Change of Premises Inspection Report

Date of Inspection: 27 April 2010
Length of inspection: 3 hours
Inspectors: Jenny McLaughlin, Bhavna Mehta

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the change of premises application.

Date of Executive Licensing Panel: 20 May 2010

Purpose of the inspection report:
The purpose of the inspection is to assess whether centres comply with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection to meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence variation application.

Centre details

Centre Name	Sunderland Fertility Centre
Centre Number	0096
Centre Address	Fertility Department Sunderland Royal Hospital Kayll Road Sunderland Tyne & Wear SR4 7TP
Telephone Number	0191 5699779
Person Responsible	Mr Menem Yossry
Licence Holder	Mr Ken Bremner
Date of Licence Expiry	31/05/2014
Licence Number	L0096/20/b

Contents

Report to Licence Committee

Brief description and history of the centre:

The Sunderland Fertility Centre is a small centre that carried out approximately 120 cycles of intra uterine insemination (IUI) in the last year. The centre has held an HFEA treatment and storage licence since 1993 and is currently licensed for the following activities:

- Insemination
- Storage of sperm
- Processing of gametes
- Procurement and distribution of gametes
- Treatment with donor gametes

The centre is part of the Obstetric and Gynaecology service of City Hospitals Sunderland NHS Foundation Trust (the Trust), managed through the Division of Family Care and located within the Sunderland Royal Hospital. The centre provides treatments to both National Health Service (NHS) and self funded patients.

The Person Responsible (PR) is Mr Menem Yossry, Consultant Gynaecologist and Obstetrician. He has completed the Person Responsible Entry Programme (PREP certificate number T/1074/7), is registered with the General Medical Council (GMC) and appears suitably qualified for the role.

The centre was last inspected for licence renewal on 16 January 2009. At the time of that inspection, the centre was reported to have suitably qualified and experienced staff and to adopt appropriate clinical and laboratory procedures for licensed activity.

In February 2010, the HFEA received an application to vary the centre's licence to relocate to new premises within the Sunderland Royal Hospital grounds. According to the application form, the reason for the change of premises is that the current premises are being demolished and the centre is moving to more suitable, newly built premises. At the time of this inspection, the PR and staff reported that the centre has stopped all licensed activity pending consideration of this application to vary the licence and that the centre's equipment, except for the dewars, has been relocated to the new premises. The dewars will be relocated following approval of this variation to the licence. The PR reassured the inspection team that the Trust has agreed not to demolish the existing centre until after consideration of this application by the Executive Licensing Panel (ELP).

The new centre has been designed to provide 600 treatments per year.

The new premises comprise:

- patient waiting area
- sperm production room
- counselling room
- laboratory
- procedure room

- cryostore
- scan room
- nurse office
- secretarial office
- consultant office
- patient notes store
- two toilets.

Activities of the centre:

Type of treatment	Number of cycles 1 January 2008 – 31 December 2008
IUI	107
DI	4

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	N/A
Research	N/A

Summary for licensing decision:

Prior to moving to the new premises, the PR contacted the Authority and an application to vary the licence was received by the Authority on 22 February 2010(T19). The centre has submitted appropriately completed documentation in application to vary their licence. In accordance with HFEA Directions 0008 paragraph 18, the PR has submitted:

- a completed application form
- the application fee
- a floor plan and room schedule of the premises (including room numbers) to be specified on the licence.

According to the application form, there are no changes to the following as a result of the move:

- the index of all documents in the quality manual
- the suite of information documents to be provided to patients at the centre
- the functional organisation chart.

In considering overall compliance, the inspection team considers that there is sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The premises are suitable for licensed activities.

Recommendation to the Executive Licensing Committee:

The inspection team considers that overall there is sufficient information available to recommend the variation of the centre's licence to change the premises, subject to the submission of the following documentation by the PR*:

- air quality testing report
- a risk assessment of the movement of storage dewars to the new premises
- a list of records of validation and calibration of critical equipment.

The PR has requested that the ELP Minutes be expedited to allow the move of the dewars to the new premises as soon as possible.

*please refer to PR response and Executive review on page 7 for update since inspection.

Details of Inspection findings

The new premises to be used for licensed activities:

The new premises are located on the 2nd floor of a purpose built facility within the hospital grounds. At the time of the inspection, the premises appeared to provide private, clean and well laid out facilities suitable for the centre's licensed activities. (T17). The PR reported that the premises have been handed over by the contractors and that the building regulation certification, including health and safety and fire safety was overseen by the hospital trust. The centre is accessed by swipe cards held only by staff on the licence. Patients and visitors requiring entry into the centre must ring a telecom bell on the outside of the door. A second security door separates the patient waiting area from the treatment rooms and laboratory.

The centre will be conducting licensed activity in the following areas:

- Sperm production room
- Procedure room
- Laboratory
- Cryostore

Sperm production room
The sperm production room is separated from the main corridor of the clinic by two doors and contains an ensuite toilet. The inspection team is satisfied that the room provides a suitable, private facility for sperm production.

Procedure room
The procedure room appeared to provide for the privacy and comfort of patients undergoing treatment and contained an oxygen tank for emergency purposes.

Laboratory
The laboratory is separated from the patient waiting area and corridor by a controlled entry door. The laboratory appeared suitably equipped for licensed activity and is fitted with an air filtering system that is specified to provide grade C air quality. The laminar flow hood had been installed and a certificate of inspection indicated that it had been inspected by the manufacturer in December 2009. An infection control air sampling test report was provided at inspection but the air quality had not yet been tested (T20). The PR indicated that an air particle test was scheduled to be done by a contracted company later on the day of the inspection and that the results of this test would be submitted to the inspection team within a few days.

A cryostore is located in a separate room attached to the laboratory. It has been fitted with a low oxygen alarm and appears to provide sufficient space for the four dewars that the centre intends to transfer from the current site. The Senior Biomedical Scientist reported that all the storage dewars are fitted with battery operated low-level nitrogen alarms which are linked to the hospital switchboard and a dedicated emergency number. The dewars will be moved by centre staff from the current licensed premises to the new premises following approval from the Authority to vary the centre's licence. The inspection team was concerned that the centre could not provide documented evidence that the risk of moving the dewars had been assessed and that measures to mitigate any risks to the stored sperm samples had been put in place (T74, T75, T105, T106, T108).

The PR reported that the Trust's laboratory services, including the fertility laboratory, are currently CPA accredited. This was verified on the CPA website (T21).

The PR reported that all critical equipment has been validated and that equipment would be checked for proper operation before they are put into use at the new facility. However, a list of critical equipment and records of validation and calibration of critical equipment were not available at inspection (T22, T24).

Areas of proposed practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Areas of potential non compliance in the proposed activities and practices at the new centre

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Premises and facilities – the centre could not demonstrate that the processing of gametes at the new premises would take place in an environment of at least Grade C air quality, with a background environment of at least Grade D.	Licence condition T20	The centre should submit the air quality test results to the Inspectorate, confirming that the laboratory meets the air quality requirements.	5 May 2010	Air qulaity has been tested, report attached	The certificates of air quality tests show that the working air quality was Grade A and the background air quality was Grade C. The tests were carried out on the 04/05/2010. No further action required.

Storage, transportation and use of gametes – The centre could not demonstrate how they were going to ensure that the quality and safety of the stored sperm samples would be maintained during their transfer to the new premises.	Licence conditions T74, T75, T105, T106, T108	The centre should conduct and submit to the Inspectorate a risk assessment for the transport of the storage dewars by centre staff to the new premises. The risk assessment should include the measures that will be put into place to ensure that the safety and quality of the stored gametes is maintained. The assessment should also consider any risks to those responsible for the transportation of the dewars.	5 May 2010	Detailed plan has been developed and risk assessed, attached	The risk assessment demonstrates how the staff will ensure that the quality and safety of the stored sperm samples would be maintained during their transfer to the new premises. No further action required.
Equipment and materials - a list of all critical equipment and records of validation and calibration of critical equipment were not available at inspection.	Licence conditions T22, T24	The centre should provide the inspection team with a list of all critical equipment and records of validation and calibration.	5 May 2010	Records of validation attached	A list of all critical equipment and an audit plan for validation and calibration of critical equipment has been received. The audit plan will be reviewed at the next inspection. No further action required.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

20 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 6

Sunderland Fertility Centre (0096), Application to vary the licence for change of premises

Members of the Panel:	
Mark Bennett, Director of Finance & Facilities (Chair) Peter Thompson, Director of Strategy & Information Juliet Tizzard – Acting Director of Strategy & Information	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Panel:

- papers for Executive Licensing Panel (67 pages)
- additional bundle in accordance with Direction 0008

The Panel also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers which included a new premises application, a new premises inspection report, an email request from the PR to expedite the minutes and previous Committee minutes.

2. The Panel noted that this is a small centre that has carried out approximately 120 cycles of intra uterine insemination (IUI) in the last year. The centre has held an HFEA treatment and storage licence since 1993.

3. The Panel noted that the reason for the change is that the current premises are being demolished and the centre is moving to more suitable, newly-built premises within the Sunderland Royal Hospital grounds.

4. The Panel noted that the PR and staff reported during the inspection that the centre has stopped all licensed activity pending consideration of this application to vary the licence and that the centre's equipment, except for the dewars, has been relocated to the new premises.

5. The Panel noted that the dewars will not be relocated until approval of this variation to the licence, and that the PR reassured the inspection team that the Trust has agreed not to demolish the existing centre until after consideration of this application by the Executive Licensing Panel.

6. The Panel noted the risk assessment and other documents provided by the centre within the papers that relate to the transfer of the dewars.

7. The Panel noted the floor plan of the new premises and that they have been designed to provide 600 treatments per year.

8. The Panel noted that the inspectorate has stated within the report that the centre has completed documentation in the application to vary its licence in accordance with HFEA Directions 0008 and paragraph 18A of the Act (as amended).

9. The Panel noted that the PR has submitted the following documentation as required by Direction 0008, and found the information to be suitable:
   • a completed application form
   • the application fee
   • a floor plan and room schedule of the premises (including room numbers) to be specified on the licence.

10. The Panel noted within the application form that there have been no changes to the following areas as a result of the move:
    • the index of all documents in the quality manual
    • the suite of information documents to be provided to patients at the centre
    • the functional organisation chart.

11. The Panel noted that the PR is Mr Menem Yossry, a Consultant Gynaecologist and Obstetrician, and that he has completed the Person Responsible Entry Programme and is registered with the General Medical Council (GMC).

12. The Panel considered the PR to be suitably qualified for the role, and has the character, qualifications and experience to discharge his duties under section 17A of the HFEA Act (as amended).

13. The Panel noted that an inspection of the proposed new premises took place on 27 April 2010 and the inspectorate considers the premises and equipment to be suitable.

14. The Panel noted the inspectorate's recommendation to vary the centre's licence for the change of premises.

The Panel's Decision

15. The Panel noted that security at the premises was considered by the inspectorate to be appropriate and compliant with the Code of Practice requirements.

16. The Panel noted that the centre has CPA accreditation and the PR is in the process of reviewing all processes and risk assessments for changes required due to the new work place.

17. The Panel noted that it was in receipt of updated staff details for the licence, and the appropriate application form and all other relevant documentation on which to make a decision.

18. The Panel agreed to vary the centre's licence for the change of premises.

Signed.....Date 24 May 2010.
Mark Bennett (Chair)