A low oxygen monitoring system needs to be fitted and a procedure written for responding to its activation.
- The dewar audit protocol should be reviewed to include the frequency of auditing of all stored samples.
- Laboratory equipment and processes need to be validated.
- The suitability of the procurement facilities to be reviewed.
- An emergency trolley and an oxygen supply must be made available in the recovery area.

- Access to a back up power supply should be secured so that gamete and embryo quality and safety can be protected in the event of a power failure.
- A risk assessment needs to be performed for the transfer of notes between two sites.
- Patient information for OHSS requires reviewing to make it more appropriate regarding symptoms of OHSS.
- Document staff induction process.
- Develop a procedure for emergency transfer of patients to a hospital.

Subject to successful resolution of issues highlighted in this report the HFEA inspection team would support the centre's application for a Treatment and Storage licence and request the Licence Committee to agree to grant an initial licence for one year.

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 of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Business planning
- Clinical governance
- Knowledge of the legal requirements and COP

Summary of Findings
Comprehensive documentation including an organisational chart showing main functions and lines of accountability within the centre were submitted with the application. Additional information was also made available during the visit. Documents were reviewed by the inspection team and were considered to be satisfactory. CREATE has been a satellite centre for the London Fertility Centre (LFC) for a considerable time and key members of staff have extensive experience of working in the fertility field. A Quality Manager has been appointed to ensure that the centre complies with HFEA Standards and the requirements of the EU Tissue and Cells Directive. The proposed PR stated that regular meetings are held to discuss practice related issues and these will continue in the future with the agenda also including HFEA related issues. Where possible all staff attend meetings and have access to the minutes. Evidence of recently held meetings was seen during the visit. The centre has an adverse incident reporting policy in place. Staff interviewed were aware of the procedure for reporting to the HFEA. In the event of an emergency, contingency arrangements will be in place with LFC (0086) and St George's Hospital. The proposed PR also stated that, if required, any difficult cases will be referred to the LFC (0086) ethics committee. The centre has both a business plan and a Business Manager in place. Assessment of the completed PR Entry Programme submitted with the application by the proposed PR indicated a satisfactory knowledge of the legal requirements and the Code of Practice, 7th Edition. This was further evidenced during discussions between the proposed PR and the inspectorate.

Areas for improvement
Risk management procedures should be developed to allow proactive identification through risk assessment (S.9.4.3 (b)) A list of third party agreements was seen by the inspectorate. Some agreements still need to be formalised as the centre are awaiting replies from some organisations they consider to be third parties (S.4.2.10).
Points to consider/action for next inspection
Resolution of areas highlighted for improvement and monitoring of above findings.

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: *(Delete areas not being reported on)*

- '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

Summary of Findings
Discussions held with staff and evidence seen during the visit showed that currently patients' confidentiality is given due consideration. All notes are stored in a secure area, to which only members of staff have access. Evidence of respect for the privacy and dignity of patients was seen during the visit; all patient consultations take place in private rooms. There are procedures in place to ensure that proper account is taken of the Welfare of the Child when considering treatment. Currently a patient satisfaction feedback system is in place to capture feedback on the quality of the service being provided and members of staff informed the inspection team that this will continue in the future. A counselling service will be provided by a designated fertility counsellor and reference to this is made in the patient information leaflets. Patients will be able to book appointments via staff or directly with the counsellor. No charge will be made for the initial session and the proposed PR stated that this may change to three sessions in the future. Counselling notes will be kept in a secure place. At present there are no plans for recruitment of donors. Donor samples will be purchased from sperm banks who will be responsible for monitoring the 10 family limit. The centre has a complaints procedure in place which also references HFEA contact details.
Areas for improvement
The centre should develop systems for the continual evaluation and improvement of the quality of its service as required by S. 9 of the 7th Code of Practice (CoP).
Points to consider/action for next inspection
Resolution of areas highlighted for improvement and monitoring of above findings.

3. Premises and Equipment

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

Summary of findings from inspection: *(Delete areas not being reported on)*

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

Summary of Findings
All areas seen during the visit appeared clean and well presented. There is controlled access to both sites and the inspection team considered the facilities to be suitable for the proposed activities. The inspectorate considered the centre's cryostore facilities to be adequate for the anticipated volume of work. Laboratory staff stated that all dewars will be alarmed and linked to an auto dialler system. There is a procedure in place for responding to alarms. A spare dewar will be kept for emergency use. The laboratory staff stated that an effective traceability system will be in place for materials that come in contact with gametes and embryos. In addition, where possible CE marked consumables will be used. The centre has an air quality monitoring system in place to ensure that laboratory processes will take place in an environment of at least Grade C air quality, with the background air quality in the laboratory area being of at least Grade D, thus ensuring compliance with the EU Tissues and Cells Directive requirements. Logs of parameters related to the performance of key equipment are kept including incubator temperatures and % carbon dioxide, and fridge temperature, and evidence of this was seen during the visit. Maintenance contracts are in place for key pieces of equipment and evidence of this was made available to the inspectorate.
Areas for improvement
• The laboratory cryostore facilities are not fitted with a low oxygen monitoring system. The absence of a low oxygen level alarm could pose a risk to staff entering the area. The PR should ensure that risks inherent in the use and handling of biological material are identified and minimised in line with the requirements of A.10.4. • The dewar audit protocol should be reviewed to include the required frequency of auditing in line with the requirements of S.7.8.12. • The validation of key laboratory processes needs to be undertaken (S.7.8.3). • A seat in the male production room is cloth covered. It is recommended that the appropriateness of the procurement facilities is reviewed in consideration of the requirements of standard licence condition A.6.5.

- No emergency trolley or oxygen supply was noted in the recovery area. The centre should ensure that the clinical facilities available are equipped with backup and emergency clinical facilities equivalent to those which are standard practice in other medical provision and appropriate to the degree of risk involved in any planned procedure and able to cope with predictable emergencies (S.6.3.4).

- Currently the centre does not have access to a back up power supply. The provision of these facilities should be reviewed in consideration of the recommendations of HFEA Alert 20.

Points to consider/action for next inspection

Resolution of areas highlighted for improvement and monitoring of above findings.

4. Information

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

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

Summary of Findings
The information management system, both computerised and paper based, was seen in operation during the visit and was considered to be well organised. All information is stored in accordance with confidentiality requirements in lockable cabinets Patient information submitted for inspection was reviewed by the inspectorate and considered appropriate and included the following: • Contact details for out of hours emergencies. • Risks associated with treatment. • Contact details for queries, treatment costs and what screening needs to be done. The proposed PR stated that she was aware of the procedure for notifying the HFEA of all treatments that will be carried out at the centre. There are procedures in place for obtaining informed consent to treatment. Evidence of this was seen in documentation submitted for the inspection and from discussions held with staff.
Areas for improvement
Although the medical notes will be kept in a secure area, the premises are split over two sites. The PR should assess whether there are any risks associated with the transfer of notes between the two sites. Patient information on OHSS does not include all of the symptoms of OHSS**.** It is recommended that the information be reviewed to ensure that patients are informed about the possible side effects of their proposed treatment (G.5.3.1.(h)).
Points to consider/action for next inspection
Resolution of areas highlighted for improvement and monitoring of above findings.

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: *(Delete areas not being reported on)*

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

Summary of Findings

The centre has policies and procedures in place for the assessment of patients. Subject to installation of remaining equipment and any subsequent training of staff the centre is expected to have safe handling systems, laboratory procedures and clinical procedures in place. Equipment to be fitted will be tested and validated before being brought into service.

The current staff consists of**:**

GMC registered doctors	4
NMC registered nurses	2
HPC registered scientists	2
Scientists working towards registration	--
Support staff (receptionists, record managers, quality and risk managers etc)	4
Counsellors	1

The inspection team considered the current staffing level at the centre to be adequate for the anticipated initial workload but the centre is also recruiting additional staff. The recruitment of staff and their suitability to work at the centre is the responsibility of the centre's management team.

Viral positive patients will not be treated at the centre but will be referred elsewhere.

The proposed PR informed the inspection team that mandatory training will be arranged when the start-up staff team are all in place and they will undergo an induction.

The centre has witnessing protocols in place which were considered by the inspectorate to be compliant (G.13).

There are policies in place to ensure that staff are competent to perform required procedures, have access to training and are able to maintain their CPD.

Areas for improvement

The Nurse Manager informed the inspection team that staff would undergo part of the induction at another centre where procedures are currently carried out. Prior to the commencement of licensed activities however, personnel must be provided with initial/basic training, as required. The training programme must ensure and document that each individual: (a) has demonstrated confidence in the performance of their designed tasks,

(b) has an adequate knowledge and understanding of the scientific/ technical processes and principles relevant to their designated tasks, (c) understands the organisational framework, quality system and Health & Safety rules of the Centre in which they work, and (d) is adequately informed of the broader ethical, legal and regulatory context of their work. (A.10.11.

The inspection team emphasised the importance of having a documented procedure detailing how the centre should respond in the event of a patient emergency. All members of the team need to know who to contact and how the patient will be transferred to a hospital.

Points to consider/action for next inspection
Resolution of areas highlighted for improvement and monitoring of above findings.

Topic 1

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **organisation**

- A risk management structure needs to be fully developed to ensure risk assessments are conducted for key processes, procedures, level of activity and of the work areas.
- Formalising of all third party agreements.

To be monitored at the time of the next inspection.

Topic 2

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **quality**

- Development of procedures for conducting regular audits of practice.

To be monitored at the time of the next inspection.

Topic 3

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises**

- The safety of cryostore facilities should be reviewed;
- The suitability of the procurement facilities to be reviewed;.
- The provision of emergency clinical facilities to be reviewed;
- Access to a back up power supply to be reviewed.
- Commissioning and/or validation of equipment to be complete.
- Air quality to be monitored following installation and /or relocation of equipment.

To be complete before the commencement of licensed treatment activity and the HFEA to be notified of the outcome of the review.

Topic 4

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information**

- Risk assessment needs to be conducted for transfer of notes between two sites.
- Patient information for OHSS to be reviewed.

To be complete before the commencement of licensed treatment activity and the HFEA to be notified of the outcome of the review.

Topic 5

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **laboratory and clinical practices**

- Personnel must be provided with initial/basic training, as required and the training should be documented.
- Development of a procedure for an emergency transfer of patients to a hospital.

To be complete before the commencement of licensed treatment activity.

Next Action

The centre staff to ensure that resolution of areas highlighted in report are completed as soon as possible and the Executive is kept updated on the progress.

Report compiled by____Parvez Qureshi _____

Designation_____Inspector_____

Date_____3rd July 2008_____

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number…..…0299……

Name of PR……..….Geeta Nargund …….

Date of Inspection….03.06.2008…….....

Date of Response….18.07.2008……....

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

(Comments taken from PR response received).

1. Organisation:

- Risk management procedures recommended have been undertaken.
- Third party agreements are in place
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2. Quality of Service

- Audit procedure is in place for conducting regular audits of practice.
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3. Premises and Equipment

- The laboratory cryostore facility has been fitted with a low oxygen alarm with two repeaters at both doors that allow access to the area
- The Dewar audit protocol has been amended to include the two-yearly physical audit of sample numbers
- The suitability of procurement facilities has been reviewed
- A process validation has been undertaken for key processes and procedures. documentation
- The seat in the semen production room will have a clean sheet placed upon it for each patient producing a sample. The seat will be replaced with a material that be wiped clean
- The emergency trolley and oxygen supply are in place
- The back up power supply will be fitted next week (prior to commencement of treatment cycles). A contract has been agreed with the supplier.
- All laboratory equipment has been commissioned and/or validated.

4. Information

- A risk assessment and protocol have been established for moving notes within and between the two sites.
- The patient information on OHSS has been reviewed and amended to include additional symptoms.

5. Laboratory and Clinical practice

- An induction and competency document (basic training included) for personnel is in place
- An agreement and procedure for an emergency transfer of patients has been developed.

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

Signed……Hard signed copy received from PR …….

Name…… Geeta Nargund ……..……

Date……18.07.2008……..……..

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).

Factual corrections have been made where necessary.

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 this section of the report to:
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

24 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 2

CREATE Centre for Reproduction and Advanced Technology (0299)
Initial licence application

Members of the Committee:	In Attendance:
Anna Carragher, Lay Member – Chair	Debra Bloor, Head of Inspection
Ruth Fasht, Lay Member	Claudia Lally, Committee Secretary
Present via conference telephone: Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee	Providing Legal Advice to the Committee: Mary Timms, Field Fisher Waterhouse

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 (30 pages)
- one tabled paper: response to the report by the Person Responsible (2 pages).

1. The papers for this item were presented by Parvez Qureshi. Mr Qureshi informed the Committee that this centre is currently operating as a satellite centre. The centre proposes conducting about 600 natural and mild stimulation treatment cycles per year. Mr Qureshi reported the proposed Person Responsible has submitted a Person Responsible Entry Programme (PREP) assessment which was judged to have been satisfactorily completed.

2. Mr Qureshi reported that the inspection visit to the centre showed it to be reasonably well organised with a Quality Management System in place. The quality of service was considered appropriate and the premises were well presented. Laboratory facilities were considered suitable and patient information, policies and written clinical procedures at the centre were all inspected and considered appropriate, as were staffing levels.

3. Mr Qureshi drew the Committee's attention to the response to the report by the prospective Person Responsible. He suggested that this response indicated that appropriate action has been taken in respect of all the issues raised at the inspection visit.

The Committee's Decision

4. The Committee took into account the fact that the proposed Person Responsible had completed her PREP assessment to the satisfaction of the Executive. On this basis the Committee agreed that it was satisfied as to the suitability of the proposed Person Responsible.

5. The Committee noted Mr Qureshi's comments about the inspection visit and on the basis of these remarks and particularly on Mr Qureshi's statement to the effect that all the areas for improvement identified at the inspection have been dealt with to the satisfaction of the Executive, agreed that they were satisfied as to the suitability of the centre premises and as to the use of suitable practices at the centre. The Committee noted that the premises to be licensed are 3-5 Pepys road and not the nearby site which is used for administration purposes.

6. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination and decided to grant a licence for a period of 12 months, which is the usual length of time for an initial licence.

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