Executive Licensing Panel - minutes

Centre 0162 (Queens Medical Centre Fertility Unit)

Variation of Licensed Premises

Tuesday, 21 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Howard Ryan Yvonne Akinmodun	Director of Strategy and Corporate Affairs Report Developer Head of Human Resources
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 Queen's Medical Centre Fertility Unit has been licensed by the HFEA for treatment and storage of gametes since 1992. The centre is an NHS clinic located within the Queen's Medical Campus, which is part of Nottingham University Hospitals NHS Trust.

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

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

1.4. The panel noted that the centre's licence was last renewed in 2016, for a period of four years, with no additional conditions. The licence renewal inspection report made recommendations in relation to two major areas of non-compliance; one recommendation has been fully implemented: A second, concerning the safety of the centre's cryostore, was addressed through adopting appropriate risk control measures while plans were implemented to develop a new cryostore. The licensing of this new cryostore is the subject of the report being considered by the Executive Licensing Panel (ELP).

1.5. The panel noted that an interim inspection, conducted on 16 January 2018, confirmed the steps taken by the Person Responsible (PR) to control the risks highlighted in the renewal report, to identify new estates for the relocation of the cryostore, and to secure capital resources for the project. Recommendations were made in relation to two major and one 'other' non-compliance. Two recommendations were fully implemented, while the final recommendation has been addressed through the new cryostore project.

1.6. The PR submitted a licence variation application in November 2018 vary the centre's licence to include a new room (Room 1352) as part of the licensed premises and for the room to be used for storing gametes and embryos. The executive has performed an on-site inspection of the new cryostore and this report provides a summary of evidence for its compliance and suitability for licensing.

1.7. An inspection was carried out of the proposed premises on 2 April 2019 and one major area of practice was identified regarding validation of the dewar and monitoring and alarm equipment. The panel noted that since the inspection, the PR has fully implemented the recommendation made in the report.

1.8. The panel noted that the inspectorate considered there is sufficient information available to recommend the variation of the centre's licence, without additional conditions, to include room 1352 as part of the licensed premises, and for the room to be used for storing gametes and embryos.

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 include room 1352 as part of the licensed premised, and for the room to be used for storing gametes and embryos.

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.

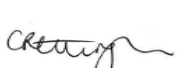
3.3. The panel was satisfied that the premises are suitable for the conduct of licensed activities.

3.4. The panel endorsed the inspectorate's recommendation to approve the variation of the centre's licence, without additional conditions, to include room 1352 as part of the licensed premises, and for the room to be used for storing gametes and embryos.

4. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

28 May 2019

Licence Variation Application Report

Inspectors: Lesley Brown (Lead), Nicola Lawrence (Observer).
Date of inspection: 2 April 2019
Date of Executive Licensing Panel: 21 May 2019
Purpose of report: Assessment of the centre's application to vary its licence to add another room to the licensed premises for use as a cryostore.

Centre details

Centre name	Queens Medical Centre Fertility Unit
Centre number	0162
Licence number	L/0162/15/b
Centre address	Fertility Clinic (NHS), B Floor, East Block, Queens Medical Centre, Derby Road, Nottingham, NG7 2UH, United Kingdom
Person Responsible	Matthew Tomlinson
Licence Holder	Andrew Marshall
Date licence issued	1 July 2016
Licence expiry date	30 June 2020
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

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

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

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

The centre's licence was last renewed in 2016, for a period of four years, with no additional conditions. The licence renewal inspection report made recommendations in relation to two major areas of non-compliance. One recommendation has been fully implemented: A second, concerning the safety of the centre's cryostore, was addressed through adopting appropriate risk control measures while plans were implemented to develop a new cryostore. The licensing of this new cryostore is the subject of this report.

An interim inspection on 16 January 2018 confirmed the steps taken by the Person Responsible (PR) to control the risks highlighted in the renewal report, to identify new estates for the relocation of the cryostore, and to secure capital resources for the project. Recommendations were made in relation to two major and one 'other' non compliances. Two recommendations were fully implemented while the final recommendation has been addressed through the new cryostore project.

This licence was varied to change the Licence Holder (LH) on 27 September 2018 and to change the PR on 15 January 2019.

An application has been submitted by the PR at centre 0162 to vary the centre's licence to include a new room (Room 1352) as part of the licensed premises and for the room to be used for storing gametes and embryos. The executive has performed an on-site inspection of the new cryostore and this report provides a summary of evidence for its compliance and suitability for licensing.

Summary for licensing decision

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

- the room to be added to the licence is suitable for storing gametes and embryos;
- the practices to be used for storing gametes and embryos are suitable;
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, for variation of their licensed premises.

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

The PR has since implemented the following recommendation:

Major area of non-compliance:

- The PR should ensure that equipment used to provide gamete and embryo storage in the room has been validated.

Recommendation to the Executive Licensing Panel

The inspection team considers that overall there is sufficient information available to recommend the variation of this centre's licence without additional conditions, to include room 1352 as part of the licensed premises, and for the room to be used for storing gametes and embryos.

Details of assessment findings

The licence variation application

An application was submitted by the PR on 20 November 2018 to vary the centre's licence to include a new room (Room 1352) to be used for storing cryopreserved gametes and embryos. The new cryostore will be located on floor A of the hospital. Only the relocation of the cryostore is relevant to this application, since other areas of the fertility suite will remain at their current location on floor B. A second phase of works is planned for the 2019-2020 financial year, to relocate the remainder of the fertility suite to floor B in the immediate vicinity of the proposed cryostore.

The new cryostore is needed because, currently, the centre's liquid nitrogen tank is stored at a distance that exceeds the recommendations of the British Compressed Gas Association for the movement of heavy pressurised vessels.

The applicant has complied with the following requirements of General Direction 0008 H (14) in submitting:

- an application form;
- a floor plan showing room 1352

Details of the inspection findings

Key documents were requested from the centre in support of the change of premises application, 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)).

A site visit was conducted on 2 April 2019, two working days after the completed cryostore was signed over to centre staff. Relevant documents were also reviewed on site and later on 5 April 2019 having been forwarded by the PR to the inspector.

On the basis of these assessments it was concluded that the centre's proposed new premises are suitable for the conduct of licensed activities, with one non compliance noted:

- The proposed cryostore is within the same building as the centre, so it is lawful to add the proposed cryostore to the premises authorised by the centre's licence. A floor plan has been provided detailing the room's location.

- The room is under the control of the PR, is secure and access to it is limited to specific members of the laboratory team authorised by the PR.

- The room has been refurbished to meet the requirements of the relevant health technical memoranda and health building notes.

- A fire safety inspection has been performed and has confirmed the room to be safe.

- A thorough clean of the cryostore is planned, and will be repeated once the licence has been varied and existing cryostore equipment is relocated to the new premises.

- The room has been fitted with appropriate safety signage.

- The room has been equipped with an appropriate oxygen monitoring system, with displays and alarms inside and outside the room, and a boosted extraction system to clear any nitrogen spillages. A completion certificate and validation of the oxygen monitoring system has been issued. Further validation will be performed after all cryostore equipment has been relocated.

- A storage system, i.e. a dewar (filled with liquid nitrogen but not containing licensed material) connected to the monitoring and alarm equipment, has been installed in the cryostore for validation purposes and to demonstrate suitable equipment with which to undertake licensed activity. As the building and installation work was only completed two working days prior to the inspection, the validation of the dewar and monitoring and alarm equipment has not yet been completed, due to there being insufficient time for data collection (see recommendation 1). Preliminary data suggests there are no problems with the equipment.

- The PR outlined plans to re-validate dewars and their monitoring devices when they are transferred from the old to the new cryostorage room, assuming the licence variation is approved. This work will be undertaken as part of normal activity compliant with the centre's standard licence conditions.

- The centre's critical processes related to cryopreservation are not affected by the addition of this new cryostore to the licensed premises, and were considered appropriate at the time of the last renewal inspection in January 2016 and the interim inspection in January 2018.

- The PR has advised that standard operating procedures (SOPs) relevant to the new cryostore have been prepared, including one defining working practices to cater for the new cryostore being on Floor A and the centre's laboratory on B floor. The draft documents were reviewed on inspection and were considered suitable. They have not been fully ratified however as the current SOP versions will remain active until the licence variation is granted.

- The new cryostore has been risk assessed, as have the activities to be undertaken within it, and the movement of stored material between it and the centre's premises on B floor.

- Staff with access to the new cryostorage room have had appropriate induction and training to allow them to use the room safely. Further training of all relevant staff, including training provided by the company supplying the oxygen monitoring equipment, is scheduled once the new cryostore is licensed and equipment can be relocated from the existing cryostore.

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 to a 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 to a 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
A dewar has been installed and connected to the monitoring and alarm equipment in the proposed cryostore. Data collection for validation purposes is in progress but had not been completed at the time of inspection. SLC T24, SLC T25	The PR should complete the validation of the dewar and monitoring and alarm equipment and submit the validation documentation when responding to this report.	Room validation has included: 1. monitoring O2 levels and changes in rate of air extraction in response to initiating O2 alarm and 2. Removing liquid nitrogen (LN2) alarm probe to generate alarm. Both procedures worked satisfactorily with 1. Extract fan speed increasing once O2 alarm triggered and 2. Alarm call triggered to incall mobile telephone as soon as LN2 probe removed. One anomaly occurred with the alarm receiver failing (root cause was a short circuit) which meant that validation ceased for 1 week. This was	The Executive acknowledges the PR's response and receipt of the validation documentation as requested. No further action.

		an unexpected and rare fault with a piece of equipment that is considered an 'industry standard' and in use in very many centres. This has now been rectifed.	

Other areas of practice that require 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
None			

Additional information from the Person Responsible
Validation data is available for the performance of the automated freezers (Polaris 13) which have now been in use for more than 1 year and these have provided both satisfactory temperature profiles as well as generation of alarms when required in a 'test-situation'. Once the effectiveness of the automated call out has been demonstrated in the new cryoroom, it should be considered low risk to move to the new premises. Freezers will simply be wheeled carefully to the new location, using 2 members of staff and a key-controlled lift. A revised (draft) SOP is also attached which describes the modified procedures for managing the cryostore and its associated equipment.