New Premises Site Visit Report

Name of Applicant	Mr Ertan Saridogan
Address of Proposed Premises	Elizabeth Garrett Anderson Wing University College Hospital 235 Euston Road London, NW1 2BU
Has the applicant been licensed before	Yes
If yes: Centre Number and Address of previous premises	Centre number 0167 Elizabeth Garrett Anderson & Obstetric Hospital Huntley Street London, WC1E 6DH
Inspector(s)	Parvez Qureshi Wil Lenton Paula Nolan (observing)
Date of visit	28 August 2008
Date of any previous visits to these premises	N/A

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 HCC and HTA.

Brief Description of the Centre

The Reproductive Medicine Unit is part of the University College London Hospitals NHS Foundation Trust. It is currently based at the Elizabeth Garrett Anderson & Obstetric Hospital, Huntley Street, WC1E 6DH. The unit will be relocating to a new site within the University College London Hospital grounds.

The new premises will consist of:

- A large reception area, adjacent to the patient waiting area.
- An ultrasound room.
- Counselling room.
- Two rooms with IT facilities for staff to carry out administrative work.
- There is a dedicated room for nursing consultations.
- There is another room for the Clinical Nurse Specialists to see patients in private and also to store treatment records in lockable filing cabinets.
- A lockable store room where it is intended to store older treatment records in filing cabinets.

Cryostore – this will house the cryostorage dewars.

- There are appropriate alarm systems in place to monitor oxygen levels.
- Two floor level extraction vents have been installed, one of which is on continuously. The second vent is designed to trigger when a drop in oxygen is detected.

Laboratory facilities - this is where semen analyses, sperm preparation for IUI and cryopreservation will be performed.

- It is a positive pressure laboratory designed to meet the EUTD requirements for air quality.
- There are two semen production rooms which appeared to be appropriately furnished.

Both the clinical and laboratory areas have dedicated areas for utilities as well as bathroom facilities for patients and staff. There is also a staff rest room in the laboratory area.

The current cryostore facilities will remain licensed premises for a brief period pending the move. The Person Responsible (PR) should inform the HFEA when the old cryostore facility is no longer to be included on the licence.

The inspection team noted that recommendation made during the renewal inspection, conducted in May 2007, have been complied with.

An interim inspection was also carried out in conjunction with the new premises site visit and the findings of which will be presented to a Licence Committee in due course.

Summing up meeting notes

The centre's current organisational structure was considered compliant with requirements. Procedures for quality management appeared well developed. It is recommended that the centre implements systems for evaluation and continual improvement as appropriate. The following areas identified during inspection will need to be addressed by the PR):

- To carry out a risk assessment for the safe transportation of the cryo dewars prior to the move to the new premises.
- Establish air quality in the laboratory under working conditions.
- Validation of air quality monitoring and development of a Standard Operating Procedure (SOP) for ongoing monitoring.
- Maintenance of logs of parameters related to the performance of key equipment and development of SOPs.
- Commissioning, re-calibration and validation of interim inspection of the centre was also conducted on the same day as the new key equipment prior to commencement of licensed activities.
- The PR should review the arrangement for keeping confidential patient notes in areas accessible to patients.

Subject to successful resolution of issues highlighted during the inspection the HFEA inspection team would support the centre's application for a change of premises.

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

Summary of Findings
Organisation, leadership and management are unchanged since the last renewal inspection. A coherent business plan is in place for the centre's activities and redevelopment within the Women's Health Division inside the trust. The PR explained that there is potential for expanding the service through collaborative working with the oncology services based within the Trust (storage of oncology patient samples). The PR stated that the centre will have room to accommodate this workload and explained that he would assess staffing and equipment levels if the treatment load increases.
Areas for improvement
None.
Points to consider/action for next inspection
None. .

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)*

- Counselling facilities and services

Summary of Findings
All counselling sessions will take place in a specified room. The PR stated that the counselling notes will be kept separately from the patients' treatment notes in a secure place.
Areas for improvement
None.
Points to consider/action for next inspection
None.

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 were well presented. However these areas will need a final clean prior to commencement of services. There is controlled access to the unit. The inspection team considered the facilities to be suitable for the proposed activities. The inspectorate considered the centre's new cryoprestorage facilities will be adequate for the anticipated volume of work. The dewars will be fitted with low level nitrogen monitors and alarms. Liquid nitrogen will be piped from a storage vessel on the ground floor. There are two floor level extraction vents of which the first is on continuously. The second vent will be triggered in the event of a drop in oxygen levels. The Head of Laboratory stated that all dewars will be alarmed and linked to an auto dialler system. 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 a background air quality in the laboratory of at least Grade D, thus ensuring compliance. This activity will be coordinated by the Trust's infection control team. Maintenance contracts are in place for existing equipment that will be transferred to the new unit. Contracts for new equipment to be installed in the new unit have been drawn up and evidence of this was made available to the inspectorate.
Areas for improvement
The PR is to ensure that: • A risk assessment for the safe transfer of the cryo dewars prior to move • Measurement of air quality is established under working conditions • Validate how often air quality is monitored and produce a protocol to reflect this • Logs of parameters related to the performance of key equipment are kept including SOPs. • Key equipment to be commissioned, re-calibrated and validated prior to commencement of licensable activity.
Points to consider/action for next inspection
Resolution of areas highlighted for improvement.

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)*

Summary of Findings
None.
Areas for improvement
None.
Points to consider/action for next inspection
None.

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)*

Summary of Findings
None.
Areas for improvement
None.
Points to consider/action for next inspection
None.

Topic 1

(a) The applicant meets the requirements for **organisation.**

Topic 2

(a) The applicant meets the requirements for **quality** as per the last renewal inspection.

Topic 3

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

Action needed:	To be completed by:
• To perform a risk assessment for the safe transfer of the dewars prior to move. • Establish air quality when equipment and staff in facility under working conditions. • Develop a protocol of how often air quality is monitored. • Ensure logs of parameters related to the performance of key equipment are kept including SOPs. • Key equipment will need to be re-calibrated and validated prior to the commencement of service.	To be completed before the commencement of licensed treatment activity and the HFEA to be notified of the outcome.

The following conditions apply:

None

Topic 4

(a) The applicant meets the requirements for **information** as per the last renewal inspection.

Topic 5

(a) The applicant meets the requirements for **laboratory and clinical practices** as per the last renewal inspection.

Next Action

The PR to ensure that recommended actions are implemented before the commencement of licensed treatment activity and the HFEA to be notified of the outcome.

Report compiled by Paula Nolan/Parvez Qureshi

Designation Inspectors

Date 29.09.2008

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number……..0167…….

Name of PR……Ertan Saridogan…….

Date of Inspection……..28 August 2008…….....

Date of Response……07.10.2008…….....

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

(Comments taken from PR response received)

- A risk assessment for the safe transportation of cryobanks has been carried out.
- Plans are in place to monitor air quality in operation after the move.
- A SOP is being developed for air quality measurement. We are hoping that the trust infection control team will purchase an air quality monitorisation system and this will be used at regular intervals to monitor air quality.
- SOPs for the maintenance of key equipment have been developed since the inspection.
- Re-calibration and validation data for the existing and new key equipment, respectively, will be available when we move our existing equipment to the new premises.
- Confidential patient notes will be kept in lockable filing cabinets in lockable store room which is not accessible to patients.

New premises will undergo another cleaning before the are operational

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

Signed…… Ertan Saridogan ……

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).

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

27 October 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Reproductive Medicine Unit, London (0167)
Interim Inspection

Members of the Committee:	In Attendance:
Walter Merricks, Lay Member – Chair	Debra Bloor, Head of Inspection
David Archard, Lay Member	Claudia Lally, Committee Secretary
Jennifer Hunt, Senior Infertility Counsellor, IVF Hammersmith	Providing Legal Advice to the Committee: Graham Miles, Morgan Cole

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 (22 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 provides IUI, donor insemination and storage for gametes (mainly for oncology patients). It will be locating to new, purpose-built premises in November. These premises were approved by a Licence Committee on 15 October 2008.

2. Mr Qureshi reported that a number of areas for improvement were identified at the interim inspection. He explained that some of these will be addressed by the move to the new premises. Mr Qureshi pointed to the response by the Person Responsible which showed the progress being made to address the remaining issues.

The Committee's Decision

3. The Committee noted the interim inspection report and agreed that they were satisfied that the areas for improvement were being progressed satisfactorily.

4. The Committee noted that the centre will be moving to new premises which have already been inspected. The Committee agreed that the centre's licence should continue with no additional conditions.

Signed……. … Date……..
Walter Merricks (Chair)