Interim Inspection Report

Aberdeen Fertility Centre
0019

Date of Inspection: 8 September 2009
Date of Licence Committee: 3 December 2009

Centre Details

Person Responsible	Dr Mark Hamilton
Nominal Licensee	Mrs Alison McTavish
Centre name	Aberdeen Fertility Centre
Centre number	0019
Centre address	Aberdeen Fertility Centre, Department of Obstetrics & Gynaecology, Aberdeen Maternity Hospital, Foresterhill, Aberdeen, Scotland, AB25 2ZD
Type of inspection	Interim
Inspector(s)	Mr Parvez Qureshi (Lead) Mrs Sarah Brain Miss Angela Sutherland Mr Chris Hall (Observer)
Fee paid	Not applicable
Licence expiry date	31st January 2011
NHS/ Private/ Both	Both

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About the Inspection:

This inspection visit was carried out on 8 September 2009 and lasted for 7 hours.

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

Aberdeen Fertility Centre has been licensed since 1992 and offers a variety of treatments to NHS and self-funded patients. There are no additional conditions on its licence. Within the centre there are two units: the Assisted Reproduction Unit and the Fertility Unit, these operate under the same licence.

Around 700 (including 94 IUI) treatment cycles were carried out at the centre for the time period January to December 2008. The treatment volumes were lower than the previous year, this is likely to be because the centre was closed for part of the period whilst refurbishment was undertaken.

An organisational chart is in place indicating key roles and lines of accountability. The centre is open for business seven days a week from 7.45am to 4.15pm.

Activities of the Centre[1] for the time period from 01/01/2008 – 31/12/2008

In vitro fertilisation (IVF)	280
Intracytoplasmic sperm injection (ICSI)	165
Frozen embryo transfer (FET)	117
Donor insemination (DI)	40
Intra uterine insemination (IUI)	94
Storage gametes/embryos	Yes

Summary for Licence Committee

This report documents the evaluation the centre's compliance with the requirements of the 7th Code of Practice which was in force at the time of the inspection. On 1 October 2009 the 8th Code of Practice, amended legislation and revised statutory licence conditions came into force. To accommodate this transition, the centre's compliance at the time of the inspection is referenced to the 7th COP while recommendations for improvement are referenced to the 8th COP.

In considering overall compliance, the executive considers that it has sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- The Person Responsible (PR) is appropriately qualified to discharge his duties, as outlined in Section 17 of the HF&E Act (1990). In considering overall compliance the PR is considered to have discharged his duties under S.17 of the HFE Act.
- The premises and equipment inspected are largely suitable for the treatment procedures for which the centre is licensed. Improvements should however be

[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.

considered relating to the following:
    - Validation of laboratory equipment;
    - Review of security procedures to prevent unauthorised access to records.
- The centres practices are considered largely suitable: Some improvements are recommended in relation to:
    - Validation of laboratory practices and processes;
    - Documentation of staff competence;
    - Recording of information required for traceability;
    - Witnessing procedures.

The inspector considers that there is sufficient information on which to recommend the continuation of the centre's licence. This is subject to compliance with recommendations within the prescribed timeframes.

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 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
In the 12 month period to 20 August 2009, this centre took an average of 31 days to pay HFEA invoices. This was non compliant with the requirements of standard licence condition A.13.3 of the 7th Code of Practice (COP).	The PR should review and consider whether there are barriers to the prompt payment of HFEA invoices.	Progress to be monitored.
Not all equipment has been validated and validation of key processes and procedures has not yet been undertaken. This was non compliant with the	In compliance with T24 and T72 of the 8th COP, all critical equipment and technical devices must be identified and validated, and critical processing procedures	The plan should be submitted to the HFEA by 8 November 2009. Progress with

requirements of standard licence conditions A.10.13 and A.11.11 of the 7th Code of Practice (COP).	must be validated. It is recommended that the centre draw up a plan for validation which takes into account the particular needs of the unit and prioritises the validation of equipment and processes considered to be most likely to impact on the quality of the service.	implementation of the plan to be included in a quarterly update to be submitted to the HFEA until validation is complete.
Staff competency is not documented for some of the staff. This was non compliant with the requirements of standard licence conditions A.10.11 of the 7th Code of Practice (COP).	In compliance with standard licence condition T15 (b) of the 8th COP, personnel must be provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks.	Progress with completion of assessments to be included in the quarterly progress update submitted to the HFEA.
The centre has a procedure in place for traceability of materials that come into contact with gametes. The laboratory manager explained that the incubator letter and shelf is added to laboratory sheets – a space for this was seen on the laboratory sheets but in two sets of records reviewed in the course of the inspection this information had not been documented.	In compliance with the requirements of T90 of the 8th COP the centre must record such information as is necessary to facilitate the traceability of any information relating to the quality or safety of gametes and embryos.	It is expected that this information can readily be recorded immediately.
A discrepancy in relation to the documentation of witnessing was found in one of the six sets of patient records audited at inspection. This was non compliant with the requirements of A.3.5 of the 7th COP.	In compliance with T71 of the 8th COP the PR should ensure that a record is kept in each patient's/donor's medical records of witnessing checks. It is recommended that an audit of witnessing activities is included in the centre's annual audit schedule.	To be monitored.

Non-Compliance

Area for improvement	Action required	Time scale
Although the inspection team saw no evidence that patient confidentiality has been breached they did not consider that the centre has clear security procedures to prevent unauthorised access to records as recommended in guidelines G.10.2 of the 7th COP.	In consideration of guidelines at 30.6 of the 8th COP, the PR should review security procedures to prevent unauthorised access to records.	The PR should inform the HFEA when the review is complete and of any corrective actions taken as a result of the review.
A witnessing template sheet used at the time of frozen embryo transfer was considered non compliant with guidelines at G. 13.1.1(i) of the 7th COP. It was also noted that the freeze and IUI witnessing sheets do not provide a space for the time of the witnessing step to be documented. This was non compliant with guidelines at G.13.2.1 of the 7th COP.	The PR should give consideration to the guidelines provided at 18.4 (i) and 18.7 of the 8th COP in relation to the requirements to cross-refer information from the storage container and the patient or donor records against the thaw dish or tube and documentation of the date and time of witnessing procedures in patient records.	The PR should inform the HFEA when the review is complete and of any corrective actions taken as a result of the review.

Recommendations

Area for improvement	Action required	Time scale
None.		

Changes/ improvements since last inspection

Recommendations	Action Taken
The centre has taken 38 days on average to pay HFEA invoices. The PR should be aware that the HFEA payment terms are 28 days. Payment out with these terms is a breach of standard licence condition A.13.3 of the 7th COP which states that **i**n consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	In the 12 month period to 20 August 2009, this centre took an average of 31 days to pay HFEA invoices. This remains in breach of standard licence condition A.13.3 of the 7th COP but it is acknowledged that the centre has made improvement in the time taken to pay invoices.

Incubators are cleaned regularly according to the senior embryologist. However, it was noted on inspection that up to date records of this are not maintained. Standard 6.4.2 of the 7th COP requires that maintenance, servicing, cleaning and disinfection and sanitation of all critical equipment must be performed regularly and recorded accordingly.	A log of cleaning of incubators and the laboratory is maintained and was reviewed in the course of the interim inspection.
Processes and equipment within the laboratory have not yet been subjected to formal validation. Licence condition A.11.11 and Code of Practice Standards 7.8.3 and 6.4.2 of the 7th COP requires that a programme of validation for equipment and laboratory processes should be introduced.	Records for validation of the freezing machine, ISCI rig, hot blocks, centrifuge, dewars and flow hoods were seen at inspection. It was noted however that the microscopes and new pipettes had not been validated. Processes have not yet been validated. This remains non compliant with T24 and T72 of the 8th COP.
The PR entry programme has not been fully completed by the PR. Standard 4.1.5 of the 7th COP requires that the PR shall have successfully completed the HFEA's PR assessment process	The PR has completed unit two of the PR entry programme. It was completed satisfactorily.
The complaints notice displayed in the waiting room does not include the name of the complaints officer.	The complaints notice was seen displayed in the waiting room with the name of the complaints officer on it.
A register of complaints which logs their investigation and corrective action is not in place.	The centre's complaints log was reviewed by the inspectorate and it showed evidence of corrective action being taken to resolve complaints**.**
There is no formal on-call rota for response to the low nitrogen alarm.	The laboratory manager explained that there is a list of staff who can be contacted in emergencies. Staff reported that this system is sufficient for the centre's current needs.
Documented agreements with third parties to be reviewed so that they are in compliance with Guidance 2.1.2.	All third party agreements were found to be in place and in compliance with Guidance 2.1.2.
There is no system currently in place to ensure that samples produced at home belong to the patient being treated.	At inspection evidence was seen that a declaration form is in use.

A system for verification of patient identity is not currently in place.	A system is in place which requires photographic ID to be provided by all patients.
From the laboratory sheets which are currently in use it is not possible to determine which incubators the embryos have been cultured in.	The laboratory manager explained that the incubator letter and shelf is added to laboratory sheets – a space for this was seen on the laboratory sheets but during audit of records it was noted that it had not been routinely completed. The failure to record this information routinely remains non compliant with the requirements of T90 of the 8th COP which requires that the centre must record such information as is necessary to facilitate the traceability of any information relating to the quality or safety of gametes and embryos.
It was noted that witnessing records did not include the time that the procedure was undertaken.	The witnessing time needs to be added to sperm freeze sheet and IUI witnessing sheet.
Laboratory protocols and records did not include the witnessing of movement of oocytes between dishes at the time of cumulus removal prior to ICSI procedures or the disposal of embryos.	Laboratory sheets have been updated and evidence of this was seen during the inspection.
In view of the discrepancies noted in the witnessing practice, all relevant protocols should be reviewed and revised where necessary.	Some revisions to laboratory witnessing sheets are required as described above.
The centre should assess the risks associated with the simultaneous treatment of patients of similar names and consider introducing systems to minimise the risks.	This has been addressed in a number of ways including patients having different colour coded notes.
It is recommended that contingency plans for the provision of the counselling service is agreed upon and documented	A backup counsellor is now available.

Additional licence conditions and actions taken by centre since last inspection

None.

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
Overall the inspectorate considered the centre to be well organised and managed. An organisational chart that defines accountability and relationships was submitted to the HFEA before the inspection and this was further demonstrated by staff who were interviewed during the course of the inspection. The inspectorate noted that key members of staff have extensive experience of working in the fertility field. There are documented procedures in place for the identification, notification and investigation of incidents. A review of the centre's incident log showed that the HFEA had been informed of all relevant incidents within the required timeframe. The PR stated that centre has access to an ethics committee however no cases have been referred to it. A risk management structure is in place to ensure risk assessments are conducted for key processes and procedures as required. On the day of the inspection, a risk management meeting was attended by a member of the inspectorate and was considered to be a very effective multidisciplinary approach to early detection and minimisation of risk across different areas of the centre. Documented evidence was seen of the management and dissemination of HFEA Alerts. The centre's complaints log was reviewed by the inspectorate and it showed evidence of corrective action being taken to resolve complaints**.** In the event of an emergency, contingency arrangements are in place with Ninewells Hospital (centre 0004) for continuation of service.

A review of centre's import/export log showed that the one recent export under General Directions had been conducted and this was reported to the HFEA via the notification of transfer form.

Evidence was seen that all third party agreements are in place and their content is compliant with HFEA requirements.

In addition to departmental meetings, regular multi-disciplinary team meetings are held at the centre to discuss practice related issues. The minutes of these meetings are made available to all staff and this was confirmed by members of staff who met with the inspection team. A review of minutes of recently held meetings showed that a wide range of topics are discussed including HFEA related issues.

Areas for improvement
In the 12 month period to 20 August 2009, this centre took an average of 31 days to pay HFEA invoices. This was non compliant with the requirements of standard licence condition A.13.3 of the 7th Code of Practice (COP).
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
Some improvements required.
Areas not covered on this inspection
All areas covered.

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]
For the time period from 1 January 2005 to 31 December 2007 the centre's live birth rates were in line with national averages for all treatment types and age bands. In the time period from 1 January 2008 to 31 December 2008 the centre provided 94 cycles of IUI and reported 13 clinical pregnancies.
Areas of firm compliance
The centre's Quality Management System (QMS) includes a quality policy and a quality manual. There are arrangements in place for conducting audits of practice including reviews of patient satisfaction and outcome of treatments. The findings of audits are discussed at unit meetings and any areas of concern are subject to corrective action. Members of staff are also encouraged to make suggestions about the quality of service being provided by the centre. Any changes to the QMS are presented at business meetings. The minutes are published and changes are highlighted. At a more detailed level matters are addressed in the meetings for the various teams in the clinic. Comprehensive minutes of QMS annual review were submitted for the inspection and these showed progress made in achieving quality objectives set in the previous year, staff commented that they found the annual QMS review helpful. The Quality Manager gave examples of the work that has been undertaken to prepare for the changes in the new HFEA Act and Code of Practice. Seventeen patient questionnaires have been returned to the HFEA. Mixed responses were made by patients regarding their experience at the centre. Patients commented that the centre staff were friendly, professional and supportive. Patients also found the information evenings held at the centre to be informative. The Quality Manager informed the inspectorate that patient satisfaction/feedback is monitored and this is considered a useful mechanism for letting staff know how they are performing. An effective document control procedure in place. This was evident from the review of the

documents submitted for the inspection and those reviewed at the centre during the course of the inspection.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
All areas covered.

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
All clinical, laboratory and counselling facilities seen during the visit appeared to be clean and well presented with controlled access. Since the refurbishment in 2007, no major changes have been made to the premises The men's production rooms were considered to be appropriate for their intended purpose. The laboratory facilities were considered to be adequate for the volume of work being conducted. There is controlled access to the facilities. All storage tanks are stored in the cryoroom and locked and are fitted with low nitrogen level alarms. Access to the cryostore is controlled. The cryostore is fitted with a low oxygen level monitor. A SOP for responding to the low oxygen alarm is posted outside the cryoroom. Hazard notices are also displayed outside the cryoroom. Environmental parameters of the fridge and incubators are logged on an electronic monitoring system. Laboratory staff confirmed that an alarm sounds if the conditions rise/fall outside of set parameters. General laboratory cleaning and incubator cleaning logs are maintained. Laboratory processes take place in an environment of at least Grade C air quality and the background air quality in the laboratory area is at least Grade D. The air quality in the laboratory area is monitored and the results are logged accordingly. Evidence of this was seen during the course of the inspection. The scientific inspector noted that the freezing machine and flow hoods had been serviced recently. In the event of a power failure the centre has access to a back up power supply. Staff facilities include toilet accommodation, a rest area with basic catering facilities. A changing area and storage for personal effects.
Areas for improvement

Maintenance staff access the plant room after hours via the room where patient records are stored. Centre staff informed the inspection team that the cabinet containing records is locked after hours and they did not consider security of the records likely to be compromised

The inspection team noted that the door to the nursing office where records are also kept was open when the room was unoccupied. Although the inspection team saw no evidence that patient confidentiality has been compromised they did not consider that the centre has clear security procedures to prevent unauthorised access to records as recommended in guidelines G.10.2 of the 7th COP.

It was noted that the majority of equipment has been validated but some validations remain outstanding including those for the microscope and recently acquired pipettes. This was non complaint with the requirements of standard licence conditions A.10.13 of the 7th Code of Practice (COP).

Areas for consideration

None.

Executive recommendations for Licence Committee

In consideration of guidelines at 30.6 of the 8th COP, the PR should review security procedures to prevent unauthorised access to records stored in the nursing office. The PR should inform the HFEA when the review is complete and of any corrective actions taken as a result of the review.

In compliance with T24 of the 8th COP, all critical equipment and technical devices must be identified and validated. It is recommended that the centre draw up a plan for validation which takes into account the particular needs of the unit and prioritises the validation of equipment considered to be most likely to impact on the quality of the service.

Evaluation

Some improvement required.

Areas not covered on this inspection

All areas covered.

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
Patients are provided with relevant information at their initial consultation and there are procedures in place to ensure that patients receive complete information prior to starting any treatment. However, specific patient information was not reviewed in the course of this inspection as it was considered to be compliant at the time of the renewal inspection in June 2007 The following information was also seen on display during the course of the inspection:- • The centre's treatment licence and complaints procedure which included the complaints officer's name. • Counselling information. Five patient records were reviewed during the course of the inspection. All consent forms and welfare of the child assessment forms were present and compatible with treatment. Access to health records is restricted to authorised staff only. The centre has a procedure in place for those patients who require a copy of their medical notes a charge is made for this. No issues were raised by the HFEA registry regarding quality of data being submitted by the centre.
Areas for improvement
None.
Areas for consideration
None.
Executive recommendations for Licence Committee
None.
Evaluation
No improvement required.
Areas not covered on this inspection
Specific patient information documents were not audited.

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	4
NMC registered nurses	8
Non NMC registered clinical staff	3
HPC registered scientists	4.4
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	6
Counsellors	1

Summary of laboratory audit
An audit of embryos in storage was submitted before inspection and a rolling sperm audit was submitted subsequently. No discrepancies were noted.
Summary of spot check of stored material
A spot check of stored material was not carried out during this inspection.
Areas of firm compliance
Records of continuous professional development (CPD) undertaken by staff are maintained. Staff are encouraged to attend seminars and conferences. Evidence of this was seen for staff from all disciplines. The centre has policies in place for the assessment of patients seeking treatments and for screening of patients. This was evident from the review of the documentation submitted for inspection and was further confirmed by staff who met with the inspection team. An elective single embryo transfer (ESET) policy has been developed by the centre to address the risk of multiple births. A log of elective single embryo transfer (ESET) is

maintained. The centre has been auditing their multiple pregnancy rates and evidence of this was seen by the inspectorate. A log of non-conformity with SET policy has also been maintained. The PR stated that most of the deviation from SET has arisen where individual patients' have made the choice to have two embryos transferred despite being provided with information on the risks.

Arrangements are in place for laboratory staff to participate in external review of sperm assessment performance through the National External Quality Assessment Service (NEQAS). Evidence of this was made available for the inspection. The laboratory staff have been involved in the ACE pilot scheme on comparisons of embryo morphology. They also have an internal quality control (QC) programme. Evidence was seen of a recent QC check on embryo quality grading by staff.

The centre's protocol for transportation and receipt of gametes and embryos was found to be compliant with the recommendations of HFEA Alert 21.

Patients are made aware of the counselling service at their initial consultation. The counsellor is member of the British Infertility Counselling Association (BICA). Her CPD is well maintained and she receives regular supervision. If required, a backup counsellor is available. All counselling sessions take place in comfortable surroundings and the notes are kept in a secure place separate from other patient notes .Counselling is provided independently of clinical decision. Appointments can be booked by clinic staff or by patients contacting the counsellor directly. The counsellor stated that she was well supported by the centre staff and was able to discuss any difficult cases with them within the boundaries of confidentiality requirements (i.e. she would discuss this with the individual first and get their consent). She tries to attend the centre's meetings and the minutes of the meeting are circulated to her. If required, she does conduct telephone counselling for those patients who live far away from the centre. The counsellor stated that she generally does 2 or 3 sessions with patients but it is open ended and they can come back at any time. Most are short-term though and are generally related to failed treatments, those considering treatment and donation.
She undertakes questionnaire surveys over a period of time (e.g. 6 months), this data is collated recorded and reviewed.

The counselling audit supplied for the inspection confirmed that there were a total of 217 referrals between January and December 2008.

Trainee members of staff undergo an induction programme and have their competence assessed.

Areas for improvement

Not all staff have had their competence to perform designated tasks assessed. This was non compliant with the requirements of standard licence conditions A.10.11 of the 7th Code of Practice (COP).

The validation of all key processes in the laboratory has not been undertaken. This was non compliant with the requirements of standard licence conditions A.10.13 and A.11.11 of the 7th Code of Practice (COP).

The centre has a procedure in place for traceability of materials that come into contact with

gametes. The laboratory manager explained that the incubator letter and shelf is added to laboratory sheets – a space for this was seen on the laboratory sheets but during audit of records it was noted that this information had not been documented.
A witnessing template sheet used at the time of frozen embryo transfer was reviewed in the course of the inspection. This sheet did not reference the requirement to cross check the patient information against the labelling on the dish to which embryos are transferred for thawing. This is non compliant with guidelines at G. 13.1.1(i) of the 7th COP.

A discrepancy in relation to the documentation of witnessing was found in one of the six sets of patient records audited at inspection. The discrepancy related to a failure to document witnessing at insemination during an IUI procedure. This was non compliant with the requirements of A.3.5 of the 7th COP.

It was also noted that the freeze and IUI witnessing sheets do not provide a space for the time of the witnessing step to be documented. This was non compliant with guidelines at G.13.2.1 of the 7th COP.

Areas for consideration

There is a clinical procedure in place for management of ovarian hyperstimulation syndrome (OHSS). However, two cases of OHSS had not been reported to the HFEA and the PR was reminded to report severe and critical incidence of OHSS requiring hospital admission to the HFEA.

The centre confirmed that the andrology laboratory is not CPA accredited. If the laboratory carries out diagnostic semen analysis then the centre should obtain CPA accreditation.

Executive recommendations for Licence Committee

In compliance with standard licence condition T15 (b) of the 8th COP, personnel must be provided with initial/basic training, updated training as required. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed tasks.

In compliance with T72 of the 8th COP critical processing procedures must be validated. It is recommended that the centre draw up a plan for validation which takes into account the particular needs of the unit and prioritises the validation of equipment and processes considered to be most likely to impact on the quality of the service.

In compliance with the requirements of T90 of the 8th COP the centre must record such information as is necessary to facilitate the traceability of any information relating to the quality or safety of gametes and embryos.

In compliance with T71 of the 8th COP the PR should ensure that a record is kept in each patient's/donor's medical records of witnessing checks. It is acknowledged that only a small sample of records was reviewed in the course of the inspection however, it is recommended that an audit of witnessing activities is included in the centre's annual audit schedule.

The PR should give consideration to the guidelines provided at 18.4 (i) and 18.7 of the 8th COP in relation to the requirements to cross-refer information from the storage container and the patient or donor records against the thaw dish or tube and documentation of the date and

time of witnessing procedures in patient records.
Evaluation
Some improvements required.
Areas not covered on this inspection
All areas covered.

Report compiled by:

Name……Parvez Qureshi…….

Designation……..Inspector…….

Date……5 October 2009……

Appendix A: Centre staff interviewed

PR and six other members of staff.

Appendix B: Licence history for previous 3 years

Licence Committee 17 December 2007

The Committee unanimously decided to grant a licence with no additional conditions. Due to the quantity of the recommendations made in the inspection report, and the fact that some of the concerns which underlie these recommendations date back to the previous inspection of the centre, the Committee agreed that this licence should be for three years.

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

Licence Committee 26 July 2007
Notification of new laboratory and theatre premises. The Committee noted the content of Ms Hopper's report and agreed that they were happy for licensed treatment to commence in the centre's newly refurbished premises.

Licence Committee 26 April 2007
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.

Licence Committee 18 January 2007
The Committee noted that the requirements of Chair's letter CH(05)04 should have been met by August 2005, and expressed their concern about this having not yet happened. The Committee agreed that the centre should conduct an assessment of the risk involved in this dewar being disconnected from the auto-dialler system and should submit this assessment to the Executive within two weeks of receiving these minutes. The Committee asked the Executive to ensure that this is received and to report back to the Committee if it is not received. The Committee agreed that the centre's licence should continue with no additional conditions.

2006
No business taken to LC.

Appendix C: Response of Person Responsible to the inspection report

Centre Number…….0019…….

Name of PR……..Dr Mark Hamilton ……..

Date of Inspection……8 September 2009…….

Date of Response……7th November 2009……

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

Signed……Signed copy received from PR……..

Name……..Dr Mark Hamilton…….

Date……7th November 2009…….

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.

None.

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

None.

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

(Comments taken from PR response received)

1. <u>Validation of equipment and processes</u>
   It was reassuring on the day of inspection that there was evidence of appropriate validation with respect to all but two items of laboratory equipment.

   <u>Action</u>
   We are carrying out an inventory of all our laboratory equipment and those items lacking supportive validation documentation will have that in place by mid-December. Discussion of process validation will also take place within the management team.

2. Staff Competencies

I was not clear on which staff we lacked information. I thought we had this covered in that all staff members have personal development files which include records of initial basic training and subsequent records alluding to confidence in their roles.

In the nursing and administrative teams a record kept of personal knowledge of OP's. More detailed record of competence/confidence in every task they undertake is likely to be impractical.

Our laboratory team carry out a multiplicity of tasks which could be considered worthy of competency recording. We need to strike a balance of what is essential, desirable and not required before committing to a lot of administrative work in checking these activities more than we do in the course of KPI recording.

Medical staff members keep records of practical procedures performed and outcomes and these are reviewed in quarterly appraisal discussions.

Action

We will discuss the issue of competency assessment in forthcoming management meetings and determine a course of action.

3. Traceability issues

The tracking of dishes from incubator shelf to incubator shelf has been discussed in the laboratory team. Immediate steps were taken to address the discrepancies in the specific records of the day.

Action

Members have been reminded to fill in the necessary details in lab sheets and this will be subject to forthcoming audit.

4. Discrepancies in witnessing records

The lack of signature for a specific witnessing step in one of the six sets of notes inspected was addressed on the day of inspection.

A witnessing document did not refer to the use of dishes in the transfer of cryopreserved embryos.

Action

Audits of witnessing records are planned in the forthcoming year to check on adherence by embryology staff to the witnessing SOP's.

The witnessing template sheet for cryopreserved embryo transfer has been amended.

5. Patient confidentiality

Since the inspection we have had discussions about the security systems in place in the Centre. We feel that the systems in place are robust with locks present on all doors which lead to offices containing records. I do not think it is correct as might be inferred from the report to suggest that an open door to a nursing office constituted at the time a major security risk. With the flow of staff in our corridors the notion of an

unauthorised person being likely to access a patient file is out of touch with the reality of working in a hospital setting where the default position is one of compliant patients and staff of all kinds seeking to serve.

Action
Further discussion of security arrangements within management meetings will take place.

6. Invoice payment
As was explained at the time of inspection we audited the process for settling HFEA invoices and have found that the central University Finance Office had received invoices in a timely fashion but thereafter there were delays which accounted for breaches in the Code's standard on payment targets. The improvement since last year has been encouraging but we will endeavour to the best of our ability to meet the target of 28 days.

Action
Payment times will be audited on a regular basis in the forthcoming financial year and continued liaison with the University Finance Office is planned.

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

HFEA Executive Licensing Panel Meeting

3 December 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 5

Aberdeen Fertility Centre (0019), Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Ian Peacock, Analyst Programmer	Committee Administrator: Joanne McAlpine

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 (34 pages)
- no papers were tabled for this item

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers for this item which included an interim inspection report, a response from the Person Responsible and the previous 3 years of Licence Committee minutes.
2. The Panel noted that this centre has been licensed since 1992 and offers a variety of treatments to NHS and self-funded patients. The centre has carried out 94 IUI treatment cycles between January and December 2008.
3. The Panel noted that the Person Responsible has completed his PR entry programme and meets the requirements of section 17 of the HFE Act 1990 (as amended), and noted that there are no issues regarding the character, qualifications or experience or ability to discharge the necessary duties
4. The Panel noted the PR's response on page 25 of the inspection report, and found it to be very comprehensive.
5. The Panel noted that there are some recommendations made by the inspectorate in the report and endorsed the inspectorate's recommendations on page 6 of the inspection report with regards to validation of laboratory equipment, documentation of staff competence and recording of information required for traceability.
6. The Panel noted the breach on witnessing and the security of staff having access to the laboratory area within the report, noted the PR's response that addressed these areas and was satisfied with actions taken.

<u>The Panel's Decision</u>

7. The Panel agreed to continue the centre's licence with no additional conditions, however requires the Person Responsible to submit the validation plan to the inspectorate by the 31 December 2009, as stated in the PR's response.

Signed..... Date.....14 December 2009
Peter Thompson (Chair)