Renewal Inspection Report

CREATE
Centre for Reproduction and Advanced Technology
0299

Date of Inspection: 30 April 2009
Date of Licence Committee: 15 July 2009

Centre Details

Person Responsible	Mrs Geeta Nargund
Nominal Licensee	Professor Stuart Campbell
Centre name	CREATE Centre for Reproduction and Advanced Technology
Centre number	0299
Centre address	3-5 Pepys Road West Wimbledon London SW20 8NJ
Type of inspection	Renewal
Inspector(s)	Parvez Qureshi (Lead)
	Andy Glew (External)
	Angela Sutherland
	Bhavna Mehta(Observing)
Fee paid	Yes
Licence expiry date	31 July 2009
NHS/ Private/ Both	Private

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About the Inspection:

This inspection visit was carried out on 30 April 2009 and lasted for 7 hours.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

CREATE Centre for Reproduction and Advanced Technology has been licensed since August 2008 and there are no additional conditions on the centre's licence. The centre mainly offers natural and mild stimulation in-vitro fertilisation (IVF) treatments. Around 200 treatment cycles were carried out at the centre between August - December 2008.

The premises consist of two separate sites. The main site houses the laboratory facilities where all the licensed activities take place and the second site is used for administrative purposes. Since the initial inspection, no major changes have been made to the premises. However, the centre's management have acquired additional space adjacent to the main site and anticipate using this for administrative purposes and for housing of a cryostore.

An organisational chart is in place indicating key roles and lines of accountability. The business hours at the centre are Monday to Friday from 8.00am to 6.00 pm and weekend as required.

The Person Responsible (PR) has completed the HFEA PR Entry Programme and has extensive experience of working in the fertility field. She is a Consultant in IVF and Fertility Services and is registered with the General Medical Council (GMC).

Activities of the Centre for the time period from August – December 2008* (* Unverified data supplied by the centre)

In vitro fertilisation (IVF)	97
Intracytoplasmic sperm injection (ICSI)	69
Intra uterine insemination (IUI)	37
Storage gametes/embryos	Yes

Summary for Licence Committee

The inspection team considered the centre to be well organised and managed. However, Some improvements are required in the centre's organisation, quality of service, premises and equipment and laboratory and clinical processes. These improvements relate to the following aspects of the centre's practice:

- Establishment of third party agreements with services and suppliers S.4.2.10(b) and standard licence condition A.5.
- The centre should establish documented procedures for personnel management that ensure that all staff have job descriptions. S.6.2.2(a).
- Full implementation of the quality management system S.5.2.4 (a) and S.5.2.4(d).
- Staff competency and training need to be documented. S.7.7.2 A.10.11.
- Validation of all key processes and procedures have not yet been established S 7.8.3 and standard licence condition A.11.11.
- Review of the appropriateness of the procurement facilities A.6.5.
- The protocol for transportation and receipt of gametes and embryos is not fully compliant with HFEA Alert 21 and S.7.7.
- Witnessing is not compliant with guidelines G.13.1.
- Access to records and information held electronically is not compliant with guidelines G.10.2.

- Review of security procedures to prevent unauthorised access to records and information held on paper, electronically or in any other type of system G.10.2.
- Review current procedures for access to the premises and ensure security of the centre and staff is not compromised. S.6.3.2.

Centre's information was found to be compliant.

The centre should comply with the recommendations within the suggested timescales. The inspection team supports the renewal of the centre's treatment and storage licence for a period of 3 years.

The centre's licence will expire on 31 July 2009. Therefore, the executive requests that the Licence Committee expedites the approval of the minutes for this agenda item and communicates its decision to the executive and the PR as soon as possible.

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		X	
2. Quality of the service		X	
3. Premises and Equipment		X	
4. Information	X		
5. Laboratory and clinical processes		X	

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
Establishment of third party agreements with services and suppliers does not meet the requirements of S.4.2.10(b) and standard licence condition A.5.	The centre should ensure that all third party agreements are in place with services and suppliers.	Progress to be monitored at the time of the next inspection.
The centre shall establish documented procedures for personnel management that ensure that all staff have job descriptions S.6.2.2(a).	All staff working at centre should be issued with job descriptions.	Progress to be monitored at the time of the next inspection.
A quality manual is in place. However, implementation of the quality management system is not fully compliant with the requirements of S.5.2.4 (a) and S.5.2.4(d)	Full implementation of the quality management system is required to make it more effective. This includes updating the quality manual to show the legal identity of the centre and an outline of the processes and documentation required to establish the QMS.	Progress to be monitored at the time of the next inspection.

Review current procedures for access to the premises and ensure security is of the centre and staff is not compromised S.6.3.2 and S.6.3.2.	PR should review current procedures for access to the premises.	Immediately.
Review of the appropriateness of the procurement facilities A.6.5.	The PR needs to put measures in place to ensure privacy and dignity are maintained.	Progress to be monitored at the time of the next inspection.
Staff competency and training is not documented S.7.7.2 A.10.11	Personnel must be provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks.	On going. Progress to be monitored at the time of the next inspection.
Validation of all key processes and procedures has not yet been established S 6.4.2(a), S 7.8.3 and standard licence condition A.11.11	A plan for validation should be drawn up which takes into account the particular needs of the unit and prioritises the validation of those processes considered to be most likely to impact on the quality of the service.	Progress to be monitored at the time of the next inspection.
The protocol for transportation and receipt of gametes and embryos was not fully compliant with HFEA Alert 21. and S.7.7	The transportation protocol should be reviewed and revised as required to ensure compliance with the recommendations of Alert 21.	Immediately.

Non-Compliance

Area for improvement	Action required	Time scale
Witnessing is not compliant with guidelines G.13.1	Review of witnessing procedure to be undertaken.	Progress to be monitored at the time of the next inspection.
Access to records and information held electronically is not compliant with guidelines G.10.2	The centre should have clear security procedures to prevent unauthorised access to records. The security procedures should be appropriate for the type of record keeping system, including where information is held on paper, electronically	Immediately.

	or in any other type of system.	

Recommendations

Area for improvement	Action required	Time scale
None.		

Changes/ improvements since last inspection

Recommendations	Action Taken
The risk management structure needs to be fully developed to ensure risk assessments are conducted for key processes and procedures, the activity level and for the work areas.	Evidence seen of risk assessments being conducted
Third party agreements should be finalised.	All have been finalised except for one.
A procedure for conducting regular audits of practice must be developed.	Procedure in place. Evidenced during the inspection
A low oxygen monitoring system needs to be fitted and a procedure written for responding to its activation.	Evidenced during inspection.
The dewar audit protocol should be reviewed to include the frequency of auditing of all stored samples.	This has been addressed.
Laboratory equipment and processes need to be validated.	In progress.
The suitability of the procurement facilities to be reviewed.	To be addressed.
An emergency trolley and an oxygen supply must be made available in the recovery area.	This has been addressed and was evidenced during the inspection
Access to a back up power supply should be secured so that gamete and embryo quality and safety can be protected in the event of a power failure.	This has been addressed and was evidenced during the inspection.
A risk assessment needs to be performed for the transfer of notes between two sites.	This has been addressed.
Patient information for OHSS requires reviewing to make it more appropriate regarding symptoms of OHSS.	Patient information for OHSS been updated.
Document staff induction process.	Not in place for all staff.
Develop a procedure for emergency transfer of patients to a hospital.	Procedure has been developed and was evidenced during the inspection.

Additional licence conditions and actions taken by centre since last inspection

None.

Report of inspection findings

1.Organisation

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Overall the inspectorate considered the centre to be well organised and managed. An organisational chart is in place that defines accountability and relationships was submitted to the HFEA pre-inspection and this was further demonstrated by staff who were interviewed during the course of the inspection. Additional laboratory, clinical and administrative staff have recently been recruited to meet an anticipated increase in workload. The inspectorate noted that key members of staff have extensive experience of working in the fertility field. There are documented procedures in place for the identification, notification and investigation of incidents. A review of the centre's incident log showed that the HFEA had been informed of all relevant incidents within the required timeframe. The PR stated that the centre has access to an ethics committee however no case has been referred to it. A risk management structure is in place to ensure risk assessments are conducted for key processes and procedures as required. Documented evidence was seen for the management and dissemination of HFEA Alerts and was considered to be appropriate. The centre's complaints log was reviewed and it showed evidence of corrective action taken to resolve complaints**.** In the event of an emergency, contingency arrangements are in place with London Fertility Centre (0086) for continuation of service. Arrangements are also in place for patients who need to contact staff outside working hours and this information is provided to patients at their initial consultation**.**

A review of centre's import/export log showed that a total of three imports were carried out and these were in compliance with the HFEA Directions.

Regular multi-disciplinary team meetings are held at the centre to discuss practice related issues. The minutes of these meetings are made available to all staff via email and this was confirmed by members of staff who met with the inspection team. A review of minutes of recently held meetings showed that a wide range of topics are discussed including HFEA related issues.

No issues have been raised by the HFEA finance department regarding payment of fees.

Areas for improvement

Evidence was seen that a number of third party agreements are in place. However, the PR needs to ensure that all outstanding third party agreements with services and suppliers are established.

Areas for consideration

None.

Executive recommendations for Licence Committee

The PR should ensure that all third party agreements are in place to ensure compliance with S.4.2.10 and standard licence condition A.5.

Evaluation

Improvement required.

Areas not covered on this inspection

All areas covered.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
The centre started to provide licensed treatments in August 2008. Therefore, at the time of the inspection no verified data on treatment cycles was available other than the information submitted for the inspection showing around 200 treatments had been carried out by the end of 2008.
Areas of firm compliance
The centre's Quality Management System (QMS) includes a quality policy and a quality manual. There are arrangements in place for conducting audits of practice including reviews of patient satisfaction and outcome of treatments. The inspection team was informed by the staff that findings of audits are discussed at unit meetings and any areas of concern are subject to corrective action. Evidence of this was noted during review of minutes of recently held unit meetings. No patient questionnaires have been returned to the HFEA. However, during the course of the inspection two patients were interviewed and the responses made by them were complimentary regarding their experience at the centre. Patients commented that the centre staff were supportive. There is an effective document control procedure in place. This was evident from the review of the documents submitted for the inspection and those reviewed at the centre during the course of the inspection.
Areas for improvement
The quality manual requires updating to show the legal identity of the centre and an outline of the processes and documentation required to establish the quality management system (QMS).
Areas for consideration
None.

Executive recommendations for Licence Committee
Evidence of implementation of the QMS was made available to the inspectorate and overall it was considered to be compliant with the Code of Practice 7th edition. However, full implementation of the quality management system (QMS) is required to make it more effective. No evidence of the application of the QMS was noted in relation to the following: • Legal identity of the centre in the quality manual S.5.2.4(a). • An outline of the processes and documentation required to establish the QMS S.5.2.4(d).
Evaluation
Some improvement required.
Areas not covered on this inspection
All areas covered.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Since the initial inspection of the centre, no major changes have been made to the premises. All clinical, laboratory and counselling facilities seen during the visit appeared to be clean and well presented. The laboratory facilities were considered to be adequate for the volume of work being conducted. There is controlled access to the facilities. The cryostore is fitted with a low oxygen level monitor. All dewars are alarmed and there is a procedure in place for responding to alarms. In the event of a power failure the centre has access to a back up power supply. Currently all key pieces of laboratory equipment are under warranty. All critical equipment such as incubators and dewars are monitored on a regular basis. Logs of these activities are kept and these were reviewed during the course of the inspection and considered to be appropriate. Laboratory processes take place in an environment of at least Grade C air quality with the background air quality in the laboratory area being of at least Grade D. The air quality in the laboratory area is monitored every two months and the results are logged accordingly. Evidence of this was made available during the course of the inspection. The inspection team considered the current staff facilities to be appropriate and this was further confirmed by the members of staff. . .
Areas for improvement
The main entrance to the centre is via two sets of double doors. Immediately entering through the first set of doors there is a bell on the wall which is used by visitors to alert the receptionist of their arrival. However, on the day of the inspection the members of inspection team were able to enter the premise via the unlocked doors without using this procedure and move freely around the reception area without staff being aware of their presence. The centre has procedures in place for secure storage of medical records. However, the

inspection team noted that computer back up tapes and a number of laboratory records were stored in an office with easy access to them.

The men's production room was considered to be not appropriate for its intended purpose, the PR needs to put measures in place to ensure privacy and dignity are maintained.

Areas for consideration

None.

Executive recommendations for Licence Committee

PR should review current procedures for access to the premises and ensure security of the centre and staff is not compromised S.6.3.2.

The centre should have clear security procedures to prevent unauthorised access to records. The procedures should be appropriate for the type of record keeping system, including where information is held on paper, electronically or in any other type of system G.10.2.

The PR needs to ensure the appropriateness of the procurement facilities is reviewed in consideration of the requirements of A.6.5.

Evaluation

Some improvements required.

Areas not covered on this inspection

All areas covered.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
The patient information submitted for the inspection was overall considered to be appropriate and included contact details for out of hours emergencies, risks associated with treatment and cost of various treatments. Patients are provided with relevant information at their initial consultation and there are checklists in place to ensure that patients do receive complete information prior to starting any treatment. The following information was also seen on display during the course of the inspection:- • The centre's treatment licence and complaints procedure. • Counselling information. Five patient records were reviewed during the course of the inspection. The notes were found to be well organised. They contained evidence of completion of welfare of the child assessment and consent forms which appeared to be compliant with HFEA requirements. Access to health records is restricted to authorised staff only. Patients who require a copy of their medical notes have to complete an application form and provide relevant documentation for identity verification purposes prior to the release of a copy their notes. No issues were raised by the HFEA registry regarding quality of data being submitted by the centre.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	4.5
NMC registered nurses	2
Non NMC registered clinical staff	1
HPC registered scientists	2
Scientists working towards registration	1
Support staff (receptionists, record managers, quality and risk managers etc)	8
Counsellors	2

Summary of laboratory audit
An audit of cryopreserved material was submitted for the inspection. It was noticed that a number of minor administrative errors were identified during the audit. However, the inspection team was informed by the laboratory staff that these errors were rectified.
Summary of spot check of stored material
An audit of samples from storage database to dewars and vice versa was carried out. No discrepancies were found.
Areas of firm compliance
Continuous professional development (CPD) for staff is well maintained and staff are encouraged to attend seminars and conferences. The centre has policies in place for the assessment of patients seeking treatments and for screening of patients. This was evident from the review of the documentation submitted for inspection and was further confirmed by staff who were interviewed. An elective single embryo transfer (ESET) policy has been developed by the centre to

address the risk of multiple births. A log of ESET was made available for the inspectorate for patients who had been considered for ESET. The centre's 3 embryo transfer (3ET) log showed that 12 patients had 3 embryo transferred and all of them were above 40 years of age.

The emergency trolley located in the recovery area is checked on a weekly basis. A log of this is maintained and was seen by the inspectorate.

The centre has a clinical procedure in place for management of ovarian hyperstimulation syndrome (OHSS). The PR stated that as the centre mainly uses mild stimulation and natural cycles this helps to reduce the risk of OHSS.

Arrangements are in place for laboratory staff to participate in external review of sperm assessment performance through the National External Quality Assessment Service (NEQAS). Review of a recent assessment carried out by laboratory staff showed that their results were comparable with NEQAS.

The centre has an effective traceability system in place for materials that come into contact with gametes. A system of unique coding of patients to assist the traceability of gametes is also in place.

All patients are made aware of counselling service at their initial consultation. The counsellor is member of the British Infertility Counselling Association (BICA). Her CPD is well maintained and she receives regular supervision. If required, a backup counsellor is available. All counselling sessions take place in comfortable surroundings either at the centre or at the counsellor's private practice. All notes are kept in a secure place. Counselling is provided independently of clinical decision. Patients can book appointments by contacting the counsellor directly. The counsellor stated that she was well supported by the centre staff and was able to discuss any difficult cases with them.

The counselling audit supplied for the inspection showed that on average 3 to 4 patients per month are seen by the counsellor, with implication counselling the most frequently attended.

The centre has a procedure is in place to ensure that gametes and embryos are not stored beyond the maximum consented storage period.

Areas for improvement

The inspectorate noted that not all staff working at centre have been issued with job descriptions.

Competency and training for all laboratory staff have not been documented.

The centre's protocol for transportation and receipt of gametes was reviewed against the requirements of HFEA Alert 21 and was found to be not fully compliant. The protocol did not cover a procedure if labelling on the samples has degraded in anyway.

The validation of all key processes and procedures in the laboratory has not been established.

A witnessing protocol is in place, however a number of witnessing stages were not being carried out including those for the ICSI procedure.
Areas for consideration
None.
Executive recommendations for Licence Committee
The centre shall establish documented procedures for personnel management that ensure that all staff have job descriptions. S.6.2.2(a). Staff must be provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks to ensure compliance with S.6.2.9 and A.10.9. The centre's protocol for transportation and receipt of gametes should be reviewed to ensure that it meets the requirements of HFEA Alert 21. A plan for validation should be drawn up which takes into account the particular needs of the unit and prioritise the validation of those processes considered to be most likely to impact on the quality of the service. S 6.4.2(a), S 7.8.3 and standard licence condition A.11.11. The witnessing procedures require review to ensure full compliance with G.13.1.
Evaluation
Some improvements required.
Areas not covered on this inspection
Screening of donors.

Report compiled by:

Name……Parvez Qureshi…….

Designation……..Inspector…….

Date……...04 06.2009……

Appendix A: Centre staff interviewed

PR and five other members of staff.

Appendix B: Licence history for previous 3 years

2008

Licence Committee 24 July 2008
The Committee agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination and decided to grant a licence for a period of 12 months.

Appendix C: Response of Person Responsible to the inspection report

Centre Number…….0299……

Name of PR……..Geeta Nargund……..

Date of Inspection……30.04.2009……....

Date of Response……19.06.2009…….

I have read the inspection report and agree to meet the requirements of the report.

Signed……Hard signed copy received from PR……

Name……Geeta Nargund…….

Date……19.06.2009……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

Breach 5

- The male production room is fit-for-purpose and has been approved by the inspectorate team at the last inspection. The facility has not changed in any way and we have not received any concerns or complaints from men using the facility.
- The concern raised at the recent inspection was not that of the appropriateness of the facilities themselves but of the need of a vacant/occupied sign so no other patients were placed in the room. The Lead Embryologist feels this in itself can cause problems if the sign is not changed correctly. It has always been the practice at CREATE that only one embryologist is assigned to prepare/analyse the sperm of the day and is solely responsible for placing male patients in the room, this has been risk assessed and found to be fit-for-purpose and so no breaches have occurred.

Breach 7

- Validation of key processes has taken place and the document submitted to the HFEA at the time of the last inspection in June 2008. This document is in the process of being reviewed as with all processes at CREATE.

Breach 8

- The transportation protocol is fully compliant with the HFEA Alert 21; however concern was raised that the protocol did not raise the issue of receiving material that was not correctly labelled. The protocol has been amended to address this issue (HFEA Alert 21 & S 7.7)

Non-Compliance 1

- Witnessing is compliant with guidelines G.13.1 however concerns were raised that the ICSI procedure was not signed for at every step. The Lead Embryologist explained that it is not feasible to sign for every step of the procedure as multiple steps were repeated multiple times. Instead, a single embryologist is responsible for witnessing the entirety of the ICSI process and signs as such on the witnessing sheet. This process has been risk assessed and found to be fit-for-purpose.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

The centre provides cost-effective care in IVF and related procedures. The protocols used for clinical management are individualised, science- based, safe and patient-friendly. We have not had a single case of OHSS. We have received several letters of compliments from patients. We have established an Ethics Committee and patient support group. The centre is proud of its achievements so far. We thank the HFEA for its ongoing support.

3. Please state any actions you have taken or are planning to take following the inspection with time scales

Breach 1

- Ongoing as new suppliers come on board

Breach 2

- The only job description (JD) which needed to be written was that of the Quality Manager. The Lead Embryologist acts as the Quality Manager. It was previously included in Lead Embryologist's JD.Following the inspection, a separate job description has been written for the Quality Manager and the Senior Embryologist job description has been amended for the pre-registered Embryologist (sent pre-report)

Breach 3

-The legal identity of the company has been incorporated in the Quality Manual.

- A step-by-step guide of how to add documents to the quality manual has been written

Breach 4

- As stated in recent letter, we have installed an entry phone system (intercom system).All the doors remain locked at all times**.** Anyone wishing to gain access to the building must first press the buzzer. It will allow a member of staff inside the building to identify them through the intercom and grant access via the door release. The member of staff will then identify the visitor/patient in person and allows them into the main lobby.

- Furthermore, we have also installed secure code locks to staff room and reception

office**.** This ensures that that all areas with patient information are locked with code locks.

- This has addressed any concerns regarding access to premises, security, access to records (S.6.3.2.& SG 10.2)

Breach 6

- Ongoing as staff development progresses

Non-Compliance 2

- Door to staff room/office is locked by combination lock. This was done immediately after the inspection as stated above.

We welcome comments about the inspection on the inspection feedback form, a copy of which should have been provided at the inspection. If you require a copy of the feedback form, please let us know.

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF