Executive Licensing Panel - minutes

Centre 0144 (Nuffield Health Woking Hospital)

Variation of Licensed Premises

Variation of Name

Tuesday, 29 October 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Howard Ryan	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Data Analyst
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 Nuffield Health Woking Hospital is located in Surrey and has held a treatment and storage licence with the HFEA since 1994. It provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

1.2. The panel noted that in the 12 months to 31 August 2019, the centre had provided 1324 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large sized centre.

1.3. The panel noted that a renewal inspection of the centre was conducted on 16 and 17 April 2019. Recommendations were made to address one major and one 'other' area of non-compliance. The Person Responsible (PR) has provided evidence that all of these recommendations are being implemented.

1.4. The PR submitted a licence variation application in August 2019 to vary its licence to change premises. The centre wishes to continue providing licensed treatment to patients at the current location until 16 December 2019, at which time it intends to close and move to the new premises, with licensed treatment beginning again week beginning 6 January 2020.

1.5. An inspection was carried out of the proposed premises on 17 September 2019 and three major areas of practice, requiring additional work, were identified; equipment, staff and suitability of premises. The panel noted that since the inspection, the PR has fully implemented the recommendation relating to staff and had provided a commitment to implement the non-compliances regarding equipment and suitability of premises.

1.6. 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.

1.7. The panel noted that, should the application be approved, the centre wishes to continue to operate at the 'old' premises at Woking Hospital, Victoria Wing, Shores Road, Woking until its annual laboratory shut down in mid-December, when it intends to stop treating patients until the first full week in January. The centre has requested that the variation of licence, if granted, is not implemented until licensed treatment will have ceased at the old premises. The Executive recommends that the variation of licence is deferred until 13 December 2019.

1.8. The panel noted that there will be a period of time, after the licence is varied, when the centre will need to store gametes and embryos at the centre's 'old' premises at Woking Hospital. A Special Direction has therefore been requested to be in force from the date the licence is varied, for three months, to allow storage of gametes and embryos at the 'old' premises. The Executive considered the storage facilities at the 'old' premises to be suitable at the last inspection, noting that satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction.

1.9. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

2. Consideration of application

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

5 Hillview Road
Woking
Surrey
GU22 7HW

2.4. The panel noted, that the inspectorate recommends the approval of this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable storage of gametes and embryos at the centre's 'old' premises for a period of three months from when the licence is varied on 13 December 2019.

2.5. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. The Executive recommended the renewal of the centre's ITE import certificate in line with the change to the address on its licence.

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 regarding equipment and the suitability of premises had been implemented, the panel endorsed the inspectorate's recommendation to change the centre's licensed premises, with effect from 13 December 2019 to:

5 Hillview Road
Woking
Surrey
GU22 7HW

3.5. The panel endorsed the inspectorate's recommendation to approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended) to enable storage of gametes and embryos at the centre's 'old' premises for a period of three months, after the licence is varied, from 13 December 2019, to 12 March 2020.

3.6. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the change to the address on its licence.

4. Variation of Centre Name

4.1. The panel noted that the centre had also submitted an application to change its name, but this was incorrectly submitted on the 'variation of premises' application form. The correct name has been confirmed by the PR via email. The centre wishes to change its name from Nuffield Health Woking Hospital to Nuffield Health Assisted Conception Services.

5. Consideration of application

5.1. The panel noted that the name is presently Nuffield Health Woking Hospital and the centre now wishes to be known as Nuffield Health Assisted Conception Services.

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

5.3. The panel noted the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the change to centre's name on its licence.

6. Decision

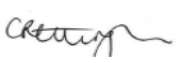
6.1. After considering the recommendation of the inspectorate and the supporting documentation, the panel changed the name of the centre to Nuffield Health Assisted Conception Services, subject to the non-compliances, in connection with the variation of premises, being fully implemented.

6.2. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the change to the name on its licence.

7. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

4 November 2019

Change of Premises Inspection Report

Centre name: Nuffield Health Woking Hospital
Centre number: 0144
Date licence issued: 1 October 2019
Licence expiry date: 30 September 2023
Additional conditions applied to this licence: None
Date of inspection: 17 September 2019
Inspectors: Mhairi West and Polly Todd
Date of Executive Licensing Panel: 29 October 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

The Nuffield Health Woking Hospital is located in Surrey and has held a Treatment and Storage licence with the HFEA since 1994. It provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

The centre provided 1324 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2019. In relation to activity levels this is a large centre.

The centre was last inspected on 16 and 17 April 2019 when a renewal inspection was performed. Recommendations were made to three major and one 'other' area of non-compliance. The PR has provided evidence that all of these recommendations are being implemented.

The centre submitted an application on 7 August 2019 to vary its licence to change premises.

The centre wishes to continue providing licensed treatment to patients at the current location until 16 December 2019, at which time it intends to close and move to the new premises, with licensed treatment beginning again week beginning 6 January 2020.

The centre has also submitted an application to change its name

Summary and recommendations for the Executive Licensing Panel

The Executive Licensing Panel (ELP) is asked to note that at the time of the inspection there were three areas of practice that required additional work.

The PR has fully implemented the following recommendation;

- the PR must ensure that staff have taken part in an induction process for the new clinic.

The PR has committed to implementing the following recommendations;

- the PR should confirm that the emergency resuscitation equipment is in place and that the dewars and associated monitoring alarm systems have been tested and validated once they have been moved to the new premises before licensed treatment commences.
- the PR must not commence licenced treatment until they have provided evidence that the proposed new premises are suitable for conduct of licenced treatment.

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:
5 Hillview Road
Woking
Surrey
GU22 7HW

The centre has also submitted an application to change its name. The requested new name was submitted on the 'variation of premises' application form but the form was completed incorrectly. The correct name has been confirmed by the PR via email. The centre wishes to change its name from 'Nuffield Health Woking Hospital' to 'Nuffield Health Assisted Conception Services'.

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, the centre wishes to continue to operate at the 'old' premises at Woking Hospital, Victoria Wing, Shores Road, Woking until its annual laboratory shut down in mid December, when it intends to stop treating patients until the first full week in January. The centre has requested that the variation of licence, if granted, is not implemented until licensed treatment will have ceased at the old premises.

The executive recommends that, if this application is granted, that the variation of licence is deferred until 13 December 2019.

Assuming the ELP approves this application, there will be a period of time after the licence is varied when the centre will need to store gametes and embryos at the centre's 'old' premises at Nuffield Health Woking Hospital. A Special Direction has therefore been requested to be in force from the date the licence is varied, for three months, to allow storage of gametes and embryos at the 'old' premises. The executive considered the storage facilities at the 'old' premises to be suitable at the last inspection and note that

satisfactory arrangements have been made by the PR for their on-going security and suitability during the term of the Special Direction. It is recommended therefore 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).

The centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. The executive recommends the renewal of the centre's ITE import certificate in line with the changes to the centre's name and address on its licence.

Details of Inspection findings

1. 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 17 September 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 issued by the contractor to the centre was provided.
    - Confirmation of a fire safety inspection was provided, and will be further updated once the new premises have been in use (see recommendation 3).
    - Security measures in place at the new premises, including those relating to storage of gametes and embryos and confidential records were inspected during the visit and were considered to be suitable.
    - Documentation confirming that processing of gametes and embryos 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 laboratory director confirmed that repeat air quality and settle plate monitoring will also be carried out prior to commencing licensed activities in the new premises (see recommendation 3).
    - Privacy, comfort and confidentiality for patients have been considered in the planning of the new premises. Designated counselling, scanning, consulting and male production rooms are available and appear fit for purpose.
    - Confirmation of a deep clean prior to laboratory work starting will be provided prior to licenced treatment commencing (see recommendation 3).
    - Relevant standard operating procedures had been updated to reflect physical differences in premises.

2. The centre has suitable equipment. A full set of critical laboratory equipment sufficient to be able to perform licensed treatment is already in situ and evidence has been provided of installation and validation.

3. Testing and re-validation of the dewars and related monitoring alarms will be undertaken by the centre when they have been transferred from the current to the new premises.

4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection on 16 and 17 April 2019. 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.

5. However, 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 confirm the following;

   - installation of the emergency resuscitation equipment (see recommendation 1).
   - testing and re-validation of the dewars and the associated alarms has been undertaken once the cryostore has been moved to the new premises (see recommendation 1).
   - staff induction to the new premises has been completed (see recommendation 2).
   - air quality testing has been repeated and meets the required standard (see recommendation 3).
   - a final deep clean has been undertaken (see recommendation 3).

   The PR has also agreed to provide evidence of a fire risk assessment once the new premises have been in operation for the required length of time (see recommendation 3).

6. 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 Emergency resuscitation equipment is not yet present in the unit. Testing and re-validation of the dewars and related monitoring alarms should be undertaken by the centre once they have been transferred from the current to the new premises. SLC T24, GD 0008.	The PR should confirm that the emergency resuscitation equipment is in place before licensed treatment commences. The PR should ensure that the dewars and associated monitoring alarm systems have been tested and validated once they have been moved to the new premises. Evidence of this validation should be provided to their inspector before licensed treatment commences on 6th January 2020.	The resuscitation equipment has been ordered and will be in place before licensed treatment begins. The new laboratory cryo storage facilities including a new dewar has been tested and validated as noted in the report. I confirm that the whole system will be retested and validated once the existing dewars and alarm equipment have been moved and installed. A validation report will be forwarded as requested	The executive acknowledges the PR’s response and commitment to implementing the recommendation. Further action required.

2. Staff The inspection team observed the planned induction program, but staff induction to the new premises had not been carried out at the time of inspection. SLC T15.	The PR must ensure that staff have taken part in an induction process for the new clinic. The PR should provide evidence to the centre's inspector that a staff induction process has taken place, which must be before licensed activity commences on 6th January 2020.	The majority of staff have already had an induction. I confirm that a staff induction process is continuing and a report will be forwarded as requested.	The executive acknowledges the PR's response and implementation of this recommendation. Since the return of this report, the PR has provided confirmation that all staff have now been inducted in the new premises. No further action required.
3. Suitability of Premises Once all equipment and furnishings have been moved into the new centre the following will be required; • Confirmation that processing of gametes and embryos will take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality. • Confirmation that a deep clean has taken place. Once the new centre has been in operation for the required period, a fire risk assessment is required.	The PR must not commence licenced treatment until they have provided evidence that the proposed new premises are suitable for conduct of licenced treatment. The PR should provide confirmation to their inspector that the laboratory air quality is compliant with SLC T20 and that a final deep clean has taken place before licensed activity commences. The PR should provide the centre's inspector with evidence of a fire risk assessment of the 'in use' building by 6th April 2020.	Air quality testing has already occurred in the new laboratory with the new equipment as noted in the report and has surpassed the requirements as specified. I confirm re testing will occur once all existing equipment that is being retained has been relocated and when a deep clean has occurred, with a report to be submitted as requested The "main hospital" director who is the nominated fire officer is aware that a fire risk assessment is required and we will supply a report as	The executive acknowledges the PR's response and commitment to implementing the recommendation. Further action required.

SLC T17 and T20.		requested	

‘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