Interim Inspection Report

Queen's Medical Centre, Nottingham

Centre 0162

Date of Inspection: 14 February 2008

Date of Licence Committee: 24 July 2008

CENTRE DETAILS

Centre Name	Queen's Medical Centre Fertility Unit.
Centre Number	0168
Licence Number	L0162-13-a
Centre Address	Floor B, East Block, Queen's Medical Centre, Derby Road, Nottingham. NG7 2UH
Type of Inspection	Interim
Person Responsible	Mr James Hopkisson
Nominal Licensee	Ms Marion Macpherson
Inspector(s)	Mrs Gillian Walsh HFEA Executive Dr Victoria Lamb HFEA Executive Mrs Elaine Suthers HFEA Executive
Licence Expiry Date	30/06/12
Fee Paid – up-to-date	Yes
NHS/Private/Both	Both

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About the Inspection:
This inspection visit was carried out on 14 February 2008 and lasted for 7 hours. The report covers the pre-inspection analysis, the visit and information received between February 2007 and January 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 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 areas for consideration' 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

Centre 0168 Queen's Medical Centre Fertility Unit has held a licence granted by the HFEA since 1992.

The Centre was last inspected by the HFEA on 8 February 2007, following which the Centre's licence for the storage of sperm and donor sperm insemination was renewed for a period of 5 years with no additional licence conditions.

Application to vary the licence, pursuant of the Human Fertilisation and Embryology Act 1909, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007, was granted by a License Committee of the HFEA on 26 May 2007.

The Centre is an NHS clinic, located within the Queen's Medical Campus, which is part of Nottingham University Hospitals NHS Trust. NHS and self-funded patients may be drawn form a catchment area covering three counties,

The Centre is open for consultation and treatment Monday to Friday from 08:00 and for treatment only on Saturdays from 08:00 to 12:00.

The centre provides partner and donor sperm insemination and recruits sperm donors The centre also provides a service to patients who require cryo-preservation of gametes for the preservation of fertility

Activities of the Centre

Licensed treatment cycles	IUI 250
Donor Insemination cycles	34
Unlicensed treatments	Ovarian stimulation
Storage of sperm	Yes

For the year 01/01/07 to 01/02/08

Summary for Licence Committee

Queen's Medical Centre provides a service for the diagnosis and management of sub-fertility and insemination with donor and partner sperm and also to those wishing to donate or store semen for the preservation of fertility. The centre treats in excess of 700 patients per annum.

The Centre appears to be well organised, with a small, experienced and cohesive team, who are keen to develop the service. The team demonstrate commitment to meeting the needs of their service users by working flexibly.

In the opinion of the Executive, current staff numbers or availability of staff is low relative to the current workload of the Centre and may not meet professional body guidelines, where guidelines are available.

The Executive believe that a review of workload and human resource is required to ensure safe working practices and capacity to ensure the regulatory work and requirements of the HFE Act and Code of Practice Standards are met.

The Executive supports the continuation of the Licence for this Centre.

Evaluations from the inspection

Topic	No Improvement 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 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	Reference	Action required and timescale
It was reported that there are insufficient staff to accommodate the workload at the centre and adequately fulfil the development and monitoring of regulatory Safety and Quality systems as required by the HFE Act and the HFEA Code of Practice. This is potentially a breach of the cited standards and of Association of British Andrologists (ABA) guidelines.	**Standard Licence Condition A.10.9** Personnel in the Centre must be in sufficient number and be qualified to perform the tasks they perform. **CoP Standard S.6.2.1** The Centre shall have sufficient numbers of staff, to ensure that the requirements of the Standards are met… **S.6.3.2** The Centre shall provide a safe working environment for all staff…and documented procedures for the health, safety and welfare of staff, including that for lone working. **S.7.8.1** The Centre's laboratory shall comply with current professional guidelines, legislation and regulation (appendix B – 2.1.Association of Biomedical Andrologists – Guidelines for good practice ref: Section B (3 / 8 / 9) Personnel 3) The should be adequate numbers of staff for the laboratory workload (approx. 1.0WTE per 1000 specimens). Centres providing a storage service for oncology patients should	It is recommended that the PR assesses the workload that can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skills mix of staff members and professional body guidelines. Activity or resources should be adjusted according to the findings of the assessment and the HFEA should be advised of the outcome of the assessment. The review should be completed within 3 months.

	be able to cover for 'out of hours' emergencies. 8). There should be sufficient staff (e.g. secretarial and admin) to meet the needs of the service. 9). There must be adequate cover for staff holiday / sickness and by trained personnel.	
Not all third party agreements have been finalised. (S.4.2.10)	Outstanding third party agreements should be finalised.	Within 3 months of licence committee date.
The gametes of one oncology patient were being stored beyond the period of patient consent. (S.7.8.11)	The PR should review procedures to ensure robust systems are in place to ensure that gametes and embryos are not stored beyond their maximum consented storage period.	The review of procedures should be completed within 3 months. Since the inspection the Centre has confirmed that stored samples have been discarded.
Many of the Centre's policies and procedures had not been reviewed within the centres own prescribed timescales. (S.5.2.5 / 6)	Effective document control must be implemented whereby documents are reviewed, revised and re-approved promptly by approved personnel.	3 months from licence committee date.

Non-Compliance

Area for improvement	Action required	Time scale
Staff are not remunerated for the provision of out of hours "on call" duties.	The PR should review the implementation of formal emergency procedures including 'on-call' in compliance with G 9.3.1 (c).	3 months from licence committee date.
The Quality Management System requires further development to fully reflect all key elements of the Centre's service.	The Centre Management (including the PR) shall demonstrate commitment to the establishment and maintenance of the QMS by, , ensuring the availability of	3 months of licence committee date.

Staff state that time and resources issues have hampered the completion of this task.	resources. (S.4.2.1 (h))	
The Quality Management System has not undergone an initial management review**.** (S.4.2.8/9)	The PR should work with the Quality Manager to conduct a scheduled review of the Quality Management System and all it's services. This review shall include, but not be limited to, consideration of changes in the volume and scope of the work, personnel or premises. The review should be recorded and include decisions and actions related to improvement of the QMS, the service provided to users and consequent resource implications.	Within 9 months of licence committee date.
Routine cleaning and decontamination of critical equipment is reported to be conducted in a timely manner but no record of this is made.(S.6.4.2 (c)).	A record of this activity should be formulated and maintained.	Immediately (Already implemented following inspection)
The majority of semen samples are produced off site at the person's home. This is potentially non compliant with COP guidance at G.2.3.	The PR should review the procedures for home procurement and ensure that the centre has appropriate documentation and Standard operating procedures in place to ensure compliance with COP requirements.	To be monitored at the time of the next inspection.

Recommendations	**Time scale**
The Centre should, given the space constraints of the building, consider how they may provide an appropriate and freely accessible, private place for the productions of semen samples on site. (s.6.3.4 (iii))	6 months to 1 year

Proposed licence variations by last L.C.

Variation granted pursuant of the amended Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

Changes/ improvements since last inspection (from PIQ)

Recommendations / Improvements	Action Taken
Review of documentation and effective document control	All laboratory held documents have been transferred to an electronic, central system.
Requirement to implement an on call service to ensure the safe response to out of hours activation laboratory alarms.	Full laboratory and nursing on call service implemented with immediate effect (staff good will)

Additional licence conditions and actions taken by centre since last inspection

Date	Action taken
	No additional licence conditions imposed since last inspection.

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

Leadership and management
The Person Responsible (PR) is a Consultant Gynaecologist and Sub-specialist in Reproductive Medicine at the Trust. His name is listed on the Specialist Register of the General Medical Council and has successfully completed the HFEA PR entry programme.(S.4.1.2 / 4 /5) .

The PR's office base is within the Centre and he is in attendance at the centre for some if not all of most working days. He may be contacted by the team should the need arise at other times. The PR has satisfied the Executive that he is fully conversant with the scope of his responsibilities as PR and his reporting obligations to the HFEA. (S.4.1.7 / 8 / 9 / 11)

An up to date organisation chart is in place, demonstrating accountabilities and reporting relationships. (S.4.2.5 & S.4.2.6).

The centre appears well organised, with good communication within the team at all levels. (S.4.1.1) Evidence of effective communication was seen in minutes of meetings. (S6.2.13)

Resource Management
Centre activities are lead by the PR and Quality Manager (QM), who is also the Consultant Scientist in Andrology for the Trust. Both the PR and QM are supported in the day to day running of the centre by a small team of 2 full time, experienced Fertility Specialist Nurses and 1 part time nurse. There are 2.4 FTE Healthcare Scientists supporting the andrology service and sperm donor bank. (S.6.2.2). Centre reception, records management and scheduling is supported by 1 administrator.

Risk Management
The Trust has a risk management strategy in place and a number of the Centre staff have been trained in risk assessment. The Quality Manager is also responsible for risk management for the andrology service. The Executive saw completed risk assessments for

the laboratory and evidence of some reporting. (S.7.8.10 S.9.4.3)

Incident Management
Incidents are managed through the Trust Incident Reporting policy. Staff asked were aware of the procedures and of HFEA requirements. (S.4.1.8, S.4.2.9, S.6.4.3, S.7.7.1 S.7.7.8, S.9.4 and A.4).

Contingency Arrangements
Two specialist fertility nurses and members of the andrology team participate in an on call service as recommended in Chair's letter CH(04)03,to advise on out of hours urgent calls from patients, or respond to alarm activation or other laboratory alarms and in support of occasional requests to provide a service to oncology patients out of hours.

The centre demonstrated good contingency plans to accommodate disruption to service by having close working links with Centre 0076. (S.6.3.4 (b)).

The Centre is supported by the Trust emergency generator back up system and an uninterrupted power supply to key equipment (S,6,3,4 (b).

Clinical Governance
The Centre feed in to the Trust Clinical Governance Agenda.

HFEA Fees
The Finance Dept. of the HFEA has reported no issues with the timely payment of fees.

Areas for improvement

Human Resources
As a result of observations made on the day and in separate discussions with staff of all grades, it became apparent to the Executive that staffing levels are inadequate for the volume of activity conducted and are non compliant with professional body guidance of the ABA (S.6.2.1).

The on call service is provided by nursing and laboratory staff runs on the good will of the staff, is not formalised with the Trust as it is not currently funded by the Trust.

Staff stated that the andrology service process in excess of 3500 samples per annum and manage the storage of approximately 700 cryo preserved samples. The Centre is also actively recruiting sperm donors to support the donor service. Staff also stated that the Centre receives approximately 700 new referrals per annum. The Centre staff reported having conducted approximately 250 IUI and 30 DI treatments in the preceding year to date . Nursing Staff reported having seen in excess of 900 patients in a 4 month period in nurse led clinics. Documentation and other evidence seen on the day supports this.

The Centre is open for consultation and treatment Monday to Friday from 08:00 until approximately 17:00 and for treatment only on Saturdays from 08:00 to 12:00. Laboratory staff described lone working on Saturdays who, during this time will, via an intercom entry system, call the nurse who is to conduct the insemination. (Located some way from the laboratory), She will then leave the clinical area and go to witness the sperm preparation

(S.6.3.2).

Staff informed the Executive that they often experience problems taking leave when they wished and that the service is put under considerable pressure should someone fall ill. Staff are commonly required to work six days and work in excess of their statutory hours to meet the needs of the service.

The Executive was informed by staff in both the clinical and laboratory areas of the Centre that they had not had the opportunity to complete, or in some instances commence some of the supporting regulatory work regarding quality and safety, as required by the HFEA . They were unable to say when this would be completed under the current workforce conditions at the Centre.

Areas for consideration

Executive recommendations for Licence Committee

It is recommended that the PR assesses the workload that can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skills mix of staff members and activity should adjusted according to the findings of the assessment.

The PR should ensure that there is adequate staffing and funding to allow the implementation of formal emergency procedures including 'on-call' in compliance with G 9.3.1 (c).

Areas not covered on this inspection

Business planning

Evaluation

Significant 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. Quality Management System
2. Quality Policy
3. Quality Manual
4. Quality Management review/evaluation
5. Monitoring and resolution of complaints
6. Staff suggestions
7. Document control
8. Live Birth Rates
9. User Satisfaction.

Live Birth Rates

Donor Insemination (From HFEA figures) [3]	No: of Cycles Initiated	No: of Couples / individuals treated	No: of Clinical Pregnancies	No: of Clinical Pregnancies as % of cycles	Live births to date	Multiple Births	l Live births for pervious year 03/06 – 02/07	Births as a % of cycles
03/07 – 02/08	28	11	5	17.86%	2	0	3	13.04%
IUI [4] (Centre's own figures) 02/07 – 01/ 08	250 (approx)	Remaining data awaited						

These figures were extracted from the HFEA register and have not been verified by the Centre and may be subject to change

At the time of writing, the Centre has yet to submit there annual IUI activity and outcome figures to the HFEA. These figures are have been provided by the Centre and are intended as an indication of current activity and so have not been verified.

Areas of firm compliance

Quality Management System

The consultant scientist in andrology is also the nominated Quality Manager for the Centre. There is a Quality Management System (QMS) in place but is not comprehensively developed to fully reflect all key elements of the Centre's service. (S.4.2.1, S.4.2.7, S.5.11 & S.6.1.1)

A quality policy has been developed and is in place and is available to all staff. (S.4.2.2/3 S.5.2.2 / 6

The Centre has not yet conducted a full management review but evidence of a number of completed audits was seen, including infection control, success rates, and health care records.

Staff Involvement / Suggestions.

There appears to be good, open communication within the team whereby staff may comment

and suggestions are valued and encouraged. Evidence of this was seen on interview this team members and in exchanges reported in the minutes of team meetings.

Complaints Management
In conjunction with Trust wide policy, the centre demonstrated an effective complaints policy and mechanism for the monitoring and resolution of complaints. Information on how and to whom a complaint should be addressed, including the HFEA was readily visible and available in patient waiting areas. The PR is nominated as the person to whom complaints are directed in the first instance. Evidence of active complaints management and corrective actions taken was seen. (S.4.2.9, S.9.2.2).

Document Control
There is a Trust wide document control system in place, whereby Trust approved documents and policies are controlled centrally and may be accessed by all Trust staff. The Andrology Service has recently introduced a new information management system. Whilst some documentation review is still outstanding, once this is done, the Quality Manager states that this, plus the Trust wide intranet will assist in ensuring effective document control and the effective communication of any revision to the users. (S5.2.5)

User Satisfaction
User satisfaction is assessed by means of the Trust feedback / comments form 'Your thoughts on our service'. A small number of patient questionnaires were returned to the HFEA all of which offered very positive comments about the service including the care and attention offered by all staff, the cleanliness of the environment, availability of counselling and the opportunity to discuss and ask questions regarding treatment options. (S.9.2.1)

Areas for improvement

Quality Management
The Quality Management System requires further development to fully reflect all areas of the Centre's Service. The Quality Manager and other team members involved in the development of the Quality Manual and of the Quality Management System state that time constraints with other duties and of meeting the needs of service users has resulted in very limited time being available to devote to these required tasks (S.6.1.1).

The Quality Management System has not yet been subject to a management review. (S.4.2.8)

Document Control
As part of the Quality Management System, it was noted by the Executive that a considerable number of Policies and Procedures in all areas of the Centre's work were overdue review and required updating. When asked staff stated that time constraints had prohibited this being done in a more timely fashion. (S.5.2.5 / 6)

Areas for consideration

Executive recommendations for Licence Committee

The Quality Management System requires development as a priority, with supporting documentation in place and existing documentation appropriately reviewed and updated, alongside a formal schedule of audit and review. The PR must ensure that the Quality Manager has the appropriate time and facilities to do this.(S.4.2.1 S.5.1 S.6.1)
Areas not covered on this inspection
All areas covered.
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. General 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

Areas of firm compliance

General Premises
The Centre is a self-contained unit within the main Queens Medical Campus. The centre had recently undergone some refurbishment and redecoration.

There is a small, enclosed reception area to which patients report on arrival.
Staff facilities are provided and were considered adequate (S.6.3.9)

Clinical facilities
There are a small number of offices and three consulting rooms which open into a central waiting area. The area appeared clean, pleasantly decorated and simply, but comfortably furnished. This area is also used for patient information sessions out of hours.
The Treatment room appeared clean, well equipped and private. S,6.3.2

Counselling facilities
There is a dedicated counselling / quiet room. S.6.3.5 There is a small, basic washroom 'en suite' to this room which is currently the only area within the centre designated for use where men may provide semen samples on site.

Laboratory facilities
The Andrology Laboratory is well equipped and appeared to be fit for use. (S.6.3.6)
Gametes are processed in an environment of the appropriate air quality, which is monitored regularly, evidence of which was seen on inspection. The Laboratory has clinical pathology accreditation. (S.7.8.1).

Facilities for cryopreserved sample storage were seen and considered by the Scientific Inspector to be appropriate. (S.6.3.7 / 8) The Centre has recently invested in new vapour phase storage vessels to increase their storage capacity. Appropriate alarm and monitoring mechanisms were seen to be in place, as was a protocol for responding to an activated alarm.

Management of equipment and materials
Trust maintenance and specialist equipment maintenance contracts for repair and preventative maintenance of equipment are reported to be in place but were not reviewed in

the course of the inspection Records of portable appliance testing (PAT) on equipment were current. (S.6.4.1/2)

Trust wide contracts for waste management and cleaning are in place, evidence of which was seen. (S.6.3.1 / 2)

Control of records
The Centre's medical records store is located behind the reception desk and access is restricted to appropriate personnel by keypad lock. Patient health records were seen to be stored securely with access limited to appropriate personnel.(S.5.2.7 S.7.2)

Areas for improvement

Provision of an accessible men's room.
The small washroom designated for this purpose may only be accessed via the Counselling room and so may not, therefore be used when Counselling sessions are taking place.

As a result of the location of the semen production room adjoining the counselling room, this washroom is not always accessible or cannot be used if there is a man using the washroom.

As a result, the majority of semen samples are produced off site at the person's home. This is potentially non compliant with COP guidance at G.2.3.

Areas for consideration

Executive recommendations for Licence Committee

The PR should review the provision of sperm production facilities and assess whether there are any risks associated with home procurement.

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. General Information
2. HFEA Alerts
3. Welfare of child
4. Donor information
5. Procurement and distribution of receipt of gametes and embryos
6. Home procurement report documentation

Areas of firm compliance

General

General information regarding the Centre, treatment options and donation was considered comprehensive and readily available on site and via the Centre's website. Patients also have access to email enquiries for non urgent queries. Evidence of patient information sessions being available was also seen.

The centre currently stores approximately 800 cryopreserved samples and processes in excess of 3500 semen samples per annum for an estimated 700 patients..

The Centre (treatment and andrology service) has comprehensive and clearly illustrated information on treatment and services available displayed on the Trust Website. Information for patients and potential donors is available to download. The website displays pictures of the centre, staff information, and information about opening times, also how to contact the centre in the event of an emergency.

When asked, staff were able to describe the HFEA Alert system. The PR was able to describe an appropriate method of disseminating this information as required to the appropriate team members.

When asked, both medical and nursing staff were able to confirm that welfare of the child consideration is addressed at both doctor consultation and in nurse consultations throughout the treatment process.

Donor information and recruitment and procurement is managed by the andrology team. Potential donors may complete an 'on line' questionnaire which is then verified and signed by the donor at the time of the initial consultation and assessment. Hard copy written information was also seen to be available.
(S.7.6.6/7/8)

Evidence that counselling is offered was seen in randomly selected donor notes.(S.7.6.3)

Appropriate procedures were seen to be in place for the receipt of samples produced off site (home procurement) S.7.7.9

Areas for improvement
It was noted that a number of Centre Polices and Procedures were overdue for review. S.5.2.5 / 6
Areas for consideration
Executive recommendations for Licence Committee
The PR must consider how best to ensure that local policies and procedures are updated in a timely manner.
Areas not covered on this inspection
Surrogacy – not arranged at this centre

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. Laboratory processes
2. Selection and Validation of laboratory procedures
3. Laboratory's documented procedures
4. Storage of gametes and embryos
5. Training and Competencies of Staff
6. Counselling
7. Witnessing

Centre Staffing *

GMC registered doctors	Up to 3 Consultants (in session) + PR and NL
NMC registered nurses	2.5 FTE
HPC registered scientists	2.4 + consultant scientist (is also Quality Manager)*
Receptionist / Admin support	1
Counsellors	1 (session basis)

*The professional and managerial duties of the consultant scientist dictate that he apportions his time between his various commitments and is therefore not exclusively available to conduct the day to day 'hands on' work of the laboratory

Spot check of stored material.

A random spot check of stored material to records and records to stored material was undertaken. No discrepancies were identified. (S.7.3)

A random check of documented witness procedure records was conduced. No discrepancies were identified.

A random check of patient treatment records for 5 patients was conduced and were found to be in good order with no discrepancies found. Consents were present and were compatible with the treatments provided.

Areas of firm compliance

Laboratory Processes
With the exception noted below, (one sample stored out of consent) the laboratory's procedures examined by the Scientific Inspector were considered to be conducted in compliance with current professional guidelines, legislation and regulations. (S.7.8 S.9.5 S.9.2.4 / 6)

An 'On-call' arrangement for responding to emergencies is in place in compliance with S.6.3.8.

The Laboratory has been awarded Clinical Pathology Association (CPA) accreditation for the aspects of laboratory work they undertake. Evidence of comprehensive laboratory risk assessments was seen.

Evidence of monthly environmental monitoring in the form of particle counts and settle plates was seen, the results for which were within recommended parameters. (S.6.3.6)

Selection and Validation
The process for validation of laboratory procedures has begun using the CASA system, evidence for which was seen on inspection. (S,7.8.3)

Storage of gametes
Facilities for the storage of cryo preserved samples was seen to be appropriate for use. (S.6.3.7 / 8) The Centre has recently invested in a new vapour phase storage vessels to increase the capacity of the storage.

Appropriate alarm and monitoring mechanisms were seen to be in place, as was a policy direction action in the event of an alarm being activated. .(S.6.4(b)).

It was noted that there is an air extraction system in the cyro store which is linked to a motion sensor and low O^2 monitor and also a continuous temperature monitoring system attached to an auto dialler and so could be monitored remotely. The Team also test the low N^2 alarms when filling tanks

Witnessing
Written evidence and observed practice indicated that witnessing procedures are conducted in accordance with HFEA guidance. (S.7.8.15 G.13)

Training and Competency
Evidence of continuing Professional Development was seen by both the Clinical and Scientific Inspectors. Laboratory staff participate in NEQAS quality assessments and hold competency 'log books'. Inter laboratory comparisons are conducted with the neighbouring Nurture laboratories. (S.4.2.9 S.9.2.6)

Clinical staff undergo in house competency assessment and each has an individual training log. Staff asked stated that all mandatory training in attended.

All professional staff were seen to be supported in attending external professional meetings and courses were funding and staff constraints permitted.

Provision of Counselling.
There is an appropriately qualified Counsellor in post. An audit of the counselling service has recently been conducted and was available to the Executive. The Counsellor participates in regular, independent professional supervision of her practice. When asked the Counsellor was able to describe an appropriate route of action in the event of an issue arising relating to a Welfare of the Child issue and other onward professional referral if required. Patient and partners may contact the Counsellor independently of the Centre. (S7.6.2/3/4)

The Counsellor confirmed that counselling records are stored securely separately from other patient records and accessible only by the Counsellor.

Areas for improvement

Laboratory
The Centre informed the Executive that they were currently storing one patient's semen samples without consent to posthumous use. The Circumstances for this were discussed at inspection. (S.7.8.11)

Current staffing constraints often mean that members of the team may be 'lone working' on Saturdays or at other times out of hours. (Described elsewhere). (S.6.3.2)

Some of the documented laboratory and clinical procedures were seen to be overdue review.(S.5.2.5)

There is currently no written log recording the cleaning and decontamination of critical equipment in place. (S6.4.2 (c)).

Areas for consideration

Executive recommendations for Licence Committee

Risk assessment and review of working practices is recommended to ensure that appropriate provision is being made to ensure the safety and welfare of staff who may be working in isolation out of hours or alone. (S.6.3.2)

A record of the routine cleaning and decontamination of key equipment should be implemented and maintained. S.6.4.2 (c)).

Areas not covered on this inspection

All areas covered.

Evaluation

Some improvement required

Report compiled by:

Name Gillian Walsh

Designation HFEA Executive - Inspector

Date 30th May 2008

Appendix A: Centre Staff interviewed

The Person Responsible and five members of the Centre team.

A number of patients attending the Centre on the day also kindly consented to be interviewed by the Inspection team.

Appendix B: Licence history for previous 3 years

May 2007

Variation granted pursuant of the amended Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

May 2006

Interim Inspection – Licence Condition Imposed - to establish an out of hours laboratory 'on call' facility to respond to out of hours laboratory alarms as required.

April 2005

Interim Inspection – no Licence Conditions imposed.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0162

Name of PR Mr James Hopkisson

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

Signed……

Name…….

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

01 May 2008 Written confirmation – out of consent sample now appropriately discarded.

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

24 July 2008
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 9

Queen's Medical Centre, Nottingham (0162)
Interim Inspection

Members of the Committee:

Anna Carragher, Lay Member – Chair
Ruth Fasht, Lay Member
Roger Neuberg, Emeritus Consultant in Obstetrics and Gynaecology, Leicester Royal Infirmary

Present via conference telephone:
Chris Barratt, Head of the Reproductive and Developmental Biology research group, University of Dundee

In Attendance:

Debra Bloor, Head of Inspection
Claudia Lally, Committee Secretary

Providing Legal Advice to the Committee:
Mary Timms, Field Fisher Waterhouse

Declarations of Interest: 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 (33 pages)
- no papers were tabled.

1. The papers for this item were presented by Gill Walsh, HFEA Inspector. Mrs Walsh informed the Committee that this centre has held and HFEA licence since 1992 and provides partner and donor insemination and recruits sperm donors. The centre also provides a storage service to oncology patients.

2. Mrs Walsh stated that the centre is very busy and has been hindered by the fact that two key personal being on long term sick leave; both are now back at work but there are still indications that the centre is understaffed in relation to the work undertaken.

3. Mrs Walsh drew the Committee's attention to the fact that the majority of patients produce samples off site, largely because of the male production facilities which, in the opinion of the Executive were not suitable for purpose.

The Committee's Decision

4. The Committee expressed its concern about the finding in the report that centre's staffing resources were not adequate for the quantity of work being undertaken. The Committee noted that this was a breach of the Code of Practice and of licence conditions and agreed that it expected the organisation to address this issue immediately. The Committee stated that the centre should carry out an assessment of the level of work that can safely be accommodated given current staffing levels. The Committee asked the Executive to keep this issue under review and to visit the centre in 12 months time to assess progress.

5. The Committee agreed that it expected all the areas for improvement identified at the inspection to be addressed in the timescales stated in the report.

6. The Committee noted that the inspectorate found the male production room unsuitable. It asked that the centre obtain feedback on the room from patients and then act to address any problems identified in that feedback.

Signed…….. … Date……..
Anna Carragher (Chair)