Interim Inspection Report

Assisted Reproduction Unit
University Hospital of Hartlepool
OO31

Date of Inspection: 16 October 2008
Date of Licence Committee: 15 December 2008

Centre Details

Person Responsible	Dr Iona MacLeod
Nominal Licensee	Ms Susan Blowers
Centre name	Assisted Reproduction Unit ARU
Centre number	0031
Centre address	University Hospital of Hartlepool Holdforth Rd Hartlepool TS249AH
Type of inspection	Interim/New Premises
Inspector(s)	Angela Sutherland (Lead) Gill Walsh Steve Lynch (External Scientist)
Fee paid	Up to date
Licence expiry date	28 February 2010 Licence L0031-13-b

Index

About the Inspection:

This inspection visit was carried out on 16 October 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The Hartlepool General Hospital has been licensed since 1992 and has a good history of compliance with no previous conditions on its licence. A range of licensed treatments are offered to both private and NHS funded patients, most of the referrals being from Hartlepool and the surrounding areas.

Activity has decreased from 167 cycles in 2006/07 to 100 cycles in the period between 2007/08. Centre 0031 has moved to new premises with no apparent change to laboratory facilities.

The Person Responsible is appropriately qualified to discharge her duties as outlined in section 17 of the HF&E Act.

Activities of the Centre[1] for the time period from June 2007 to July 2008 (in cycles)

In vitro fertilisation (IVF)	57
Intracytoplasmic sperm injection (ICSI)	38
Frozen embryo transfer (FET)	5
Gamete intrafallopian transfer (GIFT)	0
Research	0
Storage gametes/embryos	Yes

Summary for Licence Committee

On the day of inspection it was found that the areas of Premises and Equipment and Information required no improvement, some improvement is required in the areas of Organisation and Laboratory and Clinical Processes and significant improvement is required in the area of Quality of the Service.

Improvements should be considered in the following areas:

- The payment of fees;
- Quality Management system;
- Quality manual;
- Patient feedback;
- Document control;
- Nursing competency assessment;
- Validation of processes.

Three recommendations from the last inspection have not been acted upon. These were in relation to the following areas of practice:

[1] 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 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.

- Quality management, including the dedicated role of a quality manager, the development of a quality management system and the development of a quality manual;
- Validation;
- Patient feedback.

It is recommended that the centre adopts the recommendations made in relation to these areas of improvement within the prescribed timeframes.

The centre has applied for a licence variation to permit licensable activity to occur in their new premises. The executive recommends the continuation of the centre's licence with this variation included.

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
For the year from June 2007 to July 2008 the centre took an average 32 days to pay invoices. This is a breach of standard licence condition A.13.3 of the Code of Practice.	The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days in compliance with A.13.3.	To be monitored in the course of the next inspection.
The centre does not have a quality management system that was considered by the inspectorate to be compliant with CoP S.5.1.1.	The PR should ensure availability of resources for the maintenance and development of the quality management system (CoP S.4.2.9) and that the quality management system is	To be addressed by the centre immediately and monitored in the course of the next inspection.

	subject to review as required by CoP S.4.2.9.	
While an organisational chart was provided at inspection, the centre currently does not have a quality manual that adequately reflects the requirements of CoP S.5.2.4	It is recommended that the PR ensure availability of resources for the development and maintenance of a quality manual containing a brief description of the centre, including its legal identity, the scope of the services provided and the quality policy, in compliance with CoP S.5.2.4.	To be addressed by the centre immediately and monitored in the course of the next inspection.
The quality manager reported that a patient questionnaire had been devised but this did not appear to be in permanent use and it's results were not analysed.	It is recommended that as a measure of the performance of the Quality Management System, the Centre should monitor information relating to user perception as to whether the service has met their needs and requirements. Records should be kept of the information collected and actions taken in compliance with CoP S.9.2.1.	To be addressed by the centre immediately and monitored in the course of the next inspection.
At inspection several documents were found that had not been reviewed and/or updated within a 12 month period.	The PR should ensure that all documents are regularly reviewed and revised when required, at a frequency of no more than every 12 months in compliance with CoP S.5.2.5.	To be completed by 16 February 2009.
Since the last inspection there has been one instance where a licensable procedure was performed on non-licensed premises.	The PR must review the circumstances under which this procedure was conducted on unlicensed premises and ensure future compliance with S.4(1a) of the HFE Act 1990.	Immediately.
Interviews with nursing staff and the QM at inspection revealed that nursing staff training and competency assessment is not being adequately reviewed or documented. Inspection of nursing	To ensure and provide evidence that the centre is compliant with CoP S.6.2.9 and A.10.11 it is recommend that all staff competence reviews and assessments are	To be addressed by the centre immediately and monitored in the course of the next inspection. Timeline to be provided

staff training folders provided at inspection contained no evidence of initial or annual competency assessment and sign off of critical skills.	performed and documented at intervals specified by the quality management manual. The PR should provide a timeline reflecting a programme of completion.	by 16 February 2009.
It was found at inspection that laboratory processes have not been validated.	In order to be compliant with CoP S.7.8.3, the PR should ensure that procedures are validated in accordance with professional guidelines, based on previously published studies or retrospective evaluation of the centre's own data.	To be monitored in the course of the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
3 embryo transfers Since last inspection three, three embryo transfers have taken place in women under the age of 40.	As it is noted that a three embryo transfer policy is reported to be in place, the PR should consider why it was not adhered to and make changes necessary to avoid future, similar breaches of CoP G.8.5.1.	Immediately.

Recommendations

Area for improvement	Action required	Time scale
Discussion with the PR and business manager (BM) confirmed their confidence that staffing levels are adequate for the number of treatment cycles currently performed. It is notable that the number of treatment cycles has dropped from 167 in 2006/2007 to 100 in 2007/2008. The BM discussed plans to dramatically increase cycle numbers over the next year.	It is recommended that the PR assesses how many cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Future activity should take into account the findings of the assessment (CoP A.10.9. and A.10.18). A copy of the assessment should be forwarded to the HFEA. A similar recommendation was made following the	Before any significant increase in cycle numbers.

	previous inspection but was not acted upon.	
Discussion with the ARU quality manager confirmed that while clinical governance is part of her role, to date she has been unable to dedicate more than minimal time to clinical governance and/or quality management. Currently these responsibilities are largely managed by an individual employed by the trusts maternity unit, with no formal, dedicated WTE allocated to ARU. Discussion with the Clinical Governance Manager confirmed that if (as is expected) her workload within the maternity department increases she is unlikely to be able to continue dedicating the same level of commitment to ARU.	The PR should demonstrate that there is a commitment to the establishment and maintenance of the Quality Management System and the improvement of its effectiveness by ensuring the ongoing availability of resources in compliance with S.4.2.1. The PR should provide a timeline reflecting a programme of completion.	To be monitored in the course of the next inspection. Timeline to be provided by 16 February 2009.
Inspection of meeting minutes suggested that the PR has been absent from approximately two thirds of the centre's multi disciplinary meetings.	Consideration should be given to the existence of any barriers to the PR attending unit meetings and ensuring that she is present at the centre frequently enough to carry out the responsibilities of the PR as defined by CoP S.4.1.7.	Immediately.
At inspection it was noted that there is some distance to travel between the laboratory and new cryostore room, down a corridor that is at times busy with pedestrian traffic, causing a potential hazard.	It is recommended that the PR assess the risks associated with the transfer of liquid nitrogen and cryopreserved material between the laboratory and cryostore room and make changes where appropriate, to minimise and risks identified before the facility is commissioned. (CoP S.7.8.3)	Before commissioning of the new cryostore facilities.
During the tour of the centre's new premises it was noted that non-licenced maternity unit staff are able to gain direct access to ARU	The security of patient records and stored gametes and embryos should be reviewed.	Immediately.

via an unlockable door in the shared staff room.		
It was reported by the principal embryologist that laboratory air quality is monitored annually by an external contractor.	It is recommended that air quality monitoring procedures are validated to provide documented evidence that air quality is maintained in the time intervals between testing (A.10.19).	To be completed by the time of the next inspection.

Changes/ improvements since last inspection

Recommendations from additional inspection 06.12.07 and renewal inspection 12.09.06	**Action Taken**
The NL stated that the centre's Quality Manager is also the Quality Manager for the hospital. The inspectorate informed the staff that whoever is taking the responsibility for the unit should have dedicated time, a full job description and input. The system should be brought together in line with the EUTD guidelines, the quality manual and procedures should meet the Quality Management System requirements.	At inspection on 16.10.08 it was found that while the centre has a quality manager, she has no dedicated time for quality management and is unable to allocate any time to this role as she is currently required for clinical duties. A clinical governance manager from the trust's maternity unit has been involved in some quality management for ARU but also does not have dedicated time for this work and may not be able to continue with it in the future. It remains the case that the centre does not have a quality management system or quality manual.
There should be an assessment carried out to encompass all the current facilities e.g. staff, equipment and premises to calculate throughput of the unit as a whole. If the unit then wishes to increase the workload, they should redefine the assessment.	The PR reported that staffing levels are currently adequate; however the recommended assessment was not carried out.
The laboratory consists of three chambers, one for the office, one for the work and one for storage of theatre equipment. This was cluttered, and there was little room for movement especially with all the equipment in a confined space. The housekeeping should be reviewed and updated before the next visit. It was also suggested by the embryologist that she may require a separate office space to remove paperwork from the laboratory and to increase the	New cryostore facilities are waiting to be commissioned. Inspection found that this will enable decluttering of the current facilities and reduce risk to staff.

current space.	
Currently there are 5 dewars located in the laboratory. These are placed alongside a wall and all appeared to be alarmed and a low level oxygen monitor was also present. The inspectorate considered these to be a risk as a lone embryologist works alongside these and there is potential for them to leak or for someone to knock against them.	As above.
The laboratory does not currently validate any equipment or processes so this should be considered and a programme implemented as per the guidelines.	Equipment was found to be validated at inspection but the centre has not validated key processes.
The last risk assessment (RA) was performed two years ago and this needs to be reviewed urgently to ensure that there is no danger to personnel and maybe even moving the dewars to a dedicated cryo-storage room and also incorporate the whole laboratory and space issues.	Risk assessments have been performed that appear satisfactory.
Air quality was discussed and the laboratory has the same air as the theatre by an overhead system. The embryologist stated that the air quality will be monitored in January 2008 and it was suggested that this be done with personnel working in the laboratory to gain an actual reading rather than an empty laboratory.	Air quality was found at inspection to be monitored annually by an external company.
Any staff meetings held at the unit need to be documented and made available to the appropriate staff. On many occasions staff are unable to attend meetings due to workload.	Staff meetings were found to be generally well attended and appropriately minuted although the PR was noted as absent from the majority of the meetings.
Currently there is no patient feedback procedure in place at the centre. Therefore the staff need to develop a method by which to seek patients' views as a continuous improvement measure.	At inspection the centre was found to have a patient questionnaire but this does not appear to be in permanent use and the results are not analysed.
The laboratory protocols for keeping of embryos past expiry date and the criteria used for three embryo transfer need to be amended.	These protocols were considered at inspection and appeared satisfactory.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Clinical governance: Incident and complaints management At inspection a comprehensive log was supplied that documented the system used to manage and resolve complaints and, incidents. Complaints information was clearly displayed in the patient waiting area in compliance with CoP S.9.2.2. There were no significant incidents in the centre log that had not been reported to the HFEA and all incidents appeared to have been resolved appropriately. **Third party agreements** The PR reported that all third party agreements have been obtained in compliance with standard licence condition A.5.1. All agreements were provided at inspection and a sample examined appeared compliant. **Organisation of the centre** During interview on the day of inspection the PR and senior staff confirmed that all members of staff are appropriately qualified and experienced for their roles. This was confirmed by review of staff curriculum vitae and training logs supplied at inspection. (CoP S.4.1.7) Staff interviewed during the inspection confirmed that they are encouraged to make suggestions and are kept up-to-date of changes and developments within the centre. **Risk management** At inspection the inspectorate saw a comprehensive record has been kept containing 16 up-to-date risk assessments, across all specialties. Discussion with the quality manager confirmed that all staff are involved in the assessment of risk at the centre and appropriate tools are available to all.

Contingency arrangements
The inspectorate saw a written contingency arrangement with the North East Fertility Forum. The PR was able to verbally describe contingency arrangements to cover unexpected staff absence across all specialities.

Meetings/dissemination of information
Inspection of multi-disciplinary meeting records reflected regular, well attended meetings and clear, communicative minutes. (CoP S.6.2.13)

Areas for improvement

Payment of fees
In the time period from June 2007 to July 2008 centre took an average 32 days to pay invoices. This is a breach of 1.13.3 (Appendix A) of the Code of Practice where the maximum payment time is specified as 28 days.

Areas for consideration

Resource management: staffing levels
Discussion with the PR and business manager (BM) confirmed their confidence that staffing levels are adequate for the number of cycles currently performed. It is notable that the number of cycles has dropped from 167 in 2006/2007 to 100 in 2007/2008. However, the QM currently feels unable to undertake QM responsibilities as her time is dedicated almost solely to clinical duties and the BM discussed plans to dramatically increase cycle numbers over the next year.

Clinical governance: Incident and complaints management
Discussion with the ARU quality manager confirmed that to date she has been unable to dedicate more than minimal time to clinical governance. Currently these responsibilities are largely managed by an individual employed by the trusts maternity unit, with no formal, dedicated time allocated to ARU.

Discussion with the Clinical Governance Manager confirmed that her workload within the maternity department will increase in the near future and that she is unlikely to be able to continue dedicating the same level of commitment to ARU.

Organisation of the centre/meetings:
Inspection of meeting minutes indicated that the PR has been absent from approximately two thirds of the centre's multi disciplinary meetings.

Executive recommendations for Licence Committee

The PR should review whether there are any barriers to the prompt payment of HFEA invoices and take steps to ensure the fees are paid within 28 days in compliance with A.13.3.

It is recommended that the PR assesses how many treatment cycles can safely be accommodated by the centre. The assessment should consider the centre's premises, equipment, staffing levels and the skill mix of staff members. Future activity should take into account the findings of the assessment (CoP A.10.9. and A.10.18). An assessment of the centres capacity was also recommended at the time of the last inspection but was not completed. In consideration of this, it is recommended that the assessment be completed by

16 January 2009 and that the assessment is submitted to the HFEA on completion, along with information on any actions taken as a result of the assessment. It is recommended the PR consider how clinical governance procedures can be managed effectively. Consideration should be given to the existence of any barriers to the PR attending unit meetings and ensuring that she is present at the centre, frequently enough to carry out the responsibilities of the PR as defined by CoP S.4.1.7.
Evaluation
Some improvement required.
Areas not covered on this inspection

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control
- Live birth rates

Live birth rates[1]
In the time period from 1 April 2003 to 31 March 2006 the centre's outcomes were in line with national averages.
Areas of firm compliance
Areas for improvement
Quality management system At inspection, the centre's designated quality manager reported that she is currently unable to dedicate time to quality management due to the required commitment of her time to clinical responsibilities. This was reflected by a lack of documented quality management policy, future objectives and plans, and minimal up-to-date review and evaluation of quality management procedures and policies. (CoP S.5.1.1) During interview with the maternity unit staff member who has, to date, taken responsibility for ARU's clinical governance management, it appeared that she also currently has responsibility for some aspects of quality management at the centre. She reported that she has no set time dedicated to this and may not be resourced to continue with it in the future. **Quality Manual** While an organisational chart was provided at inspection, the centre currently does not have a quality manual. **Feedback: Patient questionnaire, analysis of results** The quality manager reported that a patient questionnaire had been devised but this did not appear to be in permanent use and there was no evidence of results being analysed. **Document control** At inspection several documents were found that had not been reviewed and/or updated within a 12 month period.
Areas for consideration

Executive recommendations for Licence Committee
The PR should demonstrate that there is a commitment to the establishment and maintenance of the Quality Management System and the improvement of its effectiveness by ensuring the ongoing availability of resources in compliance with S.4.2.1.and ensuring that the quality management system is subject to review as required by CoP S.4.2.9. The PR should ensure that the quality manual contains a brief description of the centre, including its legal identity, the scope of the services provided and the quality policy, in compliance with CoP S.5.2.4. It is recommended that as a measure of the performance of the Quality Management System, the centre should monitor information relating to user perception as to whether the service has met their needs and requirements. Records should be kept of the information collected and actions taken in compliance with CoP S.9.2.1. The PR should ensure that all documents are regularly reviewed and revised when required, at a frequency of no more than every 12 months in compliance with CoP S.5.2.5. It is recommended that as a measure of the performance of the Quality Management System, the centre should monitor information relating to user perception as to whether the service has met their needs and requirements. Records should be kept of the information collected and actions taken in compliance with CoP S.9.2.1. The PR should ensure that all documents are regularly reviewed and revised when required, at a frequency of no more than every 12 months in compliance with CoP S.5.2.5.
Evaluation
Significant improvement required.
Areas not covered on this inspection

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
New premises The centre has recently moved non-licensed activity into a new purpose built unit that was completed in September 2008. At the time of inspection these facilities were noted to be spacious and well organised with a logical activity flow and good access to the existing area where licensed activity continues to take place. **Counselling facilities** Counselling is provided in quiet, comfortable and private facilities in compliance with CoP S.6.3.5. **Air quality** Air quality is assessed annually by an external contractor. At inspection records were seen of air quality in compliance with CoP A.10.21. **Storage of records** Tour of the premises and discussion with the quality manager and PR confirmed that all clinical records are stored in a dedicated locked room, inside locked cabinets only accessible by licensed staff in compliance with CoP S.7.2.1. **Laboratory facilities** Discussion with staff and observation during the inspection showed that laboratory facilities appear to be appropriate for licensed activities carried out in them. Storage dewars were appropriately alarmed and procedures for responding to emergencies are in place. Inspection of the laboratory confirmed the presence of a low O_2 monitor and extraction fans. (CoP S.6.3.8) **Storage for gametes** New cryostore facilities were also inspected and were ready to be commissioned pending licence committee approval. The premises are secured with a keypad and plans are in place to move existing dewar and low O_2 alarms in compliance with CoP S.6.4.2.

Areas for improvement
Areas for consideration
Storage for gametes At inspection it was noted that there is some distance to travel between the laboratory and the new cryostore room, down a corridor that is at times busy with pedestrian traffic. It is recommended that the PR risk assess the transfer of liquid nitrogen between the laboratory and cryostore room and make changes where appropriate, before the facility is commissioned. (CoP S.7.8.3) **Premises** During the tour of the centre's new premises it was noted that non-licensed maternity unit staff are able to gain direct access to ARU via a door in the shared staff room. To ensure the security of patient records and stored gametes and embryos in compliance with CoP S.7.2.1 and S.6.3.8, the PR should consider the a method of restricting movement within the unit to licenced staff.
Executive recommendations for Licence Committee
It is recommended that the PR risk assess the transfer of liquid nitrogen and cryopreserved material between the laboratory and cryostore room and make changes where appropriate, before the facility is commissioned. (CoP S.7.8.3) To ensure the absolute security of patient records and stored gametes and embryos, the PR should consider the placement of a lock on the staff room door to restrict movement within the unit to licensed staff.
Evaluation
No improvement required.
Areas not covered on this inspection

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Consent The QM reported at inspection that patient consent is taken only by herself or the treating consultant and that this process is guided by trust policy. An audit of consent in five sets of patient records found no discrepancies. The quality manager expressed confidence that all patients and partners are given adequate time and information before signing consent to treatment in compliance with CoP S.7.5.3. **Access to health records** The QM/senior nurse has designated responsibility for the management of requests for access to patient records in compliance with CoP S.7.2.2. Such requests are further guided by trusts policy. **Welfare of the Child** Both the PR and QM informed the inspectorate that the unit has a robust system for multidisciplinary discussion and process for escalation of potential welfare of child issues. (CoP S.7.1.4) The WOC forms were appropriately signed in all five sets of patient records randomly audited at inspection.
Areas for improvement
Areas for consideration
Executive recommendations for Licence Committee
Evaluation
No improvement required.
Areas not covered on this inspection
Information for service users.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	1-1.5(variable weekly)
NMC registered nurses	2.0
Non NMC registered clinical staff	1.0
HPC registered scientists	2.0
Scientists working towards registration	0.0
Support staff (receptionists, record managers, quality and risk managers etc)	1.5
Counsellors	As req. Aprox 0.5 WTE.

Summary of laboratory audit
A summary report of the laboratory audit of cryopreserved material was not provided with the pre inspection questionnaire but the results of an audit carried out in June 2008 were provided to the executive subsequent to the inspection. Results of the embryo audit showed no discrepancies and the sperm tank audit found one oncology sample that had been transferred from another centre that was immediately split into 2 canisters.
Summary of spot check of stored material
Two patient's samples (one sperm, one embryo) were tracked by the scientific inspector from the dewars to the laboratory workbook and to the relevant consent forms. In reverse of this, another two samples were tracked from the patient's consent forms to the laboratory workbook and to the dewars. No discrepancies were found.
Areas of firm compliance
Screening The centre does not treat viral positive patients: The PR reported that all donors and stored gametes are screened in accordance with professional body guidelines. Audit of 5 random sets of patient notes at inspection showed that all patients had been appropriately screened.

CoP S.7.8.12

Traceability
The PR reported that a full system for traceability is in place in compliance with CoP S.7.3.1and this was verified during inspection of the laboratory.

Areas for improvement

3 embryo transfers
Since last inspection, three embryos have been transferred to women under the age of 40 on three occasions. This is contrary to CoP guidance G.8.5.1. This was reported to the executive prior to inspection by the principal embryologist but the reasons for the transfers were not provided. The centre does have a three embryo transfer policy which was provided to the inspectorate.

Procurement of gametes on unlicenced premises
Since last inspection there has been one instance where sperm was surgically procured on unlicensed premises and in the absence of a third party agreement. This was reported by the centre to the HFEA as an incident.

Nurse competencies
Interviews with nursing staff and the QM at inspection revealed that nursing staff training and competency assessment is not being adequately reviewed or documented. Inspection of nursing staff training folders provided at inspection contained no evidence of initial or annual competency assessment and sign off of critical skills.

Validation
It was found at inspection that laboratory processes have not been validated.

Areas for consideration

Executive recommendations for Licence Committee

The PR should review the three embryo transfer policy to ensure there are no barriers to compliance with the policy. Where the PR chooses not to comply with COP guidance then it is recommended that the rationale for the non compliance is documented.

It is recommended that the PR consider the circumstances under which sperm was procured on unlicensed premises and make changes to ensure compliance with S.4.1(a) of the HFE Act 1990.

To ensure and evidence that the centre is compliant with CoP S.6.2.9 it is recommend that all staff competence reviews and assessments are performed and documented at intervals specified by the quality management manual

In order to be compliant with CoP S.7.8.3, the PR should ensure that procedures are validated in accordance with professional guidelines, based on previously published studies or retrospective evaluation of the centre's own data.

Evaluation

Some improvement required.
Areas not covered on this inspection

Report compiled by:

Name: Angela Sutherland…….

Designation: Inspector……..

Date……

Appendix A: Centre staff interviewed

PR: Dr Iona MacLeod
Specialist nurse
Senior Nurse
Senior embryologist
Principal embryologist
Counsellor
Clinical Governance Manager

Appendix B: Licence history for previous 3 years

Licence	Type	Active From	Expiry Date
L0031/11/a	Treatment with Storage	01/12/2005	28/02/2007
L0031/13/a	Replaced by New Version	05/07/2007	28/02/2010
L0031/12/a	Replaced by New Version	01/03/2007	28/02/2010
L0031/10/b	Replaced by New Version		28/02/2007
L0031/10/a	Replaced by New Version	01/03/2004	28/02/2007
L0031/9/b	Replaced	01/03/2001	29/02/2004

	by New Version		
L0031/9/a	Replaced by New Version	01/03/2001	29/02/2004
L0031/7/a	Replaced by New Version	15/10/1998	15/10/1999

28.01.08 Change of PR

the basis of the information before them the Committee approved the centre's application for Dr Macleod to be Person Responsible for the centre.

26.04.07 EUTD Variation

The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

18.12.06 Renewal

The Committee noted the improvements achieved by the centre, along with the additional improvements required in the inspection report. The Committee endorsed the recommendations of the inspection team and, taking the required improvements into account, decided to renew the centre's licence for a period of three years, with no additional conditions.

24.05.06 Interim

The Committee decided that the centre's licence should continue with no additional conditions.

19.12.05 Postponement of inspection

The Committee considered the information provided in the Committee papers, and, on the basis of this information, approved the application.

Appendix C: Response of Person Responsible to the inspection report

Centre Number……031……

Name of PR……Dr iona Macleod……

Date of Inspection……16th October 2008……..

Date of Response……18th November 2008……

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

Signed……

Name……Iona Macleod……

Date……25/11/08……

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

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

The Quality Manager has been given time within her job plan to address the issues of quality management and has started development of the quality management file. I intend to address all the recommendations of the report in the suggested timescales.