New Premises Site Visit Report

Name of Applicant	Centre for Assisted Reproduction Gateshead
Address of Proposed Premises	Queen Elizabeth Hospital Sheriff Hill Gateshead NE96SX
Has the applicant been licensed before	YES
If yes: Centre Number and Address of previous premises	0170 Address as above.
Inspector(s)	Angela Sutherland Sarah Hopper
Date of visit	04 December 2008
Date of any previous visits to these premises	Renewal Inspection: 16 September 2008

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.

Brief Description of the Centre

The centre is part of the Gateshead Health NHS Foundation Trust and has provided licensed treatments since 1996. The unit offers self funded and NHS funded treatments to patients from the local geographical area. The centre was last inspected in September 2007 and was granted an interim inspection "holiday" in 2006. The centre provided approximately 500 licensed treatment cycles in the time period between June 2006 and June 2008.

The Person Responsible (PR) has been in post since 1998. He completed the Person Responsible Entry Programme (PREP) on 24 September 2007 and is experienced and suitably qualified. The PR is registered with the General Medical Council and is included on the specialist register of the Royal College of Obstetrics and Gynaecology.

In December 2008 the unit intends to relocate within Queen Elizabeth Hospital to premises with significantly increased capacity. It is projected that activity will progress from an average of 270 cycles per year to 400 cycles over the first year in the new premises, and increasing to a maximum of 500 cycles per year.

The activity of this centre has to date been limited by the small physical size of its premises. It is notable that negative patient feedback focuses almost exclusively on the restricted size of this unit with consistent and enthusiastic praise for the staff's ability to provide attentive customer service in spite of this.

Details of the move

All licensed and unlicensed activity will be moving to the new premises which are in a separate building, some distance away, though within the curtilage of Queen Elizabeth Hospital.

It is also proposed that the name of the centre will be changed to **The Gateshead Fertility Unit.**

Purpose of inspection

To assess the appropriateness and to assess the suitability of the new premises with reference to the HFEA Code of Practice and the preparedness of Gateshead Centre for Assisted Reproduction resources, both in terms of staff and facilities.

The current premises were inspected prior to licence renewal on 16th September 2008. General areas of practice, including information, access to counselling and scientific practice within the centre, were not considered at the time of this inspection as these were addressed in the course of the renewal inspection. Therefore, this report comprises an assessment of the proposed new premises only.

Premises Equipment Resources and Procedures

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:

- Suitable premises
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records
- Staffing levels
- Witnessing

Summary of Findings

The new premises are located in a purpose built unit within an existing building in Queen Elizabeth Hospital.

The entrance to the new premises is secure with staff using a card swipe system and patients an intercom that is accessed via telephone at reception. There are two lifts, one key lockable and one that stops at the ground floor and centre level only.

At inspection risk assessments pertaining to the move were seen. These appeared to focus largely on the physical logistics associated with the transfer of equipment and stored gametes and embryos. The PR had sought advice from a liquid nitrogen supplier regarding the movement of liquid nitrogen filled dewers and the inspectorate were satisfied that all reasonable steps were being taken to safeguard gametes, embryos and staff during this move.

All patients have been informed in writing of the imminent transfer of samples.

The PR reported that at no time will unlicensed external or hospital staff be left unsupervised with records or stored gametes and embryos during the move.

The new unit is significantly larger than the current centre and it is proposed that cycle numbers will increase from approximately 270 per year to 400-500. In response trust approval has been obtained to recruit a full-time band 6 nurse and a full-time auxiliary nurse and to increase an existing part-time nurse's hours to full time. A full-time admin/reception position has also been created. The centre still requires a further embryologist and the PR gave assurances that workload will only be increased as staffing levels can accommodate.

Counselling facilities:

The new premises do not include a dedicated counselling room with the intention being that

sessions will take place in one of the two consultation rooms adjacent to reception. These appeared on inspection to be satisfactory for that purpose.

Procedure rooms:

Two new procedure rooms were seen, with hatch access to the laboratory. Both appeared appropriate with an emergency bell system that was demonstrated at the time of inspection. The recovery room could be accessed directly from the procedure rooms via a transfer room and was fitted with the same emergency bell system. It is fitted to accommodate up to three stretcher patients at a time and it was reported by the PR that the intention was to have a nurse present at all times that patients are in recovery.

The current premises utilise a hatch system between procedure rooms and the laboratory and the existing protocols for egg collection, IUI and embryo transfer which involve both clinical and laboratory teams (with the exception of witnessing) will not be changing.

Male production room:

This was noted to be of adequate size and was situated in a quiet part of the centre. There is a bell system for the patient to hand the sample to lab staff and the room is equipped with an emergency alarm. Both the egg collection facilities and male production room are accessible via a separate corridor to the main procedure room and recovery with separate changing/locker facilities, which appear to provide patients with increased privacy.

Cryostore facilities:

This room is accessed using a swipe card system that was active at the time of inspection. It appeared to be of adequate size and has an expel vent to the roof. A low oxygen monitor and alarms will be moved from the existing cryostore. The potential for staff to be working alone in this area was discussed and the embryologist reported that another staff member will be informed in all instances if this is to be the case.

The system for responding to alarms will not be altered. The PR reported that liquid nitrogen warning notices will be fitted before commission.

Laboratory:

The new laboratory will contain three flow hoods and appeared to be of appropriate size and layout to be fit for the intended purpose. It is accessed using a swipe card. The centre has purchased a new electronic witnessing system. Movement of the ICSI rig will be performed by external contractors. A staff training programme regarding use of the new witnessing system was described in detail at inspection.

The PR reported that it is expected that A-B air quality will be achieved in the new laboratory and it will be monitored by an external company on a 6 monthly basis.

Storage of records:

Patient records will be stored in a dedicated room outside the main unit. It currently has a key

lock with the key to be held by the nurse in charge and it was reported at inspection that the room will be further secured with a swipe card system.

Counselling records are currently stored off-site by the counsellor and this will not be changing.

Staff facilities:

Both male and female staff changing facilities were seen at inspection. They included showers and secure lockers. The new premises also include a sizable staff room with cooking and food storage facilities.

Safe equipment storage and maintenance:

At the time of inspection minimal equipment had moved to the new premises. The need to validate new equipment and re-validate already existing was discussed with the PR who provided assurance that a programme is in place to ensure this is completed.

The PR confirmed that there will be no change to maintenance and cleaning processes at the centre.

The standard of the premises and equipment

The inspectorate agreed that, subject to the validation of all equipment prior to use and the completion of the security system, the Gateshead Centre for Assisted Reproduction new premises are fit for the intended purpose.

Recommendation for licence committee

The executive are satisfied with the proposed new premises comply with the standards laid out in the HFEA Code of Practice and centre name and recommend the issue of a new licence to reflect these changes, subject to receipt of information that the following actions have been completed:

- Validation of new and old equipment after it has been moved to the new site.
- All alarms and locks are in place and have been checked, including the low oxygen and low nitrogen monitor/alarms.
- Documented air quality results that demonstrate compliance with the requirements of A.10.19
- All SOPs have been considered and updated where necessary to reflect the new environment.

Appendix A: **Centre staff interviewed**

PR and other staff members as a group discussion.

Appendix B: Licence history for previous 3 years

L0170/7/a	Expired	Treatment with Storage	01/10/2005	31/01/2006
L0170/3/d	Expired	Treatment with Storage	17/12/1998	17/01/1999
L0170/5/b	Expired	Treatment with Storage	14/02/2002	31/01/2003
R0127/1/a	Expired	Research Project		
L0170/4/a	Expired	Treatment with Storage	17/01/1999	17/01/2000
L0170/2/a	Expired	Treatment Only	17/06/1997	17/06/1998
L0170/1/a	Expired	Treatment Only	17/12/1996	17/06/1997

Licence committee meeting 17.12.07:
The Committee agreed that it was content for the centre's licence to continue.

Licence committee meeting: 02.05.07:
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Licence committee meeting: 30.11.05:
The Committee agreed to renew the centre's licence for a period of three years with no additional conditions.

Report compiled by:
Name: Angela Sutherland
Designation: HFEA Inspector
Date: 15.12.08

Appendix C: Response of Person Responsible to the inspection report

Centre Number…… ……

Name of PR…… ……

Date of Inspection……..

Date of Response……

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

Signed……

Name…… ……

Date…… ……

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.

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

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF