HFEA Executive Licensing Panel Meeting

10 January 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0033 – (Manchester Fertility) – Renewal Treatment & Storage Inspection Report

Members of the Panel:	**Committee Secretary:**
Juliet Tizzard – Interim Director of Strategy (Chair)	Dee Knoyle
Ian Peacock – Analyst Programmer	**Observing:**
Matthew Watts – Regulatory Policy Manager	Sam Hartley – Head of Governance and Licensing

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 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 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 Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a treatment and storage centre which provides a full range of licensed treatments. The Panel noted that in relation to activity levels this is a large centre.

3. The Panel noted that the centre has been licensed by the HFEA since 1990 and is on a five-year licence due to expire on 30 April 2014.

4. The Panel noted that in the 12 months to 31 August 2013, the centre provided 1031 cycles of treatment (excluding partner intrauterine insemination).

5. The Panel noted that for IVF and ICSI, HFEA-held register data for the period 1 June 2012 to 31 May 2013 show the centre's success rates are in line with national averages.

6. The Panel noted that in 2012, the centre reported 45 cycles of partner insemination with five pregnancies. This is consistent with the national average.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represented performance that was not statistically different from the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% maximum multiple live birth rate target for this period.

9. The Panel noted that at the time of the inspection on 8 and 9 October 2013, the Inspectorate observed one critical, five major and three other areas of non-compliance. The Panel noted the non-compliances and in particular the critical area of non-compliance relating to donor screening. The Panel noted that since the inspection the centre has provided the Inspectorate with an update to confirm they have reviewed their donor screening procedures, identified and implemented corrective action and confirmed that they will complete an audit and submit the results to the HFEA by April 2014. The Panel noted the PR's commitment to implement the outstanding recommendations within the prescribed timescales.

10. The Panel noted the Inspectorate's recommendation that significant improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

11. The Panel noted the Inspectorate recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional

conditions, subject to compliance with the recommendations made in this report being implemented within the prescribed timescales.

Decision

12. 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.

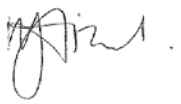
13. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended).

14. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

15. The Panel noted the non-compliances and requested that the Inspectorate report any concerns relating to the implementation of their recommendations.

16. The Panel urged the centre to work hard to fully implement all the outstanding recommendations made in this renewal inspection report within the prescribed timescales, which will be monitored by the Inspectorate.

17. The Panel endorsed the Inspectorate's recommendation to renew the centre's Treatment and Storage licence for four years, without additional conditions.



Signed: Date: 23 January 2014

Juliet Tizzard (Chair)

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: 8 and 9 October 2013
Purpose of inspection: Renewal of a licence to carry out 'Treatment and Storage'

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: Sara Parlett, Susan Jolliffe, Debra Bloor, Chris Hall, Kayleigh Roberts, Pauline Barrett (observer) and Lynne Lord (CQC, observer)

Date of Executive Licensing Panel: 10 January 2014

Centre name	Manchester Fertility
Centre number	0033
Licence number	L/0033/13/h
Centre address	Cheadle Royal Business Park, 3 Oakwood Square, Cheadle, Cheshire, SK8 3SB
Person Responsible	Dr Deborah Falconer
Licence Holder	Dr Ilan Lieberman
Date licence issued	1 May 2009
Licence expiry date	30 April 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
Manchester Fertility has held a licence with the HFEA since 1990 and provides a full range of fertility services.

The centre provided 1031 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 August 2013. In relation to activity levels this is a large centre.

The centre has a satellite arrangement with one clinic in London.

In May 2013, an ELP approved the centre's application to vary its licence to reflect a change of premises. In July 2013, an ELP approved the centre's application to change its name from 'Manchester Fertility Services Ltd' to 'Manchester Fertility'. The change of premises was approved following a desk-based assessment and this inspection represents the first formal visit to the centre at its new location. The inspection team considered that the new premises are fit for purpose and have been designed with careful consideration to security and the patient experience.

Activities of the centre:

Type of treatment	**Number of treatment cycles for the period 1 Sep 2012 – 31 Aug 2013**
In vitro fertilisation (IVF)	180
Intracytoplasmic sperm injection (ICSI)	289
Frozen embryo transfer (FET)	212
Donor insemination (DI)	350
Egg share provider (sharer)	36
Egg share recipient	32
Egg donation (non egg share)	44
	Number of treatment cycles for calendar year 2012
Partner insemination	45

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research (if applicable)	R0026 and R0171

Outcomes [1]

For IVF and ICSI, HFEA held register data for the period 1 June 2012 – 31 May 2013 show the centre's success rates are in line with national averages.

In 2012, the centre reported 45 cycles of partner insemination with five pregnancies. This is consistent with the national average.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 19%. This represented performance that was not statistically different from the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 20%. This represented performance that was not likely to be statistically different from the 15% multiple live birth rate target for this period.

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. The HFEA considers differences in a centre's success rates and multiple pregnancy rates from the national averages are only statistically significant if they occur at a significance level of $P \leq 0.002$.

[2]The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2011/12 MLBR target of 15% is calculated as equivalent to a 19% MCPR.

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 PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their 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 recommendations for improvement in relation to one critical, five major and three 'other' areas of non-compliance or areas of poor practice.

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

Other' areas of practice that require improvement:

- The PR should ensure that all screening tests are carried out by laboratories which are appropriately accredited.

The PR has given a commitment to fully implement the following recommendations:

Critical areas of concern:

- **The PR should ensure that donors are appropriately screened prior to the use and/or storage of donor gametes.**

Major areas of non compliance:

- The PR should ensure that the centre's critical procurement and processing procedures are validated.
- The PR should ensure that:
    - the specific rig used for each ICSI case is recorded;
    - the inspection finding of an incorrectly recorded batch number for one reagent is investigated;
    - further mitigation of the risks of not labelling all containers used at the time of egg collection are considered.
- The PR should ensure that quality indicators (QIs) are established and documented for all licensed activities and activities carried out in the course of providing treatment services that do not require a licence. The PR should ensure that counselling activities are audited.
- The PR should ensure that appropriate consent is obtained by its satellite centre prior to treatment.
- The PR should review procedures for welfare of the child (WoC) assessments.

‘Other’ areas of practice that require improvement:

- The PR should review and revise the centre’s provision of information standard operating procedure (SOP).
- The PR should review procedures for obtaining consent to legal parenthood.

Recommendation to the Executive Licensing Panel

Significant improvement is required in order for the centre to reflect good practice and demonstrate the quality and safety of the service it provides.

The inspection team is satisfied that the activities carried out at the centre are necessary in order to provide licensed treatment services.

The inspection team recommends the renewal of the centre’s Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

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 (Guidance note 18)

What the centre does well.

The centre's 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 ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better.

Nothing noted on this inspection.

Patient and donor selection criteria and laboratory tests

What the centre does well.

Screening of patients and donors (Guidance note 11 and 15)
The centre's procedures for screening patients and donors are partially 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.

Payments for donors (Guidance note 13)
Payments to donors are compliant with the requirements of the HFEA. 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)
People born as a result of donation are entitled to request and receive their donor's name and last known address, once they reach the age of 18. Therefore it is important that centres use donated gametes or embryos from identifiable donors. The centre is fully in line with the requirements of the HFEA to ensure the donor conceived will be able to receive this information.

What the centre could do better.

Screening of patients and donors (Guidance note 11 and 15)
An audit of seven sets of donor notes performed on inspection found that one egg donor

had completed a donation cycle without being screened for hepatitis C (Standard Licence Condition (SLC) T52b). The centre uses a checklist to ensure consents and screening are in place prior to treatment and this screening test had not been signed off on the checklist retained in the notes. The centre recognised the seriousness of this non-compliance and immediately after the inspection, the PR confirmed that the egg donor had been retrospectively screened for hepatitis C and was negative. See recommendation 1.

In four of seven sets of patient notes audited, screening tests were performed by a laboratory whose accreditation status could not be determined (SLC T51a). Patients frequently attend the centre with the results of screening tests arranged by their GP. Centre staff explained that they expect GPs to use only CPA accredited laboratories. See recommendation 7.

Good clinical practice

What the centre does well.

Multiple births (Guidance note 7)
The single biggest risk of fertility treatment is a multiple pregnancy.

The centre's achievement in meeting the multiple live birth rate and clinical pregnancy rate targets demonstrates that the centre has an effective multiple births minimisation strategy in place.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA requirements, with exceptions detailed below, to ensure it has the ability:
(a) to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
(b) identify the donor and recipient of particular gametes or embryos;
(c) to identify any person who has carried out any activity in relation to particular gametes or embryos; and
(d) 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 (Guidance note 23)
The centre has a quality management system in place that is partially compliant with HFEA requirements. A quality management system is important to ensure optimum outcomes and improve the quality and safety of the treatment and services it provides to patients.

Third party agreements (Guidance note 24)
The centre has agreements in place which cover the:
(a) procurement, testing or processing of gametes or embryos on behalf of the licensed centre, and
(b) supply of any goods or services (including distribution services) to the licensed centre which may affect the quality or safety of gametes or embryos.

Satellite centre management (Guidance note 24)
The centre has a satellite centre that prepares patients for licensed treatment which is then provided at centre 0033. This is a new service and only three satellite patients have been treated to date. A review of the satellite agreement demonstrated compliance with HFEA requirements (General Directions 0010).

Equipment and materials (Guidance note 26)
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.

Safety and suitability of premises and facilities (Guidance note 25)
All licensed activities are conducted in a suitable environment that is fit for purpose, and the risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm. All diagnostic testing is carried out in a suitable accredited laboratory, with an exception referenced in the 'patient and donor selection criteria and laboratory tests' section of this report.

Infection control
The centre has appropriate systems in place to manage and monitor the prevention and control of infection, and provides care in an environment that is compliant with HFEA requirements.

Adverse incidents (Guidance note 27)
The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all of the adverse incidents that have occurred and shares the lessons learned in order to continuously improve the services it offers.

Medicines management
The PR ensures appropriate arrangements are in place for obtaining, recording, handling, using, safe keeping, dispensing, safe administration and disposal of medicines for the purposes of licensed activity.

Pre-operative assessment and the surgical pathway
The centre has appropriate policies and procedures in place, in line with professional guidelines, to ensure all patients are safely assessed and cared for pre-, peri- and post-operatively. Appropriate procedures are in place for discharging patients and staff are trained to manage clinical emergencies.

What the centre could do better.

Process Validation (Guidance note 15)
Centre staff gave a verbal account of how they are satisfied that the critical processing procedures used are effective and do not render gametes or embryos clinically ineffective or harmful to the recipient. However, this has not been documented as a formal process validation exercise (SLC T72). See recommendation 2.

Traceability (Guidance note 19)
Two ICSI rigs are used in the laboratory, but the specific rig used in each ICSI case is not recorded (SLC T99).

An audit of five items of laboratory consumables and reagents was carried out on inspection. The batch number of one item did not match that recorded as being in use on the centre's database (SLC T99). Traceability audits are performed regularly at the centre and the last audit performed identified no concerns (SLC T36).

At egg collection it was observed that the tubes and initial dishes used during egg collection are not labelled. The centre has assessed the risks of misidentification from not labelling these containers and identified corrective action that was implemented to further mitigate the risks. This corrective action is to confirm that the egg collection hood is clear of all containers at the end of each procedure and record this as a witnessed step on the laboratory worksheet. The inspection team considered that further mitigation of the risks should be considered, including ensuring that critical work areas in theatre are incorporated into this step (SLC T101).

See Recommendation 3.

Quality management system (Guidance note 23)

The centre has not established formal QIs or objectives relevant to all licensed activities, including WoC assessment, traceability and donor recruitment, assessment and screening (SLC T35). Guidance on establishing and documenting QIs was forwarded to centre staff after the inspection. See recommendation 4.

The centre performs regular comprehensive audits of its licensed activities with two exceptions:

- The centre's procedure for WoC assessment has been audited against regulatory requirements but an audit of completion of the WoC assessment in the patient notes has not been performed. See 'welfare of the child' section of this report.
- The centre has established QIs for counselling but has not audited its counselling activities (SLC T36). See recommendation 4.

Satellite centre management (Guidance note 24)

The centre has recently established a new satellite service, led by a consultant at centre 0033 who works between Manchester and London. Three satellite patients have been treated to date at the centre; these patient notes were audited on inspection and the following issues were identified:

- In one set of notes, the HFEA WT consent form completed by the patient in April 2013 was an old version of the consent form which was replaced in 2009. This refers to previous statutory requirements for the length of time that embryos can be stored.

  The HFEA MT consent form completed by the partner in April 2013 was the correct version, but section 6 of the form had not been completed. This section documents the partner's wishes for the use of embryos in the event of his death or mental incapacity. The couple have embryos in storage from their treatment cycle.

  The female patient had not completed section 3.1 of the HFEA consent to disclosure form, recording the patient's consent to disclosure of information to certain groups of people.

See recommendation 5.

- In all three sets of notes, the WoC assessment form had not been completed by centre staff. Refer to the 'welfare of the child' section of this report.

The checklist used by centre 0033, to ensure consents are obtained and WoC assessments are performed prior to treatment was completed, with no issues documented, for all three sets of notes. See recommendations 5 and 6.

Staff engaged in licensed activity

What the centre does well.

Person Responsible (Guidance note 1)
The PR has a key role to play in implementing the requirements of the HF&E Act 1990 (as amended) and is the person under whose supervision the licensed activities are authorised. The PR has the primary (legal) responsibility under Section 17 of the HF&E Act 1990 (as amended) to secure:

- that suitable practices are used in undertaking the licensed activities;
- that other persons working under the licence are suitable and;
- that the conditions of the licence are complied with.

The 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/1161/8).

Staff (Guidance Note 2)
The centre has suitably qualified and competent staff to carry out all of the licensed activities and associated services.

What the centre could do better.

Nothing noted on this inspection.

Welfare of the child (Guidance note 8)

What the centre does well.

The centre's procedures for taking into account the welfare of the child are broadly compliant with HFEA requirements.

What the centre could do better.

In seven of 13 patient records reviewed in the course of the inspection, there was no evidence that the WoC information provided by the patients had been assessed by a member of staff (SLC T46 and T56). Whilst the inspection team had no concerns that WoC issues would not be taken into consideration by the centre, it is difficult to be fully assured without the appropriate records being maintained. WoC assessment completion does form part of the centre's checklist to be completed prior to treatment. See

recommendation 6.

Safeguarding

What the centre does well.

The centre's procedures are compliant with HFEA requirements. The centre is committed to protecting patients and staff from harm; safeguarding training is attended by all staff. Concerns are escalated to the appropriate authority where issues are raised about the possible or actual abuse or neglect of any persons attending the centre.

What the centre could do better.

Nothing noted on this inspection.

2. The experience of patients

Patient feedback

What the centre does well.

During the inspection visit the inspectors spoke to seven patients who provided feedback on their experiences. A further 13 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was generally positive, with six of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. The patients interviewed also provided positive feedback on their experiences.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provides patients with satisfactory facilities for their care.

What the centre could do better.

Nothing noted on this inspection.

Treating patients fairly

What the centre does well.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements, with one exception detailed below, ensuring that counselling support is available to patients before and during the consenting process and treatment.

Gamete sharing arrangements (Guidance note 12)
The centre's procedures for egg sharing arrangements are compliant with HFEA requirements. This ensures that:
(a) care is taken when selecting egg providers donating for benefits in kind;
(b) egg providers are fully assessed and medically suitable; and
(c) the benefit offered is the most suitable for the egg provider and recipient(s) (where relevant).

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements to protect the surrogate and the commissioning couple. Patients providing gametes in surrogacy arrangements are screened as donors in order to safeguard the health of the surrogate.

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

Treating patients fairly (Guidance note 29)
The centre treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way.

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 well being of prospective and current patients and donors.

What the centre could do better.

Counselling (Guidance note 3)
Refer to the 'quality management section' of this report.

Information (Guidance note 4)

What the centre does well.

The centre's procedures for providing information to patients and donors are compliant, with HFEA requirements, with one minor exception detailed below. 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.

Provision of costed treatment plans (Guidance note 4)
The centre provides an individual costed treatment plan to all self funded patients. This ensures that patients know the full cost of their proposed treatment before deciding on whether to proceed.

What the centre could do better.

The centre's SOP for the provision of information to patients prior to obtaining consent does not include providing information on consent to the use of embryos in staff training (SLC T33b). See recommendation 8.

Consent (Guidance note 5)

What the centre does well.

The centre's procedures for obtaining consent are compliant with HFEA requirements, with an exception detailed below. 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
The Register started operating in August 1991 and is a rich source of information about assisted reproductive technologies (ART), its outcomes and the factors that contribute to the birth of a baby following treatment. This information can be used by researchers and, in certain circumstances, linked to other health registers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment. Whereas the HFEA is permitted to disclose non-identifying information to researchers it can only provide identifying information with the consent of patients. Therefore, it is important that patients are asked to give their consent and that their wishes are accurately recorded and passed on to the HFEA. The centre's procedures for doing this ensure that the HFEA holds an accurate record of the patients consent, so that it only releases the patients

identifying information, to researchers, with their consent.

What the centre could do better.

Legal parenthood consent had been obtained appropriately in five of six sets of notes audited on inspection. The notes of one couple, in a civil partnership and using donor sperm, reviewed on inspection did not include the HFEA PP consent form. Although it is not a mandatory requirement for couples who are married or in a civil partnership to complete the form, it is a requirement if the partner wishes to be the legal parent of any child born from his/her partner's treatment after his/her death. Furthermore, the notes of three other couples who are either married or in a civil partnership were reviewed and did include the HFEA PP consent form, demonstrating inconsistency in the centre's practice (SLC T60). See recommendation 9.

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). This ensures that the centre has respect for the special status of the embryo when conducting licensed activities.

- Licensed activities only take place on licensed premises.
- Only permitted embryos are used in the provision of treatment services.
- Embryos are not selected for use in treatment for social reasons.
- Embryos are not created by embryo splitting.
- Embryos are only 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 are only 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 noted on this inspection.

Storage of gametes and embryos

What the centre does well.

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.

The centre's 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 only stores gametes and embryos in accordance with the consent of the gamete providers.

What the centre could do better.

Nothing noted on this inspection.

Distribution and receipt of gametes and embryos

What the centre does well.

The centre's procedures for distributing and receiving gametes and embryos are compliant with HFEA requirements. This ensures that all gametes/embryos sent to other licensed centres within or outside the UK are appropriately labelled and relevant information is sent to the other centre to ensure the continued quality and safety of the gametes and embryos. 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 a way that does not comprise their quality and safety.
What the centre could do better. Nothing noted on this inspection.

Use of embryos for training staff (Guidance note 22)
What the centre does well. The centre's procedures for using embryos for training staff are compliant with HFEA requirements. The centre uses embryos to train staff in vitrification. This activity has been authorised by the Authority.
What the centre could do better. Nothing noted on this inspection.

4. Information management

Record keeping and submitting information to the HFEA

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, with one exception noted in the 'welfare of the child' section of this report. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32)
The HFEA has a legal responsibility to maintain a register containing information about all licensed activities including information on donors and on any children conceived as a result of their donation. In order to maintain this Register, clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. The primary purpose for keeping this information is to allow the donor-conceived and their parents to access information about the donor and about any donor-conceived genetic siblings.

The centre's procedures for submitting information, about licensed activities, to the Authority are compliant with HFEA requirements and ensure the HFEA can supply accurate information to a donor-conceived person and their parents.

What the centre could do better.

Nothing noted on this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2012, recommendations for improvement were made in relation to one area of major non-compliance and one 'other' area of practice that requires improvement.

The PR provided information and evidence that both of these recommendations were fully implemented.

Following the centre's application to vary its licence to re-locate to new premises, an ELP approved the variation in May 2013 subject to confirmation that:

- Re-commissioned equipment has been tested and validated;
- The air quality of the laboratory environment has been re-tested once all laboratory equipment is in situ and the quality of air in critical work areas measured to demonstrate that an appropriate air quality is achieved.

The PR provided confirmation that both of these requirements were fully implemented prior to commencing licensed activities at the new premises.

Risk based assessment tool (RBAT) alerts

In the last twelve months, the centre has been issued with two performance alerts:

- December 2012: Clinical pregnancy rates following IVF in patients aged under 38.

- August 2013: Clinical pregnancy rates following DI in all patients.

The centre has undertaken reviews in response to both alerts and corrective actions were identified and implemented. No further action is required in response to these and the Executive will continue to monitor the centre's success rates.

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
1. One egg donor had completed a donation cycle without being screened for hepatitis C. The centre uses a checklist to ensure consents and screening are in place prior to treatment. However, this screening test had not been signed off on the checklist in the donor's notes. SLC T52b.	Immediately after the inspection, the PR confirmed that the egg donor had been retrospectively screened for hepatitis C and was negative. The PR has also carried out a full screening audit of all egg donors treated at the centre. The inspection team is satisfied with the actions taken by the PR to date.	The PR has taken immediate action and control measures are in place to prevent this re-occuring. A full review of screening procedures for sperm and egg donors is underway and the outcome will be submitted by 9th December. An audit is planned for the New Year and will be	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	The PR should ensure that prior to the use and/or storage of donor gametes, the laboratory tests required by SLC T52 are performed. The PR should review the centre's donor screening procedures, including the appropriate use of the donor checklist. The outcome of this review and any corrective actions identified and implemented should be submitted to the HFEA by 9 December 2013. Three months after the implementation of corrective actions, the centre should perform an audit of a random representative sample of donor records to ensure that these corrective actions are effective. This audit should be submitted to the HFEA by 9 April 2014.	submitted to the HFEA by April 2014.	

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
2. The centre has not validated its critical procurement and processing procedures. A verbal account of how the centre is satisfied that all processes are fit for purpose was given. However, this has not been documented as a formal process validation exercise. SLC T72.	The PR should provide a list of all procurement and processing procedures that are considered critical including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the time the PR responds to this report. The PR should provide monthly updates to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated	At a previous inspection the HFEA were satisfied that long established critical procurement and processing procedures had been validated by published studies, stable kpi's and process validation. Following advice from this inspection the PR will use the recommended template to retrospectively validate critical procurement and processing procedures. A list of the processes has been provided to the inspection team. Monthly updates will follow and the validation will be	The centre has submitted a list of procurement and processing procedures to be validated. The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	with the procedure and that validation will be complete by 9 April 2014. On completion of the validation programme the HFEA will ask for a sample of validation documents to be submitted for review.	completed by 9th April 2014.	
3. **Traceability** a. Two ICSI rigs are used in the laboratory, but the specific rig used for each ICSI case is not recorded. SLC T99.	a. The PR should ensure that all critical equipment coming into contact with gametes/embryos is recorded. Confirmation of this to be provided by the time the PR responds to this report.	a. The PR confirms that details of the ICSI rigs are now being recorded.	The lead inspector acknowledges the PR's response and awaits the risk assessment to be submitted for part c. by 9 January 2014.
b. An audit of five items of laboratory consumables and reagents was carried out on inspection. The batch number of one item did not match that recorded as in use on the	b. The inspection team is satisfied that this likely represents a one off error rather than a systems/process issue. The PR should investigate this error and implement any	b. The PR considers this is a one-off error and will continue with the planned regular traceability audit.	

centre's database. SLC T99. Traceability audits are performed regularly at the centre and the last audit performed identified no concerns.	appropriate corrective actions. It is recommended that the centre continues with its frequent traceability audits.		
c. At egg collection it was observed that the tubes and initial dishes used during egg collection are not labelled. The centre has assessed the risks of misidentification from not labelling these containers and identified corrective action that was implemented to further mitigate the risks. This action is to confirm that the egg collection hood is clear of all containers at the end of the procedure and record this as a witnessed step on the laboratory worksheet.	c. The PR should consider further mitigation of the risks of not labelling all containers used at the time of egg collection, including confirming that critical work areas in theatre are incorporated into the centre's witnessed check step. The HFEA should be informed of any further action taken to mitigate the risks of misidentification as a result of this practice by 9 January 2014.	c. The PR confirms that a further witnessing step has been added to the egg collection procedure and a further risk assessment will be submitted to the HFEA in due course.	

4. **Quality management system** The centre has not established formal QIs or objectives relevant to all licensed activities. SLC T35. The centre has not audited its counselling activities. SLC T36.	The PR should ensure that QIs are established and documented. Evidence of this should be submitted to the HFEA by 9 January 2014. The PR should ensure that counselling activities are audited and a copy of the report submitted to the HFEA by 9 January 2014. The PR should ensure counselling activities and the established QIs are added to the centre's audit schedule. A copy of this schedule to be submitted to the HFEA by 9 January 2014.	The quality team is reviewing and updating all documents relevant to licensed activities. Evidence will be submitted by 9th January 2014. An audit of counselling activities and established QI's is planned and has been added to the audit schedule. The PR confirms that this will be submitted to the HFEA by 9th January 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.
5. **Satellite centre arrangements** Three sets of satellite patient notes were audited and the following issues were identified in one set of notes: • The HFEA WT consent	The PR should ensure that appropriate patient consent is obtained by the satellite centre prior to treatment.	The PR acknowledges that one set of notes did not have the correct HFEA forms. The patients have been contacted to complete the correct forms	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

form completed by the patient in April 2013 was an old version of the consent form which was replaced in 2009. This refers to previous statutory requirements for the length of time that embryos can be stored. • The HFEA MT consent form completed by the partner in April 2013 was the correct version, but section 6 of the form had not been completed. This section documents the partner's wishes for the use of embryos in the event of his death or mental incapacity. The couple have five embryos in storage from their treatment cycle. • The female patient had not completed section 3.1 of the HFEA consent to disclosure form, recording the patient's consent to disclosure of information to certain groups of people.	The centre's new satellite partnership has recently been established and only three patients have been treated to date. However, as a result of this non-compliance the PR should consider the level of oversight given to satellite activities. It is recommended that an audit of satellite activities is performed and the audit report submitted to the HFEA by 9 January 2014. This audit should include the appropriate completion of the centre's checklist. The patient's notes reviewed documented that embryos remain in storage from their treatment cycle. The PR should attempt to contact the male partner to request that the MT consent form be appropriately completed to ensure his wishes for the future use of his embryos are clearly recorded. The PR should inform the HFEA when this has been achieved.	and the PR will inform the HFEA when this has been achieved. A nurse has been appointed to oversee satellite activities and an audit is planned towards the end of the year. Details of the outcome of the audit will be sent to the HFEA by 9th January 2014.	

The checklist used by centre 0033, to ensure consents are obtained prior to treatment was completed, with no issues documented for the three sets of notes. In all three sets of notes, the WoC assessment had not been completed by centre staff. Refer to recommendation 6.			
6. In seven of 13 patient records reviewed in the course of the inspection, the WoC assessment had not been signed off by a member of centre staff. WoC completion does form part of the centre's checklist to be completed prior to treatment. SLC T46 and T56. The centre has not audited completion of WoC assessments. SLC T36.	The PR should review procedures for assessing WoC. A summary report of the findings of the review including corrective actions and the timescale for implementation of the corrective actions should be submitted to the HFEA by 9 January 2014. This review should include the appropriate use of the centre's checklist to record that WoC assessments have been completed. Three months after the implementation of corrective actions, the centre should	A review is underway by the quality team and details will be sent to the HFEA by 9th January 2014. An audit of WoC assessments will be performed in the New Year and submitted by 9th April 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

	perform an audit of a random representative sample of patient records to ensure that these corrective actions are effective. This audit should be submitted to the HFEA by 9 April 2014.		

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
7. In four of seven sets of notes audited, patient screening tests were performed by a laboratory whose accreditation status could not be determined. Patients frequently attend the centre with the results of screening tests arranged by their GP. Centre staff expect GPs to be assured that only CPA accredited laboratories are used. SLC T51a.	The PR should ensure that all screening tests are carried out by laboratories which have suitable accreditation. The PR should review the centre's policy of assuming that GPs will use only CPA accredited laboratories to ensure that this is sufficiently robust to demonstrate compliance with SLC T51a. The outcome of this review and any corrective actions identified and implemented should be submitted to HFEA by 9 January 2014.	The PR confirms that this has been reviewed and patients are now informed that all screening results will be required prior to their consultation so that the laboratory can be checked for CPA accreditation.	The lead inspector acknowledges the PR's response. No further monitoring is required.
8. The centre's SOP for the provision of information to patients prior to obtaining consent, does not include information on consent to the use of embryos in staff training. SLC T33b.	The PR should review and revise the centre's provision of information SOP. A copy of this SOP to be submitted to the HFEA by 9 January 2014.	The PR confirms that the provision of information is currently being reviewed and the updated SOP will be provided to the HFEA.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

9. The notes of one couple, in a civil partnership and using donor sperm, reviewed on inspection did not include the HFEA PP consent form. Furthermore, the notes of three other couples who are married or in a civil partnership were reviewed and did include the HFEA PP consent form, demonstrating inconsistency in centre practice. SLC T60.	The PR should review procedures for obtaining consent to legal parenthood and ensure married couples or those in a civil partnership are given the opportunity to complete the HFEA PP form if they wish to be the legal parent of any child born from their partner's treatment after their death. A summary report of the review findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 9 January 2014.	The PR confirms that obtaining consent to legal parenthood is currently being reviewed and an audit of all patients this may apply to will be undertaken. A summary report of the review findings will be sent to the HFEA by 9th January 2014.	The lead inspector acknowledges the PR's response and this will be subject to on-going monitoring.

Response from the Person Responsible to this inspection report