Executive Licensing Panel - minutes

Centre 0015 (Sussex Downs Fertility Centre)

Variation of Licensed Premises

Tuesday, 24 March 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Joanne Anton Dina Halai	Director of Strategy and Corporate Affairs Policy Manager Scientific Policy 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 Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne. The centre has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services for NHS and private patients. Other licensed activities at the centre include storage of gametes and embryos. The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

1.2. The panel noted that, in the 12 months to 31 January 2020, the centre had provided 432 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a small sized centre.

1.3. The panel noted that on 31 May 2019, the Person Responsible (PR) informed the HFEA that the BMI Esperance Hospital was ceasing their services at the hospital. The Sussex Downs Fertility Centre was withdrawing from the site and there was an imminent change in ownership of the centre. The new owner (the Hospital Fertility Group (HFG) planned to relocate the centre to new premises in a few months' time. In order to continue their activities, the centre decided to lease the premises from BMI until their relocation. As part of the prelude to this move, and due to the decommissioning of some areas of the BMI Esperance hospital, several areas (where non-licensed activities took place) were required to be relocated to rooms on the ground floor. On 7 August 2019, the PR applied to vary the centre's licence to incorporate these additional areas and rooms into the centre's licensed premises. The transfer of ownership to HFG occurred on 1 October 2019.

1.4. The panel noted that the centre was last inspected on 5 and 6 November 2019, when a renewal inspection was conducted. Recommendations were made in relation to two critical, seven major and four 'other' areas of non-compliance. The PR has given a commitment to fully implementing all recommendations. The renewal inspection report was considered by the Licence Committee (LC) on 5 March 2020 and a licence was issued for three years.

1.5. The PR submitted a licence variation application on 14 February 2020 to change premises. Initially, the centre had planned to lease the premises from the BMI Group until 30 April 2020 and move to the new premises within that month, with licensed treatments beginning again later in April 2020. However, following the sale of the current premises by the BMI Group, the centre is no longer in a position to lease the premises beyond 31 March 2020, as some demolition work by the new owner of the site is to start shortly after 1 April 2020.

1.6. An inspection was carried out of the proposed premises on 3 March 2020 and four major areas of practice, requiring additional work were identified; suitability of premises, the quality management system (QMS), equipment and staff. The panel noted that since the inspection, the PR has given a commitment to fully implementing the recommendations made in the report, before commencing licenced treatments.

1.7. The panel noted that all the recommendations made in the report will need to be implemented before licensed activities can commence at the new premises.

1.8. The panel noted that if the application is approved, there will be a period of time after the licence is varied, when the centre will need to store gametes and embryos and medical records at the centre's 'old' premises at BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG until the 31 March 2020. A Special Direction has therefore been requested to be in force from the date the licence is varied until 31 March 2020, to allow storage of gametes and embryos and medical records at the 'old' premises until they are moved to the new premises.

1.9. 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. It is recommended therefore that the Executive Licensing Panel (ELP) approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended).

1.10. The panel noted that the centre's PR submitted further information on 16 March 2020 and confirmed that they wished the variation for change of premises to apply to the current licence (L0015-17-d) and the prospective new licence, to reflect a change of premises from BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG to 6 Park View, Alder Close, Eastbourne BN23 6QE.

1.11. The panel noted confirmation from the inspector that there is no change to the licensing recommendation set out in the variation to premises inspection report.

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:

6 Park View
Alder Close
Eastbourne
Nottingham
BN23 6QE

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), from the date the licence is varied until 31 March 2020, to allow storage of gametes and embryos and medical records at the 'old' premises until they are moved to the new premises.

2.5. The panel noted that the centre's renewal licence should reflect the variation of premises application, and the address stated on this should be 6 Park View, Alder Close, Eastbourne BN23 6QE.

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 concerning the suitability of premises, the QMS, equipment and staff, have been fully implemented, the panel endorsed the inspectorate's recommendation to change the centre's licenced premises to:

6 Park View
Alder Close
Eastbourne
Nottingham
BN23 6QE

3.5. The panel noted that due to current circumstances, in relation to the COVID-19 outbreak, and the recent publication of General Direction 0014, the outstanding non-compliances, due for completion by the PR, might take longer to complete; the panel requested the PR keeps the inspectorate updated.

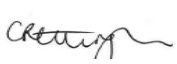
3.6. The panel endorsed the Executive's recommendation to approve this application for a Special Direction, under delegated powers provided by Section 24 5A of the HF&E Act 1990 (as amended), from the date the licence is varied until 31 March 2020, to allow storage of gametes and embryos and medical records at the 'old' premises at BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG, until they are moved to the new premises.

3.7. The panel agreed that the address, to be stated on the centre's renewal licence should be 6 Park View, Alder Close, Eastbourne, BN23 6QE, to reflect the change of premises application.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

25 March 2020

Change of Premises Inspection Report

Centre name: Sussex Downs Fertility Centre
Centre number: 0015
Date licence issued: 1 July 2016
Licence expiry date: 30 June 2020
Additional conditions applied to this licence: None
Date of inspection: 3 March 2020
Inspectors: Sandrine Oakes and Louise Winstone
Date of Executive Licensing Panel: 24 March 2020

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 variation to 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 Sussex Downs Fertility Centre is located at the BMI Esperance Hospital in Eastbourne. It has held a Treatment and Storage licence with the HFEA since 1992 and provides a full range of fertility services for NHS and private patients. Other licensed activities at the centre include storage of gametes and embryos. The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

This current licence has been varied to reflect the following changes:

- 8 January 2020 - change of Licence Holder
- 3 September 2019 - change of premises
- 12 August 2016 - change of Licence Holder

The centre provided 432 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 January 2020. In relation to activity levels this is a small centre.

On 31 May 2019, the Person Responsible (PR) informed the HFEA that the BMI Esperance Hospital was ceasing their services at the hospital. The Sussex Downs Fertility Centre was withdrawing from the site and there was an imminent change in ownership of the centre. The new owner (the Hospital Fertility Group (HFG)) planned to relocate the centre to new premises in a few months' time. In order to continue their activities, the centre decided to lease the premises from BMI until their relocation. As part of the prelude to this move, and due to the decommissioning of some areas of the BMI Esperance hospital, several areas (where non-licensed activities took place) were required to be relocated to rooms on the ground floor. On 7 August 2019, the PR applied to vary the centre's licence to incorporate these additional areas and rooms into the centre's licensed premises.

The transfer of ownership to HFG occurred on 1 October 2019.

The centre was last inspected on 5 and 6 November 2019 when a renewal inspection was conducted. Recommendations were made to two critical, seven major and four 'other' areas of non-compliance. The PR has given a commitment to fully implementing all recommendations. The report will be considered by Licence Committee on 5 March 2020.

The centre submitted an application on 14 February 2020 to vary its licence to change premises. Initially, the centre had planned to lease the premises from the BMI Group until 30 April 2020 and move to the new premises within that month, with licensed treatments beginning again later in April 2020. However, following the sale of the current premises by the BMI Group, the centre is no longer in a position to lease the premises beyond 31 March 2020, as some demolition work by the new owner of the site is to start shortly after 1 April 2020.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period December 2018 to November 2019 show the centre's success rates are in line with national averages.

In 2019, the centre reported 14 cycles of partner insemination with five pregnancies, which is in line with the national average.

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between December 2018 to November 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 3%. This represents performance that is likely to be statistically lower than the 10% multiple live birth rate target.

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 several areas of practice that required additional work.

The PR has committed to implementing the following recommendations before commencing licensed treatments:

Major areas of non-compliance:

- The PR must provide evidence that the proposed new premises are suitable for conduct of licensed treatments.
- The PR must provide evidence that all the relevant standard operating procedures (SOPs) have been updated to reflect physical differences in premises.
- The PR must provide evidence that the proposed equipment is suitable for conduct of licensed treatments.
- The PR must ensure that all staff have taken part in an induction process for 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 before licensed activity commences.

The executive notes that the new address of the centre will be:
6 Park View
Alder Close
Eastbourne
East Sussex
BN23 6QE

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 and medical records at the centre's 'old' premises at BMI The Esperance Hospital, Hartington Place, Eastbourne, East Sussex, BN21 3BG until the 31 March 2020. A Special Direction has therefore been requested to be in force from the date the licence is varied until 31 March 2020, to allow storage of gametes and embryos and medical records at the 'old' premises until they are moved to the new 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).

Centre 0015 has not been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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)). In addition to a desk-based assessment, a site visit was conducted on 3 March 2020. 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 has been provided.
  - A pre-occupation fire safety survey has been performed and no concerns have been noted. Once the new premises are occupied within the next month, a further fire risk assessment will be required (see recommendation 1G).
  - 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. The PR has confirmed that a first response 24/7 security company contract is to start the week of 9 March 2020.
  - Testing to demonstrate 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, has not yet been able to be performed. The laboratory manager 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 1A).
  - 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 licensed treatment commencing (see recommendation 1B).
  - Confirmation that all relevant SOPs have been updated to reflect physical differences in premises will be provided prior to licensed treatment commencing (see recommendation 2).

- The laboratory and clinical equipment sufficient to be able to perform licensed treatment are not yet present at the unit and therefore have not been validated and/or calibrated for use in the new premises. Confirmation of these will be provided prior to licensed treatment commencing (see recommendation 3A).

- Testing and re-validation of the dewars and related monitoring alarms cannot be undertaken by the centre until they have been transferred from the current to the new premises (see recommendation 3B).

- The centre's critical processes and procedures were reviewed at the time of the last renewal inspection on 5 and 6 November 2019. There were a number of non-compliances noted, that will be considered by Licence Committee on 5 March 2020.

However, the executive is satisfied that satisfactory actions have been taken since the renewal inspection to demonstrate that these processes and procedures are now appropriate. The centre does not intend to change any activities or the type of licence. The PR has confirmed that the Home Office has visited the new premises on 6 March 2020 and the current domestic controlled drugs licence will remain the same and will not need to be varied.

- 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 to the new premises, and prior to licensed activity commencing, the PR has agreed to ensure the following:
  - Medical gases are adequately secured in the proposed outdoor storage with safety signage in place (see recommendation 1C).
  - Waste bins are rigid lockable receptacles kept secured at all times in the proposed outdoor compound (see recommendation 1D).
  - The controlled drugs (CD) key safe is in place by the time CDs are present at the unit, and CD keys are only accessible by legally authorised personnel (see recommendation 1E).
  - Access to the laboratory corridor, recovery area and internal waste room is restricted to authorised staff (see recommendation 1F).
  - The emergency resuscitation equipment is in place at the new premises (see recommendation 3C).
  - A staff induction process has taken place for all staff (see recommendation 4).

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

This 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	Executive Review
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.

A major area of non-compliance is identified in the report by a statement that an area of practice is partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Suitability of Premises Once all equipment and furnishings have been moved into the new premises, and before licensed activity commences the following will be required: A. Confirmation that processing of gametes and embryos will take place in an environment of at least Grade C air quality, with a background	The PR must not commence licensed treatments until evidence has been provided that the proposed new premises are suitable for conduct of licensed treatments. Before licensed activity commences, the PR should provide confirmation to the centre’s inspector that: A. The laboratory air quality is compliant with SLC T20.	The licensed activty will not commennce at the new unit until all the required cleaning, validation and asseseements have been completed. A. The laboratory will ensure the air quality is compliant and	The executive notes the PR’s response and commitment to implementing this recommendation. Further action required.

environment of at least Grade D air quality. SLC T20. B. Confirmation that a deep clean has taken place. SLC T17. C. Confirmation that, when Medical gases are present at the unit, they will be adequately secured in the proposed outdoor storage with safety signage in place. Sections 8.20, 8.27, 8.29 and 8.31 and page113 Department of Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006). D. Confirmation that, when waste bins are present at the unit, they are rigid lockable receptacles kept secured at all times in the	B. A final deep clean has taken place. C. Medical gases are adequately secured in the proposed outdoor storage with safety signage in place. D. Waste bins are rigid lockable receptacles kept secured at all times in the proposed outdoor compound. E. The CD key safe is in place by the time CD are stored at the unit, and CD keys are only accessible by legally authorised personnel. F. Access to the laboratory corridor, recovery area and internal waste room is restricted to authorised staff. G. The exact occupancy start date by staff; once the new premises are occupied, confirmation that a further fire risk assessment has been performed and provide a copy of the assessment by 3 April 2020.	allow for a 2 week run through period and testing. b. The Final deep clean has been booked for 25th March c. All medical gases will be stored in the locked area in the compound and photographic evidence will be provided by 25/3/20. d. All waste bins are compliant and photographic evidence will be provided. e. The CD keys are stored with restricted access with number operated key pad which is accessed by authorised staff only - photographic evidence will be provided. f. All doors into the clinical areas including the lab have been fitted with key code locks - photogrpahic evidence will be provided. g. The final fire occupancy risk assessment will be completed prior to site occupancy and sent by the required date.	

proposed outdoor compound. 3.150, 3.151, 3.162 and 3.163 Department of Health Building Note 00-09: 'Infection control in the built environment' (2013). E. Confirmation that the CD key safe is in place by the time CD's are stored at the unit, and CD keys are only accessible by legally authorised personnel. Sections 4.5.2 and 4.5.4 Department of Health 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)' (2007). Recommendation 2 of The Association of Anaesthetists of Great-Britain and Ireland (AAGBI) 'Controlled Drugs in Perioperative Care' (2019). F. Confirmation that access to the laboratory corridor, recovery area and internal			

waste room is restricted to authorised staff. 4.76 Department of Health - Health Technical Memorandum 00 Policies and principles of healthcare engineering (2014). 3.154 Department of Health Building Note 00-09: 'Infection control in the built environment' (2013). G. Once the new centre is occupied within the next month, confirmation that a further fire risk assessment has been performed. SLC T17.			
2. Quality Management System At the time of the inspection, all relevant SOPs had not been updated to reflect physical differences in premises. SLC T32.	The PR must not commence licensed treatments until evidence has been provided that all the relevant SOPs have been updated to reflect physical differences in premises. The PR should provide confirmation to the centre's	All SOP's and patient pathways are being reviewed, by the Lead Nurse and PR and will be fit for purpose before re-commencement of licenced treatment.	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.

	inspector that all the relevant SOPs have been updated, which should be before licensed activity commences.		
3. Equipment Once all equipment and furnishings have been moved into the new premises, and before licensed activity commences the following will be required: A. The laboratory and clinical equipment sufficient to be able to perform licensed treatment are not yet present at the unit and therefore, have not been validated and/or calibrated for use in the new premises. SLCs T17, T24 and General Direction 0008. B. Testing and re-validation of the dewars and related monitoring alarms should be undertaken by the centre once they have been transferred from the	The PR must not commence licensed treatments until they have provided evidence that the proposed equipment is suitable for conduct of licensed treatments. Before licensed activity commences, the PR should provide confirmation to the centre's inspector that: A. The laboratory and clinical equipment have been validated and/or calibrated. Evidence of this validation and/or calibration should be provided. B. 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.	All the clinical equipment that is being relocated will be validated by the specialist company and relevant certification provided. A. All calibration documentaion to be provided by the end of March. B. All alarm monitoring systems will be relocated, tested and validated prior to and following the moving of the dewars and all relevant documentation provided. C. All emergency resuscitation equipment will be moved and recorded and evidence will be provided.	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.

current to the new premises. SLCs T17, T24 and general Direction 0008. C. Emergency resuscitation equipment is not yet present at the unit. The centre will be moving the equipment from the old premises, which was deemed suitable at the time of the last renewal inspection. SLCs T17 and T23.	C. The emergency resuscitation equipment is in place at the new premises.		
4. Staff At the time of the inspection, a staff induction process had started on 28 February 2020 but not taken place for all staff. SLC T15.	The PR must ensure that all staff have taken part in an induction process for the new premises. The PR should provide evidence to the centre's inspector that a staff induction process has taken place for all staff, which must be before licensed activity commences.	All staff will or already have undertaken an indepth site induction which includes Health and Safety, Fire, Patient Evacuation and I.T.as well as the new equipment training. Evidence will be provided and all training has been documented.	The executive notes the PR's response and commitment to implementing this recommendation. Further action required.

‘Other’ areas of practice that requires improvement

‘Other’ 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.

An ‘other’ area of non-compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Additional information from the Person Responsible
We will ensure the site has all the reccomended works completed - privacy glass, cables to be boxed in and the recommendations for the oxygen cylinders for phlebotomy areas. We will also ensure that all team members are involved in developing the reccomended patient pathways for all areas including the anaesthetic team.