Executive Licensing Panel - minutes

Centre 0278 (Fertility Fusion)

Renewal Inspection Report

Tuesday, 14 January 2020

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Dan Howard Anna Coundley	Director of Strategy and Corporate Affairs Chief Information Officer Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last five years.

1.2. The panel noted that Fertility Fusion has held a treatment (insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services to NHS and self-funding patients.

1.3. The panel noted that the centre also provides satellite in vitro fertilisation (IVF) services to Hewitt Fertility Centre (centre 0007) in Liverpool, Hewitt Fertility Centre, Knutsford (centre 0344) and Manchester Fertility (centre 0033). Patients who require IVF are treated at the centre up to the point of egg collection, then referred to the primary centres for completion of their treatment. Patients are then referred back to centre 0278 for follow up. The Person Responsible (PR) has estimated that the centre provides satellite services for approximately 800 cycles per year, which is an increase from 550 at the previous inspection.

1.4. The panel noted that, in 2018, the centre provided 52 cycles of partner inseminations, with ten pregnancies. This represents a clinical pregnancy rate of 19%, which is in line with the national average.

1.5. The panel noted that, in 2018, all the clinical pregnancies following partner insemination were singletons.

1.6. An inspection was carried out at the centre on the 19 November 2019.

1.7. The panel noted that at the time of the inspection, no areas of non-compliance were identified. However, the panel noted one area of non-compliance was detailed in the report, relating to the satellite services provided by this centre. This non-compliance is not relevant to the application to renew the licence at centre 0278; it is the responsibility of primary centres to ensure the compliance of the satellite services they commission, and the satellite services are authorised by the licences held by the primary centres. In this case it is recommended that the PR should liaise with the PR of the relevant primary centre, to ensure that this recommendation is effectively implemented in the prescribed timescale. The PR for the primary centre has provided a commitment to fully implementing the recommendation.

1.8. The panel noted that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet or are below the target. The centre is well led and provides a good level of patient support.

1.9. The panel noted that the inspection team recommends the renewal of the centre's treatment (insemination using partner sperm) licence for a period of four years without additional conditions.

2. Decision

2.1. The panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel particularly noted that only three patients had provided feedback on their experience of the centre, in the last 12 months, through the 'Choose a Fertility Clinic' facility available on the HFEA website; the panel suggested that the centre actively encourages patients to use this mechanism to provide feedback.

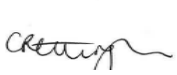
2.5. The panel congratulated the centre on the low level of non-compliances identified at the renewal inspection.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's treatment (insemination using partner sperm) licence for a period of four years, without additional conditions. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

3. Chair's signature

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

Signature



Name

Clare Ettinghausen

Date

20 January 2020

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's 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 November 2019

Purpose of inspection: Renewal of a licence to carry out Treatment (insemination using partner sperm)

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre

Inspectors: Mhairi West & Nicola Lawrence

Date of Executive Licensing Panel: 14 January 2020

Centre name	Fertility Fusion
Centre number	0278
Licence number	L/0278/4/c
Centre address	Wrightington Hospital, Hall Lane, Appley Bridge, Wigan, Lancashire, WN6 9EP, United Kingdom
Person Responsible	Mr Philip Harris
Licence Holder	Wrightington Wigan & Leigh NHS Foundation Trust
Date licence issued	1 July 2016
Licence expiry date	30 June 2020
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

Fertility Fusion has held a Treatment (insemination using partner sperm) licence with the HFEA since 2007 and provides basic fertility services to NHS and self-funding patients.

The centre also provides satellite in vitro fertilisation (IVF) services to Hewitt Fertility Centre (centre 0007) in Liverpool, Hewitt Fertility Centre, Knutsford (centre 0344) and Manchester Fertility (centre 0033). Patients who require IVF are treated at the centre up to the point of egg collection, and are then referred to the primary centres for completion of their treatment. Patients are then referred back to centre 0278 for follow up. The Person Responsible (PR) has estimated that the centre provides satellite services for approximately 800 cycles per year, which is an increase from 550 at the previous inspection.

This current licence was varied in January 2018 and in March 2018 to reflect a change of Licence Holder (LH) and a change in centre name, respectively.

The application form indicates that a further application has been submitted to change the LH again but the PR has confirmed that, as the LH for this centre is a corporate body, this is actually a change of contact details and so an application is not required.

Pregnancy outcomes[1]

In 2018, the centre reported 52 cycles of partner insemination with 10 pregnancies. This represents a clinical pregnancy rate of 19%, which is in line with the national average.

Multiple births[2]

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

In 2018, all the clinical pregnancies following partner insemination were singletons.

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

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) and standard licence conditions (SLCs), 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 PR;
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- 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 were no of areas of practice that required improvement.

There is one area of non-compliance detailed in the report that relates to the satellite services provided by this centre. This non-compliance is not relevant to the application to renew the licence at centre 0278, because it is the responsibility of primary centres to ensure the compliance of the satellite services they commission, and the satellite services are authorised by the licences held by the primary centres. In this case it is recommended that the PR should liaise with the PR of the relevant primary centre, to ensure that this recommendation is effectively implemented in the prescribed timescale. The PR for the primary centre has provided a commitment to fully implementing the recommendation.

Recommendation to the Executive Licensing Panel

The centre has no areas of non compliance and their success rates are consistent with the national average.

The centre is well led and provides a good level of patient support.

The inspection team recommends the renewal of the centre's Treatment (insemination using partner sperm) licence for a period of four years without additional conditions.

Centre 0278 does not import or export gametes or embryos and so has not applied for a Importing Tissue Establishment (ITE) import certificate from the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018.

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 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 procedures for double checking the identification of gametes and the patient to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes.

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 does not recruit donors or provide treatment with donor gametes therefore this area of inspection is not applicable.

Payments for donors (Guidance note 13; General Direction 0001)
The centre does not recruit donors or provide treatment with donor gametes therefore this area of inspection is not applicable.

Donor assisted conception (Guidance note 20)
The centre does not recruit donors or provide treatment with donor gametes therefore this area of inspection is not applicable.

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
Transports 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 suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The centre is compliant with HFEA requirements to process gametes 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, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre is providing only insemination treatments and therefore this area of practice was not relevant to this inspection.

Multiple births (Guidance note 7; General Direction 0003)
The centre provides only insemination treatments, but such treatments still expose patients to the risks of multiple pregnancies and births if incorrectly applied. The single biggest risk of fertility treatment is a multiple pregnancy and birth thus it is important for centres providing insemination treatments to have a multiple births minimisation strategy. The centre's procedures are compliant with HFEA requirements to have a multiple births minimisation strategy and to conduct regular audits and evaluations of the progress and effectiveness of the strategy.

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

- document the justification for the use of the patient's gametes in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre does not transport or distribute gametes therefore this area of practice is not applicable to this inspection.

Receipt of gametes (Guidance note15)
The centre does not receive distributed gametes from other centres therefore this area of practice is not applicable to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes or embryos therefore this area of practice is not applicable to this inspection

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes during any step from procurement to use for human application or disposal;
- to identify any person who has carried out any activity in relation to particular gametes; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is 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; General Direction 0010)
The centre is a satellite provider to the three primary centres identified earlier in this report. The primary centres to which centre 0278 is a satellite have agreements in place that are compliant with HFEA requirements. This is important to ensure that activities

performed by satellite clinics on behalf of the licensed primary centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are 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 procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. 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
Nothing identified at this inspection.

Staff engaged in licensed activity

Person Responsible (PR)
Leadership
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of medicine 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.

Leadership
The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good

governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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.

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 procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's 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)** The centre does not create embryos or perform embryo testing and therefore this area of practice is not applicable to this inspection.
What the centre could do better Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only three patients have provided feedback in the last 12 months, giving an average 3.5 star rating to the clinic. For the system to work well it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility and this will be followed up at the next inspection. The website also gives the ability for patients to comment on the cost of treatment. All of patients confirmed that they had paid what they expected to.

The centre's own most recent patient survey responses were also reviewed, and feedback was generally positive.

No patients were available to speak to inspectors during this visit.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Patient support
Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's 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 procedures are 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.

Patient support (Guidance note 3)

New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Counselling (Guidance note 3)
The centre is not required to provide counselling for basic partner IUI services however counselling is offered to all patients including those treated as part of the satellite services. 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.

Sperm sharing arrangements (Guidance note 12; General Direction 0001)
The centre does not undertake sperm sharing arrangements and therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not undertake surrogacy arrangements and therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's 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 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; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients 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;6)
The centre's 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.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre provides only basic partner treatment services under its HFEA licence. It does not provide treatment with donor gametes therefore requirements related to consent to legal parenthood were not relevant at this inspection.

However the centre does obtain consent to legal parenthood as part of their satellite service, which are authorised by the licences held by the primary centres listed earlier in the report. Because of the fertility sector's well documented problems with legal parenthood consenting, the inspection team took the opportunity to assess the compliance and effectiveness of the centre's legal parenthood consenting procedures, by discussing these procedures with staff and reviewing the results of a recent legal parenthood consenting audit. Four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
Requirements related to consent to disclosure to researchers are not relevant to basic partner IUI services, therefore this area of practice is not relevant to this inspection.

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 procedures are compliant with the requirements of the HF&E Act 1990 (as amended) because licensed activities only take place on licensed premises.

What the centre could do better
Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)
The centre's 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 and processing.

Storage of gametes and embryos (Guidance note 17)
The centre does not store gametes or embryos therefore this area of practice is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre does not create embryos or use them to train staff therefore this area of inspection is not applicable to this inspection.

What the centre could do better
Nothing identified at this inspection.

4. Information management

Record keeping and Obligations and reporting requirements
What the centre does well **Record keeping and document control (Guidance note 31)** The centre's 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; General Direction 0005)** The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements. The HFEA register audit team found no problems with the timeliness and accuracy of the centre's submission of data to the Register.
What the centre could do better Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2018, recommendations for improvement were made in relation to three 'other' areas of non compliance.

The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

On-going monitoring of centre success rates

As this centre only provides partner IUI treatment, their success rates are not subject to on-going monitoring through the HFEA risk tool and the centre has not therefore been issued with any performance alerts.

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, General 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

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.

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

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

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.

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

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

Non-compliance in the transport/satellite activities

These areas of practice that require improvement are within the centre's transport and/or satellite services. Such services are undertaken under the authority of a primary centre's licences. Therefore, the primary centre licence is responsible for non-compliances in the transport and/or satellite service.
The non-compliances and recommendations below will therefore be notified to PRs of primary centres, so they can work with the PR of the transport and/or satellite centre to implement them. These non-compliances are not considered by the licensing committee when making a decision regarding the continuation of the HFEA licence held by the satellite centre.

Area of practice and reference	Action required and timescale for action	PR's Response	Executive Review
Satellite services The audit of the satellite service carried out by primary centre 0033 was supplied but it did not robustly audit practices in relation to 'Procuring, processing and transporting gametes and embryos' (Guidance note 15). SLC T32 and SLC T36. The PR of the primary centre has been informed by their inspector, and has been given guidance regarding the weaknesses in their audit of the satellite service.	The PR should ensure that the audit of satellite activities is carried out by the primary centres, and that those audits assess all relevant activities. The PR should work with the PR of the primary centre to provide an action plan of how to address the issue identified in relation to the audit of satellite activities. A summary of the action plan should be provided to the centre's inspector by 21 January 2020, with a view to ensuring that the actions are fully implemented by 21 April 2020.	I have communicated with the PR of the primary centre 0033. An action plan will be produced and corrective actions implemented.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Further action required.

Reponses from the Person Responsible to this inspection report