Executive Licensing Panel - minutes

Centre 0201 (Edinburgh Assisted Conception Unit)

Variation of Licensed Premises

Tuesday, 11 September 2018

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Caylin Joski-Jethi (Chair) Lisa Whiting Kathleen Sarsfield Watson	Head of Intelligence Data and Insights Analyst Communications Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Julie Katsaros	Senior Governance Manager Inspector (Induction)

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 Edinburgh Assisted Conception Unit is also known as the Edinburgh Fertility and Reproductive Endocrinology Centre and is located at the Royal Infirmary of Edinburgh. The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services, including embryo testing. Other licensed activities of the centre include storage of gametes and embryos. The current licence has not been varied.

1.2. The panel noted that in the 12 months to 30 June 2018, the centre had provided 1033 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 in September 2017. Recommendations were made to address four major and four 'other' areas of non-compliance or poor practice. 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 create a new cryostore and change the current cryostore into an andrology laboratory.

1.5. The panel noted that an inspection was carried out of the proposed premises on 16 August 2018.

1.6. The panel noted that at the time of inspection, there was one major area of practice requiring additional work, concerning the final validation of the liquid nitrogen storage, supply and inter-related systems. There was also one 'other' area requiring improvement, regarding confirmation of compliance of the new liquid nitrogen storage and supply systems and cryostore with regards to health and safety, building and fire regulations. The panel noted that since the inspection, the PR has provided evidence that the 'other' area of non-compliance had been fully implemented and had given a commitment to implementing the further actions concerning the major area of non-compliance within the prescribed timescales.

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 executive recommends that the application to vary the licence to reflect a change of premises is approved subject to the remaining recommendation made in this report being implemented.

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 executive's recommendation to approve the application to vary the licence to reflect a change of premises, subject to the outstanding non-compliance, made in

the report, being fully implemented and relevant actions conducted and confirmed to the inspector prior to licenced treatment commencing in the new premises.

4. Chair's signature

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

Signature

Name

Caylin Joski-Jethi

Date

17 September 2018

Change of Premises Inspection Report

Centre name: Edinburgh Assisted Conception Unit
Centre number: 0201
Date licence issued: 1 March 2018
License expiry date: 28 February 2022
Additional conditions applied to this licence: None
Date of Inspection: 16 August 2018
Inspector: Karen Conyers
Date of Executive Licensing Panel: 11 September 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 (SLCs).

This is a report of a change of premises inspection. The inspection was a combination of a desk-based assessment and an on-site inspection.

Background

The Edinburgh Assisted Conception Unit is also known as the Edinburgh Fertility and Reproductive Endocrinology Centre and is located at the Royal Infirmary of Edinburgh.

The centre has held a licence with the HFEA since 1992 and provides a full range of fertility services including embryo testing. Other licensed activities of the centre include storage of gametes and embryos. The current licence has not been varied.

The centre provided 1033 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 June 2018. In relation to activity levels this is a large centre.

The centre was last inspected in September 2017 when a renewal inspection was performed. Recommendations were made to address four major and four 'other' areas of non-compliance or poor practice. The PR has provided evidence that all of these recommendations have been implemented.

The centre submitted an application on 16 April 2018 to vary its licensed premises to create a new cryostore and change the current cryostore into an andrology laboratory.

Summary and recommendations for the Executive Licensing Panel

The Executive Licensing Panel is asked to note that that at the time of the inspection there was one major area of non-compliance, and one 'other' area of practice requiring improvement.

Since the inspection visit the PR has confirmed that the following recommendation has been fully implemented:

'Other' area of practice that requires improvement:

- The PR should ensure that confirmation of compliance with all relevant health and safety, building and fire regulations is obtained for the new cryostore and liquid nitrogen storage and supply system.

Since the inspection visit the PR has given a commitment to implementing the following recommendation in the prescribed timescales:

Major area of non-compliance:

- The PR should ensure that the final validation of the new liquid nitrogen system is completed and that a risk assessment for the movement of the stored material is carried out before the transfer of any gametes and embryos into the new cryostore.

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

Details of Inspection findings

Once the centre's application to vary the licence is approved, stored material can be moved from the current cryostore, which will then be refurbished and equipped for use as an andrology laboratory. The current cryostore is being used for licensed activity therefore the refurbishment of this room as an andrology laboratory is considered a change of use rather than a variation to the current premises. It is anticipated that this refurbishment will take several months and will be followed up by the centre's inspector in due course.

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 16 August 2018. 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 with some exceptions noted below.

   - Confirmation of the compliance of the new liquid nitrogen storage and supply systems and cryostore with all relevant health and safety, building and fire safety regulations was not available on the day of inspection (see recommendation 2). During the inspection, the laboratory director assured the inspector that several building inspections and fire safety assessments of the refurbishment have taken place and that no issues had been raised. Therefore, she is assured that the

refurbishment is compliant with all relevant regulations but did not have any certification to that effect. Appropriate safety signage is in place.

- Security measures in place at the new premises, including those relating to storage of gametes and embryos were inspected during the visit and were considered to be suitable.

- The room has been equipped with an appropriate and validated oxygen monitoring system and a boosted extraction system to clear any nitrogen spillages.

- Documentation confirming that the current cryostore which is to be refurbished as an andrology laboratory for the processing of gametes has a background environment of at least Grade D air quality was reviewed on inspection. Following refurbishment of the room, a flow hood will be used for the processing of sperm, ensuring that this takes place in an environment of at least Grade C air quality. Air quality testing will be repeated after completion of the refurbishment, and the laboratory director will provide confirmation of compliance with SLC T20 prior to commencing licensed activity in the andrology laboratory.

- The laboratory director confirmed that a deep clean will be undertaken prior to the use of these two rooms.

- Relevant standard operating procedures have been updated to reflect physical differences in premises. The laboratory director confirmed that staff using the new cryostore room will have appropriate induction and training to allow them to use the room safely.

2. The centre has suitable equipment although the final validation of the liquid nitrogen storage, supply and inter-related systems has not yet been completed (see recommendation 1). A risk assessment for the movement of the stored material cannot be carried out until this final validation has been completed (see recommendation 1).

3. The laboratory director confirmed that testing and re-validation of the dewars, related monitoring alarms, and flow hood (in due course) will be undertaken by the centre when they have been relocated to the new rooms.

4. The centre's critical processes and procedures are unchanged and were considered appropriate at the time of the last renewal inspection in September 2017. The centre does not intend to change any activities or the type of licence.

5. Following the move, and prior to licensed activity commencing at the new premises, the PR has agreed to confirm the following;
    - a final deep clean has been undertaken,
    - testing and re-validation of the dewars and the associated alarms has been undertaken,
    - air quality testing of the andrology laboratory has been repeated and meets the required standard and

- validation of any new or relocated critical equipment has been completed after the refurbishment of the andrology laboratory but prior to commencement of licenced activity in this area.

6. The centre has complied with the requirements of General Direction 0008 (section H 14) in submitting:
    - a relevant on-line application form and
    - 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	Executive review
None identified.			

‘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	Executive review
1. The final validation of the new liquid nitrogen storage, supply and inter-related systems has not yet been completed. A risk assessment for the movement of the stored material cannot be carried out until the final validation has been completed. SLC T24.	The PR should ensure that the final validation of the new liquid nitrogen system is completed and that a risk assessment for the movement of the stored material is carried out. Confirmation that these have been completed should be provided to the centre’s inspector before the movement of any gametes and embryos into the new cryostore. The PR should also confirm to the centre’s inspector that validation of any new or relocated critical equipment is completed following the movement of storage tanks	Due to a significant shortfall in ongoing capacity for frozen material, a new larger room was refurbished for use as a liquid nitrogen storage facility when it was vacated due to relocation of the reproductive endocrinology service. In order to circumvent current challenging issues in manual handling and to satisfy current guidelines on Health and Safety and cryogenic sample storage (BCGA GN19), a new system for the automated supply of liquid nitrogen has been installed. This includes a larger bulk storage tank (2000litres) which is adjacent	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The centre’s inspector will liaise with the PR to ensure full implementation of the recommendation prior to the movement of any gametes and embryos into the new cryostore. The centre’s inspector will also liaise with the PR to ensure that validation of any new or relocated critical equipment is completed following the

	into the new cryostore, and after the refurbishment of the andrology laboratory but prior to commencement of licenced activity in this area.	to the building and a super insulated vacuum line (SIVL) for delivery into the new cryostore. The cryostorage room was designed to house up to 4x Panasonic V1500 vapour phase vessels and up to 25x35-42litre liquid nitrogen storage dewars. The system has been fully installed along with an oxygen monitoring system, a beacon low oxygen alarm and a two step extraction system which is integrated with the oxygen monitor and represents a significant improvement in the facilities for cryostorage. However, although all systems have been tested individually and draft paperwork has been issued by the subcontractors, the system as a whole needs to be validated and an IOQ carried out. We are currently awaiting two sets of subcontractors to attend together to carry this out. An initial risk assessment has been completed but this will need to be updated once the system has been fully	movement of storage tanks into the new cryostore, and after the refurbishment of the andrology laboratory but prior to commencement of licenced activity in this area. **Further action is required.**

		validated. I confirm that an IOQ and validation and an updated risk assessment will be carried out and provided to the HFEA before any material is moved into the new cryostore. In addition, all relocated tanks and dewars will be re-validated once they have been relocated. It is likely that the system will be run using initially the transport tanks to provide liquid nitrogen supply to the V1500 tanks (system in current use in G7319) and then the tanks will be moved over to the new automated filling system one by one and performance verified over an extended period of time. The alarm system runs on Wi-Fi and so there should be no issues with moving tanks from one room to another as they are very close and the new room is closer to the datalogger, but the quality and reliability of the Wi-Fi signal will be tested using several dummy alarms placed around the room during any validation exercise. All validation, IOQ and	

		verification documentation as well as the finalised risk assessment will be provided to the HFEA before release of the room as a validated cryostore.	

‘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	Executive review
2. Confirmation of compliance of the new liquid nitrogen storage and supply systems and cryostore with all relevant health and safety, building and fire regulations was not available at the time of the inspection. SLC T17.	The PR should ensure that confirmation of compliance with all relevant health and safety, building and fire regulations is obtained for the new cryostore, and liquid nitrogen storage and supply system. The PR should provide evidence of this compliance before the use of the new cryostore and liquid nitrogen supply systems.	The building warrant application (screen shot from Edinburgh City Council site) is enclosed as well as the buildings certificate. The Health and Safety File for the refurbishment is included with this application. We also had a Health and Safety Inspection by one of the NHS Lothian Health and Safety officers today and he will be providing a statement that he is happy that the room satisfies all H&S requirements. He did make a comment that additional signage should be provided to identify potential slipping hazard if the floor is wet or if coming in from outside with wet shoes. This additional signage has been added and an image is enclosed. Health and Safety aspects of the installation are covered in the	The executive acknowledges the PR’s response and his commitment to fully implementing this recommendation. The PR has provided evidence of compliance with all relevant health and safety, building and fire regulations. **No further action is required.**

		draft installation paperwork provided, including test certificates for both the SIVL system (Pages 18) the calibration of instruments used to test system pressure (Page 22) and certificates of accreditation in ISO 9001 (Page 26) and CHAS (Contractors Health and Safety Assessment Scheme; Page 28). Fire safety officers were present during several design review meetings, when the refurbishment was being planned with other professional (architects etc) to ensure that the unit complied with site fire safety regulations. The original fire track for entry of fire engines to given access to EFREC and gynaecology wards has been untouched, the exit fire path from EFREC adjacent to the new cryostorage room has been re-instated and is now bigger than the previous fire path and with easier access, the fire safety equipment (extinguishers) have been relocated slightly farther down the wall as	

		recommended and the fire doors remain unchanged.	

Additional information from the Person Responsible
This facility represents a significant upgrade to our current facilities and will provide a larger capacity for cryostorage over the coming years as well as improve conditions for staff who three times a week have to move extremely heavy transport tanks to the current bulk storage tank which is 300metres from the building. In some years when there have been significant adverse weather conditions, this has proved very challenging and has been provoked regular requests for improvements to the system from staff during feedback exercises. The addition of a larger and higher efficiency bulk tank improves our contingency as it means we will need fewer deliveries and could, if there is ever a problem with delivery, manage for up to 2 weeks with 2000litres of liquid nitrogen. Installation of an automated supply system which does not rely on regular filling of transport tanks also reduces the requirement for staff to attend every 2-3 days over the Christmas period as the system is fully alarmed so if there were any issues with filling the on-call embryologist would be alerted. The system also represents a very significant improvement in Health and Safety standards as represented by current BCGA guidelines (BCGA GN19, BCGA CP27, BCGA CP39, BCGA GN11). The new decant system is controlled by a foot pedal which requires to be physically depressed to continue decanting, thereby leaving both hands free to direct the hose accurately and cutting off the flow when the foot pressure is removed. The current mechanism of decant is via a transport tank which has an open/close valve which requires one had to control the flow and the other hand to control the hose. This valve would continue to allow escape of liquid nitrogen even if the person decanting were to faint or collapse, thereby significantly endangering life by asphyxiation. The safe operation of the current system relies on staff using a "buddy" system but this is entirely dependent on staff compliance. In addition, the new extraction system is a standalone system used only by EFREC, is fully integrated with the oxygen monitoring system and is designed to increase flow rate significantly if the oxygen monitor sounds. The current system of extraction is poorly located in the cryostorage rooms, is not integrated with the oxygen alarms and is linked to the hospital extraction system which is frequently shut down for maintenance. This can cause issues if liquid nitrogen is required for freezing or thawing during times of shut down as nitrogen cannot be decanted when the extraction is off. Finally, the new bulk storage tank has a slam shut valve which is also integrated with the oxygen monitor, meaning that if the oxygen monitor sounds, the nitrogen is cut off at source. By these mechanisms the supply of nitrogen is controlled so that staff should be protected from excessive nitrogen escape which can lead to asphyxiation and death.