HFEA Licence Committee Meeting

25 September 2014

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

Minutes – Item 2

Centre 0324 (City Fertility) – Treatment and Storage Renewal Licence Inspection Report

Members of the Committee: Andy Greenfield (lay) (Chair) David Archard (lay) Debbie Barber (professional) Jane Dibblin (lay)	Legal Adviser: Dawn Brathwaite, Mills & Reeve Committee Secretary: Sam Hartley, Head of Governance and Licensing

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

The following papers were considered by the Committee:

- Renewal inspection report
- Application for licence renewal
- Licensing minutes for the past three years:
    - Variation of Licence to Change Licence Holder (18 October 2013)
    - Initial inspection report (29 November 2012)

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) ('the Act')
- 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 Directions 0000 – 0012
- Guide to Licensing

- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Background

1. City Fertility (the centre) is situated in central London and has been licensed by the HFEA since November 2012, when an initial Treatment and Storage licence was granted for a period of two years. The centre provides a full range of licensed treatments. The Committee noted that the inspection team was satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

2. The centre provided 442 cycles of treatment (excluding partner intrauterine insemination) in the 12 months leading to 31 May 2014. In relation to activity levels this is a medium-sized centre. The centre's success rates are consistent with the national average, but its multiple clinical pregnancy rates are significantly above the current target.

3. An application to vary the centre's licence to reflect a change of Licence Holder (LH) from Mr Andrew Berkley to Mr Matej Stejskal was granted by an Executive Licensing Panel (ELP) on 18 October 2013.

Discussion

4. The Committee noted that, at the time of the inspection, the Inspectorate reported that there were a number of areas of practice that required improvement, including four critical, fourteen major and eight other areas of non-compliance.

5. The Committee noted that, since the inspection, recommendations relating to one critical, one major and three other non-compliances have been completed and that the PR is in the progress of, or has committed to, fully implementing the remaining recommendations.

6. The Committee noted the Inspectorate's observations that substantial improvement is required in order for the centre to provide practices that are suitable. The Committee shared the Inspectorate's concerns regarding the significant number of non-compliances found at the centre's first renewal inspection. In particular, the Committee noted that the inspectorate's initial recommendation was to have been to not renew the centre's licence. However, it further noted that, following a meeting held with the centre's PR, Licence Holder and Medical Director, the Inspectorate then considered that the centre had provided sufficient evidence of effective implementation of the four recommendations relating to the critical non-compliances, and a robust commitment to implement all other recommendations. This led the inspectorate to conclude that the PR is likely to discharge her duty under section 17(1)(d) of the Act.

7. The Committee noted the Inspectorate's recommendation to renew the centre's Treatment and Storage licence for a period of three years without

additional conditions, subject to the recommendations made in the renewal inspection report being implemented within the prescribed timescales.

Discussion

8. The Committee referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and noted that the executive had received the supporting information required by General Direction 0008.

9. The Committee noted that the PR's qualifications and experience comply with section 16(2)(c) of the Act. It further noted that the Inspectorate stated that the PR may not have fully discharged her duties under section 17 of the Act, but has implemented significant changes since the inspection and is now expected to meet this requirement.

10. The Committee was satisfied that the licence application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application. The Committee was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report except with regard to the recommendations outstanding which relate to the premises.

11. The Committee had serious concerns regarding the number and severity of the non-compliances found at inspection. It further had concerns that the multiple clinical pregnancy rates are significantly above the current target. It concurred with the Inspectorate that substantial improvement was required to provide practices that are suitable. The Committee deliberated whether renewal in these circumstances was appropriate. In the end, the Committee recognised the progress that the PR had made in addressing the non-compliances found at inspection, and her commitment to implementing the remaining recommendations in the timescales suggested. On balance, the Committee concluded that the PR is likely to discharge her duty under section 17(1)(d) of the Act.

12. The Committee referred to 'Guidance on periods for which new or renewed licences can be granted'. The Committee took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states '[The Licence Committee] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3'. The Committee noted that it retains the power and duty to take such action as it considers appropriate and necessary to ensure fairness in a particular matter. The Committee agreed that the significance of both the number and severity of the non-compliances at the centre was such that the granting of a licence for a shorter period than the usual four years would be a fair, reasonable and proportionate approach. Such an approach would require a full renewal inspection earlier than the usual four years, at which significant improvement would be expected.

Decision

13. In light of the number and type of non-compliances, and the 'Guidance on periods for which new of renewed licences can be granted', the Committee agreed to renew the centre's treatment and storage licence for a period of two years without additional conditions.

14. The Committee requested that the Inspectorate provide an update report on the centre's progress against all recommendations, in particular in relation to those requiring an audit to be carried out, and the status of any future Third Party Agreements entered into, at its meeting in March 2015. It further agreed with the Inspectorate's recommendation for an interim inspection to be conducted, but requested that the inspection is conducted within one year of today's meeting (i.e. by 24 August 2015), rather than within one year of the renewed licence taking effect, as recommended. This interim inspection should not replace the renewal inspection that will be due within two years.

Signed: Date: 06/10/2014

Andy Greenfield (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 Licence Committee 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.

Dates of inspection: 24 - 25 June and 3 July 2014

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 initial inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Parvez Qureshi, Sara Parlett, Gill Walsh, Cathy Hodgson, Rosetta Wotton and Rozlynn Lawrence (observing)

Date of Licence Committee: 25 September 2014

Centre name	City Fertility
Centre number	0324
Licence number	L/0324/1/b
Centre address	16, St John Street, London, EC1M 4NT
Person Responsible	Ms Jane Holman
Licence Holder	Mr Matej Stejskal
Date licence issued	29 November 2012
Licence expiry date	28 November 2014
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:
City Fertility is situated in central London and has been licensed by the HFEA since November 2012 when an initial Treatment and Storage licence was granted for a period of two years.

The centre offers a full range of licensed treatments to self funded patients and provided 442 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2014. In relation to activity levels this is a medium-sized centre.

Application to vary the centre's licence to reflect a change of Licence Holder (LH) from Mr Andrew Berkley to Mr Matej Stejskal was granted by an Executive Licensing Panel (ELP) on 18 October 2013.

Subsequent to the submission of an application to renew the centre's Treatment and Storage licence, the centre applied to vary their Treatment and Storage licence to include embryo testing at this licence renewal. The centre has now decided to withdraw the application to include embryo testing at this time and so this will not be considered as part of this report.

The centre has satellite in vitro fertilisation (IVF) agreements in place with four providers in London.

The centre is registered with the Care Quality Commission (CQC) for diagnostic and screening procedures, surgical procedures and the treatment of disease, disorder or injury. The centre was last inspected by the CQC in November 2013.

Pregnancy outcomes[1]

For IVF and intracytoplasmic sperm injection (ICSI), HFEA held register data for the period March 2013 to February 2014 show that the centre's success rates are in line with national averages.

In 2013, the centre reported 48 cycles of partner insemination with eight pregnancies, which is consistent with the national average.

Multiple births[2]

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

Between March 2013 and February 2014, the centre's multiple pregnancy rate for all IVF, ICSI and frozen embryo transfer (FET) cycles for all age groups was 27%. This represents performance that is likely to be greater than the 10% multiple live birth rate target for this period.

Please refer to the multiple births section of this report for further details.

[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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

[2]The HFEA uses 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), 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);
- the PR may not have fully discharged her duty under section 17 of the HF&E Act 1990 (as amended) but has implemented significant changes since the inspection to ensure that the conditions of the centre's licence will be complied with in the future and is therefore now expected to meet this requirement;
- the licenced premises are suitable, although it is noted that it could not be determined if the premises of all satellite centres' are suitable ;
- the centre's practices are considered likely to be suitable following the implementation of corrective actions as recommended in this report;
- the application contains the supporting information required by 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 Licence Committee is asked to note that at the time of the inspection there were a number of areas of practice that require improvement, including four critical, 14 major and eight 'other' areas of non-compliance.

Since the inspection, the PR has provided evidence that the following recommendations have been implemented:

Critical areas of non compliance:

- **The PR is to ensure that the premises and facilities are secure and that patient and donor information, medicines and other materials are not at risk of loss or harm.**

Major areas of non compliance:

- The PR should take immediate action to ensure that clinical waste is managed and medical gasses are stored appropriately.

'Other' areas that requires improvement:

- The PR should review the process by which she may be assured that donor compensation and benefits in kind are made to all donors in accordance with Directions 0001.
- The PR should review the process for submitting data to the HFEA to ensure that information is provided within the timescales required by Directions 0005.
- The PR should commission a patient / donor satisfaction survey.

The PR is in the progress of implementing, or has provided a commitment to implement, the following recommendations:

Critical areas of non compliance:

- **The PR should urgently review current practice and establish robust procedures to ensure that satellite IVF providers are fulfilling HFEA requirements and that the terms of the satellite agreements are being met.**
- **The PR is required to take immediate steps to ensure that all medicines are managed and stored appropriately.**
- **The PR should undertake an urgent review of processes and procedures relating to the surgical pathway to ensure good practices are demonstrated and that record keeping is complete and accurate.**

Major areas of non compliance:

- The PR should ensure that the disposal of eggs that are not used in treatment is witnessed with immediate effect. The PR should review witnessing practices in consideration of the requirements of SLC T71 and CoP Guidance 18.4j and 18.8b.
- The PR should ensure that prior to the use and/or storage of donor gametes, all of the laboratory tests required by SLC T52 are performed and within the timeframes set by the Authority.
- The PR should ensure that all patient and donor screening is conducted by a suitably accredited laboratory.
- The PR should ensure that gametes and embryos are processed in an environment of appropriate air quality.
- The PR should undertake an audit of the implementation and effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed treatment at the centre.
- The PR should ensure that staff are competent in all of the tasks that they perform.
- The PR should ensure that audits of the provision of information and donor screening procedures against compliance with the approved protocols, the regulatory requirements and quality indicators (QIs) are performed.
- The PR should ensure that wherever possible CE marked medical devices are used.
- The PR should ensure that all critical clinical and laboratory processing procedures are validated.
- The PR should take immediate action to ensure that all incidents are reported to the HFEA; are thoroughly investigated; and also that patients should be informed as necessary. Relevant incidents should be reported to the HFEA retrospectively.
- The PR should develop a documented standard operating procedure (SOP) and patient information for the use of embryos in staff training.
- The PR should ensure effective consent to legal parenthood is obtained where applicable before treatment is provided.
- The PR should conduct a review of the process for completing medical records to ensure that the justification for treatment is documented appropriately.

'Other' areas that requires improvement:

- The PR should review the process for assessing Welfare of the Child (WoC) and completion of the supporting documentation to ensure that all couples are suitably assessed and that a review of the assessment is documented prior to licensed treatment being provided.
- The PR should ensure that, prospectively, written confirmation to satisfy all points of l Directions 0006 is obtained prior to the import/export of any sample.
- The PR should ensure that all third party agreements (TPAs) are reviewed within the specified timeframe.

- The PR should review the process for the provision of information to be provided to donor egg recipients to ensure that where treatment is offered with previously frozen donor eggs, the recipient is fully informed of all factors regarding this treatment and the centre's current post thaw survival rates.
- The PR should review process for seeking consent to disclosure from donors to ensure the consent to disclosure decision is recorded in the donor records and that decision is provided to the HFEA for inclusion on the HFEA Register.

Recommendation to the Licence Committee

The inspection team notes that the centre's success rates are consistent with the national average and that the centre's multiple clinical pregnancy rates are significantly above the current target.

Substantial improvement is required in order for the centre to provide practices that are suitable. The inspection team had significant concerns regarding the high level of non-compliance found at this, the first, licence renewal inspection. As a consequence, management review meetings were held on 30 June 2014 and 5 August 2014 in accordance with paragraph 4.6 of the HFEA's compliance and enforcement policy. It was concluded that there may be an on-going risk to patients in relation to the four critical areas of non-compliance referenced above. In accordance with paragraph 4.4 of the HFEA's compliance and enforcement policy it was agreed that formal action was warranted.

On the basis of the evidence presented in this report and in light of the concerns highlighted above, the Executive was not satisfied that the PR had discharged her duty under section 17(1)(d) of the HF&E Act 1990 (as amended) to secure that the centre's practices in relation to the four critical areas of non-compliance referenced here were suitable.

On the basis of the evidence presented in this report, and following a management review, the recommendation in the report sent to the PR was that the centre's licence should not be renewed.

Following receipt of the report, a meeting was held between the HFEA and the centre's PR, Licence Holder and Medical Director. This provided an opportunity for clarification of HFEA expectations and requirements. Subsequent to this, the PR provided a response to this report and accompanying evidence.

The Executive has considered the evidence provided by the PR in responding to this report. It is considered that the centre has provided the following:

- evidence of effective implementation of the recommendations relating to the four critical areas of non-compliances; and
- a robust commitment to the implementation of the other recommendations.

The Executive is now satisfied that the PR is likely to discharge her duty under section 17(1)(d) of the HF&E Act 1990 (as amended) to secure that the centre's practices in relation to the four critical areas of non-compliance referenced here are suitable.

The Executive considers that based on the evidence provided, a new recommendation is warranted. The Executive recommends the renewal of the centre's 'Treatment and Storage' Licence for a period of three years, rather than the standard four years, subject to the recommendations made in the renewal inspection report being implemented

within the prescribed timescales. Failure to implement the recommendations may result in the submission of a further report to the Executive Licensing Panel or Licence Committee with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The Executive also recommends that the Licence Committee requests a focused interim inspection be performed within a year of the licence renewal date

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

What the centre could do better

Witnessing (Guidance note 18)
The disposal of oocytes that are not used in treatment is not witnessed (standard licence condition (SLC) T71 and CoP Guidance 18.4j).

On occasion, the centre's standard procedure for witnessing at egg collection is modified when there are a large number of egg collection tubes to process and a dedicated witness is not available. At the time of transfer of follicular fluid from tube to petri-dish, the identifying details on both containers are read out loud by the practitioner to another embryologist performing duties elsewhere in the laboratory. They then verbally confirm the match without having observed the labelling themselves or recording the witness step at the time of the procedure. The inspection team does not consider that this fully complies with the requirements for double checking (SLC T71).

An audit of witnessing records demonstrated that the time witnessing is performed in theatre (active identification of the patient prior to egg collection/embryo transfer and labelling of egg collection tubes) is not always recorded (CoP Guidance 18.8b) (see recommendation 5).

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 procedures for screening donors are partially 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 procedures are broadly 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 procedures are compliant with HFEA requirements to ensure the donor conceived will be able to receive this information.

What the centre could do better

Screening of donors (Guidance note 11)
An audit of four sets of egg sharer notes was performed on inspection. A record of screening for syphilis could not be found for one donor (SLC T52b). The centre uses a satellite checklist to ensure screening is in place prior to treatment, but this checklist was also absent. All other laboratory screening tests for this egg sharer were performed in October 2013, but the egg collection was not performed until May 2014 (SLC T53b) (see recommendation 6).

Payments for donors (Guidance note 13; Directions 0001)
Where donors or egg sharers are recruited by the satellite clinics, the PR could not demonstrate or provide assurance that where compensation is made or a benefit in kind provided, this is compliant with Direction 0001 (see recommendation 19).

Refer also to the 'import and export' section of this inspection report and recommendation 21.

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; however please see below regarding security. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose. CQC inspected the premises of one of the centre's satellite providers (The Fertility and Gynaecology Academy) in January 2014 and considered the premises and facilities to be suitable. The HFEA inspected the premises of one other satellite provider (Harley Street Fertility Clinic) in June 2014 as part of the initial licensing process and considered the premises and facilities to be suitable.

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

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

Laboratory accreditation (Guidance note 25)
The centre's 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, with an exception detailed below. This is important to assure the quality of the services provided.

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

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

Pre-operative assessment and the surgical pathway
The centre has policies and procedures in place that are partially compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. 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 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 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, the centre keeps 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 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;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note 15)
The centre's procedures for the receipt of gametes and embryos are partially 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 procedures for import and export of gametes and embryos are broadly compliant with HFEA requirements.

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 and embryos during any step from procurement to use for human application or disposal;

- 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; and
- 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 partially 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 broadly compliant with HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are compliant with HFEA requirements, with an exception detailed below. 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 partially 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 procedures for reporting adverse incidents are partially compliant with HFEA requirements. The centre reports some adverse incidents (including serious adverse events and reactions) to the HFEA. The centre has investigated incidents that have occurred but no evidence of investigation of 'near miss' events identified on inspection was apparent. 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 (Guidance note 25)
The air quality of the centre's class II cabinets is monitored on an annual basis and meets the requirements of SLC T20. The background air quality in the laboratory, where ICSI is performed, has not been monitored for approximately 18 months. The centre's documented procedure states that air quality is monitored quarterly (see recommendation 9).

At the time of inspections, observations made by inspectors over several days showed that a door opening on to the courtyard adjoining the centre's premises was not secure. Despite this being brought to the attention of the PR and General Manager, this door was left open by staff accessing the courtyard on numerous occasions. It was also directly

observed by a member of the inspection team that access to this courtyard (and consequently the centre) could be gained by individuals from the adjoining commercial premises which are unrelated to the licensed premises. Anyone accessing the centre via the courtyard would be able to gain access to the administration office (which was unmanned at times during the inspection); unlocked cabinets in which medical records were held; and a medicines fridge containing anaesthetic and other drugs. The inspection team considered this to be a critical risk to the security of the centre and the safeguarding of confidential information and the safe management of medicines and made immediate recommendations for improvement (SLC T2, T17 and T43) (see recommendation 1).

A tour of the centre's premises showed that medical gases in the courtyard area were not stored within a secure enclosure and that the large clinical waste storage hopper was not locked. These were therefore potentially accessible by individuals from the adjoining commercial premises (SLC T17 and T2) (see recommendation 7).

Transport and satellite agreements (Guidance note 24; Direction 0010)

The centre had satellite agreements in place with four satellite treatment providers. The centre's systems for managing their satellite arrangements were not compliant with HFEA requirements. The PR could not provide assurance regarding the suitability of the premises for satellite IVF providers (SLC T17) (see recommendation 2).

Laboratory accreditation (Guidance note 25)

The centre uses a Clinical Pathology Accreditation (CPA) accredited laboratory for screening initiated by the centre. However, in two of five sets of patient notes reviewed on inspection, screening results were present from a laboratory that centre staff could not confirm was suitably accredited (SLC T21). It was also noted in egg donor / sharer notes reviewed, where donor screening is performed away from the primary centre, , the PR could not provide assurance in all cases that the testing laboratory was suitable (SLC T52) (see recommendation 8).

Multiple births (Guidance note 7; Direction 0003)

The centre is unlikely to meet the current multiple birth rate target and was issued with two HFEA risk tool alerts regarding this in February and March 2014, there has been no sustained reduction in their multiple clinical pregnancy rates since that time.

Discussions with the PR and laboratory team showed that the centre is not applying their multiple birth minimisation strategy or implementing their agreed elective single embryo transfer (eSET) criteria across all patient groups who meet the criteria for eSET, notably for patients treated as part of satellite agreements (Direction 0003) (see recommendation 10).

Receipt of gametes and embryos (Guidance note 15)

Prior to receiving eggs or embryos from another centre, patients sign an 'agreement for transport' form. This form includes the statement "We understand that in the case of importing oocytes/embryos, they can be cryopreserved or vitrified with different media and/or devices than those used by City Fertility and therefore the embryologist team at City Fertility may not be fully trained". Centre staff explained that this statement was added because when satellite clinicians request such a transfer for their patients, the embryologists are not given the opportunity to advise patients against transport if they are not confident of their competence in the procedure to use for subsequent processing. The inspection team does not consider this to be a suitable practice (SLC T2 and T12) (see recommendation 11).

Imports and exports (Guidance note 16; General Directions 0006)
The centre has imported gametes since their licence was granted. General Directions 0006 sets out the requirements under which a centre may import gametes from within the European Economic Area (EEA) and Gibraltar and requires that written confirmation is obtained that the supplying centre meets these requirements before import. The centre could not provide written confirmation to demonstrate compliance with the following requirements for one set of donor sperm imported from Denmark:

- evidence of accreditation of the donor bank in Denmark;
- that no money or other benefits had been given or received in respect of the supply of the gametes unless the money or benefit received is in accordance with Directions 0001 (General Directions 0006; Schedule 1; 1(a) and e) (see recommendation 21).

Quality management system (QMS) (Guidance note 23)
The centre has not audited provision of information and donor screening procedures provided by the centre or satellite IVF providers against compliance with the approved protocols, the regulatory requirements and quality indicators (QIs) in the last two years (SLC T36) (see recommendation 12).

Third party agreements (Guidance note 24)
An audit of five third party agreements showed that only three had been reviewed within the specified timeframe (SLC T116) (see recommendation 22).

Transport and satellite agreements (Guidance note 24; Direction 0010)
It became apparent during the course of the inspection that the patient or donor pathway provided by the satellite IVF providers is not being effectively managed or monitored by the primary centre. The centre could not adequately demonstrate that all activities performed by satellite centres on behalf of the licensed centre are suitable and meet HFEA requirements.

The centre was not able to provide evidence of the process by which the satellite centres were meeting the terms of their satellite agreement and HFEA requirements in respect of the following:

- monitoring of patients;
- offer and provision of counselling;
- provision of information prior to providing consent to treatment and / storage, donation, treatment with donor gametes or embryos, treatment requiring surrogacy or legal parenthood;
- seeking consent to treatment, storage or donation;
- screening of patients or donors by a suitably accredited laboratory within the time frames specified by the Authority.

The centre has not audited the activities performed by their satellite centres on behalf of the licensed centre against compliance with the regulatory requirements and their own approved protocols and QIs since this licence was granted (Directions 0010 and SLC T53 and T36) (see recommendation 2)

Equipment and materials (Guidance note 26)
The vitrification kit used in the laboratory is not CE marked. However, the laboratory manager provided a risk assessment to demonstrate why centre staff consider it suitable for use. A new incubator in use in the laboratory is not CE marked. The laboratory

manager explained that the manufacturer has confirmed that CE approval is in process for this equipment (SLC T30) (see recommendation 13).

Process validation (Guidance note 15)
Discussions with staff and a review of documentation available showed that the centre could not provide documented evidence of validation of clinical processes employed at the centre by either the primary or satellite centre clinicians (SLC T72). It was also noted that clinical processes employed by the primary centre clinicians and the satellite centre clinicians were different from each other so comparative assessment of outcomes is difficult. For example, at egg collection, satellite centre clinicians routinely perform extensive follicular flushing. This is not a standard procedure used by the primary centre clinicians (see recommendation 14).

The treatment pathway for one satellite IVF provider directs that the centre's embryology laboratory use a new technique for selecting sperm (PICSI) for ICSI for his patients. This process has been in use at the centre for this group of patients since October 2013 but has not been validated (SLC T72) (see recommendation 14).

Process validation documents were available for all other laboratory processes, but these did not reference specific published studies or retrospective evaluation of the centre's own results (SLC T72) (see recommendation 14).

Adverse incidents (Guidance note 27)
The centre has reported two adverse incidents to the HFEA since this licence was granted. However, a review of the centre's own incident log showed that a number of incidents pertinent to the HFEA had not been reported. Closer examination showed that four significant 'near miss' events were not logged on the centre's own incident reporting system until such time as a further incident directly related to the near miss events occurred. This incident may have resulted in the loss of oocytes. The inspection team could not determine whether the patient affected by the incident had been informed of the incident (SLC T118 and Directions 0011).

The centre's adverse incident reporting SOP was out of date (SLC T33(b) see recommendation 15).

Medicines management
Practice observed and a review of records on inspection showed;

- incomplete patient records of the prescription and administration of drugs used during egg collection;
- the controlled drug register does not record the dose of drug used, only the number of ampoules dispensed, or record the witnessed wastage of any unused portion of the ampoule dispensed;
- the controlled drug register showed that the standard controlled drugs stock check was being performed by two unqualified members of staff together;
- some medicines (for intravenous and oral administration) held in the procedure room are stored in a cupboard for which there is no lock;
- a medicines fridge in the PR's office was unlocked;
- there is no mechanism in place to account for drugs removed from stock cupboards held in the procedure room. Drugs are 'topped up' but no routine stock levels or accounting mechanism has been established or stock control audit performed.

(SLC T2 see recommendation 3).

Pre-operative assessment and the surgical pathway

Practice observed during egg collection and a review of patient records on inspection showed;

- apparently incomplete or inaccurate records of patient monitoring during conscious sedation;
- the record of drugs prescribed and administered during egg collection was incomplete;
- in one set of records reviewed, the record of monitoring and drug administration during the procedure was illegible;
- neither the name or contact details of the anaesthetist conducting the conscious sedation was recorded in the patient record;
- there was potential for the clinician conducting the egg collection to have been distracted as his mobile phone rang (but was not answered) on three occasions during the procedure;
- while consulting with the patient post operatively it was noted that the clinician was again interrupted by a call on his mobile phone.

(SLC T2, T44(c) and T47) (see recommendation 4).

Staff engaged in licensed activity

Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has academic qualifications in the field of nursing and 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/1218/8).

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

What the centre could do better

Person Responsible (Guidance note 1)
At the time of the inspection, the PR had only partially complied with HFEA requirements to fulfil her duty under section 17 of the HF&E Act 1990 (as amended) as described in the body of this report.

Staff (Guidance note 2)
Where gametes or embryos are transferred from other licensed centres, staff were unable to provide evidence for training and experience relating to certain thawing techniques. Please refer to ‘receipt of gametes and embryos’ section of this report (SLC T15 (a,b)) (see recommendation 11).

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 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 broadly compliant with HFEA requirements.

Safeguarding
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

Welfare of the child (Guidance notes 8)
An audit of ten patient and partner records conducted on inspection showed an error in one of the WoC forms reviewed. A field requiring completion by centre staff indicating the WoC had been assessed was incomplete (SLC T56) and CoP guidance 8.18 (see recommendation 20).

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 perform embryo testing and therefore this area of practice is not applicable to this inspection.

What the centre could do better

Not applicable to this inspection.

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit the inspectors spoke to two patients and their partners who provided feedback on their experiences. A further two patients also provided feedback directly to the HFEA in the time since the last inspection.

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

- provides patients with satisfactory facilities for their care.

What the centre could do better

The centre has not sought patient feedback on their satisfaction with the care provided to date (see recommendation 26).

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 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.

Counselling (Guidance note 3)
The centre's counselling procedures are partially 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. Please refer to the section of this report on satellite arrangements.

Egg sharing arrangements (Guidance note 12; Directions 0001)
The centre's procedures for egg sharing arrangements are partially 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; and
- 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 partially compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment.

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. Please see section above on patient feedback.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are partially 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

Egg sharing arrangements (Guidance note 12; Directions 0001)
Treatment involving egg sharing arrangements is provided to satellite IVF patients only. The PR could not provide assurance regarding the process followed, information provided or the offer of counselling by the satellite centres prior to treatment or whether any benefit in kind made to the egg sharer was provide in compliance with Directions 0001 (see recommendation 2 and 19).

Surrogacy (Guidance note 14)
Treatment involving surrogacy is provided to satellite IVF patients only. The PR could not provide assurance regarding the process followed, information provided or the offer of counselling made by the satellite centres prior to treatment for either the surrogate or intended parents (see recommendation 2).

Confidentiality and privacy (Guidance note 30)
Failings in the centre's security arrangements pose a risk that confidential identifying information could be disclosed although it is noted that the inspection team did not see evidence of any disclosure and are not aware of any breaches of confidentiality as a result of poor security (SLC T43) (see recommendation 1).

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to patients and donors are partially 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

Information (Guidance note 4; CH(11)02)
It was noted in the records of some egg donors recruited by a satellite centre that where a

recipient 'match' is not immediately available to use the eggs at the time of donation, the eggs may be frozen until such time as the recipient is ready to be treated. Two sets of records for satellite patients who had received treatment using frozen donated eggs were reviewed on inspection. It was not clear from the records whether the recipients were aware that frozen eggs would be used in their treatment. It could not be determined what information had been provided by the satellite centre to the recipients about the use of frozen donated eggs in their treatment. Information available at the primary centre regarding egg freezing relates to freezing the patient's own eggs for future use and so is not relevant to women considering treatment with frozen donor eggs.

It was also noted that this patient information states that a survival rate of 90% post warming (thawing) is achieved, however this is not the current survival rate for the primary centre (see recommendation 23).

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 partially 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 procedures for taking consent to disclosure to researchers are broadly 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 assisted reproductive technology (ART) and those born following ART treatment.

What the centre could do better

Consent (Guidance note 5; 6)
The centre's own audit of consent to legal parenthood conducted in accordance with Chief Executives letter (CE (14) 01) showed anomalies in the consent to legal parenthood provided by one couple (see recommendation 17).

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
An audit of patient / partner and donor consent to disclosure records held by the centre against the consent to disclosure decision submitted to the HFEA register showed that in three of seven donor records reviewed a consent to disclosure decision was not present in the donor records and no consent decision had been provided to the HFEA register. This has been a requirement for donors since August 2012 (Chair's letter CH (10)05) and Direction 0007) (see recommendation 24).

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; and
- 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 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 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 embryos.

Storage of gametes and embryos (Guidance note 17)
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. 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 procedures for using embryos for training staff are partially 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

There is no SOP for using embryos in training, including procedures in place to avoid any perceived conflict of interest (SLC T95).

Patient information covering the requirements of SLC T97 is not provided to patients when they are considering whether to consent to the use of their embryos in training (see recommendation 16).

5. Information management

Record keeping
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 partially 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; Directions 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are broadly 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.

The HFEA register audit team found some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
A review of medical records on inspection showed that in a number of instances there was no documented 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 (SLC T46(d)) (see recommendation 18).

Obligations and reporting requirements (Guidance note 32; Directions 0005)
A comparative audit of records held by the centre and treatment information provided to the HFEA showed that:

- 2% (2/132) of the IVF treatments reviewed at inspection had not been reported to the HFEA as required by Directions 0005; and
- 68% (89/132) of IVF and 92% (11/12) of the DI treatments reviewed at inspection had not been reported to the HFEA within the timeframe required by Directions 0005.

A number of issues with the submission of donor information were identified although these appear to be related to the IT system in use. Where identified, details have been provided to the centre for correction (SLC T9I, T41and Directions 0005) (see recommendation 25).

Section 3: Monitoring of the centre's performance

Following the initial licence inspection in 2012, recommendations for improvement were made in relation to one area of critical non-compliance, two areas of major non-compliance and one 'other' area 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

The centre received two HFEA risk based alerts relating to multiple pregnancy rates in February and March 2014. Refer to the multiple births section of this report for further details.

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. Suitability of premises and facilities At the time of inspection, observations made by inspectors over several days showed that a door opening on to the courtyard adjoining the centre's premises was not secure. This was considered to present a risk that persons other than centre staff could gain access to the centre, specifically to cabinets in which patient and donor records are held and a medicines fridge on the ground floor. SLC T9(b) & T17.	The PR is to ensure that the premises and facilities are secure and that patient and donor information, medicines and other materials are not at risk of harm or loss. The PR was required to review security measures and the control of access to and from the courtyard area immediately. The implementation of this recommendation was checked by a further on site visit on 27 June 2014 when the door was again noted to be open and again on 30 June 2014 when the door was observed to be secure,	PR has ensured that all premises and facilities are secured. With immediate effect post inspection the door to the courtyard was labelled to be locked at all times. Security measures were reviewed. The clinic is alarmed out of hours. Patient notes are filed only in administration office and locked at the end of each day. The medicinal fridge is now located on the first floor kept locked and within a cash	The Executive has reviewed the documents provided and acknowledges the PR's actions to implement this recommendation. No further action is required.

The PR provided assurance on the final day of inspection that this area is secure and that access to and from the courtyard is now properly controlled.	The PR should provide a summary report of the actions taken to ensure that access and egress via the side door into the courtyard is controlled at all times to ensure the centre, property and personnel are safe. This report should be provided to the centre's inspector when responding to this inspection report.	office locked at the end of the working day. Non refrigerated medicines are stored in a cupboard in the same room. Medicines stored in the theatre now are within a locked cabinet. Attached: 1) Summary report of the actions taken	
2. Satellite IVF provider activities The PR was not able to provide evidence of the process by which the satellite centres are meeting the terms of their satellite agreement and HFEA requirements in respect of the following: • monitoring of patients; • offer and provision of counselling; • provision of information to be provided prior to providing consent to treatment and / storage, donation, treatment with donor gametes or embryos, treatment requiring surrogacy or legal parenthood; • seeking consent to treatment, storage or	The PR should urgently review current practice and establish robust procedures to ensure that satellite IVF providers are fulfilling HFEA requirements and that the terms of the satellite agreements are being met. The PR should provide a summary report of the procedures to be employed to the centre's inspector when responding to this inspection report. The PR should also provide an action plan, including timescales documenting how satellite centres monitoring is to be implemented and a monthly update on progress in implementing the action plan. The PR should provide the centre's inspector with a schedule documenting the anticipated timescale for completion of these audits by the time	Activity with all Satellites addressed with immediate effect post inspection centre inspector informed. PR and Licence holder reviewed the performance of all satellites and their contracts. As a result all TPA's with satellite were terminated on the 20/8/2014. Contract with HSFC was terminated by City Fertility with immediate effect on 18.8.2014. City Fertility will not work with Satellite centres once all contracts terminated to ensure that the company is fulfilling HFEA requirements. HFEA will be informed about the end of the notice period. As all Satellites centres are terminated PR provides only Summary report of the procedures and action plan	The PR has provided evidence that the agreements with current satellite clinics have been terminated subject to a short notice period. The PR has also provided a basic plan as to how these satellite arrangements are to be managed during this time until the final agreement ceases to be effective on 20 November 2014. The Executive acknowledges the PR's response to this recommendation and further recommends that, in addition to the requirements of Direction 0010 being

donation and legal parenthood; • screening of patients or donors by a suitably accredited laboratory • screening within the time frames specified by the Authority. The centre has not audited the activities performed by their satellite centres on behalf of the licensed centre against compliance with the regulatory requirements and their own approved protocols and QIs since this licence was granted. (Direction 0010 and the Act, schedule 3 S.3 (1)(b) SLC T53(a,b) and T36) The premises of the centre's satellite facilities have not been assessed by the PR. The PR could not provide assurance regarding the suitability of the premises for two satellite IVF providers (SLC T17)	the PR responds to this report and thereafter provide a monthly update on progress and summary of audit findings to date. The PR should provide the centre's inspector with a summary of how she is to determine the suitability of the satellite provider's premises and facilities to provide satellite IVF by 3 October 2014.	for Satellites monitoring in the notice period. Attached: 2) Summary report of the procedures and action plan 3) Termination of the contracts	met, prior to any new satellite or transport agreements being considered by the centre, the PR provides the Executive with robust evidence as to how the proposed satellite or transport agreements are to be managed by the centre to ensure that going forward, all elements of the satellite or transport patient / donor pathway is complaint with HFEA requirements. No immediate further action required.
3. Medicines management Practice observed and a review of records on inspection showed; • incomplete patient records of the prescription and	The PR is required to take immediate steps to ensure that all medicines are managed and stored appropriately. The PR should conduct an urgent	PR took immediate steps to ensure that all medicines are managed. Medicines management policy was amended. All anaesthetists	The Executive has reviewed the documents provided by the PR and acknowledges the PR's action to implement this

administration of drugs used during egg collection; • the controlled drug register does not record the dose of drug used, only the number of ampoules dispensed or record the witnessed wastage of any unused portion of the ampoule dispensed; • the controlled drug register showed that the standard controlled drugs stock check was being performed by two unqualified members of staff together; • some medicines (for intravenous and oral administration) held in the procedure room are stored in a cupboard for which there is no lock; • a medicines fridge in the PR's office was unlocked; • there is no mechanism in place to account for drugs removed from stock cupboards held in the procedure room. Drugs are 'topped up' but no routine stock levels or accounting mechanism has been established or stock control audit performed. SLC T2	review of the implementation of the centre's medicines management policy and the assessment of competence of staff fulfilling medicines management tasks. The PR should review procedures in place for the storage of medicines within the centre to ensure all medicines are accounted for and are held securely and that when not in immediate use all storage, including medicines fridges, are locked. The PR should provide a copy of the outcome of that review and detail of actions implemented to ensure compliance with Home Office and other medicines management guidance to the centre's inspector when responding to this inspection report. Three months after the implementation of any actions, the centre's Accountable Officer should conduct a comprehensive audit of controlled drugs management, the outcome of which should be provided to the centre's inspector.	check CD's used. Disposal of medicines not used in theatre to be witnessed and documented. We have introduced new bar code system for drug evidence with inventory each working day in addition to a physical check on a daily basis. Audit of controlled drugs management should be forwarded to the inspector by 30.11.2014. Attached: 4) Review of the procedures for storage of medicines and centres Medicines management policy 5) The amended Medicines management policy	recommendation. The outcome of the planned audit is awaited. Further action required.

4. Preoperative assessment and the surgical pathway Practice observed during egg collection and a review of patient records on inspection showed; • incomplete or inaccurate records of patient monitoring during conscious sedation; • the record of drugs prescribed and administer during egg collection was incomplete • in one set of records reviewed, the record of monitoring and drug administration during the procedure was illegible; • neither the name or contact details of the anaesthetist conducting the conscious sedation was recorded in the patient record; • there was potential for the clinician conducting the egg collection to have been distracted as his mobile phone rang (but was not answered) on three occasions during the procedure; • while consulting with the	The PR should undertake an urgent review of processes and procedures relating to the surgical pathway to ensure good practice are demonstrated and record keeping is complete and accurate. The PR should provide a copy of this review including any actions to be implemented and the timescale for their implementation to the centre's inspector when responding to this inspection report. In order to demonstrate whether any actions have been effective, three months after the implementation of any actions, the PR is to conduct an audit of practice and documentation for patients undergoing operative procedures requiring sedation. The outcome of that audit and any further actions implemented should be provided to the centre's inspector by 3 December 2014.	PR undertook review of processes and procedures relating to surgical pathway. SOP for vaginal egg collection has been amended. The immediate measures have been taken. Audit of practice and documentation for patients should be forwarded to the inspector by 30.11.2014. Attached: 6) Review of the processes relating to surgical Pathway 7) Review meeting with anaesthetist providing anaesthesia during egg collection at the time of the inspection 8) The amended SOP for vaginal egg collection CLINNSOP01	The Executive has reviewed the documents provided by the PR and acknowledges the PR's action to implement this recommendation. The outcome of the planned audit is awaited. Further action required.

patient post operatively it was noted that the clinician was again interrupted by a call on his mobile phone, which on this occasion he took. (SLC T2, T44(c) and T47)			

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
5. Witnessing The disposal of eggs that are not used in treatment is not witnessed. SLC T71 and CoP Guidance 18.4j.	The PR should ensure that the disposal of eggs that are not used in treatment is witnessed with immediate effect. The centre's inspector should be advised of the action taken in respect to this recommendation when responding to this report.	The disposal of eggs not used in treatment and embryos not suitable for treatment are witnessed since the inspection. The witnessing procedure at the egg collection has been modified since the inspection too, all tubes being checked by 2 embryologists.	The Executive has reviewed the documents provided by the PR and acknowledges the PR's action to implement this recommendation. The outcome of the planned audit is awaited.
On occasion, the centre's standard procedure for witnessing at egg collection is modified. At the time of transfer of follicular fluid from tube to petri-dish, the identifying details on both containers is read out loud by the practitioner to another embryologist elsewhere in the laboratory. They will then verbally confirm the match without having observed the labelling	The PR should review witnessing practices in consideration of the requirements of SLC T71 and CoP Guidance 18.4j and 18.8b. The PR should report any changes made to the centre's witnessing procedures when responding to this report. Three months after implementing changes to practice the PR should undertake an audit of witnessing to	The pertinent SOPs (LABSOP17 Disposal of Human Eggs, Sperm and Embryos) and LABSOP09 (Witnessing) have been amended, as well as the witnessing sheet (LABFORM11 IVF/ICSI witness sheet). Audit should be forwarded to the inspector by	Further action required.

themselves or recording the witnessing step at the time of the procedure. The inspection team does not consider that this fully complies with the requirements for double checking. (SLC T71). An audit of witnessing records demonstrated that the time of witness steps performed in theatre (active identification of the patient prior to egg collection/embryo transfer and labelling of egg collection tubes) is not always recorded. At the disposal of embryos not suitable for treatment or storage was not documented (CoP Guidance 18.8b).	demonstrate whether the actions taken have been effective. A summary of this audit should be provided to the centre's inspector.	30.12.2014. Attached: 9) Amended SOP LABSOP17 10) Amended SOP LABSOP09 11) LABFORM11 IVF/ICSI witness sheet	
6. Donor screening An audit of four sets of egg sharer notes showed screening for syphilis could not be found for one donor. The centre uses a checklist for satellite patients to ensure screening is in place prior to treatment, but this checklist was also absent SLC T52b. It was also noted that the laboratory screening tests for this egg sharer were performed in	The PR should ensure that prior to the use and/or storage of donor gametes, all of the laboratory tests required by SLC T52 are performed and within the timeframes set by the Authority. The PR should review the process for screening donors. A summary of this review and detail of any actions implemented as a result of this review should be provided to the centre's inspector by 3 October 2014.	PR ensured that prior the use or storage of donor gametes all the test required are performed within the timeframes. SOP for screening and for donors amended. Satellites have been updated. Missing Syphilis screening result obtained by Satellite clinic, notes updates and result filed. Audit of random representative sample of	The Executive has reviewed the documents provided by the PR and acknowledges the PR's actions to implement this recommendation. The outcome of the planned audit is awaited. Further action

October 2013 however the egg collection was not performed until May 2014. This indicates that donor screening was not performed within the timescales specified by the Authority. SLC T53b.	The PR should inform the centre's inspector of the actions taken regarding the lack of syphilis screening for this particular donor when responding to this report. The PR should perform an audit of a representative sample of donor records and provide a summary of the audit to the centre's inspector by 3 October 2014. This audit should also include, if non-compliances are found, where effected donor samples have been used in the treatment of others. 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 provided to the centre's inspector by 3 February 2015.	donor records should be forwarded to the inspector by 3.2.2015. Attached: 12) Amended SOP for Donors CLINSOP2(OD Protocol) 13) Audit of a representative samples of donor records	required.
7. Suitability of premises and facilities A tour of the centre's premises showed that medical gases stored in the courtyard area were not retained within a secure enclosure and that the large clinical waste storage hopper was not locked. These were therefore potentially	The PR should take immediate action to ensure that clinical waste is managed and medical gasses are stored appropriately. When responding to this report, the PR should advise what actions have been taken to ensure that medical gases are being stored safely in accordance with guidance and that clinical waste is	PR ensured that the clinical waste and medical gasses are stored appropriately. Policy for Waste management was reviewed. Clinical waste receptacle in the courtyard locked. Keys are kept in the keys cabinet separately and all staff and cleaners instructed on a	The Executive has reviewed the documents provided by the PR and acknowledges the PR's actions to implement this recommendation.

accessible by individuals from the adjoining commercial premises SLC T2 and T17	stored securely.	special meeting. Designed member of the team to control every day. We have installed secure cage for medical gasses stored in the courtyard. The liquid nitrogen dewar will remain in the lab when not being used to refill gases. Attached: 14) Photo documentation of the gases store.	No further action required.
8. Laboratory accreditation The centre uses a CPA accredited laboratory for screening initiated by the centre. However, in two of five sets of patient notes reviewed on inspection, screening results were present from a laboratory that centre staff could not confirm was suitably accredited (SLC T21). It was also noted in egg donor / sharer notes reviewed, where donor screening is performed away from the primary centre, unless the results presented clearly indicated that the screening was performed by a suitably accredited laboratory, the PR could not provide assurance that the testing	The PR should ensure that all patient and donor screening is conducted by a suitably accredited laboratory. The PR should conduct a review of the mechanism in place for assessing the suitability of screening results provided by laboratories other than that used by the centre to ensure that the provenance of all screening tests is known by the primary centre prior to treatment or donation taking place. The outcome of this review and any actions implemented should be provided to the centre's inspector by 3 October 2014. Three months after the implementation of any changes, the PR should conduct an audit of patient / donor records to ensure that corrective actions have	A process of checking for the CPA website for confirmation of accreditation implemented. Protocol for STI´s screening CLINSOP022 amended. All patient screening and diagnostic test result must be performed by accredited laboratories. All results will be checked against the CPA website by member of staff when results are received. Patients shall be provided with a list of UK CPA accredited labs for bloods processing in case of a problem bloods will be done in house and proceeded by accredited laboratory. Audit of patient / donor records to ensure that	The Executive has reviewed the documents provided by the PR and acknowledges the PR's actions and commitment to implement this recommendation. The outcome of the planned audit is awaited. Further action required.

laboratory was suitable (SLC T52)	been effective. The PR is to provide a summary of the audit to the centre's inspector by 3 February 2015.	corrective actions have been effective should be forwarded to the inspector by 3.2.2015. Attached: 15) Amended protocol for STI´s screening CLINSOP022	
9. Procurement and processing of gametes and embryos The air quality in the centre's class II cabinets is monitored on an annual basis and meets the requirements of SLC T20. The background air quality in the laboratory, where ICSI is performed, has not been monitored for approximately 18 months. The centre's documented procedure states that air quality is monitored quarterly. SLC T20.	The PR should ensure that gametes and embryos are processed in an environment of appropriate air quality. The PR should undertake a full review of the centre's procedures to ensure that the premises comply with relevant requirements for air quality. A summary report of the review findings, including corrective actions and timescales for their implementation should be submitted to the centre's inspector by 3 October 2014. The report provided should include evidence of validation of the methodology for and frequency of monitoring.	PR has ensured that the pertinent SOP (LABSOP13 Laboratory monitoring, cleaning and maintenance) will be reviewed and amended. Lab will start monitoring the air quality in September 2014 on monthly bases in order to determine the frequency of these measurements. A summary report with corrective actions and timescales should be forwarded to the inspector by 3.10.2014.	The Executive acknowledges the PR's response and commitment to implement this recommendation. The PR to provide the summary report by 3 October 2014. Further action required
10. Multiple births The centre is unlikely to meet the current multiple birth rate target. The centre is not applying its MBMS effectively across the service. It was noted that the centre's MBMS	The PR should undertake an audit of the implementation and effectiveness of the centre's multiple births minimisation strategy and determine whether there are barriers to the effective implementation of the strategy for all patients provided with licensed	PR has undertaken the audit and in the first year of service provision our initial MBMS proved not to be effective. Based on the analysis of the outcomes and results of year 2013, PR	The Executive acknowledges the PR's response and commitment to implement this recommendation.

is not being implemented consistently where patients are 'satellite' patients. Directions 0003.	treatment at the centre. A summary report of the audit findings including corrective actions and the timescale for their implementation should be submitted to the HFEA by 3 October 2014.	has modified the strategy. The audit has been performed and the summary report with corrective actions and timescales Attached: 16) Summary report of the Audit	As per the summary report of the audit undertaken by the centre, the outcome of the planned audit in January 2015 is awaited. Further action required.
11. Receipt of gametes and embryos / staff training and competence Prior to receiving eggs or embryos from another centre, patients sign an 'agreement for transport' form. This form includes the statement "I/We understand that in the case of importing oocytes/embryos, they can be cryopreserved or vitrified with different media and/or device than those used by City Fertility and therefore the embryologist team at City Fertility may not be fully trained". Centre staff explained that this statement was added because when satellite clinicians request such a transfer for their patients, the embryologists are not given the opportunity to	The PR should ensure that staff are competent in all of the tasks that they perform. The PR should perform a review of this practice. A summary report of the findings of the review including corrective actions and the timescales for implementation of the corrective actions should be provided to the centre's inspector by 3 October 2014. The review should include an analysis of all eggs/embryos that have been transported and thawed using a technique that staff are not fully trained in and the outcomes (e.g. survival rates after warming) to attempt to identity if the quality of any gametes/embryos has been affected. It is also expected that this review be wider-ranging and link to the management of satellite partnerships	PR has decided not to accept imports of eggs and embryos that have been vitrified with different media and/or straws than the ones used by their embryologists. We will do, as requested, an audit of all eggs and embryos imported and thawed in City Fertility. We will compare the survival rate with our own rate. A summary report with corrective actions and timescales should be forwarded to the inspector by 3.10.2014.	The Executive acknowledges the PR's response. The Executive recommends that in the event the centre changes their position on the decision described in response to this report, the PR informs the Executive prior to any change in practice, how this circumstance will be managed. The PR to provide the outcome of the planned audit by 3 October 2014. Further action required.

advise patients against transport if they are not confident in the procedure to use. The inspection team does not consider this to be a suitable practice. SLC T2 and T12.	referenced in recommendation 2.		
12. Quality management system The centre has not audited provision of information and donor screening procedures against compliance with the approved protocols, the regulatory requirements and QIs in the last two years. SLC T36.	The PR should provide the centre's inspector with a schedule documenting the anticipated timescale for completion of required audits when responding to this report. The PR should provide a copy of the final audit reports to the centre inspector by 3 October 2014.	Audit to be completed on provision of information and donor screening procedures in due course. Audit should be forwarded to the inspector by 3.10.2014. Attached: 17) Complete HFEA audit schedule	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit is awaited. Further action required.

13. Equipment and materials The vitrification kit and a new incubator in use in the laboratory are not CE marked. SLC T30.	The PR should ensure that wherever possible CE marked medical devices are used. The PR should inform the centre's inspector when a CE marked vitrification kit has been introduced. It should be noted that we would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided to patients. This should be implemented by 3 January 2015. The PR should inform the centre's inspector of the anticipated time by which a CE mark is expected to be obtained for the incubator by the time the PR responds to this report.	IVF Lab has contacted the vitrification company asking about CE mark and they have confirmed that the vitrification kit is not CE marked neither in process of it. Lab is already working on introducing a new vitrification kit. HFEA will be informed. CE mark is expected to be obtained for the incubator. It is expected that the equipment will be CE marked in October 2014. Attachment: 18) Email from K-Systems director	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit is awaited. Further action required.
14. Process validation The centre could not provide documented evidence of process validation for the clinical processes undertaken by the primary centre or satellite centre clinicians, for example stimulation regimes. It was also noted that clinical processes employed by the primary centre clinicians and satellite centre clinicians were different. For example, with	The PR should ensure that all critical clinical and laboratory processing procedures are validated. Where more than one method is used for a specific procedure (for example follicular flushing at egg collection and selecting sperm for ICSI), the justification/criteria for when these techniques are applied to specific patients should be documented.	PR ensured that all clinical and laboratory processing procedures are validated. This is the list of processes validation done (Validation dates: November 2013 (1 to 10) 18/07/2014 (11), and 25/07/2014 (12). HFEA informed) 01. OOCYTE COLLECTION 02. SPERM	The Executive has reviewed the validation documents provided. The Executive does not consider that the egg collection and embryo transfer clinical validation fully satisfy the requirements of SLC

respect to follicular flushing. One of the satellite clinics requested that the embryology laboratory use a new technique for selecting sperm for ICSI (PICSI) for their patients. This process has been in use since October 2013 but has not been validated. . Process validation documents were available for all other laboratory processes, but these did not reference specific published studies or retrospective evaluation of the centre's own results. SLC T72.	The PR should review and update the existing process validation documents to ensure reference is made to specific published studies and/or retrospective evaluation of the centre's own results. The PR should provide a list of all procedures that are considered critical including the date of validation or the planned date by which validation is expected to be completed. The list should be submitted by the time the PR responds to this report. It is expected that the validation of processes where no validation documentation is available is prioritised and completed by 3 October 2014. For all other processes, validation should be completed by 3 January 2015. The PR should provide monthly updates to the HFEA on progress in completing validation.	PREPARATION 03. STANDARD INSEMINATION 04. ICSI 05. FERTILIZATION CHECK AND EMBRYO CULTURE 06. EMBRYO TRANSFER 07. SPERM FREEZING 08. ASSISTED HATCHING 09. IVM 10. VITRIFICATION AND WARMING 11. PICSI 12. FOLLICULAR FLUSHING Validations 01 to 10 will be updated with published studies and/or retrospective evaluation of our own results. This will be started now and finished, as required, by the 3 October 2014 New processes validated: 13 STIMULATION PROTOCOL VALIDATION REPORT, 14. EGG COLLECTION (CLINICAL) and 15. EMBRYOTRANSFER (CLINICAL)	T72; to specifically reference studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the centre's own results. The use of PICSI and the extent of follicular flushing at the centre is clinician dependent. It is recommended that the centre's rationale for these different patient selection criteria be included in these process validation documents. The Executive acknowledges that progress has been made in implementing these recommendations but that further action is required.

		Attached new processes validated: 19) STIMULATION PROTOCOL VALIDATION REPORT 20) EGG COLLECTION (CLINICAL) 21) EMBRYO TRANSFER (CLINICAL)	The PR should provide an update to the centre's inspector by 3 October 2014.
15. Adverse incident reporting The centre has reported two adverse incidents to the HFEA since this licence was granted. However, a review of the centre's own incident log showed that a number of incidents pertinent to the HFEA had not been reported. Closer examination showed that four significant 'near miss' events were not logged on the centre's incident reporting system until such time as a further incident directly related to the near miss events occurred. This incident may have resulted in the loss of oocytes. The inspection team could not determine whether the patient affected by the incident had been informed of the incident. SLC T118 and Directions 0011.	The PR should take immediate action to ensure that all incidents are reported to the HFEA; are thoroughly investigated; and that patients are informed as necessary. Relevant incidents should be reported to the HFEA retrospectively. The PR should review the centre's adverse incident reporting procedures. A summary report of the findings including corrective action should be provided to the centre's inspector by 3 October 2014. Six months after the implementation of any actions, the PR should audit the centre's incident records against that submitted to the HFEA. A summary of that audit should be provided to the centre's inspector by 3 May 2015.	All reportable incidents have been reported to the HFEA retrospectively. PR reviewed the SOP and instructed to report all incidents on the Incident log on Intranet (access to all). Alerts get sent to PR when new incident is reported (back up alert to Director and Head of the director's office). PR to make decision of incidents reportable to HFEA and comply with HFEA incident reporting regulations. PR is currently also sending list of in-house reporting to contact at HFEA weekly. Audit should be forwarded to the inspector by 3.5.2015.	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit to be provided to the centre's inspector by 3 May 2015. Further action required.

The centre's adverse incident reporting SOP was out of date SLC T33(b)			
16. Using embryos for staff training There is no SOP for using embryos in training, including procedures in place to avoid any perceived conflict of interest. Patient information covering the requirements of SLC T97 is not provided to patients when they are considering whether to consent to the use of their embryos in training. SLC T95 and T97.	The PR should develop a documented SOP and patient information for the use of embryos in staff training. Copies should be provided to the centre's inspector by 3 October 2014. Six months after the implementation of this SOP the PR should audit the implementation of the SOP to ensure that actions take are effective. A summary of the audit and any actions resulting from it should be provided to the centre's inspector by 3 May 2015.	LABSOP17 (Disposal of Human Eggs, Sperm and Embryos) has been modified including use of embryos in staff training. Patient information has been done as well. Audit to be done in Feb 2015—summary and actions resulting should be forwarded to the inspector by 3.5.2015. Attached: 22) Patient information	The patient information submitted covers the requirements of SLC T97. The SOP submitted includes the use of embryos for staff training, but does not include procedures in place to avoid any perceived conflict of interest. The PR should review and revise this SOP and submit it to the centre's inspector by 3 October 2014. Further action is required.
17. Consent The centre's own audit of consent to legal parenthood conducted in accordance with Chief Executives letter (CE (14) 01) showed that consent to legal parenthood was not effectively in place for one	The PR should ensure effective consent to legal parenthood is obtained where applicable before treatment is provided. The PR should conduct a review of the process for seeking consent to legal	Changes that are being implemented are to add routinely to Consent pack Legal parenthood form (for treatment with Donor Sperm) prior to attending Nurses Consultation and	The Executive acknowledges the PR's response and commitment to implement this recommendation.

couple treated.	parenthood by satellite IVF providers to ensure that appropriate consent is obtained prior to providing treatment (see recommendation 2 also). A summary of the review and any actions taken should be provided to the centre's inspector by 3 October 2014. Three months after the implementation of any actions the PR should conduct an audit of consent to legal parenthood sought by satellite IVF providers to ensure actions taken are effective. A summary of this audit and any further actions implemented should be provided to the centre's inspector by 3 February 2015.	completed with guidance of the Nurse. For patients not married or in a civil partnership only. Reinforce Satellite Clinics to ensure they comply with our policy i.e. Discuss and complete consent with their patients and guarantee a copy available for City Fertility before treatment commences. Added to the clinic Checklist (updates ongoing) Audit should be forwarded to the inspector by 3.5.2015.	The outcome of the planned audit to be provided to the centre's inspector by 3 May 2015. Further action required.
18. Record keeping A review of medical records on inspection showed that in a number of instances there was no documented 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 (SCL T 46)	The PR should conduct a review of the process for completing medical records to ensure that the justification for treatment is documented appropriately. A summary of the review and any actions implemented should be provided to the centre's inspector by 3 October 2014. Three months after the implementation of any changes the PR should conduct an audit of patient records (for both primary centre and satellite centre patients) to ensure that any actions have been effective.	PR conducted the review of the process for completing medical records. Actions implemented are to ensure consultation notes added to database are printed off and signed by member of staff performing the task before being filed in patient notes. Reinforce Satellite Clinics to ensure they comply with our policy. Guarantee a copy of their medical history is available for City Fertility before treatment	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit to be provided to the centre's inspector by 4 February 2015. Further action required.

	A summary of the audit findings and any further actions required is to be provided to the centre's inspector by 4 February 2015.	commences. Audit should be forwarded to the inspector by 4.2.2015.	

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
19. Payment of donors Where donors or egg sharers are recruited by the satellite clinics, the PR could not demonstrate or provide assurance that where compensation is made or a benefit in kind provided, this is compliant with Directions 0001.	The PR should review the process by which she may be assured that donor compensation and benefits in kind are made to all donors in accordance with Directions 0001. A summary of this review and actions implemented to ensure that compliance with Directions 0001 can be demonstrated should be provided to the centre's inspector by 3 October 2014.	PR has reviewed the process. Donor expenses claim form given to all satellite Centre for use when dealing with the donor's expenses before sending a signed copy to City Fertility.	The Executive acknowledges the PR's response and implementation of this recommendation. No further action required.
20. Welfare of the child An audit of ten patient and partner records conducted on inspection showed an error in one of the WoC form reviewed. A field requiring completion by centre staff indicating the WoC had been assessed was incomplete.	The PR should review the process for assessing WoC and completion of the supporting documentation to ensure that all couples are suitably assessed and that a review of the assessment is documented prior to licensed treatment being provided.	PR has reviewed the process. WOC consent and HFEA info leaflet will be given at the time of initial consultation appointment confirmation and ask patient to complete and bring with them on the day.	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the

(SLC T56 and CoP guidance 8:18)	A summary of this review and any actions resulting should be provided to the centre's inspector by 3 October 2014. Six months after the implementation of any actions the PR should audit the WoC process and documentation ensure any changes to practice are effective. A summary of this audit is to be provided to the centre's inspector by 3 January 2015.	Audit of WOC process and documentation should be forwarded to the inspector by 3.1.2015 Attached: 23) Welfare of the Child leaflet	planned audit to be provided to the centre's inspector by 3 January 2015. Further action required.
21. Import and export The centre could not provide written confirmation to demonstrate compliance with the following requirements for one set of donor sperm imported from Denmark: • evidence of accreditation of the donor bank in Denmark and; • that no money or other benefits had been given or received in respect of the supply of the gametes unless the money or benefit received is in accordance with Directions 0001 (General Directions 0006; Schedule 1; 1(a) and (e)	The PR should ensure that, prospectively, written confirmation to satisfy all points of Directions 0006 is obtained prior to the import/export of any sample. The PR should provide detail of the actions taken to ensure this to the centre's inspector by 3 October 2014. The PR should ensure that the written confirmation required by Directions 0006 is available for all donor sperm imported since the last inspection. This must be confirmed in writing, along with a sample of the written confirmation obtained, to the centre's inspector for review by 3 January 2015.	Lab contacted all sperm banks that have sent us sperm donor samples with request for written confirmation of Schedule 1(a) and (e) of general Directions 0006. HFEA will be updated. Documentation should be forwarded to the inspector by 3.1.2015	The Executive acknowledges the PR's response, but requests details of how the PR will ensure written confirmation to satisfy all points of Directions 0006 is obtained prior to the import/export of any future samples. This may be in the form of a revised SOP and/or updated staff training. This should be provided to the centre's inspector by 3 October 2014.

			Further action is required.
22. Third party agreements An audit of five third party agreements showed that only three had been reviewed within the specified timeframe. SLC T116.	The PR should ensure that all TPAs are reviewed within the specified timeframe. A summary report of the findings of the review including a list of all third party agreements included in the review should be provided to the HFEA by 3 January 2015. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions.	All third party agreements will be reviewed till 3.1.2015 work is in progress all satellite agreements terminated. A summary report with corrective actions and timescales should be forwarded to the inspector by 3.1.2015.	The Executive acknowledges the PR's response and commitment to implement this recommendation. The PR is to provide a summary report of the corrective actions and timescales required to the centre's inspector by 3 January 2015. Further action required.
23. Provision of information Information available at the primary centre regarding egg freezing relates to freezing the patient's own eggs for future and so is not relevant to women considering treatment with frozen donor eggs. It was also noted that this	The PR should review the process for the provision of information to be provided to donor egg recipients by the primary and satellite IVF providers to ensure that where treatment is offered with previously frozen donor eggs, the recipient if fully informed of all factors regarding this treatment and the centre's current post thaw survival rates.	PR reviewed the process. Patient information updated. Satellite Clinics to ensure they provide their recipients with our Information sheet. Provision of information well documented in their records and available for City Fertility before treatment commences. Audit should be forwarded	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit to be provided to the centre's inspector by

information states that a survival rate of 90% post warming (thawing) is achieved, however this is not the current survival rate for the primary centre.	The PR is to provide the centre's inspector with a summary of the review and a copy of patient information by 3 October 2014. Three months after the implementation of any changes the PR should conduct an audit of patient records where treatment has been provided using frozen donor eggs to ensure that the actions implemented have been effective. A summary of the audit findings should be provided to the centre's inspector by 3 February 2015.	to the inspector by 3.2.2015. Attached: 24) Amended patient information	3 February 2015. Further action required.
24. Disclosure of information, held on the HFEA Register, for use in research An audit of patient / partner and donor consent to disclosure records held by the centre against the consent to disclosure decision submitted to the HFEA register showed that in three of seven donor records reviewed a consent to disclosure decision was not present in the donor records and no consent decision had been provided to the HFEA register. This has been a requirement for donors since August 2012 (Chair's letter CH(10)05) and Direction 0007)	The PR should review the process for seeking consent to disclosure from donors to ensure a consent to disclosure decision is recorded in the donor records and that decision is provided to the HFEA for inclusion on the HFEA Register. The PR is to provide the centre's inspector with a summary of this review and any action taken by 3 October 2014. The PR should conduct an audit of donor records to ensure that, where donor consent to disclosure is present, this decision has been provided to the HFEA. Any omissions found should be reported to the HFEA register team for inclusion on the register.	PR reviewed the process for seeking consent. CD consent and info leaflet will be given at the time of initial consultation appointment confirmation and ask Donor to complete and bring with them on the day. The donor's choices will be stated on our Patient (Database) System and added to our automatic EDI registration form and submitted to HFEA at the time Donor registration is submitted i.e. when cycle has been planned. Audit of donor records should be forwarded to the inspector by 3.2.2015	The Executive acknowledges the PR's response and commitment to implement this recommendation. The outcome of the planned audit to be provided to the centre's inspector by 3 February 2015. Further action required.

	Three months after the implementation of any changes the PR should conduct a further audit of donor records to ensure that donor consent to disclosure decisions are recorded. A summary of the audit should be provided to the centre's inspector by 3 February 2015.	Attached: 25) Patient Information Sheet 26) Audit of donor records	
25. Obligations and reporting requirements (Guidance note 32; Directions 0005) A comparative audit of records held by the centre and treatment information provided to the HFEA showed that: • 2% (2/132) of the IVF treatments reviewed at inspection had not been reported to the HFEA as required by Directions 0005 and; • 68% (89/132) of IVF and 92% (11/12) of the DI treatments reviewed at inspection had not been reported to the HFEA within the timeframe required by Directions 0005. A number of issues with the submission of donor information were identified although these	The PR should review the process for submitting data to the HFEA to ensure that information is provided within the timescales required by Directions 0005. A summary of review and actions taken should be provided to the centre's inspector by 3 October 2014.	PR reviewed the process SOP amended. HFEA Registration to be completed as soon as patient has attended for Nurses Consultation and treatment cycle details decided. Patient Coordinators roll updated to comply with SOP within their roll of Patient care. Reinforce Satellite Clinics to ensure they comply with our policy i.e. Guarantee a copy of their treatment plan including dates are available for City Fertility so HFEA registration can be completed before treatment commences. Attached: 27) Updated ADMINSOP01	The Executive acknowledges the PR's response and implement of this recommendation. No further action required.

appear to be related to the IT system in use. Where identified, details have been provided to the centre for correction (SLC T9I, T41and Directions 0005)			
26. Patient and donor feedback The centre has not sought patient / donor feedback as to their satisfaction with the service since the license was granted.	The PR should commission a patient / donor satisfaction survey. The results of this survey and detail of any actions following should be provided to the centre's inspector by 3 January 2014.	Patient and donor satisfaction survey commissioned. Questionnaires now available also electronically on http://www.city-fertility.com/your-feedback/ Patient questionnaires designed to access the patient experience available in waiting room together with HFEA feedback forms. Patient questionnaires also handed over to the patient after embryo transfer. Attached; 28) Patient survey	The Executive acknowledges the PR's response and implement of this recommendation. No further action required

Reponses from the Person Responsible to this inspection report
The Inspection process has allowed us to review practice at City Fertility, and address areas that required attention to improve the quality of care for our patients. As a result we have made some immediate changes to both policies and procedures and to the team structure to ensure that we are HFEA Compliant. This has also addressed one key area of the Satellite provision and termination of these contracts will allow us to focus on our own patients significantly more and the services we provide.