Human Fertilisation and Embryology Authority

Minutes of the Executive Licensing Panel

Meeting held at HFEA, Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF on
10 July 2015

Minutes – item no. 1

Centre 0344 (Hewitt Fertility Centre, Knutsford) – Initial Treatment & Storage Licence Application

Members of the Panel:	Juliet Tizzard Director of Strategy & Corporate Affairs (Chair) Hannah Verdin Head of Regulatory Policy Ian Peacock Analyst Programmer
Members of the Executive in attendance:	Sam Hartley Head of Governance & Licensing Dee Knoyle Committee Secretary

Declarations of interest: members of the panel declared that they had no conflicts of interest in relation to this item.

The committee also had before it:

- HFEA protocol for the conduct of Licence Committee meetings and hearings
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- guidance for members of the Authority and committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- guidance on periods for which new or renewed licences should be granted
- standing orders and instrument of delegation
- indicative sanctions guidance
- HFEA directions 0000 – 0012
- guide to licensing
- compliance and enforcement policy
- policy on the publication of Authority and committee papers.

Background

1. The Hewitt Fertility Centre, Knutsford is located at:

   4 The Pavillions
   Knutsford Business Park
   Mobberley Road
   Knutsford
   Cheshire
   WA16 8ZR

2. The proposed Person Responsible (PR) has applied for a treatment and storage licence to provide a full range of fertility services. The clinic currently operates as a satellite of The Hewitt Fertility Centre in Liverpool (centre 0007).

3. An initial licence application was received by the HFEA in November 2014, before building work started. A full desk based assessment was completed and an inspection was carried out on 19 May 2015.

Consideration

4. The panel considered the papers which included an application form, inspection report and CV of the proposed Person Responsible (PR) and Licence Holder (LH).

5. The panel noted that the proposed PR, Ms Karen Schnauffer, has more than two years' practical experience which is directly relevant to the activity to be authorised by the licence as required by the HFE Act 1990 (as amended) section 16(2)(c)(i) and (ii) (including acting in the capacity of PR). The proposed PR has successfully completed the HFEA PR Entry Programme.

6. The panel noted the suitability of the proposed LH, Ms Kathryn Thomson.

7. The panel noted the report of the inspection carried out on 19 May 2015.

8. The panel noted the Inspectorate's recommendations to grant the centre a treatment and storage licence for a period of two years without additional conditions and to appoint the proposed PR and LH.

Decision

9. The panel referred to its decision tree.

10. The panel referred to its 'Guidance on periods for which new or renewed licences can be granted'. The panel noted paragraph 4.2 of the guidance which states that an initial treatment/storage/non-medical fertility services licence would normally be granted for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence.

11. The panel was satisfied that the appropriate application form was submitted.

12. The panel noted that the Inspectorate had received the supporting information required by General Directions 0008.

13. The panel was satisfied that the fee had been paid.

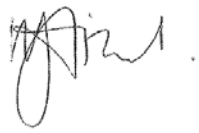
14. The panel was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

15. The panel was satisfied that the premises to be licensed (and those of relevant third parties) are suitable for the conduct of licensed activities based on evidence provided within the report.

16. The panel agreed to grant the licence for treatment and storage for a period of two years with no additional conditions.

17. The panel was satisfied that the proposed PR, Ms Karen Schnauffer, is suitable and will discharge her duty under section 17 of the HFE Act 1990 (as amended). The panel agreed to appoint Ms Karen Schnauffer as the PR when the new licence comes into effect, in accordance with section 18A of the HFE Act 1990 (as amended).

18. The panel was satisfied with the suitability of the proposed LH, Ms Kathryn Thomson, and agreed to appoint her as the Licence Holder when the new licence comes into effect.



Signed: Date: 21 July 2015
Juliet Tizzard (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an assessment and inspection, carried out to determine whether an application for a new licence will meet essential requirements. The Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 19 May 2015

Purpose of inspection: Issue of a licence to carry out treatment and storage.

Inspection details: The report covers the findings from a desk-based assessment of submitted documentation, an inspection visit and communications received from the centre.

Inspectors: Vicki Lamb and Kathryn Mangold

Date of Executive Licensing Panel: 10 July 2015

Centre name	Hewitt Fertility Centre, Knutsford
Centre number	0344
Centre address	4 The Pavilions Knutsford Business Park Mobberley Road Knutsford Cheshire WA16 8ZR
Proposed Person Responsible	Karen Schnauffer
Proposed Licence Holder	Kathryn Thomson

Contents

Section 1: Summary report

Brief description of the centre:
The Hewitt Fertility Centre, Knutsford will treat NHS and private patients in Knutsford, Cheshire. The proposed Person Responsible (PR) has applied for a treatment and storage licence. The centre will provide a full range of fertility services.

The clinic currently operates as a satellite of The Hewitt Fertility Centre in Liverpool (centre 0007).

An initial licence application was received by the HFEA in November 2014 prior to building work commencing. A full desk based assessment was followed by an inspection visit on 19 May 2015.

Centre's anticipated activity levels:

Type of treatment	Maximum number of proposed treatment cycles
In vitro fertilisation (IVF)	1000
Intracytoplasmic sperm injection (ICSI)	
Frozen embryo transfer (FET)	
Donor insemination (DI) and Partner insemination (IUI)	150

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	✓
Embryo testing	N/A

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- it is anticipated that the PR will discharge her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are considered to be suitable;
- the centre's proposed practices are considered suitable;
- the application contains the supporting information required by General Direction 0008;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there was one major and two 'other' areas of non compliance which resulted in the following recommendations:

Major area of non compliance:

- The PR should appoint a controlled drugs accountable officer and register the officer's details with the Care Quality Commission.

'Other' areas that require improvement:

- The PR should ensure that all the emergency bells are tested and are functioning correctly.
- The PR should ensure that the SOPs for conscious sedation and emergency evacuation are appropriately completed.

Since the inspection visit, all of the recommendations have been fully implemented.

Recommendation to the Executive Licensing Panel

The inspection team considers that there is sufficient information available to recommend:

- the appointment of the proposed Licence Holder;
- the appointment of the proposed Person Responsible;
- the grant of a treatment and storage licence for a period of two years.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's proposed procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This will ensure that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests
Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's proposed procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; Directions 0001)
The centre's proposed procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos. It is important that the principle of altruistic donation be upheld but at the same time donors

receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
A donor-conceived person is entitled to know details of their donor and any donor-conceived genetic siblings they may have. Parents of a donor-conceived child are able to access information on their child's donor (and about any donor-conceived genetic siblings) from the HFEA or the clinic where they received treatment.

Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre's proposed procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transport and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre's proposed procedures are compliant with requirements to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the laboratories conducting tests that impact on the quality and safety of gametes and/or embryos (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes and/or embryos in an environment of appropriate air quality.

Laboratory accreditation(Guidance note 25)
The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control
The centre's proposed systems to manage and monitor the prevention and control of infection are compliant with guidance.

Medicines management
The centre's proposed arrangements for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines are broadly compliant with guidance.

Pre-operative assessment and the surgical pathway
The centre's proposed procedures are broadly compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway with one exception relating to documentation (see below). This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; Directions 0003)
The centre's proposed procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, to keep a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's proposed procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes / embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time

limit being specified;
- in a container/package that is secure and ensures that the gametes or embryos are maintained in the specified conditions.

Receipt of gametes and embryos (Guidance note15)
The centre's proposed procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes and embryos be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's proposed procedures for import and export of gametes and embryos are compliant with HFEA requirements.

Traceability (Guidance note 19)
The centre's proposed procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability
- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal,
- to identify the donor and recipient of particular gametes or embryos,
- to identify any person who has carried out any activity in relation to particular gametes or embryos,
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
This section is not applicable as the centre is not intending to undertake any satellite or transport arrangements at present.

Equipment and materials (Guidance note 26)
The centre will use equipment and materials that are compliant with HFEA requirements. All of the equipment and materials to be used in licensed activity are designated for the purpose and will be appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's proposed procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's proposed procedures for reporting adverse incidents are compliant with HFEA requirements. The centre will report all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has processes in place to investigate all adverse incidents that may occur. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities
Whilst all the consulting and treatment rooms were fitted with emergency bells, one of the bells tested during the inspection was not functioning (SLC T17; recommendation 2).

Medicines management
The centre does not currently have a controlled drugs accountable officer (SLC T2; recommendation 1).

Quality management system
Although there is a comprehensive QMS, centre staff have not yet developed a standard operating procedure (SOP) for conscious sedation. Additionally, the emergency SOP does not include the procedure for evacuation of a collapsed patient (SLC T33b; recommendation 3).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The proposed PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T/1271/82).

Staff (Guidance note 2)
The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively. The

centre's staff are registered in accordance with the appropriate professional and/or statutory bodies.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's proposed procedures for taking into account the welfare of any child who may be born as a result of the licensed treatment, and of any other child who may be affected by that birth before treatment is provided are compliant with HFEA requirements.

Safeguarding
The centre's proposed procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
This section is not relevant as the centre will not be performing preimplantation genetic screening, embryo testing or sex selection.

What the centre could do better

Nothing identified at this inspection.

2. The experience of patients

Treating patients fairly
Counselling
Egg sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's proposed procedures are compliant with the HF& E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's proposed procedures appeared compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's proposed counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; Direction 0001)
The centre's proposed procedures for egg sharing arrangements are compliant with HFEA requirements. This is important to ensure that:

- care is taken when selecting egg providers donating for benefits in kind;
- egg providers are fully assessed and medically suitable;
- the benefit offered is the most suitable for the egg provider and recipients.

Surrogacy (Guidance note 14)
The centre will not perform surrogacy.

Complaints (Guidance note 28)
The centre's proposed procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's proposed procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's proposed procedures for providing information to patients and/or donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5 and 6)
The centre's proposed procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's proposed procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's proposed procedures are compliant with the requirements of the HF&E Act 1990 (as amended). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- licensed activities will only take place on licensed premises;
- only permitted embryos will be used in the provision of treatment services;
- embryos will not be selected for use in treatment for social reasons;
- embryos will not be created by embryo splitting;
- embryos will only be created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman;
- embryos will only be stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)
The centre's proposed procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)
The centre's proposed procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre will only store gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well **Use of embryos for training staff (Guidance note 22)** The centre's proposed procedures for using embryos for training staff are compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.
What the centre could do better Nothing identified at this inspection.

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's proposed procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
The centre's proposed procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

What the centre could do better

Nothing identified at this inspection.

Areas of practice requiring action

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, or a significant shortcoming from the statutory requirements. 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
1. The centre does not currently have a controlled drugs accountable officer (SLC T2)	The PR should appoint a controlled drugs accountable officer and register the officer’s details with the Care Quality Commission. The PR should inform the centre inspector when this has been completed which should be by the time this report is considered by a Committee.	The 'action required' by the HFEA is not deemed necessary. Dr Joanne Topping (Medical Director, Liverpool Women's NHS Foundation Trust) is registered as the Controlled Drugs Accountable Officer for Liverpool Women's NHS Foundation Trust. The Hewitt Fertility Centre Knutsford, the centre to which this application pertains, is an entity of Liverpool Women's NHS Foundation Trust and as such, Dr Topping will fulfil the role of Controlled Drugs Accountable Officer.	The Executive acknowledges the PR’s response. No further action is required.

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. Whilst all the consulting and treatment rooms were fitted with emergency bells, one of the bells tested during the inspection was not functioning (SLC T17).	The PR should ensure that all the emergency bells are tested and are functioning correctly. The PR should inform the centre inspector when this has been completed which should be by the time this report is considered by a Committee.	The faults identified within the emergency (nurse call) bell system have been rectified. A full functional audit of the emergency bell system has been performed and seen to be working effctively. Please find attached audit details.	The Executive acknowledges the PR's response. No further action is required.
3. Although there is a comprehensive QMS, centre staff have not yet developed a standard operating procedure (SOP) for conscious sedation. Additionally, the emergency SOP does not include the procedure for evacuation of a collapsed patient (SLC T33b)	The PR should ensure that the relevant SOPs are developed, and forward the completed SOPs to the centre inspector by the time this report is considered by a Committee.		The PR implemented the recommendation within the required time frame by providing an SOP for conscious sedation and a revised SOP for emergency procedures. No further action is required.

Reponses from the Person Responsible to this inspection report
The PR would like to thank the HFEA inspection team for their recommendations.