Renewal Inspection Report

Date of Inspection: 26 February 2010
Length of inspection: 7 hours
Inspectors: Bhavna Mehta
Jason Kasraie- External advisor

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 11 December 2008 and 6 May 2010.

Date of Executive Licensing Panel meeting: 6 May 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the 8th Code of Practice (CoP) to ensure that centres are providing a quality service for patients. 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 Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre Name	North Middlesex Hospital Fertility Unit
Centre Number	0289
Licence Number	E0289-1-B
Centre Address	Sterling Way Edmonton London, N18 1QX
Telephone Number	020 8887 2000
Person Responsible	Stanley Okolo
Licence Holder	Stanley Okolo
Date Licence issued	01/06/2009
Licence expiry date	31 May 2010
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
The centre is a part of the North Middlesex Hospital NHS Trust and has been licensed since July 2007. However, due to resourcing issues, licensed treatments commenced only in September 2009. The centre provides NHS funded intrauterine insemination (IUI) treatments to patients from the local area.

The unit is open for five days per week, Monday to Friday between 8:30 am to 5:00pm.

Licensing history:
May 2009: The centre applied for, and was granted, a licence for one year for a newly built facility, the North Middlesex Fertility Unit. The Licence Committee requested that the inspection team re-visit the centre prior to the renewal of the Licence.
September 2009: Additional visit to the centre as requested by the Licence Committee.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 2008
IUI	Nil

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	N/A
Storage of sperm	N/A
Storage of embryos	N/A
Research	N/A

*These data were extracted from the HFEA register for the calendar year 2008. 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.

Updated actions since the centre was inspected on 26 February 2010

No response from PR received.

Summary for licensing decision:

In considering overall compliance, the inspectorate 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 PR is suitable and that he has discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- The premises are suitable.
- The practices are suitable.
- The centre has submitted appropriately completed documentation in application for renewal of its licence (Direction 0008).
- The centre has submitted an application fee to the HFEA in accordance with requirements.

Recommendation to the Executive Licensing Panel:

The inspectorate considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of four years without additional conditions.

The inspectorate also recommends that the Executive Licensing Panel requires that the Person Responsible complies with following recommendations within the prescribed timeframes set out in the inspection report:

1. That the PR be directed to take action as requested in section 3 of this report including development of:

    a. Third Party Agreements
    b. Quality Management Systems
    c. Staff competency assessment process
    d. Validation of equipment

2. That the PR considers submitting a Change of PR Application as soon as practicable.

Details of Inspection findings

1. Risk to patients and children born as a result of treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of treatment**
- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services
- **Ensuring patients receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)
- **Ensuring donor gametes are only used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services
- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Witnessing
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

▶ Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4).
Evidence of how the centre demonstrates compliance with this principle **Welfare of the child (WoC), GN8)** The nurse described the process for taking account of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth (T56). Five sets of patient records were audited during the inspection and all were found to contain appropriate WoC documentation (T56).
What the centre does well. N/A
What they could do better. 1. Develop the standard operating procedure (SOP) for the process to be followed when

carrying out a WoC assessment (T33 (b)).
2. Establish quality indicators or objectives relevant to the assessment of the WoC (T35).
3. Audit the WoC procedures against compliance with the regulatory requirements and the centre's quality indicators every two years (T36) and
    i. Document the findings of the audit and take the required corrective actions (T36) and
    ii. Implement all relevant corrective actions (T36)
4. The staff should provide documented evidence of the assessment of their competence to carry out a WoC assessment (T15 (a)).

▶ Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7).

Evidence of how the centre demonstrates compliance with this principle

Procurement and processing (GN15)

The centre has some of the critical procurement and processing procedures documented in SOPs (Act Schedule 3A (11) 2006/86/EC; T33 (b)), including witnessing, laboratory cleaning, adverse incidents, sperm preparation and medical devises.

Quality management (GN23)

The centre subscribes to the Trust Quality Management System (QMS). The Quality Manager continues to develop and improve the QMS to meet the regulatory requirements of the HFEA. The QMS includes some of documented procedures required. During the additional visit in September 2009, the quality manager had demonstrated the QMS to the inspection team.

The centre has SOPs detailing the specifications for some critical materials and reagents used in the IUI procedure (T31).

What the centre does well.

N/A

What they could do better.

Procurement and processing (GN15)

1. Develop the SOP for all the process to be followed when carrying out the IUI treatment (T33 (b)). The PR is referred to CoP G15.1 for suggested processes.
2. Validate critical procurement and processing procedures (T72).
3. Establish quality indicators or objectives relevant to procurement and processing procedures (T35).
4. Audit the procurement and processing procedures against compliance with the regulatory requirements and the centre's quality indicators every two years (T36) and
    a. Document the findings of the audit and take the required corrective actions (T36) and
    b. Implement all relevant corrective actions (T36).
5. The staff should provide documented evidence of the assessment of their competence to carry procurement and/or processing procedures (T15 (a)).

Quality management (GN23)

1. Develop the quality manual (T33).
2. Develop training and reference manuals (T33).

3. Develop SOPs for all activities included on the centre's licence and those activities carried out in the course of providing treatment services that do not require a licence, (T33(b)).
4. Develop SOPs detailing the specifications for all critical materials and reagents used in the IUI procedure (T31).
5. Establish quality indicators for all licensed activities and other activities carried out in the course of providing treatment services that do not require a licence (T35).
6. Audit all licensed activities or activities carried out in the course of providing treatment services that do not require a licence, against compliance with the regulatory requirements and the centre's quality indicators every two years (T36) and
    a. Document the findings of the audit and take the required corrective actions (T36) and
    b. Implement all relevant corrective actions (T36).
7. Establish processes for review of the performance of the QMS to ensure continuous and systematic improvement (T36).

▶ Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates compliance with this principle

Traceability (GN19)

The requirements for traceability appear to be adequately built into the traceability SOP (T99). An audit of five sets of patient records provided evidence that this had been thoroughly completed in all cases (T102). The QM reported that only traceable items are used at the centre.

Premises and facilities (GN25)

All activities at the centre are carried out on licensed premises that appear fit for the intended purpose (T17). The centre staff confirmed that they are able to provide treatment to patients with an acceptable level of efficiency and privacy. A copy of the HFEA Certificate of Licence was displayed at the licensed premises in a position where it can easily be read (T5). The staff provided documented evidence of regular cleaning and disinfection of the premises (T26).

Equipment and materials (GN26)

Most of the equipment at the centre is still under warranty. The centre's staff were able to provide documented evidence of the maintenance and regular inspection of equipment, including the incubator, flow hood, microscope and the centrifuge, in accordance with the manufacturer's instructions (T23).

Documented evidence was provided that showed that the processing of gametes takes place in an environment of Grade A air quality, with a background environment of Grade D air quality (T20) (see section below: What the could do better).

Witnessing (GN18)

The centre has witnessing protocols in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. Witnessing checks are recorded in patient medical records. An audit of five patient records demonstrated compliance with requirements, including the name, status

and signature of both the person performing the activity and the person who witnesses the procedure (T71).

Third Party Agreements (TPA) (GN 24)
While at inspection it was observed that all TPAs are now in place (T111). A sample of TPAs reviewed at inspection were not compliant with the requirements (T114):

a) the nature of the service to be provided was not stated.
c) provision setting out how often the agreement will be reviewed and by whom was not stated.

This was discussed with the PR who expressed willingness to update the agreements to include more detail.

What the centre does well.

N/A

What they could do better.

Premises and facilities (GN25)
A programme for validation has not yet commenced. The regulatory requirements for validation of processes (T72) and all critical equipment and technical devices (T24) were discussed with the QM, who expressed willingness to commence and complete this programme. The QM requested advice regarding the implementation of a validation programme and expressed her intention to refer to the Association of Clinical Embryologists validation information and templates.

All critical processing procedures, including the choice to monitor air quality at annual intervals, must be validated in accordance with T72.

▶ Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9).

Evidence of how the centre demonstrates compliance with this principle

Staff (GN2)
The centre has a small nursing, medical and management team that appeared functional and cohesive. A clear organisational chart was provided before the inspection (T11) and analysis of staff professional development files during the inspection confirmed that they are appropriately qualified and appeared competent for the tasks they perform (T12.)

What the centre does well.
N/A

What they could do better.

Person Responsible (PR) (GN1)
The PR has completed the HFEA PR Entry Programme (T8) and is considered to have discharged his duty.

However, on the day of inspection, the PR was, only briefly, available as he had other Trust level meetings. The PR explained that, he is involved with matters at Trust level and that his time at the centre is constrained. In recognition of his duties (s17 HF&E Act), the

PR and the consultant gynaecologist have discussed that he should hand over the PR role to her. The consultant gynaecologist is also the Quality Manager (QM) and was present for the whole inspection. She demonstrated a clear understanding of the responsibilities outlined in T9 of the HFEA CoP and impressed the inspection team with her positive approach to developing and improving the services provided by the centre. The inspection team explained the requirements for the change of PR process, referring them to the HFEA website for further information on this.

Staff (GN2)
While staff appeared to be qualified to perform designated tasks at the centre, records of ongoing evaluation or review of their key competencies were incomplete (T12; T15).

▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).
Evidence of how the centre demonstrates compliance with this principle **Incidents (GN27); Complaints (GN28)** The centre has been treating patients since September 2009 and no incidents have been reported nor complaints received. The QM described the incident reporting and management SOP (Trust specific) and was able to verbally state the HFEA requirements regarding timeframes for reporting and investigating adverse incidents (T118).
What the centre does well. N/A
What they could do better. The centre must establish, implement and comply with documented procedures to report, investigate, register and transmit information about serious adverse events and serious adverse reactions that occur on any premises to which a licence relates and any relevant third party premises (T 33 (b), T118, Direction 0011).

2. Patient Experience

Focus

- **Ensuring patients and donors are treated fairly and that any treatment is conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Outcome data** – variation in quality of practice and subsequent treatment results

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Information about the cost of treatment (costed treatment plans)
    - Legal parenthood

- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
Evidence of how the centre demonstrates compliance with this principle **Fair treatment (GN29)** The centre operates within the North Middlesex NHS Trust and is therefore guided by the Trust wide Equal Opportunities and Managing Diversity Policy.
What the centre does well. **Fair treatment (GN29)** The centre uses link workers/translators employed by the Trust when patients from minority groups require assistance with, for example, completion of consent to treatment forms. **Counselling (GN3)** Although not a mandatory requirement, the centre offers support to all IUI patients.
What they could do better. N/A
▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
Evidence of how the centre demonstrates compliance with this principle A tour of the centre confirmed that patients are provided with an acceptable level of privacy and comfort within the limited size of the facilities. **Confidentiality (GN30)** Inspection of the centre and discussion with the QM confirmed that records at the centre are stored in an appropriately secure environment and there is an SOP in place to ensure

that information is only disclosed in circumstances permitted by law.

What the centre does well.

N/A

What they could do better.

N/A

▶ Give prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5).

Evidence of how the centre demonstrates compliance with this principle

Patient Information (GN4)
Before the inspection patient information sheets were provided which covered:

- Ovulation induction and/or Intrauterine insemination.
- Comments, concerns and complaints
- OHSS.
- Semen analysis-dos and do nots.
- Self injecting.

Information related to confidentiality and consent is provided to the patients verbally during consultations by centre staff.

What the centre does well.

N/A

What they could do better.

The PR should review the requirements of the CoP (G5.3; G4A; 4.1 – 4.4) and develop the information bank for patients, in addition to the information provided already provided.

▶ Ensure that patients and donors have provided all relevant consents before carrying out any licensed activity (Principle 6).

Evidence of how the centre demonstrates compliance with this principle
Consenting (GN5)
The centre has an SOP in place for the taking of effective consent (G5.3) and an audit of the consent forms in five sets of patient records found no discrepancies (T57/G5.1). Discussion with the QM confirmed that patients are provided with appropriate information before signing consent as recommended in G5.4. (See also guidance note 4 above).

What the centre does well.

N/A

What they could do better.

N/A

3. Protection of embryos- N/A as IUI only

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**
- **Inspection theme 2010 - 2012** – for this period, this should include the following:
  - Patient consent to the disclosure of information, held on the HFEA register, for use in research
  - Consent issues in relation to the storage of embryos (including cooling off period)
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

▶ Maintain accurate records and information about all licensed activities (Principle 10).
Evidence of how the centre demonstrates compliance with this principle **Records (GN 31)** The centre has an established document control procedure (T34) and all documents provided to the HFEA were seen to include identifiers and identification information as recommended by G31.4.
What the centre does well. N/A
What they could do better. N/A

5. Changes / improvements since the last inspection on 11 December 2008 and the additional visit on 23 September 2009

Breach/ Action	Action required	Time scale	Appendix C update	Update @ follow up visit	Update from PR (Oct 09)	Executive review Inspection update
No third party agreements (TPAs) have been established with laboratory suppliers.	The PR is aware of this requirement and is in the process of ensuring its completion. (Code of Practice Standard 3.1.28, 4.1.10)	Progress to be monitored at the next inspection	Third party agreement policies have been established	TPA log reviewed and a sample of agreements was reviewed at inspection- compliant with TPA guidance. <u>Recommendation</u> 1. PR asked to submit log of TPAs to HFEA as soon as possible. 2. review information in agreements.	A register of third party agreements is attached. This list will grow as we develop links with service contractors. Third Party Register.doc	Action taken. A sample of TPAs reviewed at inspection were not compliant with the requirements of Licence Condition T114: a) the nature of the service to be provided was not stated. c) provision setting out how often the agreement will be reviewed and by whom was not stated. Further action required- see body of this report for further information.

Breach/ Action	Action required	Time scale	Appendix C update	Update @ follow up visit	Update from PR (Oct 09)	Executive review Inspection update
An outline for the processes and documentation required to establish the quality management system (QMS) was not present in the quality manual (QM), in breach of Code of Practice, Standards, S.5.1.2 (d)	That the PR should consider the requirements of S.5.4.2 (d) and ensure an outline for the processes and documentation required to establish the QMS as is described within the quality manual.	Progress to be monitored at the next inspection.	None.	PR stated that this is work in progress. The centre uses the Trust policies eg incidents, complaints. These 2 SOPs are now compliant with HFEA requirements. The inspectorate discussed with the PR that the centre's QMS must meet the standards of the HFEA CoP. SOPs seen for sperm prep; semen analysis and witnessing. Validation of some processes completed: sperm prep. Quality indicators are	A Quality Manual is in place and was observed at the last inspection.	Action taken. The centre's QMS is in the very initial stages of development (Licence condition T32). Further action required- see body of this report for further information.

				being developed (clinical pregnancy/outcomes) <u>Recommendation</u> 1. where the Trust policies are used, the PR should ensure that the SOPs are complaint with the CoP. 2. develop quality indicators for sperm prep develop audit plan.		
Breach/ Action	**Action required**	**Time scale**	**Appendix C update**	**Update @ follow up inspection**	**Update from PR (Oct 09)**	**Executive review Inspection update**
A procedure for cleaning laboratory and key items of	A documented procedure for cleaning of laboratory and key	To be implemented before the provision of IUI service	None.	Cleaning SOP in place, but on day of inspection, no log seen. PR verbally confirmed that Trust service	A Lab Cleaning SOP was completed and observed at the last inspection. However we now have a cleaning schedule for the	Action taken. The laboratory cleaning SOP and log were reviewed at inspection and were compliant with the requirements of Licence Condition T26.

equipment has not been written contrary to Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23. Actions to take in the event of their malfunction or re-validation after repair are not documented, contrary	items of equipment should be established to comply with Code of Practice, Standards S.6.3.1 and Standard Licence Conditions A.10.15 and A.10.23.	s.		staff used for cleaning. **Recommended** implementation of cleaning log.	lab which has been attached. Laboratory Cleaning SOP.doc	No further action required.

to Licence Conditions A.10.12 – A.10.16						
Breach/ Action	**Action required**	**Time scale**	**Appendix C update**	**Update @ follow up inspection**	**Update from PR (Oct 09)**	**Executive review Inspection update**
It has not been demonstrated or documented that the air quality in the environment where gametes will be processed is compliant with the requirements of A.10.19.	The PR should implement an air quality monitoring programme that documents that the air quality in the laboratory and in the critical work area is compliant with the requirements of Licence	To be implemented before the provision of IUI services..	Air quality monitoring programme was established.	At inspection: 16.01.09- Grade A air in hood, but background appears non-compliant ***if test conducted at rest.*** No evidence to suggest when/how tested. Staff explained that the plan is to test quarterly. Lab staff gave verbal confirmation that no diagnosis	The air Quality has been checked on 2 separate occasions. The first was done by the Quality Control Dept from E & N Herts NHS Trust which showed Grade A air for the hood and ISO class 9 for the background. The second check was done independently by the embryologist from the Homerton Hospital who declared that the readings proved Grade A for the	Action taken. Air quality test results show Grade D background air quality and Grade A in the working area. These results meet the minimum requirements of Licence Condition T20. No further action required.

	Conditions A.10.19; A.11.11.			undertaken at clinic, but conducted by the Trust pathology lab, which is CPA accredited. **<u>Recommended</u>** Validation of air quality procedure.	hood and Grade C for background. In conclusion we have been waiting for the particle counter to be repaired before we can complete a validation of background air.	
Breach/ Action	**Action required**	**Time scale**	**Appendix C update**	**Update @ follow up inspection**	**Update from PR (Oct 09)**	**Executive review Inspection update**
Validation of critical equipment and key processes and procedures has not yet been established. This is in breach of Code of	It is recommended that a plan for validation is drawn up. The plan should take into account the particular needs of the unit and prioritise the	Progress to be monitored in the course of the next inspection.	None.	At time of inspection, all equipment was still within warranty period. (No maintenance contracts in place at time of inspection). All equipment was PAT tested; test stickers seen on equipment. File for each piece of equipment was	All critical equipment has been validated and files were observed at the last inspection.	Further action required. See body of this report for further information.

practice (Standards S.6.4.2 and S 7.8.3) Standard licence condition A.10.13, 11.11.	validation of those processes and equipment considered to be most likely to impact on the quality of the service and ensure compliance with S 7.8.3, S.6.4.2.			seen at inspection; the incubator file was reviewed; temperature checked using calibrated thermometer or PAT tested; user manual available). Reference manuals for all equipment seen on file. Sampled incubator manual; evidence of validation and monitoring (loss of temperature on incubator).		
Breach/ Action	**Action required**	**Time scale**	**Appendix C update**	**Update @ follow up inspection 23rd Sept 2009**	**Update from PR (Oct 09)**	**Executive review Inspection update**
The laboratory staff member did not appear to be included	The PR should ensure that all personnel are provided with	Progress to be monitored before next inspection.	An embryologist has been employed for 4 sessions a week (in	SLA covers nominated scientist from other HFEA licensed centre (Centre 0030). Training records	Staff competency form has been implemented and competency assessments are under way for the new Andrologist - Gulam Bahadur	Action taken. Evidence of assessment of competencies of some, but not all, new staff that was made available to the inspection team was reviewed at inspection (T12 and T15 (a)).

in the centre's competency assessment programme contrary to Licence condition A.10.9.	initial/basic training, updated training as required when procedures change or scientific knowledge develops, and adequate opportunity for relevant professional development. The training programme must ensure and document that each individual has demonstrated confidence in the performance of their designed		liaise with the Homerton Hospital.	for andrology staff seen; centre has a documented induction training procedure. Andrologist, PR and other centre staff very experienced. But evidence of competence was not available on day of inspection SLA with Herts & Essex (centre 0030- last inspection was carried out in 2008-and report states: The PR should also ensure that following initial/ basic and update training, the competence of each person to perform designated		See body of this report for further information.

	tasks in compliance with A.10.11.			activities is evaluated at intervals specified in the quality management system and re-training undertaken when required (standard licence condition 10.9 and Code of Practice standard S.6.2.9).).-verify at next inspection.		

Recommendations

Area for improvement	Action required	Time scale	Appendix C update	Update @ follow up inspection	Update from PR (Oct 09)	Executive review Inspection update
The centre did not appear to have considered the need to verify the identity of patients attending the	The PR should consider the requirement to verify patient identity at the	Progress to be monitored before next inspection.	Patients identity verification system has been started.	SOP in place, Compliant in one file checked (see comments above).		Action taken. This is not a requirement of the CoP. However, the centre's SOP for witnessing procedures details the procedure for verifying the identity of patients (T46). No further action required.

centre for treatment.	start of treatment using a photographic form of identification, such as a passport or driving licence, to ensure compliance with Code of Practice, Standards S.7.3.1, S.7.3.2 and S.7.7.1 and Guidance G.6.1.1.					

Assessment of compliance with statutory requirements

This page summaries the assessment of the extent to which the centre has complied with the Act, licence conditions and Directions.

Fully Compliant = the centre has met the statutory requirement
Not compliant = the centre has not met the statutory requirement

“X” in the assessment box denotes that compliance with the Licence Condition was not assessed during this inspection
“N/A” in the assessment box denotes that compliance with the Licence Condition is not applicable to this centre

Licence Condition	Assessment
Licensing	
T1	Fully Compliant
T2	Fully Compliant
T3	Fully Compliant
T4	Fully Compliant
T5	Fully Compliant
T6	Fully Compliant
T7	N/A
Person Responsible	
T8	Fully Compliant
T9	Fully Compliant
T10	N/A
Personnel	
T11	Fully Compliant
T12	Not Compliant
T13	X
T14	Fully Compliant
T15	Not Compliant
T16	Fully Compliant
Facilities / Premises	
T17	Fully Compliant
T18	N/A
T19	N/A
T20	Fully Compliant
T21	N/A

Licence Condition	Assessment
Equipment and Materials	
T22	Fully Compliant
T23	Fully Compliant
T24	X
T25	Fully Compliant
T26	Fully Compliant
T27	Fully Compliant
T28	Fully Compliant
T29	Fully Compliant
T30	Fully Compliant
T31	X
Quality Management	
T32	Not Compliant
T33	Not Compliant
T34	Not Compliant
T35	Not Compliant
T36	Not Compliant
Records and Information	
T37	Fully Compliant
T38	Fully Compliant
T39	Fully Compliant
T40	Fully Compliant
T41	Fully Compliant
T42	N/A
Data protection and Confidentiality	
T43	Fully Compliant
T44	Fully Compliant
T45	Fully Compliant
Patient Records	
T46	Fully Compliant

T47	Fully Compliant
T48	Fully Compliant
Patient Selection Criteria and Laboratory Tests	
T49	X
T50	N/A
T51	N/A
Donor Selection Criteria and Laboratory Tests	
T52	N/A
T53	N/A
T54	N/A
T55	N/A

Licence Condition	Assessment
Welfare of the Child, Provision of Information, Counselling and Consent	
T56	Fully Compliant
T57	Fully Compliant
T58	Fully Compliant
T59	X
T60	N/A
T61	N/A
T62	N/A
T63	N/A
T64	N/A
T65	N/A
Procurement of Gametes and Embryos	
T66	N/A
T67	N/A
T68	N/A
T69	N/A
T70	Fully Compliant
Processing and Use of Gametes and Embryos	
T71	Fully Compliant
T72	Not Compliant
T73	X
T74	N/A
Storage of Gametes and Embryos	
T75	N/A
T76	N/A
T77	N/A
T78	N/A
T79	N/A
T80	N/A
T81	N/A

T82	N/A
T83	N/A
T84	N/A
T85	N/A
Embryo Testing	
T86	N/A
T87	N/A
T88	N/A
T89	N/A
T90	N/A
T91	N/A

Licence Condition	Assessment
Use of Embryos in Training Staff	
T92	N/A
T93	N/A
T94	N/A
T96	N/A
T97	N/A
T98	N/A
Traceability and Coding	
T99	Fully Compliant
T100	Fully Compliant
T101	Fully Compliant
T102	Fully Compliant
T103	Fully Compliant
T104	Fully Compliant
Import, Export and Transportation / Distribution of Gametes and Embryos	
T105	N/A
T106	N/A
T107	N/A
T108	N/A
Receipt of Gametes and / or Embryos	
T109	N/A
T110	N/A
Third Party Agreements	
T111	Fully Compliant
T112	Fully Compliant
T113	Not Compliant
T114	Not Compliant
T115	Fully Compliant
T116	Fully Compliant
T117	Compliant

Comment [P1]: ? Not, fully or partially

Identification, investigation, reporting, recording and notification of serious adverse events and reactions	
T118	Not Compliant
T119	Compliant
T120	N/A
T121	N/A
T122	N/A

Additional Licence Conditions	
Licence Condition	**Assessment**
This centre has no additional licence conditions.	

HFEA Directions	
HFEA Directions	**Assessment**
0001 Gamete and embryo donation	N/A
0003 multiple births	N/A
0005 Collecting and recording information for the HFEA	N/A
0006 Import and export of gametes and embryos	N/A
0007 Consent	Fully compliant
0008 Form and content of applications	Fully compliant
0009 Keeping gametes and embryos in the course of carriage between premises	N/A
0010 Satellite and transport IVF	N/A
0011 Reporting adverse incidents and near misses	Fully compliant
0012 Time periods for retention of records	Fully compliant

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None					

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Quality management (GN23)	Licence condition T32 to T36; Schedule 3A (10) 2006/86/EC, Appendix 1 F.	The PR should demonstrate compliance with licence condition T33(b) (The documentation must form part of the QMS: SOPs for all activities authorised by this licence and other activities carried out in the course of providing treatment services that do not require a licence). The centre must put in place a QMS and implement this system to continually improve the quality and effectiveness of the service provided).	By 1 August 2010		
Procurement and processing (GN15)	Licence condition T72; Act Schedule 3A (11), 2006/86/EC.	Validate critical procurement and processing procedures, including the choice to monitor air quality at annual intervals, must be validated in accordance.	To be completed by the date of next inspection.		

Staff (guidance note 2)	T12 T15	The PR should commence a programme to review and assess the competence of all staff at the centre.			
Third party agreements (guidance note 24)	T113 T114	The PR should ensure that all third party agreements contain such detail as required by T113 and T114.			

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Staff	Licence condition T8-10	Consideration should be given to the variation of the licence regarding the nominated PR.	As soon as possible.		

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

6 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

North Middlesex Hospital (0289) Renewal Report

Members of the Panel:	
Mark Bennett, Director of Finance & Facilities (Chair) Peter Thompson, Director of Strategy & Information Danielle Hamm, Policy Manager	Committee Administrator: Joanne McAlpine

Declarations of Interest: members of the Panel declared that it had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

- papers for Licence Committee (56 pages)
- additional bundle of information in accordance with Direction 0008

The Panel 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 which included a renewal inspection report, an application for renewal, previous licence committee minutes, as well as an additional bundle in accordance with direction 0008.

2. The Panel noted that this centre has been licensed since July 2007 however, due to resource issues, licensed treatments commenced only in September 2009. The centre provides NHS funded IUI treatments to patients from the local area.

3. The Panel noted that the centre's current licence expires on 31 May 2010.

4. The Panel noted that there were points raised in the previous 2008 inspection report which remained outstanding at the time of this inspection (26 February 2010). In addition, there has been no response received from the PR since the last inspection on 26 February.

5. The Panel noted that there were a number of areas identified on inspection which the inspectorate recommended that the centre addressed, including: third party agreements, quality management system, staff competency assessment process, and validation of equipment.

6. However, the Panel noted that although the report identified a number of areas the centre needed to address, none were critical, That said, the Panel agreed that the centre still had some work to do.

7. The Panel noted with concern the fact that the current PR was unable to devote much time to the centre as he had other Trust business and this may be why he has been unable to address the outstanding areas as set out in the report. The Panel also noted that the inspectorate recommend that the PR should consider, in the light of those time pressures, whether he should remain in the role.

8. The Panel agreed that it had sufficient information and evidence on which to make a decision.

9. The Panel referred to the decision tree for the granting of a renewal of licence.

10. The Panel noted that it was in receipt of the appropriate application form and the appropriate fee had been paid.

11. The Panel noted the pack of additional information that had been provided to the Panel in accordance with Direction 0008, which included CV's of all staff, evidence that the QMS has been started, patient information, PR Entry programme, copies of protocols/SOP's, action plan and organisational chart.

12. The Panel noted that the Person Responsible has completed the PR Entry Programme, and the appropriate certificate has been provided in accordance with section 16A of the Act.

13. The Panel noted the PR's willingness to address the outstanding areas within the report. However, given the licensing history and the PR's availability at the centre, the Panel endorsed the inspectorate's recommendation on page 4 of the inspection report that the PR consider whether to submit an application for a change of PR (noting that the PR is also the current Licence Holder).

14. The Panel noted that the premises and practices are suitable as stated on page 8 of the inspection report.

15. The Panel noted the inspectorate's recommendation to renew the licence for a period of four years. However in the light of the number of areas still outstanding from the previous inspection in 2008, and the fact that licensed treatments had only begun properly in September 2009, the Panel considered that there was insufficient evidence within the report to justify giving a four year licence.

The Panel's Decision

16. The Panel decided to approve the renewal of licence for a period of two years with no additional conditions, in accordance with the HFEA's indicative sanctions guidance and principles.

17. The Panel endorsed the inspectorate's recommendations made within the report, and would like the PR to submit a formal action plan to the Executive by 31 August 2010, with a view to addressing all outstanding areas highlighted within the report within a year of this meeting (6 May 2011).

18. The Panel would also encourage the PR to consider submitting a Change of PR Application as soon as practicable.

Signed.....Date.....11/5/10

Mark Bennett (Chair)