Salisbury Fertility Centre 0197

Interim Inspection Report

Date of Inspection: 11th June 2008
Date of Licence Committee: 13th August 2008

CENTRE DETAILS

Centre Name	Salisbury Fertility Centre
Centre Number	0197
Licence Number	L0197-8-b
Centre Address	Salisbury District Hospital Odstock Road Salisbury SP2 9BJ
Telephone Number	01722 417 224
Type of Inspection	Interim
Person Responsible	Mr Shaun Fountain
Nominal Licensee	Mrs Ruth Blacklock
Inspector(s)	Ellie Suthers, Allison Cummings, Bryan Woodward
Fee Paid	Yes
Licence expiry date	30th April 2011
NHS/Private/Both	NHS and Self Funding

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About the Inspection:
This inspection visit was carried out on Wednesday 11th of June 2008 and lasted for 8 hours. The report covers the pre-inspection analysis, the visit and information received since the last inspection.

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

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

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

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

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

Salisbury Fertility Centre was first established as a treatment centre in 2002 and is part of the Salisbury NHS Foundation Trust. There is a satellite service with St Marys Hospital in Portsmouth.

Patients are referred from Wiltshire, Hampshire and Dorset Primary Care Trusts which forms 47% of the centres activity: the remaining 53% are self funding patients. The centre provides a range of treatments and is working towards extending its range of services in the coming years which will be detailed later in the report.

The Person Responsible (PR) is Mr Shaun Fountain, Consultant in Obstetrics and Gynaecology, who has been the lead clinician and PR since the centre opened. Mr Fountain has completed the HFEA Person Responsible Entry Programme, is registered with the General Medical Council and is suitably qualified. *(CoP S.4.1.4/5)*

Dr Mark Howard is the registered scientist responsible for overseeing scientific activities in the centre *(CoP S.4.1.3)*
The Nominal Licensee is Mrs Ruth Blacklock who is a non executive member of the board of the Salisbury NHS Foundation Trust.

The Centre has recently undergone an expansion, refurbishment of facilities and purchase of new equipment.

Activities of the Centre
Number of treatment cycles taken for the period 31/12/06 – 01/01/08

Licensed treatment cycles	IVF ICSI Frozen Embryo Transfer Egg sharing Egg donation	71 112 62 10 2
Donor Insemination		0
Unlicensed treatments		Host Surrogacy
Research		None
Storage		Yes

*This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. 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 Licence Committee

Salisbury Fertility Centre has successfully completed the transfer of activity to newly refurbished expanded premises and is bedding down its systems and processes. There is more space, dedicated consulting rooms, treatment room, office space and a dedicated production room. There has been an increase in staffed hours: nursing, secretarial and the planned appointment of two trainee embryologists. The centre has purchased a second IVF workstation, scanning machine and air quality monitoring equipment. Development of the quality management system (QMS) and computer based document management system continues.
This report notes that all recommendations from the last inspection on the 23rd January 2007 have been complied with (see page 8 of this report).

Areas for improvement from this inspection include:

- Witnessing of laboratory procedures;
- Completion of third party agreements;
- Compliance with Trust policy – emergency equipment checks;
- Continuity in reporting ICSI data.

The inspection team recommends the continuation of the Salisbury Fertility Centres' licence with no additional conditions.
The weight to be attached to the breaches and non compliance highlighted in this report is a matter for the HFEA Licence Committee.

Evaluations from the inspection

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

Breaches of the Act Standard Licence Conditions or Code of Practice: The table below sets out matters which the inspection team considers may constitute breaches of the Act, Standard Licence Conditions and/or Code of Practice and their recommended improvement actions and timescales. The weight to be given 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
1) It was observed from laboratory records that the placing of samples into storage is occasionally witnessed retrospectively. *(CoP S.7.8.15)*	All witnessing of procedures shall be completed and recorded at the time the clinical or laboratory process/procedure takes place.	Immediately

It was noted during inspection that not all agreements have been finalised with two companies providing consumables used in the laboratory. *(CoP A.5.1)*	The Centre shall establish a written agreement with a Third Party for external activities which influence the quality and safety of gametes and embryos procured or processed.	September 30th 2008

Non-Compliance

Area for improvement	Action required	Time scale
The placing of samples into storage is occasionally witnessed retrospectively	Guidelines require that all witnessing of procedures shall be completed and recorded at the time the clinical or laboratory process/procedure takes place. *(CoP S.7.8.15)* The PR should review witnessing procedures in consideration of HFEA guidelines. Where procedures deviate from guidelines, the risks of the practice should be assessed and documented.	Review to be complete by 31st August 2008.

Recommendations	Time scale
1) It was observed on inspection, and in discussion with staff, that the emergency resuscitation bag in the treatment room had not been checked regularly. The Salisbury NHS Foundation Trust has a policy which states that emergency equipment should be checked by staff weekly. It was recommended that there should be documented evidence that all emergency equipment is checked in accordance with Trust policy. Resuscitation Guidelines UK[1] state that the responsibility for checking resuscitation equipment rests with the department where the equipment is held and checking should be audited regularly. 2) It was noted at the time of inspection that there were differences between embryologists in the reporting of ICSI outcomes. It was recommended by the inspector that for the purposes of clarity and continuity that the consistency of reporting should be reviewed.	July 31st 2008

(1) Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London, The Intensive Care Society, The Resuscitation Council (UK), October 2004.

Proposed licence variations by last Licence Committee

None

Changes/ improvements since last inspection

Recommendations	Action Taken
The quarantine dewar should be individually alarmed and linked to the autodial facility	All dewars are alarmed
Recommendation that all staff have training folders to document continued professional development and competency assessments	All staff have training folders
Recommendation that there is a centre specific policy for staff induction and mandatory training recording.	New staff induction programme in place
Formal contingency arrangements to be developed with fertility unit in Exeter	Formalised in March 2007 following agreement with both Trusts
Nursing procedures under development are not version controlled or in a consistent format.	Documents are version controlled and the linked to the Document Register
The witnessing step for sperm thawing was seen to only require a tick as evidence of checking.	Record sheets for semen preparation have been amended to include a place to record the thawing of samples.
At the time of inspection not all security locks had been installed	Proximity (swipe) card security is now installed with varying levels of access to the centre and hospital.
Means of raising audible alarm recommended for the treatment room, consulting rooms and producing room	Patient alarms are present in the patient WC, treatment room and producing room. Patients are not left alone in the consultation room and no procedures take place here.
The low oxygen alarm had not been installed within the area designated as a cryo store.	An audible alarm now alerts the embryologists as well as other centre staff. Men using the adjacent producing room are warned of the action they should take should they hear the alarm.
Recommendations were made to purchase signs/door labels for the new area	Signs and sliding indicators have been installed.
Recommendations were made to update the centres security policy in light of the new centre layout.	Security policies and close down procedures have been documented
Fire officer to assesses fire safety	Fire safety has been carried out by the Trust.
Air quality within the treatment room and laboratory to be tested to ensure it meets with the standards required by the EU Tissue Directive and Standards	Air quality in the treatment and laboratory have been tested and demonstrated to be grade C in compliance with the requirements of the EUTCD.

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	Complied Y/N

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:

1. Leadership and management
2. Organisation of the centre
3. Resource management
4. Risk management
5. Incident management
6. Contingency arrangements
7. Business planning
8. Clinical governance
9. Payment of treatment fees

Areas of firm compliance
The Person Responsible (PR) is Mr Shaun Fountain, Consultant in Obstetrics and Gynaecology, who has been the lead clinician and PR since the centre opened. Mr Fountain has completed the HFEA Person Responsible Entry Programme, is registered with the General Medical Council and appears to be suitably qualified. *(CoP: S.4.1.5: S.4.1.4)* The centre has a policy in place which identifies the role and duties of the PR. **Organisation of the centre:** During the inspection the centre appeared to be operationally well organised. All pre inspection material had been submitted to the HFEA inspectorate complete and on time. All members of staff were present for the inspection and provided all the information requested both written and verbal. Each member of staff approached appeared to the inspectors to know about the inspection process and provided information and comment when asked. There are clear organisational accountability and reporting relationships that were demonstrated via an organisational chart and during interviews between the inspection team and centre staff. The centre is part of the ambulatory care directorate; evidence was seen in the form of meeting minutes and in discussion with centre staff of formal and direct communication between the centre and the main directorate managers. This communication was reiterated by the nominal licensee. *(CoP: S.4.2.6)*. The centre is open five days per week between 8am and 5pm. The PR and the Consultant Obstetrician and Gynaecologist, provide out of hours contact for patients requiring medical support or advice. Patients are informed of the out of hours procedure at the first treatment planning consultation along with possible symptoms of ovarian hyper stimulation syndrome (OHSS). This information was observed in service user literature and on discussion with staff. *(CoP G.5.3.1(h))*

Resource Management:
The PR confirmed that there is a sufficient number of staff for the activity in the centre and that he is satisfied that they are appropriately qualified with the competence to perform their designated tasks. *(CoP S.6.2.1)* Since the last inspection an extra nurse has been seconded for one day per week, there has been an increase in administrative support and two trainee embryologists have been appointed both starting in October 2008.

Incident management:
The inspectors observed a documented procedure for the identification, investigation, control and recording of adverse incidents. The documentation was seen to be up to date and complete. Staff demonstrated their knowledge and understanding of the incident reporting procedures during interviews with inspectors and in minutes of meetings. Documented evidence was observed that the requirements of reporting to the HFEA are being met.*(CoP A.4 : S.9.4.1)*
The procedure for the receipt, management and dissemination of HFEA alerts is managed via the quality manager who assesses each alert and the possible impact on the centres practises. Evidence of this was observed in the incident management log.

Contingency arrangements:
The centre has written reciprocal contingency arrangements in place with the Peninsular Centre for Reproductive Medicine in Exeter.
Contingency arrangements were observed to be in place with the Salisbury NHS Foundation Trust for back up facilities and emergency clinical facilities. *(CoP S.6.3.4 (b))*

Payment of treatment fees
The HFEA Finance department confirmed that all fees are paid on time.
(CoP A.16.3)

Areas for improvement
No areas for improvement
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee
None
Areas not covered on this inspection
Risk Management and Business Planning
Evaluation
No improvements 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. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality objectives and plans
5. Quality Management review/evaluation
6. Monitoring and resolution of complaints
7. Staff suggestions
8. Document control
9. Live Birth Rates

Live Birth Rates
For the time period April 2004 – March 2007 (total number of treatments – 364) outcomes for al treatments provided were in line with national averages. *This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA on our website is a snapshot of the state of the Register at a particular time. 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.
Areas of firm compliance
The PR and staff within the unit have demonstrated a commitment to the establishment and maintenance of a Quality Management System (QMS). *(CoP: S.4.2.1)* The development of the QMS is led by one of the senior embryologists who also has the role of quality manager. **Quality Manual:** A quality manual is being developed and is in the process of being transferred to an electronic Trust system. The quality manual is progressively being populated with both laboratory and clinical polices and standard operating procedures. *(CoP S.5.2.3)* Trust document control templates have recently been changed and as a result further work is being carried out to ensure that all policies and procedures are document controlled as per Trust policy. The quality manager has developed a rolling audit and review programme for policies, risk assessments and audits which are included in the quality manual. There is a 'quality day' scheduled for early summer which is planned to be an annual event for all staff to contribute to quality management. Since the last inspection it was noted that audits have been carried out on: all sperm dewars; all embryo dewars, patient records, witnessing processes and third party agreements. **Monitoring and resolution of complaints:** The Centre has a written procedure in place for the acknowledgment and investigation of complaints, as well as collecting suggestions and compliments from service users. The complaints process followed is as per the Salisbury NHS Foundation Trust policy. *(CoP S.9.2.2).* A centre questionnaire is given to each service user and responses analysed and

acted on where appropriate. The centre has received two complaints since the last inspection and both have been resolved.

Staff participation and suggestions:
The team is small and communication is done largely informally, the staff informed the inspectorate during interview that they are actively encouraged to take part in the decision making and development of the centre. There are numerous opportunities for staff to make suggestions about how the centre is run or how service users are treated including formal monthly meetings and informal discussions. *(CoP S.9.2.3)*

Areas for improvement

It was observed that some of the standard operating procedures and centre polices were yet to be document controlled or complete *(CoP S.5.2.5)*

Areas for consideration

None

Executive recommendations for Licence Committee

Further work is needed to complete this document control process *(CoP S.5.2.5)*

Areas not covered on this inspection

None

Evaluation

Some areas for improvement

3. Premises and Equipment

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

Summary of findings from inspection:

1. General Suitable premises
2. Clinical facilities
3. Counselling facilities
4. Laboratory facilities
5. Air quality
6. Storage facilities for gametes and embryos
7. Staff facilities
8. Management of equipment and materials
9. Control of records
10. Risk assessments

Brief Description
Fertility services are delivered across three neighbouring departments. During inspection all rooms/spaces were observed to be appropriate for licensed activities. A previous HFEA new premises inspection report confirmed suitability of premises. (report 8th August 2007) The purpose built self contained and well secured fertility centre houses a waiting room, reception, two consulting rooms, production room, treatment room, laboratory, cryo storage, administrative office and general storage. Each room is accessed either by a keypad code lock or a Trust wide proximity security card. Each member of staff carries this as part of the identification badge. Out of hours the doors are automatically locked and a metal screen is locked in place over the reception area. Egg collection is carried out in the co located day surgery theatre. It was observed by the inspector that following the egg collection procedure the eggs are transferred by the embryologist to the embryology laboratory in a transport incubator via a short corridor between the theatre and the laboratory in the main fertility centre. There is a standard operating procedure in place which, it was observed during inspection, is followed by staff. Ultrasound scanning at the time of inspection is carried out in the main obstetrics and gynaecology unit in a nearby building although a new scanning machine has been purchased by the centre and will bring all scanning procedures within the centre.
Areas of firm compliance
At the time of inspection the centre appeared to have premises and facilities suitable for the activities for which it is licensed including facilities for reception, clinical and counselling activity, laboratory work, storage of gametes and embryos. (*CoP S.6.3.2)* **Staff facilities:** Staff facilities include a small refreshment area and changing facilities with lockers for personal storage. *(CoP S.6.3.10)*

It was observed during inspection and the staff reassured the inspectorate that there is sufficient space and equipment to carry out licensed activities. *(CoP 6.3.3)*

Management of equipment and materials:
New equipment and their service contracts were observed in the laboratory including:
an incubator purchased in August 07: a laminar airflow workstation: 3 new nitrogen dewars: a particle counter and a volatile organic compound monitor used to monitor air quality. All equipment was seen to be maintained according to manufacturers' instructions.

Air Quality:
Documentation was seen to be maintained for air quality monitoring: air quality results were observed for the laboratory and embryo transfer treatment room and were found to be compliant with HFEA requirements. (Grade C) *(CoP S.6.3.6b)*

Storage facilities for gametes and embryos:
All dewars are locked and alarmed (including those newly purchased) and are stored within a secure area with restricted access within the main fertility centre. The cryo store appeared appropriate for the volume of activities conducted. *(CoP S.6.3.8)*

Counselling facilities and services:
Counselling takes place in a consulting room within the centre which has been suitably decorated with comfortable chairs creating more informal surroundings. Counselling records are kept separately to the service users' main healthcare records and are stored securely in a locked cabinet to which only the counsellor has the key. The counsellor attends service user open evenings: all service users are offered counselling. Communication between staff and the counsellor is through team meetings and informal discussion with the consent of the service user.

Areas for improvement

Although most of the third party agreements were complete it was noted that not all agreements have been finalised with two companies providing consumables used in the laboratory. *(Standard Licence Condition A.5.1)*

Areas for consideration

It was observed on inspection, and in discussion with staff, that the emergency resuscitation bag in the treatment room had not been checked regularly. The Salisbury NHS Foundation Trust has a policy which states that emergency equipment should be checked weekly. [1]

Executive recommendations for Licence Committee

Third party agreements should be finalised. *(Standard Licence Condition A.5.1)*

[1] Cardiopulmonary Resuscitation Standards For Clinical Practice And Training, A Joint Statement from The Royal College of Anaesthetists, The Royal College of Physicians of London, The Intensive Care Society, The Resuscitation Council (UK), October 2004.

The PR should review the procedures for the monitoring of resuscitation equipment in consideration of local and professional body guidelines.
Areas not covered on this inspection
Risk Assessments

Evaluation
Some improvements required

4. Information

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

Summary of findings from inspection:

1. General Information
2. Meetings and communication
3. HFEA Alerts
4. Welfare of child
5. Confidentiality and access to health records
6. Traceability and coding
7. Coding/ identification of samples
8. Information for service users/consents
9. Donor information
10. Donor registration
11. Procurement and distribution of receipt of gametes and embryos
12. Home procurement report documentation
13. Packaging &distribution
14. Labelling of packages containing procured gametes
15. Transportation, labelling of shipping container and recall
16. Receipt of gametes

Areas of firm compliance
General Information: During the inspection it was observed that the service user waiting area displayed general information including the centres licence to practice, the complaints and patient satisfaction process, availability of the counselling service and information literature on various treatments and therapies. Service users are handed individual leaflets and relevant information literature at the time of consultation with clinical staff. **Meetings and staff communication:** There is an all staff meeting on the 4th Tuesday of each month to which everyone is invited. Minutes of the meeting are taken and circulated to all staff. Embryology meetings are held on a regular basis and meeting minutes were observed by the inspectorate. Communication between the nurse coordinators is largely informal as there are only two coordinators: staff commented that as the number of nursing staff increases there may be a need to formalise this communication. **Confidentiality and access to health records:** All health records are stored in filing cabinets in the centre: none are sent to the main Trust records store. The filing cabinets are stored in the main administration office which is staffed during the day and locked over night. All typing of records and administration is carried out in the centre by HFEA licensed staff. During interview the centres administrator demonstrated previous training and a sound knowledge of information governance and the confidentiality requirements of licensed services. *(CoP S.7.2.1 & S.6.5.1)* Staff are asked to sign a confidentiality declaration, all visitors to the centre are authorised and accompanied by staff and all computers were seen to have password protection.

Information for service users/consents:
On inspection the information provided for service users considering egg sharing appeared comprehensive using plain language and in compliance with the requirements of the code of practice. Requirements for egg sharing/donor screening, including counselling and a list of clinical investigations are clearly laid out and corresponding confirmation was identified in service user health records.

The centre has documented procedures for individuals considering or giving consent to examination and treatment and storage including ensuring that a copy of the signed consent form is available for those who have given consent This was demonstrated in service user literature, in health records and on discussion with members of the centre staff. *(CoP S.7.5.5)*

Procurement and distribution of receipt of gametes and embryos:
It was observed during the inspection that there are documented standard operating procedures for the procurement, packing, distribution, and receipt of gametes and embryos. Evidence in training logs and continued professional development transcripts that procurement is carried out by appropriately trained staff. *(CoP S.7.7)*

Home procurement report documentation:
Home procurement of sperm is actively discouraged and only permitted in exceptional circumstances. An SOP was observed to require identification and the providers' signature. *(CoP S.7.7.9)*

Areas for improvement
No areas for improvement

Areas for consideration
No areas for improvement

Executive recommendations for Licence Committee
None

Areas not covered on this inspection
Donor registration Surrogacy

Evaluation
No 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. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Counselling
6. Witnessing
7. Training and professional development

Full time equivalent staff

GMC registered doctors	0.6
NMC registered nurses	1.6 (plus 1 day per week secondment)
HPC registered scientists	2
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	0.6 receptionist 0.8 administrator
Counsellors	2 counsellors available as required

Summary of laboratory audit / Audit of records
The laboratory storage audits (sperm and embryos) reported a small number of administrative issues which as part of the audit process were explained and reconciled.
Summary of spot check of stored material
A spot check was carried out on stored frozen material (sperm, oocyte and embryo) and no discrepancies were observed. All samples had appropriate identification and labelling.
Areas of firm compliance
Laboratory Processes: It was observed that there are documented procedures for the procurement, packaging, distribution and receipt of gametes and embryos in order to ensure safety and quality. Review of laboratory documentation, training logs and on discussion with staff demonstrated that the procurement of gametes is carried out by competent and trained staff *(CoP S.7.7: S.7.7.2)* Observation of standard operating procedures and discussions with staff demonstrated that laboratory procedures are in place to ensure the traceability of gametes and embryos in records kept for each treatment cycle. The laboratory notes were seen to give tracing of individual gametes and embryos including the witnessing of use and disposal. Copies of these records were seen to be kept in service user records. *(CoP S.7.3.1)*

The centre does have a policy on the number of embryos to be transferred.
It was observed in the centres documentation that ten service users have undergone the transfer of three embryos: it was noted that all patients complied with the age criteria and the reasons were documented clearly in a designated log. *(CoP G.8.5.1 & Directions D2004/2)*

Witnessing:
It was observed during the day of inspection that records were kept indicating each occasion when gametes and embryos were handled and manipulated with witnessing signatures documented as required by the centres standard operating procedure. *(CoP S.7.8.5)*

Training and professional development;
A fertility centre staff training policy is in place. The inspectorate observed training logs for the nursing and embryology staff which contained evidence of continued professional development and annual mandatory training. It was noted that staff have attended conferences and study days related to embryology and fertility.

It was noted from training logs and during discussion that all scientists are registered with the Health Professionals Council and members of Association of Clinical Embryologists. *(CoP S.6.2.1)*

Trust wide annual mandatory training is largely computer based including topics such as child protection, manual handling, clinical governance and infection control. Evidence of staff participation and timely completion was observed by the inspectorate. *(CoP S.6.2.7: S. 6.2.11)*

Areas for improvement

Standard Operating Procedures:
Some standard operating procedures need to be amended to reflect current practice, including: removing the SOP for in house making of freezing and thawing solutions as this is no longer current practice; rewording of the SOP for the thawing of embryos and an SOP should be developed for the testing of the low oxygen alarm in the cryostore. *(CoP A.10.24)*

Witnessing:
It was observed from laboratory records that the placing of samples into storage is occasionally witnessed retrospectively. All witnessing of procedures shall be completed and recorded at the time the clinical or laboratory process/procedure takes place. *(CoP S.7.8.15)*

Areas for consideration

It was noted at the time of inspection that there were differences between embryologists in the reporting of ICSI outcomes. It was recommended by the inspector that for the purposes of clarity and continuity that the consistency of reporting should be reviewed.

Executive recommendations for Licence Committee

SOPs should be revised as recommended and witnessing practices should be reviewed in consideration of HFEA guidelines.

Areas not covered on this inspection

Evaluation
Some areas for improvement

Report compiled by:

Name: Mrs Ellie Suthers

Designation: Inspector

Date 9th July 2008

Appendix A: Centre Staff interviewed

Mr Shaun Fountain – Person Responsible
7 members of staff
No service users were available on the day of inspection

Appendix B: Licence history for previous 3 years

2007
Licence Committee: 21st March 2007
Agreed to continue the centre licence with no additional conditions

Licence Committee: 26th April 2007
Agreed to vary the licence in accordance with the requirements of the EU Tissue and Cells Directive

Licence Committee: 15th August 2007
Licence Committee were present with a report itemising the change of premises within the same hospital grounds. As such no change to the centres number or licence required.

Licence Committee: 21st November 2007
Agreed to vary the centres licence to change the nominal licensee to Mrs Ruth Blacklock

2006
Licence Committee: 9th March 2007
Agreed to renew the centres licence for a period of five years and agreed to vary the licence to include ZIFT and the storage of eggs.
Previous licence condition had been complied with so removed from the licence.

2005
Licence Committee: 10th March 2005
Agreed to renew the centres licence for twelve months with one condition.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number: 0197

Name of PR; Mr Shaun Fountain

Date of Inspection: 11th June 2008

Date of Response……

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

Signed……

Name……

Date……

1. 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).

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

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