Executive Licensing Panel - minutes

Centre 0162 (Queens Medical Centre Fertility Unit)

Variation of Licensed Premises

Variation of Name

Tuesday, 12 November 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Richard Sydee (Chair) Niamh Marren Danielle Vincent	Director of Finance and Resources Regulatory Policy Manager Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice.
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The panel noted that Queens Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic which is located within the Queens Medical Campus which is part of Nottingham University Hospitals NHS Trust.

1.2. The panel noted that the centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and to store their sperm for the preservation of fertility.

1.3. The panel noted that in the 12 months to 28 February 2019, the centre had provided 120 cycles of treatment (intrauterine insemination). In relation to activity levels this is a small sized centre.

1.4. The panel noted that the centre's licence was last renewed in 2016, for a period of four years, with no additional conditions. The licence renewal inspection report made recommendations in relation to two major areas of non-compliance; both of these have been fully implemented.

1.5. The Person Responsible (PR) submitted a licence variation application on 24 July 2019 to vary its licensed premises. The following rooms were to be relocated from the current premises on 'B' floor to a new purpose-built department on 'A' floor:

- Reception/waiting room
- Laboratory
- Male production rooms
- Treatment rooms
- Consulting rooms
- Counselling rooms
- New facility for sperm storage records and clinic records

1.6. The panel noted that the PR had informed the inspectorate that the outpatient clinic and ultrasound scanning rooms will remain on 'B' floor, at the current location, until space becomes available at the new premises. The PR confirmed that no licensed activity takes place in the outpatient clinic or ultrasound scanning rooms.

1.7. The panel noted that the centre wishes to continue providing licensed treatment to patients at the current location, until the variation of the licence, to reflect a change of premises is approved, at which time it intends to close and move to the new premises over a weekend (when there is no patient activity), with no planned break in licensed treatment. However, there may be a short period of time after the new licence is issued when the centre will want to continue licensed activity at the old premises.

1.8. An inspection was carried out of the proposed premises on 21 October 2019 and two major areas of practice, requiring additional work, were identified; equipment and suitability of premises. The panel noted that since the inspection, the PR has given a commitment to fully implementing the recommendations made in the report.

1.9. The panel noted that the outstanding evidence will need to be provided before the proposed new premises can be deemed suitable for the conduct of licensed activities.

1.10. The panel noted that a Special Direction has been requested by the PR to be in force for three months, following variation of the centre's licence, to allow for continued licensed activity at the 'old' premises. It is recommended that the panel approve this application for a Special Direction under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

2. Consideration of application

2.1. The panel considered the papers, which included an executive summary, application form and licensing minutes for the past four years.

2.2. The panel noted that the information provided fulfils the requirements for this type of licence variation application, as defined in General Directions 0008.

2.3. The panel noted the inspectorate recommends the approval of the application to vary the licence to reflect the change of premises to the following address:

A Floor
West Block
Nottingham University Hospital
Derby Road
Nottingham
NG7 2UH

2.4. The panel noted that the inspectorate recommends the approval of the application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable licenced activities to continue at the 'old' premises, for a period of three months, from when the licence is varied.

3. Decision

3.1. The panel was satisfied that the appropriate application had been submitted and that the application contained the supporting information required by General Directions 0008.

3.2. The panel was satisfied that the application fee was submitted to the HFEA in accordance with requirements.

3.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. Subject to confirmation, from the PR, that the non-compliances surrounding equipment and suitability of premises, have been fully implemented, the panel endorsed the inspectorate's recommendation to change the centre's licensed premises to:

A Floor
West Block
Nottingham University Hospital
Derby Road
Nottingham
NG7 2UH

3.5. The panel endorsed the Executive's recommendation to approve the application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable licenced activities to continue at the centre's 'old' address for a period of three months, after the licence is varied.

4. Variation of Centre Name

4.1. The panel noted that the centre had also submitted an application to change its name. The requested new name was submitted on the 'variation of premises' application form. The centre wishes to change its name from Queens Medical Centre Fertility Unit to Fertility Unit, Nottingham University Hospital.

5. Consideration of application

5.1. The panel noted that the name is presently Queens Medical Centre Fertility Unit and the centre now wishes to be known as Fertility Unit, Nottingham University Hospital.

5.2. The panel noted the inspectorate's recommendation to approve the variation of licence to change the centre's name.

6. Decision

6.1. After considering the recommendation of the inspectorate and the supporting documentation, the panel changed the name of the centre to Fertility Unit, Nottingham University Hospital.

7. Chair's signature

7.1. I confirm this is a true and accurate record of the meeting.

Signature

Name

Richard Sydee

Date

18 November 2019

Change of Premises Inspection Report

Centre name: Queen's Medical Centre Fertility Unit
Centre number: 0162
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 21 October 2019
Inspectors: Polly Todd
Date of Executive Licensing Panel: 12 November 2019

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years and must, by law, be inspected every two years. Inspections are also carried out when centres apply to vary their licence to change premises. The full inspection prior to a licence being granted, renewed or varied assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of a change of premises inspection. The inspection was scheduled (rather than unannounced) and the report covers the findings from a desk-based assessment of submitted documentation, the inspection visit and communications received from the centre.

Background

Queen's Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic which is located within the Queen's Medical Campus which is part of Nottingham University Hospitals NHS Trust.

The centre provides a service for the diagnosis and treatment of sub-fertility and insemination with partner or donor sperm. The centre also incorporates the andrology department which provides a service for those wishing to donate sperm and for those wishing to store their sperm for the preservation of fertility.

In the 12 months to 28 February 2019, the centre provided 120 cycles of treatment (intrauterine insemination). In relation to activity levels this is a small centre.

The centre's licence was last renewed in 2016, for a period of four years, with no additional conditions. The licence renewal inspection report made recommendations in relation to two major areas of non-compliance. Both recommendations have been fully implemented.

The licence was varied for a change of Licence Holder (LH) on 27 September 2018 and 6 June 2016, for a change of Person Responsible (PR) on 15 January 2019, and to include a new room as part of the licensed premises to be used for storing gametes and embryos on 21 May 2019.

The centre submitted an application on 24 July 2019 to vary its licensed premises. The following rooms were to be relocated from the current premises on 'B' floor to a new purpose-built department on 'A' floor:

- reception/waiting room;
- laboratory;
- male production rooms;
- treatment rooms;
- consulting rooms;
- counselling room;
- new facility for sperm storage records and clinic records.

The PR informed the executive that the outpatient clinic and ultrasound scanning rooms will remain on 'B' floor at the current location until space becomes available at the new premises. The PR confirmed that no licensed activity takes place in the outpatient clinic or ultrasound scanning rooms.

The centre wishes to continue providing licensed treatment to patients at the current location until the variation of the licence to reflect a change of premises is approved, at which time it intends to close and move to the new premises over a weekend (when there is no patient activity), with no planned break in licensed treatment. However, there may be a short period of time after the new licence is issued when the centre will want to continue licensed activity at the old premises.

The centre is due to have its licence renewal inspection on 3 December 2019.

Summary for the Executive Licensing Panel

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre to conclude that:

- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for change of their licensed premises.

Recommendation to the Executive Licensing Panel

The Executive Licensing Panel is asked to note that that at the time of the inspection there were two areas of major non-compliance requiring improvement.

The PR has given a commitment to fully implementing the following recommendations:

- The PR should ensure that equipment is appropriately fitted prior to use, and that critical equipment has been tested and validated.
- The PR should ensure that arrangements for emergency resuscitation are in place before licensed treatment commences at the new premises.

The Executive recommends that the application to vary the licence to reflect a change of premises is approved subject to the recommendations made in this report being implemented.

The Executive notes that the new address of the centre will be:

A Floor,
West Block,
Nottingham University Hospital,
Derby Road,
Nottingham,
NG7 2UH.

The centre has also submitted an application to change its name. The requested new name was submitted on the 'variation of premises' application form. The centre wishes to change its name from 'Queen's Medical Centre Fertility Unit' to 'Fertility Unit, Nottingham University Hospital'.

The executive recommends that the application to vary the licence to reflect a change of premises name is approved.

Assuming the ELP approves this application, there will be a short period of time after the new licence is issued when the centre will want to continue licensed activity at the old premises. A Special Direction has therefore been requested by the PR to be in force for three months following variation of the centre's licence, to allow for continued licensed activity at the 'old' premises. It is recommended that the ELP approve this application for a Special Direction under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

Details of Inspection findings

Key documents were requested from the centre in support of the change of premises application assessment, to provide assurance that the premises and equipment in the proposed new facilities are suitable and satisfy the requirements of the Act in relation to the granting of a licence (HF&E Act 1990 (as amended) S16 (2)(d) and (e)).

On completion of the desk based assessment, a site visit was conducted on 21 October 2019. On the basis of these assessments, and as documented below, it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities:

- Confirmation that the clinical spaces were designed to meet the requirements of the relevant health technical memoranda and health building notes has been provided.
- Confirmation of the building completion certification/sign off issued by the contractor to the centre was provided.
- Confirmation of a fire safety inspection was provided.
- Security measures in place at the new premises, including those relating to storage of gametes and confidential records, were inspected during the visit and were considered to be suitable.
- Documentation confirming that processing of gametes will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality, was reviewed. The PR confirmed that repeat air quality and settle plate monitoring will also be carried out prior to commencing licensed activities in the new premises.
- Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated counselling, consulting and male production rooms are available and appear fit for purpose.
- Confirmation of a deep clean prior to laboratory work starting has been provided.
- Relevant standard operating procedures have been updated to reflect physical differences in premises.

1. The centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment is in situ. However, validation of this equipment has not been completed, see recommendation 1.

2. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection on 27 January 2016. The centre does not intend to change any activities or the type of licence. Relevant standard operating procedures have been updated to reflect physical differences in premises.

   Some evidence is still outstanding, as detailed below. This evidence will need to be provided before the proposed new premises can be deemed as suitable for the conduct of licensed activities. Following the move, and prior to licensed

activity commencing at the new premises, the PR has agreed to provide the following:

- confirmation that the water dispenser has been appropriately fitted, and confirmation of testing and re-validation of critical equipment, see recommendation 1.
- confirmation of emergency resuscitation arrangements, see recommendation 2.

3. The centre has complied with the requirements of General Direction 0008 (section H 14) in submitting:
    - a relevant on-line application form;
    - a floor plan of the premises to be referenced on the licence.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance 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.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Equipment The water dispenser in the patients’ waiting room is attached to the water supply in the wall by a large piece of accessible copper piping, rather than being directly attached to the supply. This pipe runs down in front of a plug socket, visible and accessible to patients. Testing and re-validation of critical equipment has not been undertaken by the centre.	The PR should ensure that equipment is appropriately fitted prior to use. The PR should address this non-compliance and provide confirmation to the centre’s inspector, that a suitable fixing has been fitted prior to use by patients or staff. The PR should ensure that critical equipment has been tested and validated. Evidence of this validation should be provided to the centre’s inspector before licensed	This was a temporary T piece added in case a coffee machine was installed. Since the department has now decided against this, in the short term the pipe and socket has been covered over and made inaccessible to patients. Contractors have been informed and will address this very soon The QC Dept (Pharmacy) have performed settle plate/particle counting for air quality 22nd-23rd October. A preliminary report will be available on 24th	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action is required.

SLCs T23, T25.	treatment commences.	October with final reports a week later This evidence will be added to our over-arching validation document fert.pol.004. The new flow hood has been installed and commissioned. currently in use. Reports from QC will support its use.	
2. Suitability of Premises There are currently no suitable arrangements in place for emergency resuscitation. SLC T2.	The PR should ensure that arrangements for emergency resuscitation are in place before licensed treatment commences at the new premises. This may take the form of a written arrangement with a neighbouring clinical department or having appropriate resuscitation equipment in the clinic. Evidence of compliance with this recommendation should be provided to the centre's inspector before patients are seen at the centre.	Currently there is no local crash trolley. However the emergency Dept (A&E, ED) is around the corridor and available on 2222. The resuscitation lead, matron and Directorate Head nurses have been consulted and consensus is that a full crash trolley is unnecessary. In the medium term, the intention is to obtain: a 'grab bag', a local defibrillator and bottled oxygen, according to Resuscitation (Adult and Paediatric) Policy CL/CGP/001. Compliance will be addessed before the commencement of licensed activities	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action is required.

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible