Licence Renewal Inspection Report for Treatment and Storage Centres

Agora Gynaecology and Fertility Centre
0254

Date of Inspection: 31st August 2007
Date of Licence Committee: 17th December 2007

TRIM: 06/3144

CENTRE DETAILS

Centre Name	Agora Gynaecology and Fertility Centre
Centre Number	0254
Licence Number	L0254-1-a
Centre Address	Ellen Street Brighton and Hove BN3 3LN
Telephone Number	01273-229410
Type of Inspection	First Renewal Inspection
Person Responsible	Dr. Carole Gilling-Smith
Nominal Licensee	Mr. Hossam Abdalla
Inspector(s)	Tony Knox Sarah Hopper Neelam Sood
Fee Paid – up-to-date	
Licence expiry date	31st January 2008
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on 31st August 2007 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received between January 2007 and August 2007.

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, Regulations, Code of Practice and 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 Overall Improvements Required – given to centres generally where there are no legal requirements, breaches or conditions that need to be imposed, or any comments in the area for improvement sections of the report. This means that an acceptable standard has been reached without any improvements needed.
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.

NB: Where there are very minor issues to be addressed these are noted in the "minor issues to be addressed" section for each topic, and this will facilitate the evaluation of 'no improvements required'. 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

The centre is a privately owned unit, occupying the third floor of the Agora Building, and provides licensed treatments to both private and NHS funded patients in the surrounding areas. The design of the unit took into consideration the requirements of the EU Tissue and Cells Directive and as such meets with those requirements, and was granted their initial licence to include the requirements of this Directive.

All key members of staff have extensive experience within the reproductive medicine field. The PR previously held the title of PR at the Chelsea and Westminster Hospital fertility unit, the NL is the PR at the Lister Hospital Fertility Unit in London, the Accredited Consultant was previously the PR at the Homerton Hospital Fertility Unit in London, the Senior Embryologist was previously in post at the Hammersmith Hospital Fertility Unit and the lead nurse was previously in post for several years at the Bridge Fertility Unit in London.

A very thorough quality management system is in place and staff are currently working towards ISO 9001:2000 accreditation, with an inspection planned for October 2007.

Activities of the Centre

Licensed treatment cycles	IVF ICSI IUI FET	25 25 72 3
Donor Insemination		2
Unlicensed treatments	Follicle tracking Ovulation Induction	
Research		No
Storage		Yes

Summary for Licence Committee

The centre is run by highly qualified and professional staff. Items indicated within the report noting improvements to be made, including rectification of breaches had, in most cases, already been identified by centre staff and measures were in place to ensure that the corrections needed were being implemented. The inspectorate recommends the renewal of the centres license for a period of three years pending rectification of the breaches noted.

Risk Assessment

The centre has a robust system in place, backed up by documented policies and procedures for conducting risk assessments in all critical areas within the centre. Evidence of risk assessments performed were provided during the course of the inspection.

Following the inspection, a general risk score of 11% was awarded the centre.

Overall judgement of the effectiveness of the centre

No overall Improvements required	Some Improvement required	Significant Improvement required
	X	

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 or Regulations, Standards, Conditions and Directions

Breach	Action required	Time scale
Two storage dewars within the cryostore were seen at inspection to not be alarmed. Staff reported that these had been ordered but had not arrived. Evidence was provided post inspection that this had been a delay on the part of the supplier. (See section three).	All storage dewars within the cryostore to be alarmed.	Immediate.
During an audit of the patient notes, it was evidenced that not all witnessing steps had been completed in accordance with the requirements of the Code of Practice Version 7 or Witnessing Directions. (See outcome of audit of records in section 4 and Section 5)	All witnessing steps to be conducted in accordance with the requirements of the Code of Practice version 7 and Witnessing Directions.	Immediate

Non-Compliance

Area for improvement	Action required	Time scale
Ensuring patient privacy at the main reception desk. (See section 2).	System to be devised to ensure sensitive patient conversations cannot be overheard in the waiting room by other patients.	Immediate

Recommendations	Time scale
Although evidence was provided during the inspection that records of traceability were maintained, it was noted that a procedure to document this requirement was not in place. It was recommended therefore that a policy be documented.	Within three months.
To establish links with the Lister Hospital fertility unit in London for conducting external reviews of their current practice.	Within six months.
Staffing levels within the Embryology and Nursing Departments to be monitored and increased in accordance with requirements. (See section 1).	Ongoing

Proposed licence variations

None

Requirements by previous Licence Committee minutes	Date
None	N/A

Changes/ improvements since last inspection	Date
None	N/A

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
N/A	N/A

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 findings from inspection

1. General organisation of the centre
2. Quality management system
3. Continual improvement
4. Corrective action
5. Preventive action
6. Internal audit
7. Establishment and review of contracts with third parties and transport
8. Transportation, labelling of shipping container and recall
9. Incident Reporting
10. Alerts
11. Notification of serious adverse reactions
12. Equality and Diversity
13. Risk Management
14. Donors
15. External reviews
16. Contingency arrangements

Areas of firm compliance
• The centre was seen to be well organised with all staff interviewed being aware of their responsibilities. • The centre has a robust quality management system in place, has assigned a quality manager, is currently working towards accreditation with ISO 9001:2000, and holds regular meetings with staff at the centre to discuss quality issues and Clinical Governance. Evidence of these meetings was provided to inspectors in the form of minutes taken from the meetings. • Systems are in place for staff to review audit outcomes and to discuss ways in which improvements can be made. The staff are currently reviewing ways of improving patient confidentiality at the main reception desk as a direct result of reviewing comments and suggestions made by patients. • Evidence was provided of third party agreements in place for all suppliers and services used by the centre. These were considered by the inspectorate to be fully comprehensive. • Since opening, there has been one incident reported to the HFEA in accordance with correct procedure. Upon investigation, it was considered that this was a “near miss” incident, with no detrimental effect on either patients, their gametes or embryos or the premises and staff. • HFEA alerts are circulated to all staff upon arrival and where relevant, risk assessments are conducted based on the alerts received.

- There is a robust risk management system in place with risk assessments being performed as necessary. Evidence of risk assessments conducted since opening were provided which include sole working, weekend working, gas safety, all areas of the unit have been assessed and legionella.
- There are no reported problems from the HFEA Finance Department regarding late payment of treatment fees.
- The centre have a fully documented contingency third party agreement in place with the Lister Hospital Fertility Unit in London. Contingencies for equipment failure were also available.

Areas for improvement

- It was noted that whilst current staffing levels were able to meet with the requirements of the treatment cycles being performed, a recent increase in patient numbers provided by gaining an IUI contract from the local NHS Trust has put additional strain on the current resources particularly within the embryology and nursing departments. The PR noted that an additional embryologist is being recruited currently and there are plans to increase nursing staff. Once recruited, the staff changes will be notified to the HFEA.

Minor issues to be addressed

None

Areas not covered on this inspection

All areas covered

Evaluation

Some improvement required

2. Quality of service

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

Summary of findings from inspection:

1. Live Birth Rates
2. Confidentiality and access to health records
3. Needs and requirements of users
4. Assessment of user satisfaction
5. Quality objectives and plans
6. Quality Manager
7. Quality Review
8. Counselling
9. Welfare of the Child
10. Monitoring and resolutions of complaints
11. Staff suggestions
12. Patient choice
13. Egg Sharing and Surrogacy

Live Birth Rates
As the centre only opened in January 2007, it is currently too early to have any live birth data for analysis.
Areas of firm compliance
• Staff interviewed confirmed that all difficult 'Welfare of the Child' cases are discussed initially within a multidisciplinary team meeting to ascertain whether treatment should be provided. Where a general consensus cannot be reached, a referral of that case would be taken to an Ethics Committee. It was noted by the PR that to date, referral to an Ethics Committee has not been required. • Current patient records are housed within the administration office in locked cabinets. This office is situated behind the Reception desk, which is staffed at all times. The door to this area is secured. Archive records are held within the computer server room within locked cabinets. This area is accessed via a keypad entry system, has motion detectors within the room connected to an alarm system, which in turn is connected to the local police station. There is a confidentiality policy in place and all contractors and visitors to the centre are required to sign a confidentiality declaration either as part of their service level agreement/third party contract, or upon arrival at the unit. All staff are required to sign a confidentiality declaration and are provided with training in confidentiality upon induction. • Patients are provided with all treatment options available to them during initial consultation and in the provision of patient information prior to the consultation. All patients interviewed confirmed their satisfaction with the treatment options provided to them. • A centre specific patient satisfaction survey is in place at the centre. It was noted that although a full audit of the responses has not yet been conducted (due to the number received), comments made are considered and appropriate actions taken to make improvements to the centre on an ongoing basis. This includes providing additional

soundproofing between the operating theatre and the recovery area, and the provision of music playing in both areas as a result of a comment stating that conversations could be heard between the two rooms by patients. The PR noted that the first full audit of the centres' patient questionnaires was scheduled for October 2007. Four HFEA patient questionnaires were received prior to the inspection. All comments received were complimentary of the unit, the service offered and professionalism of the staff.

- The centre reported receipt of five complaints since opening in January. Evidence was provided to show that all complaints had been dealt with in accordance with the documented policy and procedure, and all had been effectively closed.
- Although the counsellor was not available for interview, it was explained that one of the four consulting rooms would be used to conduct counselling session at the unit. Counselling notes are taken and held securely on site within a locked cabinet to which, only the counsellor has access. The PR also noted that if required, access to a 'backup' counsellor could also be made available from the Lister Hospital Fertility Unit, however, this had not been necessary to organise. It was reported that there was no current waiting list.
- There is a procedure in place for the protection of children.

Areas for improvement

- Due to the open plan nature of the reception/waiting area, conversations between the receptionist and patients either telephoning or making payment can be overheard by other patients in the waiting room. Staff at the centre confirmed that they were aware of this problem and were currently being addressed. The accounts function is planned to move to the current nurses office. This will ensure that patients can discuss their payments in privacy. Means of ensuring telephone calls are taken and then passed onto other staff members away from the reception desk are currently being explored.
- Evidence was seen in all patient notes inspected that a 'Welfare of the Child' assessment had been performed. It was however noted in two cases that the assessment form had been incorrectly completed. (See outcome of audit of records in section 4).

Minor issues to be addressed

None

Areas not covered on this inspection

- Egg sharing and surrogacy are not offered currently at the centre.
- The centre does not currently operate a donor sperm bank at present.
- An interview with the counsellor was not conducted as she was on annual leave at the time of the inspection.

Evaluation

Some improvement required.

3. Premises and Equipment

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

Summary of findings from inspection:

1. Any Changes
2. Suitable premises
3. Safe working with environment
4. Clinical facilities
5. Counselling facilities
6. Laboratory facilities
7. Storage facilities for gametes and embryos
8. Air quality
9. Staff facilities
10. Suitable equipment
11. Management of equipment and materials
12. Alarms
13. O2 alarms
14. Handling and manipulation of gametes and embryos
15. Dewars

Areas of firm compliance
• The premises are well maintained and considered fit for purpose by the inspectorate. The unit consists of: - o A large comfortable waiting/reception area including a small play area for children. The HFEA license, Health Care Commission license and complaints procedure were clearly displayed. Patient questionnaires were available to patients as well as a box for their collection as well as patient comments/suggestions. o An administration/finance office containing secure current notes storage. o A nursing administration office. o A secure computer server and archive notes room. o A scan room o A treatment room used primarily for IUI treatment and for taking patient blood samples. o Three consulting rooms which can also be used by the independent counsellor. o A staff refreshment/meeting room. This area is also used for providing patient presentations during open evenings at the unit. o The PR office/consulting room. o Sluice room. o Office shared by the senior embryologist and lead nurse. o Changing room. o Fully equipped embryology/semenology laboratory o Cryostore o Operating theatre used for egg collections under IV sedation only. Access provision is made from this room to the laboratory, a drug room/preparation room and to the adjoining recovery area. o Recovery area containing three bays. Two of the bays contained comfortable

reclining chairs and the third bay contained a trolley.
    - Producing room considered by the inspectorate to be fit for purpose, with hatch access to the laboratory. This ensures that after the sample is produced, the patient leaves the sample inside the hatch and then presses a bell to notify staff within the laboratory that the sample has been left.
    - Clinical waste storage area
    - Toilet providing easy access to disabled patients. This area is also equipped with baby changing facilities.
    - Access to the rear stairs leading down to a room on the ground floor where gas cylinders and liquid nitrogen stores are kept. Gases are piped up to the laboratory area. A procedure is in place for the safe transfer of liquid nitrogen from the ground floor to the third floor using a lift at the front of the building. Staff occupying other floors of the Agora Building, have been made aware of the procedure for transferring the liquid nitrogen to the third floor, signs have been made to inform those members of staff not to use the lift when it is being transferred, and a procedure is in place to ensure that the nitrogen is put into the lift on the ground floor and is collected by a member of staff on the third floor. No member of staff travels up in the lift with the nitrogen container.
- Service and maintenance records were evidenced during the inspection showing that all critical equipment had been serviced, maintained and calibrated in accordance with manufacturers guidelines.
- One near miss incident has been reported since the unit opened in January. This incident referred to a faulty door on an incubator. The incubator was not in use at the time, a backup incubator was made available for the safety of the samples and the manufacturer was contacted immediately to ensure the problem can be rectified.
- An autodialing facility and emergency procedures for responding to damaged vessels is in place.
- Handling and manipulation of gametes are performed in accordance with Code of Practice version 7 requirements.

Areas for improvement

- There are currently four storage dewars within the cryostore. Only two of the dewars were seen to be alarmed at the time of the inspection. It was reported that an additional two alarms have been ordered but these had not been delivered to date. Upon receipt, staff will notify the HFEA immediately of their installation.

Minor issues to be addressed

None

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvement required.

4. Information

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

Summary of findings from inspection:

1. Meetings and communication
2. Information management
3. Quality manual
4. Document control
5. Control of Records
6. Donor registration
7. Receipt of gametes
8. Home Procurement documentation
9. Traceability
10. Material donated to research
11. Coding
12. Information for users This section includes: Access to data
13. Tracking live birth events
14. Storage records
15. Information to the HFEA
16. Counsellor records
17. Import/export
18. 3 embryo transfer
19. Donor Information
20. Storage and release of gametes and embryos
21. Storage forms
22. Anonymity
23. Labelling of packages containing procured gametes
24. Validations
25. Screening
26. Audit
27. Consents

Outcome of audit of records
An audit was conducted on 15 sets of patient notes. All notes audited were seen to be well maintained and structured to enable swift access to relevant information. On two Welfare of the Child (HFEA), assessment forms, it was noted that a box had been ticked to state that treatment should not be provided for couples who had received treatment. The PR noted that these were administrative errors and additional focus would be given to ensuring that these were not repeated in the future. It was noted that two sets of patient notes contained patient identification for only one partner rather than for both. The PR noted that this would be rectified. All other consent forms were seen to have been completed appropriately.

During an audit of witnessing steps within five sets of patient notes, the following was found: -

- One set of notes provided no evidence that a movement of gametes between dishes during an ICSI procedure had been witnessed.
- The embryologist had not been witnessed when discarding embryos at the end of treatment despite there being space for the recording of this step on the lab sheets.
- Some witnessing steps were not recorded with either a time the procedure was witnessed or by operator identification.

These issues were raised with the senior embryologist and PR during the feedback session. It was agreed that these omissions would be rectified and all witnessing steps would be conducted in accordance with Directions.

Areas of firm compliance

- Regular minuted multidisciplinary meetings are held within the centre where issues such as patient care, quality management, audits, success rates and audit outcomes are discussed. Evidence was provided during the inspection of the minutes created.
- All patient information, policies and procedures at the centre were seen to be version controlled and contained a review date. Access to all centre information is held securely on computer with restricted access control. Any modifications considered necessary are circulated to all staff for input prior to changes being made. Once completed, the new version is signed off, circulated for use and older versions of the paperwork are taken out of circulation.
- There is a robust quality manual in place for the centre.
- Patient notes were seen to be stored securely.
- It was noted that the centre intends to start their own sperm donor bank later in the year for their own patients initially.
- The transportation and receipt of gametes are under conditions that ensure their safety and quality. Evidence was provided of a suitable third party agreement with a courier used for the transportation, and it was further noted by the senior embryologist that the purchase of a data logger (which records temperature) is to be purchased which will travel with the shipper so that conditions during transportation can be monitored.
- Records were evidenced of all batches of media and items of plastic ware being maintained for traceability.
- A procedure is in place and was considered fit for purpose for the tracking of live birth events.
- There was no reported problems of late reporting from the Registry Department of the HFEA and it was noted that the centres' only incident had been reported within the required timeframe.
- Counselling records are kept within a locked storage unit within the centre with access restricted to the independent counsellor only.
- Screening was seen to be conducted in accordance with the requirements of treatment at the centre.
- The senior embryologist confirmed that all equipment within the lab has a test run and validation processes conducted prior to being put into general use.

Areas for improvement
• Although evidence was provided during the inspection of records being maintained for traceability, it was noted that a procedure was not in place detailing the steps to be performed. It was recommended that this be documented.
Minor issues to be addressed
None
Areas not covered on this inspection
The centre has conducted no import or export of samples.

Evaluation
Some improvement required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

1. General
2. Staffing Personnel Records
3. Criminal convictions
4. Initial /basic training and update training
5. Competence
6. Annual joint review
7. Continuing education and professional development
8. Procedures
9. Clinical Processes
10. Clinical treatment
11. Viral positive patients
12. Cross infection
13. Laboratory Processes
14. Emergency procedures
15. Handling and manipulation of gametes and embryos
16. Participation in inter-Centre comparisons and inter-Laboratory comparisons

Full time equivalent staff

GMC registered doctors	3
NMC registered nurses	2 + bank staff as required
HPC registered scientists	1
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	2
Counsellors	1

Summary of laboratory audit
A laboratory audit has not yet been produced for the samples in storage at the unit. This is primarily due to the fact that samples have only commenced being stored at this unit since January 2007.
Summary of spot check of stored material
One set of embryos was tracked from records to tank and another set from tank to records. No discrepancies were noted. One sperm sample was tracked from records to tank and one from tank to records. No discrepancies were noted.

Areas of firm compliance
• Human resources policies are in place and considered fit for purpose to ensure staff are recruited with appropriate qualifications, are registered with their professional bodies and that consideration is given to both equality and diversity and past criminal convictions prior to employment. • There is an appropriate induction policy and program in place for all new employees which includes specific training in confidentiality requirements and the Code of Practice. • Staff appraisals are conducted initially after three months of employment and then annually thereafter. Evidence of staff competencies are maintained and signed off by appropriately qualified members of staff within the unit. • Evidence was provided to show that staff needs for continuing professional development have been and continue to be addressed and provided for appropriately. This was confirmed during staff interviews. • Emergency procedures were seen to have been documented for responding to damaged vessels within the laboratory and in the responding to emergencies within the unit. All staff were seen to have received an update in basic life support and two members of staff were seen to have been qualified to advanced life support standard. The emergency crash trolley for the unit and associated emergency equipment was seen have been checked daily. • Staff at the centre noted that currently there is no provision at the centre for the treatment of viral positive patients. It was noted that any patient presenting at the centre requiring treatment of this nature would currently be referred to the Chelsea and Westminster fertility unit in London. • The senior embryologist reported that no unscreened samples are stored at the centre. • A data logger is on place linked to all critical equipment within the laboratory to maintain records of its performance.
Areas for improvement
See section one regarding staffing levels. • At present, no inter-laboratory reviews of practice are conducted. It was noted by the senior embryologist and PR however that such a program could be established with the Lister Hospital fertility Unit in London. • During an audit of the patient notes, it was evidenced that not all witnessing steps had been completed in accordance with the requirements of the Code of Practice Version 7 or Witnessing Directions. (See outcome of audit of records in section 4).
Minor issues to be addressed
None.

Areas not covered on this inspection
All areas covered.

Evaluation
Significant improvement required.

Report compiled by:

Name TONY KNOX

Designation Inspector

Date 1st September 2007

Appendix A: Centre Staff interviewed

PR – Dr. Carole Gilling-Smith
Four other members of the centre staff.

Appendix B: Licence history for previous 3 years

2007

Licence Committee 2nd May 2007
Approval given to vary the centres license in accordance with the requirements of the EU Tissue and Cells Directive.

Licence Committee 18th January 2007
Approval provided for the opening of the Agora centre.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0254

Name of PR Dr. Carole Gilling-Smith

Date of Inspection 31.8.07

Date of Response 15.10.07

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

The following actions have taken place:

1. The two storage dewars within the cryostore that were not alarmed at the time of inspection were alarmed on the next working day 2.9.07. the alarms had been ordered on 2.8.07 and the company providing the alarms admitted they had delivered the alarms with considerable delay. Tony Knox was provided with the relevant correspondence.
2. All steps in our laboratory are now witnessed irrespective of the circumstances. The Agora has introduced a witnessing step during the disposal of embryos.
3. All calls of a sensitive nature are passed from the front reception desk to the back office to be dealt with by other staff so that conversations cannot be heard by other patients in the waiting room.
4. Our patients Account manager is now located in a separate office near the waiting room so that payment queries can be conducted in privacy.
5. We have carried out update training of all nursing staff to ensure Welfare of the Child forms are filled out correctly.
6. A traceability SOP is currently being written.
7. We are in the process of establishing a link with the Lister Hospital Fertility Clinic to allow external review of our clinical and laboratory practice.
8. We have in the past and continue to monitor our staffing levels to ensure these are matched to ongoing and predicted activity.

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

Signed……

Name……

Date……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

At the end of the inspection we were led to believe that the Agora had some minor improvements to make but it was not made clear to any of us, particularly to the PR, that we had breached the Act and that significant improvement was required in any areas.

1. We have addressed the two issues raised as Breach of the Act, namely the alarming of the two additional storage dewars and that not all witnessing steps had been completed within the requirements of the Code of Practice Version 7. We argue however that the dewars would have been alarmed at the time of the inspection is the supplier had not delayed, which was unforeseen, and that the absence of witnessing steps in the case identified during inspection was reasonable under the circumstances. The case identified involved a lengthy MESA where the stripping of the eggs before injection at 8pm in the evening was not witnessed as all staff had left. There were no other cases requiring laboratory work at this time and the only other IVF of ICSI cases that day had been inseminated (witnessed) much earlier on. As PR I deemed it reasonable to allow the stripping of the eggs to take place unwitnessed at this time as all other cases had been completed and witnessed and it was now very late in the evening. The nominal licensee agrees this was reasonable too given our current staffing numbers.
2. The Code states “appropriate” witnessing for disposal of gametes or embryos. We consider the present level of witnessing appropriate until extra embryology staff are employed. All disposal of any frozen samples will be witnessed by two staff as per SOP.
3. Under 1. Organisation under areas for improvement we do not feel that our current workload necessitates increased permanent staffing levels. We have a number of bank nursing, embryology and medical staff we can call on to match current fluctuations in workload and a robust system within our quality management system to ensure permanent staff will be recruited once the need arises. There is very little we feel that could be done to improve the system we already have in place.
4. Under 2. Quality of service under areas for improvement we have spoken to our front desk reception staff and now all calls of a sensitive nature are passed to the back office. Our Patient’s Account Manager is now located in a separate office near the waiting room so that payment queries can be conducted in privacy. The incorrect completion of the welfare of the child form has been addressed through update training of all nurse involved during nurse consultation.
5. Under 4. Information under areas for improvement traceability it was recommended that a SOP be put in place. This is a recommendation not a necessity as the actual records are maintained for traceability.
6. Under 5. Laboratory and Clinical Practice we agree with the suggestions made for improvement. Issues over witnessing addressed previously. As a new unit there has not been the scope yet to conduct an inter laboratory audit. As one of the directors and Nominal licensee Mr. Abdalla is also the PR at the Lister Fertility Clinic there is

already ongoing comparisons being made of protocols, statistics etc and an inter-laboratory review of practice should be undertaken in the near future once we have established sufficient cycle numbers.

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

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

17 December 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 3

Agora Gynaecology and Fertility Centre (0254)
Licence Renewal

Members of the Committee:

Jennifer Hunt, Lay Member – Chair
David Archard, Lay Member
Sally Cheshire, Lay Member

In Attendance:

Trish Davies, Director of Regulation / Deputy Chief Executive
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Sarah Ellson, Field Fisher Waterhouse Solicitors

Conflicts of Interest: Hossam Abdalla declared a conflict of interest in relation to this item and left the meeting. Other 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:

- papers for Licence Committee (35 pages)
- no papers were tabled.

1. The papers for this item were presented by Tony Knox, HFEA Inspector. Mr Knox informed the Committee that this centre has been licensed since the beginning of 2007, this being its first renewal inspection. The centre is being run by a highly qualified team and has an 11% risk score. Mr Knox summarised the main points of the inspection report and drew the Committee's attention to the Person Responsible's comments at the back of the report. Mr Knox further reported that the centre has addressed or is in the process of addressing the breaches and recommendations identified in the report.

2. Mr Knox drew the Committee's attention to the fact that a delay on the part of the supplier contributed to the fact that two of the storage dewars were without alarms on the day of the inspection visit. This was noted by the Committee.

3. The Committee agreed that they were satisfied as to the suitability of the Person Responsible, the centre premises and the use of suitable practices at the centre. The Committee further agreed that it was satisfied that it had sufficient and satisfactory information on which to make a decision on the licence renewal.

4. The Committee unanimously decided to renew the centre's licence. Because the centre has been licensed for one year only, the Committee agreed that this licence should be for three years.

5. As the centre has only just been invoiced for its new licence the Committee requested that the licence only be issued pending receipt of the licence fee.

Signed..... Jennifer Hunt ... Date... 3/1/08
Jennifer Hunt (Chair)