Interim Inspection Report

Wessex Fertility Limited
Centre 0057

Date of Inspection: 27th February 2008

Date of Licence Committee: 12 May 2008

CENTRE DETAILS

Centre Name	Wessex Fertility Limited
Centre Number	0057
Licence Number	L0057/15/a
Centre Address	Anglesea House 72-74 Anglesea Road Southampton SO15 5QS
Inspection date	27 February 2008
Licence Committee date	12 May 2008
Inspector(s)	Allison Cummings
	Dr Andrew Leonard
Fee Paid - date	Not due
Person Responsible	Dr Sue Ingamells
Nominal Licensee	Ms Claire Stollery
Licence expiry date	31 July 2009

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About the Inspection:

This inspection visit was carried out on the 27th February 2008 and lasted for 6 hours. The report covers the pre-inspection analysis, the visit and information received between March 2007 and February 2008.

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

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

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

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

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

Wessex Fertility Limited is located on the outskirts of Southampton in a purpose built two-storey building. The laboratory, theatre and recovery area are all located on the ground floor with secure access. The waiting area, consultation/treatment rooms, administration and staff facilities are all located on the second level. Improvements to the premises since the last inspection in January 2007 include a more private reception area and refurbishment of the male production room.

The centre was first licensed in 1992 and treats private and NHS patients. They have a satellite IVF arrangement with the Royal Bournemouth NHS Foundation Trust (HFEA centre 0288) and the BMI 'The Hampshire Clinic' (HFEA centre 0285). It is a busy IVF centre providing almost 600 cycles of licensed treatments a year, the majority being self funded. The centre appears to be well managed and organised.

The centre is open to patients from 8am to 4pm Monday to Friday and 8am to 12pm on Saturdays. The centre plans to introduce evening clinics in April 2008 to increase patient access to the service and also to maximise their utilisation of the facilities. The doctors and embryologists are available 24 hours a day on a rota system.

The Person Responsible (PR) has been in post since February 2005. She is a consultant gynaecologist and obstetrician and has extensive experience within the reproductive medicine field. A management buyout of the centre occurred in December 2007 and the PR together with another consultant who works at the centre are now the new owners. The Nominal Licensee, Claire Stollery, remains in post although it is expected that this will change in the near future. To date, the buyout has had no impact on staffing and the day-to-day management of the centre.

The PR reported that now the management buyout has taken place, they are looking to invest and improve several aspects of the service that she has felt needed to be addressed for some time. These business plans also involve a review of success rates and appropriate investment to improve them and support safe business expansion

Two consultant fertility specialists (inclusive of the PR) are in post although one is currently on extended leave. To cover the workload, the consultant/PR from Royal Bournemouth NHS Foundation Trust works at the centre two mornings/week although in time, this will revert to one morning/week. Another consultant will join the team in April 2008.

Wessex Fertility Limited is involved in two research projects, one of which uses human embryos donated for research. The research takes place at the University of Southampton, also licensed by the HFEA (R0142).

Activities of the Centre

Licensed treatment cycles	554*	IVF and ICSI (with own gametes or donor eggs/sperm). IUI is now also licensed by the HFEA and the centre is expected to report their activity for 5 July – 31 December 2007 by 31 March 2008.
Donor Insemination cycles	28*	
Unlicensed Treatments	✓	Ovulation induction Tubal surgery Surgical sperm retrieval and assessment
Storage	✓	Eggs, sperm and embryos.

* The information that we publish on our website is a snap shot of data provided to us by licensed centres at a particular time. This information may be subject to change as individual centres notify us of amendments. Before publication, we perform a preliminary validation process on the data, and ask the centres to confirm its accuracy, for which they remain responsible.

Summary for Licence Committee

The executive recommends the continuation of the centre's licence and additionally recommends that the PR regularly updates the executive of the progress towards improving the centre's success rates.

Risk Assessment

Following the inspection, a medium risk score of 21% was allocated to the centre.

Evaluations from the inspection

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

Breaches of the Act, Standard Licence Conditions or Code of Practice:

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

Breach	Action required	Time scale
Standard 9.4.2 (c) notification of the HFEA, by the Person Responsible, of Adverse Incidents and the subsequent provision of a confirmation/conclusion report.	Notification of the HFEA of adverse incidents. A single incident log should be maintained and all staff should be made aware of HFEA incident requirements.	With immediate effect.
In the audit of one medical record, it was noted that the male partner had consented to posthumous use of embryos in a surrogacy arrangement. However he had not undergone appropriate screening as a donor, in accordance with standard licence condition A.7.1.	Donors should be appropriately screened in accordance with Standard Licence Condition A.7.1 in cases where the patient consents to posthumous use of gametes/embryos involving procedures requiring donation. The PR should consider the implications of this and audit material in store to establish whether there is other material with similar screening requirements.	With immediate effect.
Standard 7.8.3 - procedure validation is not yet performed.	Laboratory procedures should be validated.	31 August 2008
Standard 9.2.6 – inter-laboratory comparisons have not yet been undertaken.	The PR should implement inter-laboratory comparisons.	31 August 2008

Non-Compliance	Action required	Time scale
The centre's method of witnessing (manual or electronic) has not been risk assessed in accordance with CH (07)02.	Submit risk assessment to the executive. On the day of the inspection, the laboratory manager agreed to make this work a matter of priority.	30 April 2008
Excess sperm is used for testing of	Patients will be provided with	With

non-CE marked consumables. The inspectorate was told that male partners do not consent for this use of their sperm. This is not in accordance with Guidance 6.7.2 (d).	proper information before giving consent to the use of their gametes.	immediate effect.

Recommendations	Time scale
With respect to the lack of hazard signage on the door leading into the laboratory where dewars are kept, it is recommended the PR assess the risks to staff, gain advice from their local health and safety representative and refer to Standard 4.2.3 (d) which requires that there is a commitment to the health, safety and welfare of all staff and visitors to the centre.	31 May 2008

Proposed licence variations

None.

Changes/ improvements since last inspection

Recommendation from last inspection	Action taken
Communication – Review and improve the effectiveness of meetings and the dissemination of any outcomes.	The inspectorate reviewed the systems for communicating to staff and found that a variety of methods had been developed subsequent to the last inspection. Refer to section 1: organisation for further detail.
Male Production Room and the disabled toilet facilities - dual purpose of the room require consideration	The executive set a six month timescale for the centre to make improvements. At the most recent inspection, it was noted the facilities are still dual purpose however it has been refurbished to a more comfortable standard.
The entrance to the centre needs to be signposted.	The inspectorate considered the signage to be adequate at the most recent inspection.

Additional licence conditions and actions taken by centre since last inspection

The previous licence was issued without any additional conditions.

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
Evidence is drawn from:

- Leadership and management
- Organisation of the Centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
• The centre has a clearly defined management structure which regulates all activities within it. Clear reporting lines are in place. The PR reported that an organisational chart has recently been updated. • The inspectorate was shown a documented emergency contingency plan with Bath Assisted Conception Unit (centre 0139) as well as service level agreements with their satellite centres. • The PR reported that now the management buyout has been secured, they are looking to invest and improve several aspects of the service she has felt needed to be addressed for some time. These business plans also involve a review of success rates and appropriate investment to improve them and support safe business expansion. • The inspectorate was informed that defined mechanisms are in place for disseminating Alerts from the HFEA and the Health Care Commission to relevant staff, via email and for discussion and the development of action plans in response to them. The laboratory manager reported that she has recently reviewed all Alerts to ensure the centre's policies and procedures are compliant with them. The review concluded that most were compliant and all examples of non-compliance were corrected.
Areas for improvement
• Two incident logs were produced on inspection, one held by the laboratory and the second held by the nurse manager, the latter containing the most recent incidents. The inspectorate found two had not been reported to the HFEA because for one, the PR considered it was not an incident but a near miss, and for the other, no reasons were given. The inspectorate recommended a single log be kept and that all centre staff should be made aware of HFEA definitions, expectations and reporting procedures surrounding adverse incidents as outlined in the Code of Practice and Standard Licence Conditions.

Areas for consideration
• Regular departmental meetings are held within each disciplines as well as a weekly centre management board meeting. All staff meetings used to be scheduled on a weekly basis although the inspectorate found that these had not occurred over recent months during the management buyout. The PR reported that in future all staff meetings will be held monthly. Minutes of the departmental meetings were seen by the inspectorate and the PR reported that they are distributed electronically. E-mail is also used to distribute essential urgent information and the practice manager provided an example of its use relating how it was used to modify the fire mustering point which was tested in a fire alarm test soon thereafter.
Executive recommendations for Licence Committee
A single incident log should be maintained and all staff should be made aware of HFEA incident requirements.
Areas not covered on this inspection
None.
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:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Live Birth Rates

The clinical pregnancy rates reported below were taken from a report run prior to the inspection date:

	IVF	FET after IVF	ICSI	FET after ICSI	DI
Clinical pregnancy rate per treatment cycle started: 01/01/07-31/12/07*	16.81%	22.73%	14.79%	10.94%	17.86%
Live birth rate per treatment cycle: 01/01/06 - 31/12/06*	21.63%	17.31%	17.57%	11.76%	8.33%

* The information that we publish on our website is a snap shot of data provided to us by licensed centres at a particular time. This information may be subject to change as individual centres notify us of amendments. Before publication, we perform a preliminary validation process on the data, and ask the centres to confirm its accuracy, for which they remain responsible.

- The PR reported that she is aware that something (unknown) has significantly affected their success rates for IVF/ICSI fresh cycles. For example, the clinical pregnancy rate for IVF with fresh embryos was 16.81% in 2007 and 25% in 2006, while corresponding figures for ICSI with fresh embryos were 14.79% in 2007 and 20.27% in 2006. It should be noted that this data is not corrected for age. The inspectorate was informed that the centre has had an action plan in place since October 2007 to address the problem, involving changes in laboratory equipment and processes and tighter control of stimulation regimes. The cause has not yet been identified. It was agreed that the action plan be submitted to the executive and this has now been received. Plans to seek external consultancy will be activated if improvements are not seen by March 31 2008.
- HFEA verified data from March 2002 to April 2005 indicated when data is age stratified, the centre's success rates in the age groups <35 years, 35-37 years, 38-39 years and 40-42 years are comparable with the national averages, for IVF/ICSI fresh and frozen cycles.

- For donor insemination, HFEA verified data from March 2002 to April 2005 indicated the centre's success rates are significantly lower than the national averages in age groups <35 years and 35-39 years but are comparable with the national average in age group 40-42 years. It should be noted that although clinical pregnancy rate data for 2007 is unverified, these have almost doubled relative to 2006, from 8.3% to 17.9%.
- According to data provided before inspection, three embryo transfers were performed in seven patients in 2007, all over 40 years of age.
- The centre has an ovarian hyperstimulation syndrome rate of 0.86%, well below the 2% rate which is considered acceptable by HFEA.

Areas of firm compliance

- Patient records were seen to be stored in good order within a lockable room isolated beyond the administration area. The room was seen to be fire-alarmed. The inspectorate considered that the premises ensure patient privacy and dignity are protected and in discussions with the PR and staff, attention and respect for patient privacy and dignity were clearly expressed.
- A sample of complaints from their register were seen by the inspectorate. These included information about the investigation together with the corrective action taken. Clear protocols are in place with regards to the complaints process and a named person is responsible for receiving and processing complaints. A comments/complaints poster was seen in the patient waiting area.
- The PR reported that the counselling service is available to patients on Tuesday afternoons and Saturday mornings. An audit supplied to the inspectorate indicated that 80 couples and 109 individuals attended counselling for the 2007 calendar year.
- Patient questionnaires were seen on display in the waiting area. The practice manager reported that action taken as a result of feedback included refurbishment of the male production room.

Areas for improvement

None.

Areas for consideration

None.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

- Choice of treatments
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Evaluation

No improvements required.

3. Premises and Equipment

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

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/accidents

Areas of firm compliance
• The centre is in relatively new premises which the inspectorate considered was finished to a high quality which provide a well designed and equipped clinical and laboratory environment, considered by the inspectorate to be suitable for licensed activities. Patient areas were found to be pleasant and comfortable, albeit the reception is close to the waiting area and patients are always moved to the administration area for private conversations. The practice manager reported that a new reception area will soon be constructed which will provide more privacy for patients than at present for such conversations. The centre's licence was displayed in the reception area. • The inspectorate was informed that the centre has an alarm system which is 'live' at night. The main entrance door is unlocked during the day and provides access to the stairs to the first floor reception and waiting area. Leading off from this area are the consulting rooms, administration area, medical record storage room and staff rest room, with access being controlled visually by the receptionist and administration staff. The front door also opens on a key card operated door to a corridor which provides access to the treatment and recovery areas, then the laboratory, offices, the cryostore, the emergency generator and finally a fire door opening to the building rear. The centre is locked nightly by the weekly key holder, four senior staff members are on this rota. • The centre has a diesel powered emergency generator and the practice manager stated that it is serviced 6 monthly and is tested monthly, which has the capacity to support all electrical requirements in the event of failure of the normal supply. • An emergency trolley was present in the recovery room and this was seen to be checked daily by a known signatory. • The storage dewars are locked in a room opposite the laboratory while the laboratory was on a corridor with key card controlled access. A low level oxygen monitor and alarm and an air extraction system was noted in the cryostore. If the low level oxygen monitor is activated, the cryostore air extraction system is boosted and an audible alarm activated. • Cleaning logs were observed for laboratory equipment. • Daily monitoring checks were seen to be performed on key pieces of equipment such as incubators and air flow hoods. There is a documented system for monitoring equipment performance and safety. Regular review of monitoring data has been implemented. • Equipment servicing and maintenance logs were present and all equipment was within servicing intervals and had been PAT tested. • The inspectorate was informed the laboratory air quality meets HFEA requirements and that particle counts are done monthly to ensure the standard is maintained. A comprehensive

protocol for air particle counting was provided to the inspectorate. More recently, a microbiological monitoring protocol has been devised so that settle and contact plate testing occurs every six months in the class II workstations. The inspectorate was informed the first settle/contact plate testing was to be performed in the week after the inspection; regular testing will be implemented thereafter.

- The centre has recently invested in two new incubators with another two on order. It also has three incubators for preparation work, eg pre-warming media. Three new air flow cabinets have also been fitted. Documentation was available for the commissioning and validation of these items of equipment. Subsequent performance validation checks have also been logged for incubators (temperature; carbon dioxide level; outcome rates for large oocyte batches split between two incubators) and air flow cabinets (temperature on hotplate; air quality). The validation SOP was observed on inspection. Temperatures are validated with two thermocouples which are serviced and calibrated annually, comparison between them being used to indicate if one is out of calibration and requires interim servicing.
- The equipment validation is, in part, driven by the centre perceiving that success rates should be higher, and is part of the action plan developed by the centre to rectify this issue. To this end they have also undertaken several visits at other IVF laboratories, and have reviewed all procedures in the centre. Embryo quality and ICSI survival rates are rising but this has had, as yet, no effect on pregnancy rates.

Areas for improvement

None.

Areas for consideration

- The dewars were seen to be kept in the laboratory. The inspection team were concerned that staff may enter the room if the low oxygen alarm sounded, putting themselves at risk of asphyxiation. The inspectorate recommended the PR assess the risks to staff, gain advice from their local health and safety representative and refer to Standard 4.2.3 (d) which requires a commitment to the health, safety and welfare of all staff and visitors to the centre.

Executive recommendations for Licence Committee

None.

Areas not covered on this inspection

None.

Evaluation

No improvements required.

4. Information

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

Summary of findings from inspection:

- Information management
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of medical records audit
• Three medical records were audited for completeness with respect to patient consent. In one, the inspectorate noted that the male partner had consented to surrogacy using their embryos however he had not undergone appropriate screening for use as a donor, in accordance with standard licence condition A.7.1. The inspectorate recommend that the centre audit material in store for donation and ensure that sperm is appropriately screened in future donor and surrogacy cases and that centre's procedures reflect the necessary changes. • The audited records were seen to be well organised and information was easy to locate.
Areas of firm compliance
• The inspectorate were informed that the centre's server is secure and protected from external unauthorised access. • The centre report information to the HFEA in an accurate and timely manner. • The samples of protocols seen were appropriately document controlled.
Areas for improvement
See Outcome of medical records audit above.
Issues for consideration
None.
Executive recommendations for Licence Committee
All donor and surrogacy material should be appropriately screened and procedures should be updated and implemented to reflect the changes.
Areas not covered on this inspection
Information to donors
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:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	1.8
NMC registered nurses	5
HPC registered scientists	3
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	7.6

Summary of laboratory audit
• An audit report of patient's own stored sperm was supplied to the inspectorate. The audit took place from 17 - 24 October 2007. All samples were present although the report identified six non-conformities in that consent forms had expired and needed renewing. A record of the consequent investigation and corrective actions were seen. • Audit reports for stored embryos were also provided to the inspectorate. Laboratory staff carried out an audit of a 10% subset of samples from two tanks in the last year. A complete audit of their third tank was also performed when samples were transferred into it from a tank which is now designated as an empty contingency reserve. All investigations and corrective actions required were recorded. The centre should note that Standard 7.8.12, contains the requirement that audit of stored material can now be performed every 2 years rather than annually.
Summary of spot check of stored material
• A spot check of stored material performed on the day of inspection showed no discrepancies.
Areas of firm compliance
• Batch logging is performed to facilitate traceability, the dates of use of a consumables batch being logged to allow comparison with patient treatment dates. The inspectorate was informed that all consumables are CE marked or verified as ART compatible using human

sperm.
- An example of a competency assessment for a fertility staff nurse was shown to the inspectorate. The PR reported that the centre is moving to a system whereby an individual's results and performance are monitored and available for review.
- Evidence was provided to show that staff needs for continuing professional development have been and continue to be addressed.
- The andrologists reported that they participate in the UK NEQAS scheme - a form of external review.

Areas for improvement

- Excess sperm is used for testing of non-CE marked consumables. The inspectorate was told that male partners do not consent for this use of their sperm. Guidance at 6.7.2 (d) of the Code of Practice recommends patients be provided with proper information before giving their consent to the use of gametes.
- Process validation is not yet performed. Staff interviewed were advised that it is now a requirement in accordance with Standard 7.8.3.
- Inter-laboratory comparisons were discussed with the laboratory manager who stated that whilst they have made several visits to other centres, inter-laboratory comparisons are not recorded. The inspectorate recommended that the centre implement this practice in accordance with Standard 9.2.6.
- The inspectorate found the centre had not yet considered the most suitable method of witnessing (electronic or manual) for their local situation as requested in CH (07)02. The laboratory manager responded that the risk assessment of their chosen system will take priority.

Areas for consideration

- Audit tools for witnessing and transport hazards of gametes and embryos circulated to PR's nationally late 2007 did not reach the PR due to an error on the HFEA's part in that the incorrect email address was used to send the correspondence to. This has now been rectified and the audit tools have been received by the PR.
- Laboratory staff carried out an audit of an estimated 40% of cryopreserved embryos in the last year. Standard S.7.8.12 (b) requires the reconciliation of the centre's records with material in storage once every two years and it is anticipated that the audit of the remaining 60% of cryopreserved embryos will be completed within that timescale.

Executive recommendations for Licence Committee

Informed consent should be gained from patients when excess sperm is used to test non-CE marked consumables.
Procedure validation should be undertaken.
Inter-laboratory comparisons should be formalised.
Witnessing procedures must be assessed and any proposed new protocol must be risk assessed.

Areas not covered on this inspection

None.

Evaluation
Some improvements required.

Report compiled by:

Name: Allison Cummings

Designation: Inspector

Date: 25 March 2008

Appendix A: Centre Staff interviewed

The PR and six other staff.

Appendix B: Licensing History

May 2007: Variation of Licence under the EUTCD legislation
The Committee agreed to vary the centre's licence to incorporate the requirements of the EUTCD.

16 April 2007: Consideration of interim inspection report
An interim inspection was carried out on 9th January 2007. In response to the inspection findings, the Committee agreed that the centre should continue with no additional conditions.

21 June 2006: Consideration of renewal inspection report
The Committee noted that the centre had previously been granted a one year licence. They decided to renew the centre's licence for a period of three years with no additional conditions.

11 July 2005: Variation of licence to recognise a new Nominal Licensee
The Committee considered the information supplied in the committee papers and agreed to recognise Dr Aileen Hamill as Nominal Licensee for the centre.

11 April 2005: Consideration of renewal inspection report
The Committee noted that the centre has recently become a stand-alone centre and with this in mind agreed to renew the centre's licence for a period of one year.

9 February 2005: Variation of licence to recognise a new Person Responsible and Nominal Licensee
The Committee considered the applications for change of Person Responsible and change of Nominal Licensee. The Committee noted that the applications for variation were made with the consent of the existing Person Responsible and the existing Nominal Licensee respectively. Members agreed that both applications were appropriate, and agreed to vary the licence to recognise the new post-holders.

Appendix C: Response of the Person Responsible to the Report

Centre Number 0057

Name of PR Dr Sue Ingamells

Date of Inspection 27th Feb 2008

Date of Responses

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

Issue	Action required	Time scale
Amalgamation of the incident log into one		
Comment/response: This has already been completed and we now have a single log book		
Procedure validation		
Comment/Response: Validation will be completed by 31.08.08		
Interlaboratory comparisons		
Comment/Response We need clarification as to what is required here and will be seeking more advise from our inspector		
The use of excess sperm for product testing		
Comment/Response: A consent form for this has been produced and will be used when next required		
Appropriate screening for post humous use of gametes		
Comment/Response: In WT and MT forms page 5 section 6ii line 7 it states that it is preferable to test again after 6 months. We are happy to put in place the additional screening required as recommended but would like clarification on this point. Please would you advise us based on this statement as to whether you would still like a second screening to be performed for all patients. A full audit of all our frozen embryos and communication to patients will take some time to complete but will be carried out as a priority if this is mandatory.		

Non-Compliance

Area for improvement	Action required	Time scale
Witnessing		
Comment/Response: We will be continuing to use a manual witnessing method and this has already been risk assessed**.**		

Recommendations	Actions/Time scale
Male production room and disabled toilet	
Comment/Response:A full refit takes place on 24.04.08 with new décor and new lighting and pictures	
Fitting a low oxygen monitor and attaching signage	
Comment/Response: Engineer will be fitting this monitor in May, the signage has been ordered and we are awaiting delivery	

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).

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