Executive Licensing Panel - minutes

Centre 0148 (Shropshire and Mid Wales Fertility Centre)

Variation of Licensed Premises

Friday, 22 June 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Lisa Whiting Niamh Marren	Director of Strategy and Corporate Affairs Data and Insights Analyst Regulatory Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Karen Conyers	Inspector

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:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Background

1.1. The Shropshire and Mid-Wales Fertility Centre has been licensed by the HFEA since 1994 and provides a full range of fertility services.

1.2. The panel noted that in the 12 months to April 2018, the centre had provided 615 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium centre.

1.3. The panel noted that a renewal inspection of the centre was conducted on 13 and 14 June 2017. Recommendations were made to address four major areas of non-compliance and the Person Responsible (PR) has provided evidence that all of these recommendations have been implemented.

1.4. The PR submitted a licence variation application to vary the licence relocate to new premises.

1.5. The panel noted that the PR would like to commence treating patients, at the new premises, on 16 July 2018. Movement of the cryostore is planned to occur earlier, if the application is approved.

1.6. An inspection was carried out of the proposed premises on 6 June 2018 and there were three major areas of practice requiring additional work, concerning equipment, suitability of premises and staff. There was also one 'other' area of non-compliance concerning premises. The panel noted the Executive Update confirming that the recommendations concerning suitability of premises and staff had been implemented. The PR is due to submit further information, concerning equipment and premises, by 13 July 2018 and 22 June 2018 respectively.

1.7. The panel noted, that if the change of premises is approved, 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 Royal Shrewsbury Hospital North. 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.

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 that the inspectorate recommends the approval of the application to vary the licence to reflect a change of premises to the following address:

Severn Fields Health Village
Sundorne Road
Shrewsbury
Shropshire SY1 4RQ

2.4. The panel noted 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 storage of gametes and embryos at the centre's 'old' premises at Royal Shrewsbury Hospital North, for a period of three months after 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. The panel endorsed the inspectorate's recommendation to change the centre's licensed premises to:

Severn Fields Health Village
Sundorne Road
Shrewsbury
Shropshire SY1 4RQ

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 at Royal Shrewsbury Hospital North, for a period of three months after the licence is varied.

4. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

26 June 2018

Change of Premises Inspection Report

Centre name: Shropshire and Mid-Wales Fertility Centre
Centre number: 0148
Date licence issued: 1 December 2017
Licence expiry date: 30 November 2021
Additional conditions applied to this licence: None
Date of inspection: 6 June 2018
Inspectors: Mhairi West (lead), Janet Kirkland MacHattie & Vicki Lamb
Date of Executive Licensing Panel: 22 June 2018

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 Shropshire and Mid-Wales Fertility Centre has been licensed by the HFEA since 1994. The centre provides a full range of fertility services to patients.

The centre provided 615 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to April 2018. In relation to activity levels this is a medium centre.

The centre was last inspected on 13 and 14 June 2017 when a renewal inspection was performed. Recommendations were made to address four major areas of non compliance. The PR has provided evidence that all of these recommendations have been implemented.

The centre submitted an application on 8 April 2018 to vary its licence to relocate to new premises.

The PR would like to commence treating patients on 16 July 2018. Movement of the cryostore is planned to occur earlier, if this application is approved.

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 four areas of practice that required additional work. The PR has committed to implementing the following recommendations:

Major areas of non compliance:

- The PR must not commence licenced treatment until all validation of equipment and the cryostore alarm system has been completed. 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.
- The PR must not commence licenced treatment until they have provided evidence that the proposed new premises are suitable for conduct of licensed treatment.
- The PR must ensure that staff have taken part in an induction process for the new clinic.

Other area of non-compliance:

- The PR should ensure that all medical gases are stored according to medical gas safe storage regulations.

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:
Severn Fields Health Village
Sundorne Road
Shrewsbury
Shropshire SY1 4RQ

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 Royal Shrewsbury Hospital North. 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).

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 6 June 2018.

   The following evidence has been provided:

- 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. This includes a fire safety assessment.
- 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.
- 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.
- Relevant standard operating procedures have been updated to reflect physical differences in premises.

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.

- 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 has not been provided (see recommendation 2).
- Confirmation that the cryostore alarm systems have been validated in preparation for the move of stored material from the old premises to the new has not been provided (see recommendation 1).
- A final date for a deep clean prior to laboratory work starting has not been provided (see recommendation 2).
- Confirmation of staff induction to the new premises has taken place and evidence of life support training for the clinical and nursing teams has not yet been provided (see recommendation 3).

2. The centre is going to use the same equipment as was present in the old premises. This was considered suitable at the last renewal inspection in June 2017. The laboratory and clinical equipment sufficient to be able to perform licensed treatment was not present in the new premises on the day of inspection. It is being transferred from the old premises and should be in situ by 7 June. Validation of the critical laboratory and clinical equipment post move will then be required (see recommendation 1).

3. An emergency crash trolley is not yet present in the unit (see recommendation 1).

4. Both the cryostore and the outside plant area were found to have insufficient warning signage relating to the presence of liquid nitrogen and gases within (see recommendation 4).

5. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in June 2017. 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.

6. Once the contents of the cryostore have been moved to the new premises, under the allowance of the Special Direction, testing and re-validation of the dewars and monitoring alarms should be undertaken (see recommendation 1).

7. The centre has complied with the following requirements of General Direction 0008 (section H 14):
   - 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 noted			

‘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 laboratory and clinical equipment sufficient to be able to perform licensed treatment was not in situ and therefore has not been validated for use in the new premises. The cryostore alarm systems have not been validated in preparation for the move of stored material from the old premises to the new, after the licence has been granted. An emergency crash trolley is not yet present in the unit.	The PR must not commence licenced treatment until all validation of equipment and the cryostore alarm system has been performed. Evidence that this validation has been completed should be provided to their inspector by 13 June 2018. The PR should confirm that the emergency crash trolley is in place before licensed treatment commences.	Evidence of the validation of the cryostore oxygen alarms was provided on the 8/6/18. Evidence of the validation of the dewar alarm system will be provided prior to the 13th June. The emergency crash trolley will be transported to the new department when we move- we are happy to provide evidence of this when we move. We require the crash trolley in the current department until the move to new premises. We hope to move the dewars and alarms on the 14th of July	The executive acknowledges the PR’s response and commitment to implementing the recommendation. Evidence of the validation of the cryostore oxygen alarm system has been received. No further action is required. After discussion with the PR, the centre now plans to move the dewars and alarms on 7 July, if this application is approved, and will submit evidence of validation of the system and associated alarms by 13 July.

SLC T24, General Direction (GD) 0008. 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 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 by 13 July. A tabled update will be provided to ELP.	(if we receive a licence) and so will not be able to provide evidence by the 13th July as the dewars will not have been moved. The liquid nitrogen alarm system (which monitors the levels of LN2 in tanks and dials out to an on call system is being validated at the moment and the results of this will be forwarded by the 13th June.	An update will be provided to the ELP prior to their meeting on progress with validation of other laboratory and clinical equipment.
2. Suitability of Premises 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, has not been provided. SLC T20. Confirmation that a deep clean will take place before licensed treatment commences has not been provided.	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 evidence to their inspector that the laboratory air quality is compliant with SLC T20 by 13 June 2018 at the latest. The PR should provide confirmation when the deep clean has taken place, which must be before licensed activity commences.	We have no plans to provide licenced treatment prior to receiving a licence. Air quality monitoring is being undertaken on the 8th June and results will be with the HFEA prior to the 13th June. A deep clean is being performed on the 11th June and confirmation will be provided to the HFEA by the 13th June	The executive acknowledges the PR's response and commitment to implementing the recommendation. An update will be provided to the ELP prior to their meeting.

SLC T17.	A tabled update will be provided to ELP		
3. Staff Evidence of staff induction to the new premises was not provided, including confirmation of life-support training for clinical and nursing teams. 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 their inspector that a staff induction process, including life support training, has taken place, which must be before licensed activity commences.	All staff have taken part in a local induction process. Evidence will be provided to the inspector by the 13th June.	The executive acknowledges the PR's response and commitment to implementing the recommendation. An update will be provided to the ELP prior to their meeting.

‘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
4. Premises Both the cryostore and the outside plant area were found to have insufficient warning signage relating to the presence of liquid nitrogen and/or medical gases within. SLC T17, DH Health Technical Memorandum 02-01: Medical gas pipeline systems; part B operational management.	The PR should ensure that all medical gases are stored according to medical gas safe storage regulations. The PR should confirm to the centre’s inspector that this has been completed by 22 September 2018.		The PR has provided evidence to the inspector of warning signage on the cryoroom door. Further action in relation to warning signage on the outside plant area is required by 22 September 2018.

Additional information from the Person Responsible