Renewal Inspection Report

Date of Inspection: 17 February 2010
Length of inspection: 7 hours
Inspectors: Mr Parvez Qureshi (Lead, HFEA)
Mr Andy Glew (External Advisor)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between February 2009 and January 2010.

Date of Executive Licensing Panel: 20 May 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres are providing a quality service for patients. 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 Authority's Licence Committee/ Executive Licensing Panel which make the decision about the centre's licence renewal application.

Centre details

Centre Name	Fertility Unit, Barking Havering and Redbridge Hospitals Trust
Centre Number	0291
Licence Number	E0291-2-B
Centre Address	Queens Hospital, Rom Valley Way Romford Essex RM 7 0AG
Telephone Number	01708 504 398
Person Responsible	Mr Satha M Sathanandan
Licence Holder	Mrs Carol Drummond
Date Licence issued	1 October 2009
Licence expiry date	31 July 2010
Additional conditions	N/A

Version: 0

applied to this licence	

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Report to Licence Committee / Executive Licensing Panel

Brief description of the centre and its licensing history:
The Fertility Unit, Barking Havering and Redbridge Hospitals Trust has been licensed since 2007 and provides basic partner services.

The centre provided 188 intra uterine insemination (IUI) licensed treatment cycles in 2008.

Since the previous inspection in February 2009, no major changes other than the addition of a male production room have been made to the premises. However, additional laboratory equipment has been installed since the last inspection.

The Person Responsible (PR) is a consultant gynaecologist and obstetrician and is registered with the General Medical Council and is also a member of the Royal College of Obstetricians and Gynaecologists (RCOG).

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 January 2008 – 31 December 2008
Intra uterine insemination	188

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

*These data were extracted from the HFEA register for the period 1 January 2008 – 31 December 2008 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.

Summary for licensing decision:

In considering overall compliance, the Inspectorate considers that it has sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR is suitable and has discharged his duty under section 17 of the HF&E Act 1990 (as amended). The PR has successfully completed the HFEA's PR Entry Program
- the premises are considered largely suitable
- the practices are considered largely suitable
- the centre has submitted appropriately completed documentation in accordance with General Directions 0008, in application for renewal of its licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

Recommendation to the Licence Committee / Executive Licensing Panel:

The Inspectorate consider that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions. The centre has addressed most of the recommendations made in the previous inspection report but further development in a number of areas is required and progress should be monitored by the Inspectorate.

The Inspectorate also recommends that the Executive Licensing Panel requires that the PR complies with the following recommendations within the prescribed timeframes set out in the inspection report:

- Validate all critical processing procedures. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.

- Implement a programme to validate all critical equipment and processes at the centre.

- Ensure that whenever possible only CE marked medical devices are used.

- Establish required standards of quality and safety, in the form of quality indicators for all licensed activities.

- Implement a quality management system (QMS) to continually improve the quality and effectiveness of the services it provides.

- Ensure that audits of licensed activities against compliance with protocols, regulatory requirements and quality indicators are performed in an independent way, at least every two years. Findings and corrective actions must be documented.

- Review the current witnessing standard operating procedure (SOP) to include all the witnessing requirements.

- Develop an SOP for the process to be followed when carrying out welfare of child (WoC) assessments.

- Develop an SOP for actions to be taken in the event of malfunction or failure of equipment.

- Establish a written agreement with all third parties who provide goods or services that influence the quality and safety of gametes and also maintain a complete list of third party agreements. The PR should review the content of the current third party agreements to ensure that they are compliant with requirements. The ability of all the third parties to meet the requirements of licence conditions and the guidance in the HFEA Code of Practice (CoP) should be evaluated.

- Risk assess or review practice in order to ensure that no unauthorised access is possible to the premises.

- Ensure that exchange of all personal information is carried out in private.

However, post inspection information submitted by the centre indicates that most of the recommendations made during the inspection have been addressed by the PR and others are in the process of being addressed.

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of treatment**
- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services
- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)
- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Witnessing

▶ Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4).
Evidence of how the centre demonstrates compliance with this principle: **Welfare of the Child – Guidance Note 8** Prior to any woman being provided with treatment services an account is taken of the welfare of any child who may be born as a result of the treatment. Evidence of this was seen from an audit of six patients' notes which contained WoC forms completed and signed by both partners (T56) The Nurse Co-ordinator was able to provide documented evidence of the assessment of her competency to carry out WoC assessments. (T15(a)) In cases where further information has been sought or discussion has taken place regarding WoC, the views of those consulted and the views of the patients are documented in the patient records.(Cop 8.18)
What the centre does well:
What they could do better. **The Quality management system – Guidance Note 23** The centre should develop an SOP for the process to be followed when carrying out a WoC assessment. [T33(b)] Quality indicators relevant to assessment of WoC have not been established (T35) and regular audits of patient records should be conducted to ensure completed WoC forms are in place. (T36**)**

▶ Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7).
Evidence of how the centre demonstrates compliance with this principle **Procuring and processing gametes – Guidance Note 15** The centre has procurement and processing SOPs in place for IUI and home procurement. Prior to any processing, a sperm sample is checked to ensure it is accurately labelled with the patient's name and a unique identifier. This is documented in a laboratory log to ensure the identification of the gametes from procurement to use. (T70) Laboratory staff were able to provide documented evidence of the assessment of their competency in procurement and processing. (T15(a)) **Traceability – Guidance Note 19** The centre has an SOP in place ensuring that all gametes and relevant data, relating to anything coming into contact with those gametes, are traceable from procurement to patient treatment. (T99, T100) All containers used in the course of procurement and processing of sperm are labelled with the patient's name and a further unique identifier. (T101) Evidence of traceability information being documented by the centre staff to facilitate the traceability of the gametes and relevant data relating to all products coming into contact with the gametes was seen during the inspection. (T102) Laboratory staff were able to provide documented evidence of the receipt of training in traceability procedures. **The quality management system – Guidance Note 23** The centre's QMS consists of a quality manual, SOPs, guidelines, training and reference material and reporting forms. (T33) A QMS review was undertaken by the centre in January 2010. The details of the findings were made available for the inspection team. The review included reference to the centre's quality policy being reviewed to ensure compliance with the HFEA's requirements. In addition, the centre's document control system, patient feedback, audits and analyses of preventive actions were also reviewed.
What the centre does well. The centre has established quality indicators relevant to procurement, processing, traceability and witnessing (T35). Evidence of regular witnessing audits being conducted by laboratory staff was made available to the inspection team showing that a wide range of criteria are audited. (T36)
What they could do better. **Procurement and processing - Guidance Note 15):** The centre has conducted some validation of laboratory equipment, however, not all critical procurement and processing procedures have been validated. The centre staff need to ensure that all critical processing procedures are validated and these procedures must not render the gametes clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures. (T72) Currently a sperm sample which is produced at home, following verification by the centre staff, is not documented in the patient's notes. (T68)

The centre has established quality indicators relevant to procurement and processing procedures. (T35) However, to date these have not been audited. (T36) The staff reported that an audit has been planned for October /December 2010.

Witnessing – Guidance Note 18
A SOP for witnessing is in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. The laboratory staff reported that only one sperm sample is processed in the laboratory at a time. An audit of six sets of patients' notes was found to contain a record of the witnessing checks of the person performing the procedure and of the person witnessing the procedure. However, these records only included the respective signatures and the time of witnessing and not the name and status of the persons involved in the process. (T71) With respect to these findings, the PR should review the current witnessing SOP in order to establish that all the requirements of licence condition T71 are being met. Compliance with this requirement could be achieved by maintaining a separate record of the name, job title and signature of everyone who carries out or witnesses laboratory and clinical procedures. (CoP 18.8)

The quality management system – Guidance Note 23
The PR should ensure that the centre fully implements a QMS to continually improve the quality and effectiveness of the service it provides in accordance with the conditions of its licence and the guidance on good practice as set out in the HFEA's CoP. (T32)

The Trust Quality Systems Manager reported that currently the Trust was in the process of acquiring ISO registration and she was working with the centre's quality manager to review and update the centre's QMS inline with HFEA requirements. In this respect, a number of documents were made available to the inspection team showing progress made up to the time of the inspection.

The centre has not established quality indicators for all activities authorised by its licence and other activities carried out in the course of providing treatment services that do not require a licence. (T35) and it has not audited against compliance with all the approved protocols, the regulatory requirements and quality indicators in the last two years (T36)

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates compliance with this principle

Premises and facilities – Guidance Note 25
All activities at the centre are carried out on licensed premises which appeared to be clean and well presented including the recently acquired sperm production room situated next to the laboratory. (T17) A copy of the Certificate of Licence was seen displayed in the waiting room. (T5) The cleaning and disinfection of the premises is undertaken by the Trust on a regular basis, and a cleaning schedule was seen during the inspection. (T26)

The centre provided documented evidence that the processing of sperm takes place in an environment of at least Grade C air quality, with a background environment of at least

Grade D air quality. (T20)

Equipment and materials – Guidance Note 26
Identifying information of the equipment and materials that are used in the course of procurement and processing of sperm samples is documented. (T22) Maintenance contracts are in place for the air flow hood, incubator, centrifuge and the microscope, heated block and the fridge. (T26) The fridge and heating block temperatures are monitored. (T24)

What the centre does well
Since the last inspection in February 2009 the centre has acquired a sperm production room.

What they could do better.

Third party agreements – Guidance Note 24
Not all third party agreements have been established with those third parties who provide goods and services that influence the quality and safety of gametes. (T111, T115)

The inspection team noted that all the centre's third party agreements had been written by the third party instead of centre staff. The PR should review the content of all the third party agreements to ensure they are compliant with the requirements of standard licence condition T114. In addition the centre has not evaluated the ability of all the third parties to meet the requirements (T112) and the guidance set out in the HFEA CoP.

Premises and facilities – Guidance Note 25
Access to the premises is controlled. However, the inspection team noted that one of the clinical rooms had a large number of files in boxes waiting to be archived. The boxes were not secured, but the room was locked. A second clinical room had crates of files securely tagged waiting to be archived, but had IUI records in a cabinet without a key. The centre staff should risk assess or review this practice in order to ensure no unauthorised access is possible.

The inspection team noted that the waiting room situated next to the laboratory and near the antenatal ward was not discrete enough for private conversation relating to reporting of sperm results. Staff reported that plans have been drawn to partition this area in the future. However, the PR should ensure that exchange of personal information is carried out in private (i.e., cannot be overlooked or overheard by others). Cop 25.7

Equipment and materials – Guidance Note 26
Only some of the equipment used in the laboratory has been validated. Laboratory staff need to put measures in place to ensure all critical equipment is validated before use. (T24) There are documented procedures in place for the operation of all critical equipment. However, there is no SOP in place outlining the actions to be taken in the event of malfunction or failure of equipment. (T27) CE marked devices are used, but not on every occasion. (T30)

▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).
Evidence of how the centre demonstrates compliance with this principle **Staff – Guidance Note 2** An organisation chart is in place which defines accountability and reporting relationships. (T11) All staff in the centre are qualified and competent for the tasks they perform and this was evidenced during the inspection. The centre has assessed the workforce requirements within the last year. (Cop 25.10) The PR reported that currently they are operating with an almost full staff complement and he considered that the number of staff was adequate for the current volume of work being undertaken by the centre. (T12) Documented evidence was seen of staff having adequate opportunity for relevant professional development.(T15) The PR is the centre's nominated registered medical practitioner and therefore is able to advise on and oversee the medical activities. The centre also has access to a nominated registered scientist to advise on and oversee scientific activities. (T16)
What the centre does well. Staff who met with the inspection team appeared committed to providing safe clinical and laboratory practice.
What they could do better.
▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).
Evidence of how the centre demonstrates compliance with this principle **Adverse incidents – Guidance Note 27** There is a procedure in place for reporting adverse incidents to the HFEA. (T118) The centre staff were able to demonstrate this during their discussion with the inspection team. A review of the centre's incident log showed that since the last inspection in February 2009, no reportable adverse incidents to the HFEA had taken place at the centre.

Complaints - Guidance Note 28 Since the last inspection of the centre in February 2009, the HFEA has not received any complaints regarding this centre. The centre's complaints procedure was seen during the inspection and provided evidence that complaints reported to the centre were being investigated and managed in line with centre policy and information.
What the centre does well.
What they could do better.

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
  - Patient consent to the disclosure of information, held on the HFEA register, for use in research

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
Evidence of how the centre demonstrates compliance with this principle **Treating people fairly – Guidance Note 29** Members of staff reported that the centre follows the Trust policy on treating patients fairly and this ensures that all licensed activities are conducted in a non-discriminatory manner.
What the centre does well.
What they could do better.
▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
Evidence of how the centre demonstrates compliance with this principle **Confidentiality and privacy – Guidance Note 30** Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that overall respect for privacy, confidentiality, dignity, comfort and well being of patients is maintained. All information at the centre is kept confidential and there is a procedure in place to ensure that information is only disclosed in circumstances permitted by law. (T43. T33(b))
What the centre does well.
What they could do better.

The PR should develop a SOP to ensure that all information is kept confidential and only disclosed in circumstances permitted by law [T43 and T33(b)]
▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).
Evidence of how the centre demonstrates compliance with this principle **Information to be provided prior to consent – Guidance Note 4** Patient information submitted pre-inspection and that seen during the course of the inspection was found to provide information about the nature of the treatment, consequences and risks, analytical tests, confidentiality and consent. (T58) Review of patients' notes showed that a checklist for providing information is in place and being used.
What the centre does well.
What they could do better.
▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).
Evidence of how the centre demonstrates compliance with this principle **Consent to treatment and disclosure of information – Guidance Note 5** Six sets of patient notes were examined during the inspection and found to contain effective consent for the use of gametes in partner treatment, and for the disclosure of information for research purposes. (CoP 5.1, HF&E Act 1990 (as amended) Section 33) The centre has a SOP in place for taking patient consent to treatment. (T33b) The Nurse Co-ordinator reported that passport verified identity is checked when consent is provided. (CoP 5.10).
What the centre does well.
What they could do better. Conduct an audit of patient records on a regular basis to verify that patient and partner consent is documented in compliance with regulatory requirements.

3. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers

▶ Maintain accurate records and information about all licensed activities (Principle 10)
Evidence of how the centre demonstrates compliance with this principle **Record keeping and document control – Guidance Note 31** The centre's system for controlling documents was discussed with the Trust Quality Systems Manager and the centre's Quality Manager. They reported that the centre does have a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use. (T34) Evidence of this was seen during the course of the inspection. Currently the centre is in the process of reviewing and updating its QMS. Patient notes audited during the inspection were found to contain the information required by standard licence condition T46.
What the centre does well.
What they could do better.
▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including: maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).
Evidence of how the centre demonstrates compliance with this principle **Obligations and reporting requirements of centres – Guidance Note 32** Members of staff interviewed during the inspection demonstrated an awareness and understanding of legal obligations and recent changes to the CoP. All staff co-operated fully during the inspection and made all documents and records available to the inspection team. (T3)
What the centre does well.
What they could do better.

5. Changes / improvements since the last inspection on 9 February 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
Validation of critical equipment and of key processes and procedures has not yet been established. Standard licence condition A11.11 and A.10.13 Code of Practice (CoP) 7th **Guidance Note 26 (8th Ed)**	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the validation of those processes and equipment considered to be most likely to impact on the quality of the service and ensure compliance with A.10.11 and A.10.13. CoP 7th	Evidence was seen on the validation of the air flow cabinet and the test tube heating block. However, validation documents are not in place for all critical equipment. Also not all process validation documents are in place. The laboratory staff reported that they intend to use the templates from the Association of Clinical Embryologists (ACE) website.
A QMS has not been established. S.5.1.2 (d) CoP 7th Quality indicators for laboratory have not been established. S.4.2.4, S.4.2.8 and S.4.2.9. CoP 7th **Guidance Note 23 (8th Ed)**	A QMS should be established and reviewed in accordance with CoP Standard. Once established, the centre should continually improve the effectiveness of the quality management system through the use of the quality policy, quality objectives evaluation activities, corrective and preventive actions and management review in line with the requirements of S.9.5 CoP 7th	A framework for a QMS has been established and staff appeared to be committed to its continual improvement. Currently the centre's QMS is being reviewed and updated. This will include quality indicators for laboratory and other areas of practice.
The organisational chart reflects the structure of the organisation but with no lines of responsibility. The chart does not indicate to whom the staff report. S 4.1.1 – 4.1.3 CoP 7th **Guidance Note 23 (8th Ed)**	The PR should review the organisational chart to ensure that the chart clearly defines accountability and reporting relationships.	An organisation chart is in place which defines accountability and reporting relationships.
Air quality in the flow hood in the laboratory in which gametes are processed has been measured but the report was not available at	In compliance with A.10.19 CoP 7th it must be demonstrated that gametes are processed in an environment of at least Grade	Processing of sperm takes place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality.

the time of inspection. This is non-compliant with standard licence conditions which require that It must be demonstrated and documented that the chosen environment achieves the quality and safety required. A.10.19 CoP 7th **Guidance Note 25 8th Ed)**	C air.	
The PR had not provided information to the HFEA about the number of cycles of IUI provided or the outcomes of those treatments for the time period from January 2008 – 31 December 2008 as required by Directions D2008/6 (no longer in use). Standard licence condition A.2.8 CoP 7th **Guidance Note 32 (8th Ed)**	The PR should ensure that information requested is provided to the HFEA promptly in compliance with standard licence condition A.2.8 CoP 7th	This was actioned, following the last inspection.
A document control system is in place however not all documents seen on the day of inspection were being reviewed or controlled according to the requirements S.5.2.5 (b), S.5.2.6 (b) CoP 7th **Guidance Note 23 (8th Ed)**	The PR should review documents to ensure they contain appropriate document control information compliant with Code of Practice, Standards S.5.2.6 (b), and are scheduled for annual review to ensure accuracy and future compliance with Code of Practice, Standards, S.5.2.5 (b) CoP 7th	This is being addressed as part of the review and updating of the centre's QMS.
The HFEA payment terms are 28 days and the centre has not paid the annual fee despite reminders to the centre. Standard licence condition A13.3 and as	The PR should review the arrangement for payment of invoices and ensure that there are no barriers to the prompt payment of invoices.	Fees are up to date.

defined in section 16(6) of the Act. (CoP 7th)		
Although it was reported that a patient questionnaire is given to patients the user feedback on the service provided at the centre has not yet been audited. S.9.1 CoP 7th **Guidance Note 23 (8th Ed)**	The PR is encouraged to begin the process of collating user feedback on the general service to ensure compliance with Code of Practice Standard S.9.2.1 CoP 7th This Standard requires that as a measure of the performance of the quality management system, the centre shall monitor information relating to user perception as to whether the service has met their needs and requirements. The Standard also specifies that the methods used to obtain feedback should include user surveys regarding all aspects of the service.	The staff reported that since the last inspection an audit of patient feedback has been conducted and action has been taken where necessary.
The centre does not participate in inter-centre (clinical or laboratory) comparisons. S. 9.2.6, S.9.5.4 CoP 7th **Guidance Note 23 (8th Ed)**	The PR and the Quality Manger should consider participating in inter-centre comparisons such as those organised by professional bodies and inter laboratory comparisons and these comparisons need to be evaluated and documented in compliance with S.9.2.6. A CoP 7th record shall be kept of corrective and preventive actions taken. S.9.5.4 CoP 7th	Laboratory staff have signed up for National External Quality Assessment Service (NEQAS).
Both members of the staff interviewed were unaware of the HFEA Alerts. S.6.2.13 CoP 7th **Guidance Note 2 (8th Ed)**	The PR should ensure that the centre has an effective means for communication of information to the staff regarding Alerts issued by the HFEA.	Staff were aware recent HFEA alerts and reported that alerts have been discussed at team meetings.
The centre has no procedure to evaluate the laboratory procedures for hazards to laboratory staff. S 7.8.3 CoP 7th	The PR should ensure that procedures are evaluated for hazards to laboratory staff and precautions put in place to minimise potential hazards	Lone worker risk assessment has been done.

Guidance Note 25 (8th Ed)		
At the time of inspection the inspection team did not see any documentation of competency assessments or training logs. S. 6.2.11, S.6.2.9) and.A.10.11 CoP 7th **Guidance Note 2 (8th Ed)**	Staff at the centre should take part in regular professional development. Following initial/basic training the competence of each person to perform designated activities shall be evaluated and at intervals and retraining undertaken when required. Training should be documented .	Documentation of competency assessments is being done.
On review of the witnessing documentation in a sample of patient records, at one stage one witnessing step was never carried out. G 13.1.1 and G.13.2 CoP 7th	The PR should review the guidance at G.13.1.1 CoP 7th which recommends that witnessing protocols are in place to double check the identification of samples and the patients or donors to whom they relate, at the time specified clinical or laboratory procedures take place. Guidance at G.13.2 CoP 7th recommends that the checking of identification of samples and patients/donors, and witnessing of these checks, should be recorded at the time the clinical and laboratory procedures (outlined in section G.13.1 CoP 7th) take place.	Witnessing is done by nurses who witness all processing tubes in advance. No errors were identified in a recent audit of witnessing conducted by the nurses. Laboratory staff reported that only one sample is processed at a time.
Patients produce sperm samples off site as the centre has no facilities for sperm production. Guidance at G.2.3.1 of the CoP 7th states that centres should normally only use sperm which has been obtained directly from the provider. In exceptional circumstances the centre may use sperm produced by a man at home. **Guidance Note 15**	The PR should review the procedures for production of semen off site and assess the risks of this procedure.	A dedicated sperm production room is now available next to the laboratory. Laboratory staff reported that currently 20% of sperm samples are produced on-site and 80% are produced at home. The IUI form doubles up as a verification form but does not indicate whether the sample is produced at home or not.

(8th Ed)		However, a sample produced at home is documented in the laboratory log book.

Assessment of compliance with statutory requirements

This page summaries the assessment of the extent to which the centre has complied with the Act, licence conditions and Directions.

Fully Compliant = the centre has met the statutory requirement
Not compliant = the centre has not met the statutory requirement

“X” in the assessment box denotes that compliance with the Licence Condition was not assessed during this inspection
“N/A” in the assessment box denotes that compliance with the Licence Condition is not applicable to this centre

Licence Condition	Assessment
Licensing	
T1	Fully compliant
T2	Fully compliant
T3	Fully compliant
T4	Fully compliant
T5	Fully compliant
T6	N/A
T7	N/A
Person Responsible	
T8	Fully compliant
T9	Fully compliant
T10	N/A
Personnel	
T11	Fully compliant
T12	Fully compliant
T13	Fully compliant
T14	Fully compliant
T15	Fully compliant
T16	Fully compliant
Facilities / Premises	
T17	Fully compliant
T18	N/A
T19	N/A
T20	Fully compliant
T21	N/A

Licence Condition	Assessment
Equipment and Materials	
T22	Fully compliant
T23	Fully compliant
T24	Not compliant
T25	Fully compliant
T26	Fully compliant
T27	Not compliant
T28	Fully compliant
T29	N/A
T30	Not compliant
T31	Fully compliant
Quality Management	
T32	Not compliant
T33	Not compliant
T34	Fully compliant
T35	Not compliant
T36	Not compliant
Records and Information	
T37	Fully compliant
T38	Fully compliant
T39	Fully compliant
T40	Fully compliant
T41	Fully compliant
T42	N/A
Data protection and Confidentiality	
T43	Not compliant
T44	Fully compliant
T45	Fully compliant
Patient Records	
T46	Fully compliant
T47	Fully compliant
T48	Fully compliant
Patient Selection Criteria and Laboratory Tests	
T49	Fully compliant
T50	N/A
T51	N/A
Donor Selection Criteria and Laboratory Tests	
T52	N/A
T53	N/A
T54	N/A
T55	N/A

Licence Condition	Assessment
Welfare of the Child, Provision of Information, Counselling and Consent	
T56	Fully compliant
T57	N/A
T58	Fully compliant
T59	Fully compliant
T60	N/A
T61	N/A
T62	N/A
T63	N/A
T64	N/A
T65	N/A
Procurement of Gametes and Embryos	
T66	N/A
T67	N/A
T68	Fully compliant
T69	N/A
T70	Fully compliant
Processing and Use of Gametes and Embryos	
T71	Not compliant
T72	Not compliant
T73	N/A
T74	N/A
Storage of Gametes and Embryos	
T55	N/A
T76	N/A
T77	N/A
T78	N/A
T79	N/A
T80	N/A
T81	N/A
T82	N/A
T83	N/A
T84	N/A
T85	N/A
Embryo Testing	
T86	N/A
T87	N/A
T88	N/A
T89	N/A
T90	N/A
T91	N/A

Licence Condition	Assessment
Use of Embryos in Training Staff	
T92	N/A
T93	N/A
T94	N/A
T96	N/A
T97	N/A
T98	N/A
Traceability and Coding	
T99	Fully compliant
T100	Fully compliant
T101	Fully compliant
T102	Fully compliant
T103	X
T104	X
Import, Export and Transportation / Distribution of Gametes and Embryos	
T105	N/A
T106	N/A
T107	N/A
T108	N/A
Receipt of Gametes and / or Embryos	
T109	N/A
T110	N/A
Third Party Agreements	
T111	Not compliant
T112	Not compliant
T113	Not compliant
T114	Not compliant
T115	Not compliant
T116	Not compliant
T117	N/A
Identification, investigation, reporting, recording and notification of serious adverse events and reactions	
T118	Fully compliant
T119	Fully compliant
T120	N/A
T121	N/A
T122	X

Additional Licence Conditions	
Licence Condition	**Assessment**
None.	

HFEA Directions	
HFEA Directions	**Assessment**
0001 Gamete and embryo donation	N/A
0003 multiple births	N/A
0005 Collecting and recording information for the HFEA	N/A
0006 Import and export of gametes and embryos	N/A
0007 Consent	Fully compliant
0008 Form and content of applications	Fully compliant
0009 Keeping gametes and embryos in the course of carriage between premises	N/A
0010 Satellite and transport IVF	N/A
0011 Reporting adverse incidents and near misses	Fully compliant
0012 Time periods for retention of records	Fully compliant

Areas of practice that require the attention of the Person Responsible

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 direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None identified at the time of this inspection					

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 or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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	Reference	Action required	Timescale for action	PR Response	Executive Review
Procurement and processing The centre has not validated critical processing procedures.	Standard licence condition T72 CoP Guidance Note 15	The PR should validate all critical processing procedures. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.	To be submitted to the Inspectorate by 1 July 2010.	All the critical processing is currently being validated and on completion will be submitted to the inspectorate by 1st of July 2010.	The inspectorate considers this to be an acceptable response and the validation will be followed up.

Equipment and materials The centre has not validated all critical equipment.	Standard licence condition T24 CoP Guidance Note 26	The PR should ensure that all critical equipment and technical devices are identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with a critical measuring function must be calibrated against a traceable standard if available.	To be submitted to the Inspectorate by 1 July 2010.	Our IUI laboratory houses four critical equipment. 1. A class two cabinet, 2. A centrifuge, 3. A Heating block and 4. A phase contrast microscope. Documents confirming compliance of Guidance Note 26 were shown to the inspectorate during the inspection and were accepted. These are standard piece of equipment used in most of the ART laboratories around the world. The functionality of this equipment was validated by calibrating them against the manufacturer's specifications. Documents are enclosed. (A1	At inspection, validation documents were seen for the air flow cabinet and the test tube heating block. Evidence of calibration received. However, evidence of validation in the form of a report remains outstanding. The inspectorate recommends that the centre refers to ACE guidelines.

A SOP for all actions to be taken in the event of malfunction or failure of equipment is not available.	T27 CoP Guidance Note 26	The PR should ensure that procedures for the operation of each piece of critical equipment must be established and these procedures must document the action to be taken in the event of malfunctions or failure.	By the time PR responds to this report.	A SOP is currently incorporated in our QSM a copy is enclosed for your information. (A2)	The inspectorate considers this to be an acceptable response.
Not all CE marked devices are used.	T30 Guidance Note 26	The PR should ensure wherever possible only CE marked medical devices are be used.	To be monitored at the next inspection.	The guidance Note 26 suggest 'wherever possible', we have been using CE marked devices wherever possible.	The inspectorate considers this to be an acceptable response.
Witnessing Review of current witnessing SOP	Standard licence condition T71 CoP Guidance Note 23	The PR must ensure that the centre has witnessing protocols in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory	By the time PR responds to this report.	It is rather disturbing that a witnessing protocol advocated by the last inspection team, and currently in use was not acceptable by the present inspectorate. We need to have continuity within the	The inspectorate has reviewed the submitted documents and no further action is required.

		process/procedure takes place. A record must be kept in each patient's medical records. These records must include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.		inspectorate teams. On advice of the present inspection team we have changed our witnessing protocol and a risk assessment was carried out, a copy has been sent along with revised laboratory forms and witnessing protocol. (A3)	
The quality management system A SOP for WoC assessment is required. Quality indicators for all activities and audit against compliance with approved protocols and regulatory requirements should be established.	Standard licence conditions T33 CoP Guidance Note 23 T35 and T36	The PR should develop a SOP for the process to be followed when carrying out WoC assessment. The PR should establish required standards of quality and safety, in the form of quality indicators for all licensed activities and audit against compliance with	By the time PR responds to this report To be monitored at the next inspection	A SOP is currently being incorporated in our QSM; a copy is enclosed for your information. (A4) I am concerned that although the Quality Indicators were examined by the Inspectorate, he found them not to be in existence. Currently, audits are being scheduled for each of these quality	The executive considers this to be an acceptable response. At inspection, quality indicators relevant to procurement, processing, traceability and witnessing were evidenced. However, those relevant to assessment of WoC were not available.

QMS should be implemented.	T32	approved protocols and regulatory requirements. The centre must put in place a QMS to continually improve the quality and effectiveness of the services it provides.	To be monitored at the next inspection .	Indicators (A5) 80% of the QMS is now in draft version being proof read and the remaining 20% will be available for inspection by the end of April. It is proposed that we will apply for our ISO inspection after summer break.	The inspector considers this to be an acceptable response. To be monitored at the time of next inspection.

Third party agreements Not all third party agreements have been established and a complete list of all third parties is not in place.	Guidance Note 24 Standard licence conditions T111 and T115	The PR must establish a written agreement with those third parties who provide goods or services that influence the quality and safety of gametes and the centre must keep a complete list of agreements that they have established with third parties.	By the time PR responds to this report.	This is also disturbing, as a list of all the third party is in place. The third party agreements in our file are the same as those approved by the inspection team last year. Again it appears	The inspectorate considers this to be an acceptable response. Progress to be monitored at the time of next inspection.
Review of content of the third party agreements.	T114	The PR should review the content of the all third party agreements to ensure that they are compliant with the requirements of standard licence condition T114.	By the time PR responds to this report.	that there is inconsistency between the inspection teams. As per the advice of the inspectorate the contents of the	
The centre has not evaluated the ability of all the third parties to meet the requirements of licence conditions and guidance in CoP.	T112	The centre must evaluate the ability of third parties to meet the requirements of T112 and the guidance in CoP.	To be monitored at the next inspection	third party agreement will be reviewed and the ability of all third parties to meet the requirements of the licence conditions will be evaluated and will be in place for next inspection.	

Confidentiality and privacy No SOP is in place to ensure that all information is kept confidential.	Guidance Note 30 T43 and T33(b)	The centre must have a SOP to ensure that all information is kept confidential and only disclosed in circumstances permitted by law.	By the time PR responds to this report.	An SOP is being incorporated in our QMS and is enclosed for your information. (A6)	The inspectorate considers this to be an acceptable response.

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 good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Premises and facilities – Access to the premises should be assessed.	Guidance Note 25	The PR should risk assess or review practice in order to ensure no unauthorised access is possible to the clinical rooms housing the patient notes.	By the time PR responds to this report.	We have assessed the access to the premises and a copy of this assessment is enclosed. (A7)	The inspectorate considers this to be an acceptable response.
Patients' privacy should be assessed.	CoP 25.7	PR should ensure that exchange of all personal information is carried out in private (i.e., cannot be overlooked or overheard by others).	To be monitored at the time of the next inspection	A SOP is currently being developed to take into consideration the confidentiality of the patients. (6)	The inspectorate considers this to an acceptable response. To be monitored at the next inspection.

Additional information from the Person Responsible
In view of the above responses, the 'Recommendation **to the Licence Committee / Executive Licensing Panel' has** to be amended as I do not agree with the following points as they are in place. 1. Implement a programme to validate all critical equipment and processes at the centre. 2. Establish required standards of quality and safety, in the form of quality indicators for all licensed activities. 3. Review the current witnessing standard operating procedure (SOP) I believe that we are fully compliant under T17,T24,T30,T35 and T36, therefore the 'Recommendation to the Licence Committee has to be altered accordingly.

HFEA Executive Licensing Panel Meeting

20 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 3

Fertility Unit, Barking Havering and Redbridge Hospitals Trust (0291) Renewal Report

Members of the Panel:	
Mark Bennett, Director of Finance & Facilities (Chair) Peter Thompson, Director of Strategy & Information Juliet Tizzard, Acting Director of Strategy & Information	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Panel:

- papers for Licence Committee (60 pages)
- additional bundle of information in accordance with Direction 0008

The Panel also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers which included a renewal inspection report, an application for the renewal of licence and previous licence committee minutes from the past three years.

2. The Panel noted that the inspection took place on 17 February 2010 and lasted 7 hours.

3. The Panel noted that this is an IUI centre and has been licensed since 2007 providing basic partner services.

4. The Panel noted that since the previous inspection in February 2009, no major changes had occurred other than the addition of a male production room to the premises.

5. The Panel noted that the centre has provided 188 IUI treatment cycles in the period of 2008.

6. The Panel noted that the centre was licensed initially for two years in 2007, which was renewed for one year in 2009.

7. The Panel noted that the centre had addressed most of the areas highlighted in the previous inspection report but the inspectorate reported that further improvement in a number of areas was required.

8. The Panel noted the recommendations made by the inspectorate on page five and six of the inspection report, and that since the inspection the Person Responsible (PR) has addressed, or is in the process of addressing, these recommendations.

9. The Panel noted that the previous Licence Committee minutes of 28 May 2009 stated that it would expect to see significant improvement in the Quality Management System at the next inspection.

10. The Panel noted the PR's response on page 35 of the report taking issue with the inspectorate's recommendations regarding licence conditions T17, T24, T30, T35 and T36. The PR believes that the centre is compliant with those licence conditions and requested that the recommendations be altered accordingly.

11. The Panel noted that none of the recommendations made within the report concerned critical areas.

12. The Panel noted that the centre has started to implement its Quality Management System, but it remains in draft form. The PR has stated that it will be in place by the end of April 2010 and that there was a commitment to apply for ISO accreditation after the summer.

<u>The Panel's Decision</u>

13. The Panel concluded that although some recommendations remain outstanding at the centre, none concerned critical areas. The Panel agreed that the centre had made significant improvement since the last inspection but that there were still areas that needed to be addressed.

14. The Panel noted the inspectorate's recommendation to renew the centre's licence for a period of four years with no additional conditions.

15. The Panel noted that it was in receipt of a signed application form and that the fee had been paid.

16. The Panel noted that the PR is a Consultant Gynaecologist and obstetrician and is registered with the General Medical Council and is also a member of the Royal College of Obstetricians and Gynaecologists and has the appropriate experience to discharge his duties under section 17 of the HFE Act 1990 (as amended).

17. The Panel noted that the premises and practices are suitable as stated in the inspection report.

18. The Panel referred to the regulatory principles for granting and renewing of licences, and agreed that the centre met the specified requirements

19. The Panel noted the previous licence history but concluded that, given the significant improvement since the last inspection, the licence should be renewed for a period of four years with no conditions. However, the Panel urged the PR to fully implement the Quality Management System and address any outstanding recommendations.

Signed.....Date...2/6/10
Mark Bennett (Chair)