Interim Inspection Report

Date of Inspection: 18 May 2010
Length of inspection: 7 hours
Inspectors: Andy Leonard; Gill Walsh

Inspection details:
This report covers the pre-inspection analysis, the visit and information received from the centre between 25 August 2009 and 18 May 2010.

Date of Executive Licensing Panel: 12 August 2010

Purpose of the Inspection report
The purpose of the inspection is to assess a centre's compliance with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice, 8th edition (CoP) to ensure that centres are providing a quality service for patients. The report summarises the findings of the interim 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 continuation of the centre's licence.

Centre details

Centre Name	Oxford Fertility Unit
Centre Number	0035
Licence Number	L0035/12/c
Centre Address	Institute for Reproductive Sciences, Oxford Business Park North, Oxford, OX4 2HW
Telephone Number	Oxford Fertility Unit
Person Responsible	Mr Tim Child
Licence Holder	Mrs Janet Talbot
Date Licence issued	21 September 2009
Licence expiry date	30 September 2013
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:
With regard to overall compliance, the inspectorate considers that it has sufficient information drawn from documentation submitted by the centre prior to the inspection and from observations and interviews conducted during the inspection and in the post inspection period to conclude that:

- The Person Responsible (PR) is considered by the inspectorate to have discharged his duties under S.17 of the HF&E Act 1990 (as amended). It is noted that compliance with the requirements of the last inspection report has been achieved with one exception.

- Premises, processes and procedures used in the conduct of licensed activities were suitable.

- The PR has already taken appropriate corrective actions in response to the report which have removed non-compliances in the following areas:
  - Consenting for storage
  - Multiple births
  - Equipment traceability

- Improvements have been recommended in the following areas of practice which the PR has agreed to implement within the required time limits:
  - Safety signage
  - Quality indicator monitoring
  - Review of procedures against HFEA requirements
  - Third party agreements
  - Competency assessments
  - The accreditation of diagnostic services
  - Procedures for laboratory equipment operation and maintenance
  - Payment of HFEA invoices

- The PR has provided some explanation for non-compliance with CoP Guidance 11.15, regarding sperm donor screening practices, and notes that the centre are compliant with Licence Condition T52 in this area of practice.

The inspectorate recommends the continuation of the centre's licence without additional conditions and that the Executive Licensing Panel requires that the PR complies with the recommendations detailed in this report within the prescribed timeframes.

Details of Inspection findings

Brief description of the centre and its licensing history:

The Oxford Fertility Unit (OFU) was first established as a HFEA licensed clinic in 1992 and in 2009 re-located from the John Radcliffe Hospital, Oxford, to purpose built premises at the Oxford Business Park (North), approximately 3 miles away. These new premises were inspected by the HFEA on 25 August 2009 and a new treatment and storage licence was granted on the 21 September 2009, such that licensed activity could commence at the new premises, as HFEA centre 0035, on 1 October 2009.

Centre 0035 provides a full range of licensed treatments to self-funded and NHS patients including: In vitro fertilisation (IVF); Intracytoplasmic sperm injection (ICSI); embryo transfer; Frozen embryo transfer (FET); intrauterine insemination (IUI); sperm, oocyte and embryo storage; donor sperm and oocyte procurement and processing; treatment with donor gametes and embryos; oocyte sharing; preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD). The centre is the only one in the UK currently providing in-vitro maturation of oocytes with IVF or ICSI treatment.

The PR is accredited with the General Medical Council (GMC) as both Consultant Obstetrician & Gynaecologist and a sub-specialist in reproductive medicine. He is also a designated consultant for the Centre. All other senior staff are considered to be appropriately trained and experienced.

The Centre performed 1452 licensed treatment cycles in the year 1 February 2009 – 31 January 2010 and is currently open 7 days a week, 08.00 to 16.30 Monday to Friday and 08.00 to 12.00 on Saturday and Sunday. A member of medical staff is contactable 24 hours a day, 7 days a week via an emergency number provided in patient information and also by the Centre answerphone. There have been no significant changes in activity or patient demographics since the last inspection.

*Activities of the Centre in the year 1 November 2008 – 31 October 2009:

Type of treatment	Treatment cycles
IVF	624
ICSI	481
FET	222
Egg Share	3
Egg donor	7
DI	115
Other licensable activities	**✓ or not applicable (N/A)**
Storage of eggs	✓
Storage of sperm	✓
Storage of embryos	✓
Research	R0111; R0143. Donates to R0111, R0143 and R0149 at centre 0311

*These data were extracted from the HFEA register for the period indicated above. The data may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems

Version: 0

Trim:

Updated actions since the centre was inspected on 18 May 2010, as of 30 July 2010:

A. The PR has already taken appropriate corrective actions in response to the report (Areas of practice that require the attention of the PR, page 31) which have removed non-compliances in the following areas:

Consenting for storage

The centre had a set of embryos in storage for which storage has been consented by letter, in the opinion of the LM, but not by a valid HFEA storage consent form, contrary to Direction 0007, paragraph 1.

The PR states that the centre contacted the patients regarding the embryo storage consent and described the legal requirements. The patient couple did not provided consents for further storage and the embryos have therefore been allowed to perish.

Multiple births

The multiple pregnancy rate at the centre in all patients increased from 24 to 27% between 2008 and 2009. It is possible that the 27% multiple pregnancy rate will lead to a multiple birth rate above the 24% target for 2009, non-compliant with Direction 0003 (version 1).

A MBMS review for Jan-May 2010 was provided by the PR on 20 July 2010. It indicates, relative to 2009, a decline in the multiple pregnancy rate (from 29 to 19%) and an increase in eSET (from 10 to 32% of total ETs). These positive results have been produced while maintaining the overall pregnancy and implantation rates, relative to 2009 data, at 34% and ca. 27%, respectively. These data suggest the centre is likely to meet the multiple birth rate target for 2010/2011 of 20%. No further specific action is therefore necessary besides the monitoring and review of the MBMS normally performed by the centre.

Equipment traceability

The centre did not have a procedure to ensure the traceability of equipment in the laboratory and it was not clear that equipment traceability data was collected, non-compliant with CoP Guidance 19.1c.

The centre on 30 July 2010 provided evidence that key equipment is documented on the patient's laboratory work sheet and that a procedure is now in place which documents the equipment traceability practices at the centre. The centre is now compliant regarding this matter and no further action needs to be taken.

B. Improvements have been recommended in the following areas of practice which the PR has agreed to implement within the required time limits:

- Competency assessments
- The accreditation of diagnostic services
- Safety signage
- Third party agreements
- Quality indicator monitoring
- Review of procedures against HFEA requirements
- Procedures for laboratory equipment operation and maintenance

- Payment of HFEA invoices

The Executive will monitor the implementation of these proposed actions and ensure they occur within the time scales defined in this report.

1. Focus of inspections for 2010-12

Witnessing

Evidence of how the centre demonstrates compliance with Guidance Note 18 of the CoP, including the requirement to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

The centre uses an electronic witnessing system, recently installed, and/or manual witnessing, to identify sample containers against the patient at all critical points of the clinical and laboratory processes (Licence Condition T71). Manual witnessing is also performed while the electronic witnessing system undergoes final validation, and will continue as the sole form of witnessing when samples are placed into or removed from storage and during sperm freezing. All witnessing is carried out contemporaneously (Licence Condition T71).

The centre has witnessing protocols for manual and electronic witnessing which have been recently assessed by the Laboratory Manager (LM) for compliance with CoP guidance note 18 (Licence Condition T33b and T36). The electronic witnessing protocol includes manual witnessing steps at key steps, e.g. patient identification. It was reviewed by the inspectorate and was seen to detail contemporaneous witnessing checks at all critical steps required by CoP guidance 18.4. The manual witnessing procedure was reviewed on inspection in May 2009 and was seen then to be compliant with HFEA requirements.

Manually witnessed procedures are all timed, dated and signed by the processor and witness contemporaneously in the patient records. A record of electronic witnessing is printed and placed in each patient record after treatment (CoP Guidance 18.7). Each record is reviewed for errors by the embryologist printing the record and these are noted for subsequent analysis. The SOP for electronic witnessing requires manual witnessing to be used in the event of electronic witnessing system errors, so the inspectorate were assured there was no risk associated with errors in electronic witnessing. Appropriate witnessing documentation was seen in ten sets of patient records reviewed on inspection.

Quality indicators are established for witnessing, the quality objective being that 100% of witnessing steps are performed, as indicated by their correct recording in patient records reviewed retrospectively. As stated above, errors in electronic witnessing are also recorded and analysed as a quality indicator (Licence Condition T35)

Staff were said to be trained and competency assessed to perform manual and electronic witnessing at induction and annually thereafter. Existing staff were trained and competency assessed when the electronic witnessing system was fitted and competency assessment will be repeated next year (Licence Conditions T12 and T15a)

What the centre does well.

The installation of the electronic witnessing system and its extended testing and validation period, with manual witnessing operating in parallel, were considered to be examples of best practice at the centre.

What they could do better: No issues identified

Parenthood

Evidence of how the centre demonstrates compliance with Guidance Note 6 of the Code of Practice in relation to legal parenthood:

The centre has established written procedures which ensure that: 1) Consent forms are completed for parenthood prior to treatment with donor gametes and embryos; 2) Patients are fully informed about parenthood laws prior to signing consent forms (Licence Condition T33b). The partner's consent (or absence of consent) for the patient's treatment with donor gametes is also recorded.

Procedures were provided which also ensured that: 1) Where a patient has withdrawn her consent to her nominated second parent being treated as the legal parent, or has more recently consented to a different person being the legal parent, that the original nominated second parent is notified in writing of the withdrawal of consent (Licence Condition T65). 2) Treatment is not provided when a person has withdrawn their consent to be the second parent of a child without telling the women being treated (Licence Condition T64b).

Written and verbal information regarding parenthood legislation is provided by nurses during consultation with patients using donor gametes. All patients in this group are advised of their right to withdraw consent. Nurses taking consents for legal parenthood have had several learning sessions regarding the changes in the law in this area and the protocol to follow to inform patients regarding legal parenthood and to take legal parenthood consent. Taking consent for legal parenthood is included within the consenting competency assessment undertaken by all nursing staff (Licence Conditions T12 and T15a).

What the centre does well: Nothing noted at inspection

What they could do better: No issues identified

Patient consent to the disclosure of information, held on the HFEA Register, for use in research

Evidence that the centre provides information to patients about the disclosure of identifying information, held on the HFEA Register, for use in research. (Guidance Note 5, section 5.26 of the Code of Practice)

In discussion, centre staff demonstrated their awareness and understanding of the CoP requirements related to disclosure of information for use in research. The new HFEA consent forms which came into force on 1 October 2009 are used by nursing staff to consent all patients. These include the facility to consent to disclosure of information to researchers.

The inspectorate considers consenting practices with respect to the disclosure of registry information to researchers were compliant.

What the centre does well: Nothing noted at inspection

What they could do better. Nothing noted at inspection

Information about the cost of treatment

Evidence of how the centre demonstrates that it has introduced personalised costed treatment plans for all patients in compliance with Guidance Note 4, section 4.3 of the Code of Practice.

Both self funding and NHS funded patients are provided with services at the centre. Self funding patients are provided with a price list on which the cost of the treatment package they require is highlighted. Costs of treatment are also discussed with patients in the privacy of a dedicated finance office at the initial patient registration consultation when identification is also confirmed. In most cases the package price covers all costs and there are very few additional costs which might arise. Those that may are also provided on the price list and are discussed with the patients if the need for those additional treatments arise. The inspectorate consider the cost information provided to patients was clear and easily understood.

What the centre does well: Nothing noted at inspection.

What they could do better. Nothing noted at inspection.

Consent issues in relation to the storage of embryos (including cooling off period)

Evidence of how the centre demonstrates compliance with Schedule 3 of the Human Fertilisation and Embryology Act 1990 (as amended) and Guidance Note 5 of the Code of Practice relating to the withdrawal of consent to storage of embryos intended for use in treatment:

The centre has revised its standard operating procedure (SOP) for embryo storage review to reflect the change in the initial embryo statutory storage period to 10 years.

The centre sends an annual letter to patients with forms to withdraw storage consent if they so wish, or to sign for payment of another year's storage fee. One year before expiry of the statutory or consented storage period, patients are advised regarding the impending expiry and asked if they wish to seek an extension. If they fail to respond, further attempts to contact them are made in writing and by telephone. In the absence of any response, the embryos are discarded at the end of the week in which the storage period expires.

Gametes and embryos in storage have been audited against the storage records within the last two years (CoP guidance 17.16). The consents for storage are checked in patient records annually at the time that the storage review letter is sent out. The consent expiry date for gametes and embryos is detailed in the storage records so that material close to storage expiry can be easily noted and investigated.

Storage procedures include the provision for a one year 'cooling off' period', to be used when one partner withdraws their embryo storage consent, and conflict resolution procedures. The right to withdraw storage consent is discussed with patients before such consents are signed. Patients also receive a written document in duplicate regarding the implications and conditions of storage, which includes the possibility of one or both partners withdrawing storage consent and the process which is then followed, including a one year 'cooling off' period which can not be used to store embryos beyond their statutory storage period. Patients sign one copy of this document and it is kept in the patient records.

What the centre does well: Nothing noted at inspection

What they could do better.
The centre currently has a set of embryos for which storage has been consented by letter, in the opinion of the LM, but not by a valid HFEA storage consent form, contrary to Direction 0007, paragraph 1. The centre is currently in discussions with the patient to obtain a completed HFEA storage consent form for these embryos.

Multiple Births

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice in relation to multiple births:

The centre has a multiple births minimisation strategy (MBMS) with elective single embryo transfer (eSET) criteria, which was submitted to the HFEA in compliance with Direction 0003.

The MBMS is discussed with patient couples at initial consultation, at information provision consultations with nurses and also at group information sessions. Patients are provided with written information regarding the MBMS and the risks of multiple birth.

In compliance with Direction 0003, a log of non-compliance with eSET criteria is maintained which details the reasons for non-acceptance of eSET. Patients rejecting eSET are provided with information regarding the risks of multiple births and this is noted in the patient records, along with the reasons for rejection.

Multiple births are monitored and the MBMS is reviewed on a six monthly basis. A review and revision of the MBMS, undertaken in January 2010 was provided to the inspectorate. In 2009, all patients aged <35 years with two or more good quality embryos at day five were recommended for eSET. The centre achieved an 82% compliance with eSET recommendations in 2009, indicating that patients are well informed of the risks of multiple births and are accepting of the MBMS. The 2009 multiple pregnancy rate in the eSET target group was 23%, down from almost 35% in 2008, while the clinical pregnancy rate in the target group increased from 38% to 48% between 2008 and 2009. The MBMS review also noted however that in the total patient set, the centre's multiple pregnancy rate increased from 26% to 29% between 2008 and 2009. This was thought to have resulted from a much increased frequency of blastocyst culture and transfer in 2009, notably in patients aged between 35 and 38 years who were outside of eSET criteria. The review also noted that in patients having day three embryo transfer, there was a significant chance of twins when two embryos were transferred, but also that the clinical pregnancy rate dropped considerably in those having eSET.

In response to these findings the centre modified their eSET criteria and from 1 February 2010 have recommended eSET in patients aged <38 years, with one or more good quality embryos (grade 3Bb or better) at day five. These criteria are applied to patients in their first and second cycle of fresh IVF treatment. Day five blastocyst transfers are undertaken wherever possible in patients recommended for eSET.

Evidence of how the centre demonstrates compliance with Guidance Note 7 of the Code of Practice in relation to multiple births: *Continued*

Recent audit data suggests a reduction in the multiple pregnancy rate in the target group from 29% in 2009 to 16% in the 3 months since the implementation of the revised MBMS. There was no effect on the pregnancy rate, which remained at 35%.
What the centre does well: The frequent monitoring and audit of multiple births and review of the MBMS, indicate the centre is actively implementing the requirements of Direction 0003 to minimise multiple births at the centre.
What they could do better. According to HFEA registry data, the multiple pregnancy rate at the centre in all patients increased from 24 to 27% between 2008 and 2009 (the centre's own figures were 26% to 29%, respectively), while the eSET rate was 2% in 2008 and 5.5% in 2009. It is likely that the 27% multiple pregnancy rate at the centre will lead to a multiple birth rate above the 24% target for 2009, non-compliant with Direction 0003 (version 1). The inspectorate recognises however the recent review of the MBMS which targets eSET at a wider patient group, which may allow the centre to comply with the 20% multiple birth rate target for 2009/10 (Directions 0003, version 2). The inspectorate also notes the on-going six monthly MBMS audit and review, which will allow the centre to respond if the target seems unlikely to be met. The inspectorate recommends that the PR continues to monitor the centre's MBMS and how it is applied, as planned, to ensure that the 20% MBR target is achieved.

2. Changes/improvements since the inspection on 21 August 2009

Area of practice	Observations on this inspection
1. Confirmation that SOPs and area risk assessments have all been reviewed and are fit for use in the new premises, to ensure compliance with HFEA CoP S.6.3.2 and Licence Conditions A.10.4, A.10.12 and A.10.24. By 30 September at the latest.	The PR confirmed in the last inspection report that the centre had reviewed all SOPs and process and risk assessments and that they were compliant with HFEA CoP S.6.3.2 and Licence Conditions A.10.4, A.10.12 and A.10.24. Area fire risk assessments were provided on 2 November 2009. A Health and Safety assessment for the new centre was provided by email on 14 September 2009. On inspection, the centre was seen to have a multiple SOPs which are stored on the centre's server and accessible to all personnel through computer terminals found throughout the centre. SOPs provided on inspection had all been reviewed within the last year. An index of SOPs provided on inspection indicated that all SOPs had been recently reviewed and that the range of SOPs was appropriate for the licensed activities undertaken at the centre. The Laboratory Manager (LM) also considered that SOPs had been prepared to cover all areas of the centre's activities. On inspection, risk assessments for the liquid nitrogen systems and the electronic witnessing system were observed. All SOPs were said to contain risk control measures embedded within them. The building has an operations log which states how the building's systems should be operated and maintained. It also details the annual systems checks which need to be performed to ensure that the systems continue to operate according to specification. These checks are logged and audited externally. The log was inspected and all checks were found to be up to date. The building's log also details the building's risk assessments which need to be annually reviewed and these were also seen to be up to date.
2. Confirmation that he has made an assessment that no other risk assessments or SOPs need to be prepared to enable safe working practices in the new premises, to ensure compliance with HFEA CoP S.6.3.2 and Licence Conditions A.10.4, A.10.12 and A.10.24	The PR confirmed in the last inspection report that he had made an overall assessment of the SOPs and risk assessment and that no other risk assessments or SOPs were needed to ensure safe working practices in the new premises (HFEA CoP S.6.3.2 and Licence Conditions A.10.4, A.10.12 and A.10.24). As stated above, the SOPs and risk assessments developed by the centre were considered by the inspectorate to be appropriate for the licensed activities which it undertakes.
3. Confirmation that review of the quality manual and other	The PR confirmed in the last inspection report that he had reviewed the quality manual and other documentation used

documentation used within the Centre for changes required due to the move, has been completed, to ensure compliance with Licence Condition A.10.24	within the centre and that no further changes, other than those already notified, were required due to the move. On inspection, the documentation sampled indicated that the centre had a quality manual, audit mechanisms and patient information appropriate for the licensed activities undertaken. Those documents inspected had all been recently reviewed.
4. Fire safety certification from the inspection scheduled for the 5th or 7th September 2009, to ensure compliance with HFEA CoP S.6.3.2.	A fire risk assessment, floor plans and fire safety report were provided by email on 14 September 2009. On inspection the inspectorate noted that these documents remain active as they were prepared in September 2009. They will be reviewed annually.
5. The building's Health and Safety inspection report or certification showing the building has passed Health and Safety inspection, to ensure compliance with HFEA CoP S.6.3.2.	The building completion certificate and Health and Safety assessment were provided by email on 14 September 2009. Some installation certificates were provided, e.g. the cooling system, electrical system, emergency lighting, fire alarms, security system, gas works, water supply, heating system, while others associated with the environmental system were said to be outstanding e.g.: Airflow test; Pipeline pressure test; Lighting test; Air change rates; Temperatures; Room classification; Industrial gas pipeline final test; Manifold test. A building log was also provided. On inspection, outstanding installation certificates were seen to be in place, except for the manifold test certificate. This is held by the contracted supplier of the liquid nitrogen systems, who have a contracted responsibility to maintain the system safely and therefore keep the certificate themselves.
6. Confirmation that the requirement for health and safety signage has been reviewed throughout the Centre premises and that, where necessary, appropriate signage is being displayed, to ensure compliance with HFEA CoP S.6.3.2.	The PR confirmed in the last inspection report that he would ensure health and safety signage was reviewed throughout the Centre premises On inspection it was observed that health and safety signage was absent in several areas. The PR said that health and safety management had recently changed, and an external consultancy would now provide a Health and Safety service which would include a review of signage at the centre. This review needs to be performed to ensure that appropriate health and safety signage is displayed, for risk control purposes, and that the PR complies with his responsibilities. under Licence Condition T9b, i.e. that the premises are suitable for the licensed activities which are undertaken there.
7. Confirmation that the integrated security system	The PR confirmed in the last inspection report that the integrated security system and BMS would be tested and

and Building Monitoring System (BMS) has been tested, validated and certificated as in full working order, to ensure compliance with Licence Condition A.10.23.	validated on 11 September 2009 and that a certificate of installation would be provided. Certificates for the installation and testing of the BMS and security system were observed on this inspection.
8. Confirmation that the air cleaning equipment has been tested, validated and certificated as in full working order, to ensure compliance with Licence Conditions A.10.13 and A.10.19.	The PR confirmed in the last inspection report that the air cleaning equipment had been tested, validated and certificated as in full working order. An installation certificate was provided by email. On inspection, the air cleaning system installation and testing certification was observed. Records of maintenance of the air cleaning system were also provided. These scheduled maintenance checks are listed in the building's log and were seen there to have been signed off as completed.
9. To ensure compliance with Licence Condition A.10.23, clarification of the access to licensed premises provided to staff from the site management company and their security team, even for emergency purposes. The proposed PR should also confirm that any staff from the site management company with access have been assessed by the PR as being of appropriate character and have been informed of the confidentiality requirements of the HFE Act (1990) with amendments.	The PR confirmed in the last inspection report that the site management company would open the building each morning on arrival of a staff member and lock the building with the last member leaving in the evening. They were also to supply a 24 hour, 7 days a week, 365 days per year emergency assess to the building. The PR confirmed in the last inspection report that the staff from the site management company with access were CRB checked and that he considered them of appropriate character and had informed them of the confidentiality requirements of the HFE Act (1990) as amended. This issue was considered to be satisfactorily addressed and was not followed up on inspection.
10. A documented assessment of the treatment capacity of the new premises, to ensure compliance with HFEA CoP S.6.1.1.	The PR stated in the last inspection report that the patient treatment areas and laboratory space had more than doubled from the previous premises, and that the centre was therefore well inside its patient treatment capacity and compliant with HFEA CoP S.6.1.1 On inspection, the PR stated that an assessment of the centre's capacity had been documented and a resource-activity risk assessment for the staffing level was provided. The PR also provided the minutes of the last quality

	management review in January 2010, in which it was documented that staff and equipment resources had been reviewed against the centre's activity.
11. Confirmation that the quality policy and complaint's procedure are displayed in patient waiting areas, to ensure compliance with HFEA CoP S.4.2.3 and G.11.3.2	The PR confirmed in the last inspection report that the quality policy and complaint's procedure are displayed in patient waiting areas, to ensure compliance with HFEA CoP S.4.2.3 and G.11.3.2. The quality policy and complaints procedure were seen to be prominently displayed in areas on the ground and first floors which are open to patients. The centre's treatment and storage and research licences were also displayed.
12. Confirmation that the clinical area has been appropriately equipped and that equipment has been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Condition A.10.13 and HFEA CoP S.6.3.3 and S.6.3.4.	The PR confirmed in the last inspection report that the clinical area will be appropriately equipped and that all equipment will be tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Condition A.10.13 and HFEA CoP S.6.3.3 and S.6.3.4. Validation and installation documentation for equipment and building services was completed. An email from the LM on 26 November 2009 provided sample validation documents for a hot block, a cabinet and an incubator. On inspection, the Lead Nurse provided a file containing documents pertaining to clinical equipment, confirming the recalibration, safety testing and acceptance for use of all equipment transferred from the centre's former premises. Commissioning validation of new equipment in clinical areas, performed by the manufacturer's engineers, was also provided. Evidence of portable electrical appliance testing was also present. A list of new equipment still under manufacturer's warranty and service schedules for transferred equipment arranged was also observed. No scheduled service dates were seen to have been exceeded.
13. Confirmation that an assessment of the Centre premises has been performed to ensure protection of patient privacy and confidentiality of patients and records associated with them, to ensure compliance with Licence Condition A.6.5, HFEA CoP S.6.3.4 and HFE	The PR confirmed in the last inspection report that an assessment of the Centre premises has been performed and that protection of patient privacy and confidentiality of patients and records associated with them was ensured. On inspection, an audit of confidentiality within the centre was provided which was considered detailed and good evidence of compliance. It included an assessment of unsecured patient records and the ability to overhear conversations within rooms. Some non-conformities were detailed and

Act (1990) as amended, Section 33.	appropriate action plans were documented in the audit report. It was noted on inspection that all visitors to the centre, including patients, are signed in and out in a visitor's log. This is held on the receptionist's desk and can not be inspected by unlicensed persons. All visitors, including patients, sign a confidentiality agreement. The centre's key-card security system prevents access to private areas by unauthorised staff.
14. Confirmation that the embryo transfer room windows have been removed or blanked out in some way to protect patient privacy, and that the door seals have been installed to maintain the clean air environment, to assist compliance with Licence Conditions A.6.5 and A.10.19.	The PR confirmed in the last inspection report that the embryo transfer room windows had been blanked out to protect patient privacy, and that door seals had been installed to maintain the clean air environment. On inspection, these changes were seen to have been completed.
15. To ensure compliance with Licence Condition A.10.13, confirmation that the laboratory has been fully equipped according to the plans provided and discussed on inspection and that equipment has been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009.	The PR confirmed in the last inspection report that the laboratory would be fully equipped according to the plans provided and discussed on inspection, and that equipment would be tested and certificated as being in full working order, and that validation, where required, would be completed by 30 November 2009. Validation and installation documentation for equipment was provided, e.g. the LM sent an email with validation documents for a hotblock, an air flow cabinet and an incubator, on 26 November 2009. On inspection, the LM provided validation documents for all critical equipment in the laboratory, based on cut-down versions of the validation documents produced by the Association of Clinical Embryologists. Validation documents for the air flow cabinets, hot blocks and plates, incubators,
15. *Continued*	refridgerators and the electronic witnessing system were included. The validations included certification of installation and commissioning, as well as data from functionality, alarm systems and simulated failure testing. Evidence of portable electrical appliance testing was also present.
16. To ensure compliance with Licence Condition A.10.19, a documented assessment of air quality in	The PR confirmed in the last inspection report that a documented assessment of air quality in the background and in the critical work area in the laboratory would be carried out in accordance with the Centre's air quality monitoring

the background and in the critical work area in the laboratory, carried out in accordance with the Centre's air quality monitoring procedure. If a full air quality assessment can not be performed by the start of licensed treatment, a schedule for achieving compliant air quality should be provided, as should a risk assessment for performing licensed activities in the absence of all test results confirming compliant air quality is in place.	procedure and that the assessment passed the quality required. Results were provided to the Lead Inspector. Validated air testing reports for the embryo transfer rooms and the laboratory (background and critical work areas) were provided on 2 November 2010 which showed all rooms were compliant with HFEA requirements. On inspection, air quality testing data was supplied which indicated that air quality in the laboratories is assessed monthly by an external company, using active air sampling, and swab and contact plate testing. Air quality is consistently Grade A in the critical work areas and Grade D or better in the background laboratory air, i.e. compliant with HFEA requirements. Occasional individual swab test failures at Grade D in the background were said to be due to the swab having been taken from a relatively inaccessible location, e.g. from the work surfaces amongst incubator cabling. Actions have been taken to limit such failures, which were considered by the inspection team to be appropriate.
17. To ensure compliance with HFEA CoP S.6.3.2 and S.6.3.3, a documented bacteriological assessment of the embryo transfer rooms and egg collection theatre, in support of their cleanliness and safety, or a risk assessment for performing licensed activities in the absence of such results.	The PR confirmed in the last inspection report that a risk assessment on the possibility of bacteriological contamination in the embryo transfer and egg collection rooms had been performed. Subsequent air quality testing, after deep-cleaning, indicated they were microbiologically clean and the centre considered them fit for purpose. These test results were provided to the HFEA by email on 6 October 2010. On inspection it was determined that the centre do not consider that on-going air quality assessment of the procedure rooms is required, nor is it a regulatory requirement. The rooms are cleaned daily and have a clean air supply.
18. Confirmation that the UPS system has been completed and has been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Conditions A.10.13	The PR confirmed in the last inspection report that the UPS system would be completed, tested and certificated as being in full working order, by 30 November 2009. On inspection, an installation and testing certificate for the UPS was provided. The UPS system has been tested and shown to perform to specification, providing an estimated 4 hours of emergency back-up power to crucial electrical systems. The system is constantly monitored by the supplier and this performance monitoring is available to the centre via the supplier's website, and provides a component of the equipment's validation, in addition to the installation certificate and the design specification.

19. Confirmation that the facilities monitoring system (FMS) has been completed and has been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Conditions A.10.13 and A.10.21.	The PR confirmed in the last inspection report that the facilities monitoring system (FMS) would be completed, tested, certificated as being in full working order, and validated, by 30 November 2009. A certificate for the installation and validation of the FMS was provided on inspection. There has recently been a failure of the FMS caused by incorrect switching between the generator and the uninterruptible power supply, during a general power failure. This was reported to the HFEA and investigated by the centre. A redesigned automatic switch is soon to be fitted which will correct this problem.
20. Confirmation that the nitrogen storage tank and autofiller manifold have been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Conditions A.10.12 and A.10.13.	The PR confirmed in the last inspection report that the nitrogen storage tank and autofiller manifold would be tested and certificated as being in full working order, and validated, by 30 November 2009. On inspection, it was determined that the liquid nitrogen delivery systems are provided on contract and that the contracting company holds all installation and safety certification. That company are contractually obliged for the safety of the system. An email was provided from the company detailing this information and stating that the system was safe.
21 Confirmation that the low oxygen monitors in the laboratory areas have been tested and certificated as being in full working order, and that validation, where required, will be completed by 30 November 2009, to ensure compliance with Licence Condition A.10.13 and CH(04)03	The PR confirmed in the last inspection report that the low oxygen monitors in the laboratory areas would be tested, certificated as being in full working order, and validated by 30 November 2009. On inspection, an oxygen monitoring system service certificate, dated 13 October 2009, was provided which indicated that the monitoring systems had been serviced and verified as functioning correctly.
22. Clarification of the server back-up arrangements. Where is server data backed up to and has the confidentiality, safety and security of this arrangement been confirmed?	The PR confirmed in the last inspection report that the server would be backed-up to an off-site server based within the University of Oxford IT Department on the John Radcliffe Hospital site. Back-up would occur using a secure encrypted connection and the confidentiality, safety and security of this arrangement had been confirmed. On inspection, it was determined that this server back-up

	mechanism has been established. The centre has also installed a second server within the building, on which the main server is regularly backed-up. The security and confidentiality of these systems was said by centre staff to have been validated.
23. Confirmation that the PR continues to attempt to ensure the improvement in WoC assessment, to comply with Licence Condition A.12.4.	The PR confirmed in the last inspection report that he would continue to ensure improvement in WoC assessment through regular audit of this area. The PR provided and discussed a WoC assessment audit report, dated March 2010. Twenty sets of patient records were audited for WoC assessment and 9 were found to have no or an incomplete assessment performed. In response, the WoC assessment process has been modified and a single person, the patient services manager, must sign that an appropriate WoC assessment has been performed before treatment commences. It was considered by the PR that as this function could be performed by several people in the past, nobody took responsibility to do it. Thus this change should remedy matters. The centre will re-audit in June 2010 to verify that the procedural change has had the desired effect and that WoC assessment is always performed before treatment commences.
23. *Continued*	The inspectorate reviewed 10 sets of patient records from the last year's activity on inspection and found no errors in WoC assessment, thus the centre's audit may have amplified to scale of the problem, though the inspectorate commend the action taken.
24. Confirmation that all process and equipment validation will be completed by 30th November 2009, as previously required by Licence Committee on 30th July 2009	The PR confirmed in the last inspection report that all process and equipment validation would be completed by 30 November 2009, as previously required by Licence Committee on 30 July 2009. On inspection, appropriate validation of laboratory and clinical equipment was seen to have been performed. The processes used at the centre were also said to have been validated. As an example of their common practice, the SOP for embryo transfer was provided and it was seen that the process was validated by referencing to professional body guidelines. It was also stated that historical quality indicator monitoring data and success rates can be used to validated the centre's processes.
25. Confirmation that all staff	The PR confirmed in the last inspection report that all staff at

at the Centre have received their 2-3 day building induction training, to ensure compliance with HFEA CoP S.6.2.7.	the centre would receive a two day building induction and training course. On inspection it was said by the LM that all staff had been provided with this training and that it was detailed in staff training records.
26. The donor screening protocol should be revised to takes into account the new professional body guidance issued in December 2008, to ensure compliance with HFEA CoP G.4.9.1.	The PR confirmed in the last inspection report that the donor screening protocols had been revised to take into account the professional body guidance. The sperm donor screening SOP was provided prior to this inspection. It was detailed and defined a process which was compliant with Licence Condition T52. It differed from professional body guidelines (PBG; Human Fertility (2008) 11; 201-210) in two ways and was thus non-compliant with CoP Guidance 11.15. The first deviation is that the procedure allows the recruitment of sperm donors up to and including 45 years of age (PBG states 40 years), the second is that HTLV
26. *Continued*	testing is only provided in persons considered at high risk (PBG states HTLV 1 and 2 testing should be applied in all potential donors). The PR explained that he had been advised by a local consultant microbiologist that HTLV incidence in Oxford is extremely low. The PR should consider modifying the donor selection procedure to bring it into line with PBG, compliant with CoP Guidance 11.15, or document the rationale for any deviations from PBG.
27. Confirmation that the new computerised traceability control system, if installed, has been tested and certificated as being in full working order, and that validation, where required, will be completed by 30th November 2009, to ensure compliance with Licence Condition A.3.1 and A.10.13	The PR confirmed in the last inspection report that the traceability control system would be tested, certificated as being in full working order, and validated, by 30 November 2009. On inspection, the LM stated that the electronic traceability system would not be implemented. A manual traceability procedure is still used in the centre and this was provided to the inspectorate. This protocol is discussed below in 'areas of concern-8'.
28. Confirmation that the new electronic witnessing system, if installed, has been tested validated and certificated as	The PR confirmed in the last inspection report that the new electronic witnessing system would be tested validated and certificated as being in full working order.

being in full working order, to ensure compliance with Licence Conditions A.3.5 and A.10.13.	On inspection it was described that the electronic witnessing system has been operating at the centre for some months. Installation certification and validation documentation were available for inspection. The electronic system is undergoing validation testing against the manual witnessing process, which is operated in parallel.

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) 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.

Area of concern-1	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
HFEA Registry reported two weeks before inspection that the centre had 180 uncleared errors in registry data reported between 1 July 2007 and 1 May 2010, non-compliant with Direction 0005	Centre staff said that 140 errors had arisen due to use of an old version of the electronic data interface (EDI). These errors have been corrected and a new version of the EDI system is being fitted to improve the accuracy of data input. The remaining 40 errors resulted from an incompatibility between the EDI reporting forms and treatments which have included in vitro maturation (IVM).	This is the only centre in the country providing treatments including IVM, thus the EDI report forms are not designed to include this process. The issue has been referred to HFEA Registry. Centre staff should liaise with HFEA Registry, as appropriate, to ensure that errors in registry data are cleared, as required by Direction 0005.

Area of concern-2	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
HFEA Finance reported before inspection that invoices in the year to 6 March 2010 had been paid in an average of 31 days (range 8 – 53 days). Since the invoice in July 2009 which took 53 days to be paid, the centre has taken under 37 days to pay each invoice.	This issue was discussed with the PR. The inspectorate accept that the centre is one of the quickest to pay HFEA invoices and that since the centre moved to new premises in September 2009, invoices have been paid within 31 days.	The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue. The PR is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to meet the 28 day payment deadline.

Area of concern-3	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR assessed the centre as being less than fully compliant with Licence Condition T35, regarding the monitoring and audit of quality indicators (QIs), associated quality objectives, counselling, the submission of data to the HFEA, embryo biopsy, PGS and PGD procedures, witnessing, traceability, and the training licence.	The LM provided evidence that QIs for embryo biopsy, the PGS and PGS processes, traceability and witnessing are monitored and audited. The centre's counsellor provided an annual counselling audit (for the year to 1 April 2010) during the inspection, albeit she accepted that quality indicators were in development in the counselling area. Consents for training are verified by the embryologists on the day of treatment, however there are no documented QIs relevant to the training licence. Evidence for QI monitoring in many other clinical and laboratory areas was available on inspection, though it was noted by the Clinical Inspector that QIs for patient privacy and confidentiality need to be developed.	Given the audits already performed, the centre needs to develop quality indicator monitoring and audit for HFEA data submission, counselling provision and patient confidentiality and privacy, to be compliant with Licence Condition T35. The PR should ensure that the monitoring mechanisms, audit frequencies and responsibilities for all quality indicators, as well as associated quality objectives, are documented in procedures, to comply with CoP guidance 23.19 – 23.22. This was discussed with the Quality Manager (QM) who clarified that documented procedures are in development which will describe the multiple QIs monitored and audited within the centre.

Area of concern-4	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR assessed the centre as being less than fully compliant with Licence Condition T36, regarding the audit against HFEA regulatory requirements of procedures for: donor selection and recruitment, counselling provision,	The LM provided evidence that the procedures for embryo biopsy, PGS and PGD procedures, traceability and the training licence were audited against the revised regulatory requirements in October 2009. The Lead Nurse provided an audit of	The procedures associated with counselling provision; donor recruitment and selection, patient confidentiality and the submission of data to the HFEA, have not been recently audited against HFEA regulatory requirements. This is a breach of licence condition T36. To comply with licence condition T36, the PR should have these procedures audited against HFEA regulatory

Area of concern-4; *Continued*		
submission of data to the HFEA, maintaining patient confidentiality, embryo biopsy, PGS and PGD procedures, traceability and licensed training.	patient privacy and confidentiality within the centre, though this did not include a review of procedures against the regulatory requirements.	requirements to ensure compliance. Non-conformities and corrective actions should be documented.

Area of concern-5	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
The PR stated in the SAQ that third party agreements (TPAs) were not in place with all suppliers of goods and services that influence the quality and safety of gametes and embryos, non-compliant with Licence Condition T111. Third parties have also not all been evaluated for their compliance with HFEA requirements, notably the PGD service provider, non-compliant with Licence Condition T112. .	Evidence presented on inspection indicated that two TPAs remain to be developed. A TPA is in place with the PGD service provider, and this service has been evaluated for compliance with HFEA requirements. Satellite services have also been evaluated for compliance. The LM has reviewed all TPAs to ensure their content complies with the requirements of Licence Condition T114.	The PR should ensure the final two TPAs are developed to comply with Licence Condition T111. The PR should also ensure that all service providers are regularly evaluated for their compliance with HFEA Licence Conditions and other requirements, to comply with Licence Condition T112.

Area of concern-6	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
The PR stated in the SAQ that competency assessment has not been performed for donor selection and recruitment, PGD procedures, cryostorage, witnessing, traceability, ICSI and	The LM and Lead Nurse provided evidence on inspection that competency assessment has been performed and documented for multiple activities including traceability and ICSI and PGD procedures. The	Competency assessments have been performed in multiple actvities however to ensure full compliance with Licence Conditions T12 and T15a, competency assessments need to be completed and documented for all relevant staff for witnessing, donor selection and recruitment, cryostorage and for the submission of data to the HFEA.

Area of concern-6; *Continued*		
the submission of data to the HFEA	LM also stated that competency assessments for cryostorage processes have been performed for all embryologists, but remain to be formally documented for one of them. All staff using the electronic witnessing system have been trained, but some staff have yet to be formally competency assessed in this activity.	

Area of concern-7	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR did not provide an answer regarding the methodology used to screen embryo donors. The PR also indicated the centre was not fully compliant in having procedures for flagging whether further donor screening tests are required.	The LM stated that antibody reactivity, rather than nucleic acid, testing is used by the CPA-accredited laboratory which screens all donors at the centre. The donor recruitment and screening procedure includes the possibility of further tests depending on the origin of the donors and whether other risk factors are present.	The inspectorate considers that the donor screening procedures at the centre are compliant with Licence Condition requirements. As discussed above, there are minor deviations in the donor screening protocol from professional body guidelines, non-compliant with CoP Guidance 11.15. The reasons for this should be documented.

Area of concern-8	Inspection findings	Assessment of whether the action taken meets

		requirement or whether any further action is required
In the SAQ, the PR indicated the centre did not have a documented procedure to ensure traceability. There was also uncertainty that all relevant traceability data is collected.	The LM provided the centre's 'IVF plating out and traceability' protocol. This document describes a mechanism by which traceability data for all consumables is recorded. No evidence was provided to indicate that key equipment used in gamete and embryo processing is recorded.	The centre has a procedure to ensure traceability of consumables in the laboratory, however this procedure did not discuss the recording of which equipment is used in gamete and embryo processing. To ensure full compliance with CoP Guidance 19.1c, the PR should ensure that a traceability procedure documents that each item of equipment which could impact on gamete and embryo quality and safety, is documented in patient records. The PR should ensure that such records are maintained for traceability purposes.

Area of concern-9	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
In the SAQ, the PR indicated that the centre was not fully compliant with the requirement that all SOPs should state specifications for the critical materials and reagents used in the procedures	This was discussed with the LM who provided evidence that critical materials and reagents used in the laboratory are detailed in SOPs. The LM considered that the centre was fully compliant with the requirements of Licence Condition T31.	The inspectorate found no evidence that the centre was non-compliant with Licence Condition T31.

Area of concern-10	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**

In the SAQ, the PR indicated that the centre was not fully compliant with Licence Condition T21; i.e. with the requirement that all diagnostic services used in support of patient treatment are appropriately accredited.	The PR scored the centre as such due to a longstanding issue, last raised in the centre's inspection report from May 2009. The centre has an estradiol assay machine which allows estradiol monitoring during ovarian stimulation. This service is not accredited but neither is it considered by the PR to be diagnostic or investigatory. Diagnostic estradiol assays are sent to a CPA accredited laboratory. The possible need to accredit this service has been raised by the inspectorate in previous inspection reports. No opinion on the matter has been expressed by the Licence Committee, suggesting it is not a regulatory issue or, if it is, that it is of minor importance. Another issue related to accreditation is that the PGD service is unaccredited. The PGD manager has however provided strong evidence that the service is working towards accreditation and that it should be in place by September 2010.	The PR does not consider the service to be diagnostic or investigatory. The inspectorate are minded to agree with this opinion as it is used to monitor estradiol levels once ovarian stimulation has commenced and treatment has been decided upon; i.e. it is not diagnostic or investigatory, such tests results impact on treatment selection. Licence Committee's previous responses to the issue also suggest it is not a regulatory issue or is of minor importance. The inspectorate therefore considers that this issue is not non-compliant with Licence Condition T21. The lack of accreditation of the PGD service is however non-compliant with Licence Condition T21, as the service provides test results which may determine if an embryo is transferred or not. The PR should advise the manager of the PGD service that the centre must use a PGD service which is appropriately accredited. The PGD service should therefore gain appropriate accreditation as rapidly as possible. The PR should advise the Executive when this will be.

Area of concern-11	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
In the SAQ, the PR indicated	On inspection it was stated, with	Equipment usage procedures should be modified to include

that the centre was not fully compliant with Licence Conditions T24, T25 and T27. Thus there is uncertainty that all equipment is validated, is re-validated after repair before re-entry into service and that procedures state what to do in the event of equipment failure.	appropriate evidence, that all critical equipment had been validated, compliant with Licence Condition T24. It was also stated by the LM that all equipment failures were brought to her attention and that after repair, equipment would be re-validated before re-entering service. She also said however that these common practices were not documented in procedures, non-compliant with Licence Conditions T25 and T27	the actions to be taken in response to suspicion of failure, i.e. report to the LM, to comply with Licence Condition T27. It is also recommended that the procedures state that the equipment is immediately labelled as malfunctioning. The equipment maintenance and repair procedure should detail that all equipment returned to the centre after repair is revalidated before being used in licensed activities, to ensure compliance with Licence Condition T25.

Area of concern-12	**Inspection findings**	**Assessment of whether the action taken meets requirement or whether any further action is required**
In the SAQ, the PR states that the centre has not reported any incidents in the last year. Pre-inspection analysis of incidents reported to the HFEA indicated the SAQ response was incorrect.	The SAQ answer was provided in error. Inspection of the centre's incident log against HFEA records indicated that all HFEA reportable incidents recorded in the log had been reported already to the HFEA.	There are no regulatory issues associated with this area of concern. An error was made in the SAQ response. Indeed the inspectorate considers incident reporting and investigation at the centre to be robust and compliant with Licence Conditions T118 and T119

Area of concern-13	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
In the SAQ, the PR assessed the centre as being less than fully compliant regarding the logging of the centre staff who perform identity checks on patients and donors, non-compliant with Licence Condition T46	The Lead Nurse stated that identification of patient couples and donors is achieved when they register at the centre. At registration, they attend with photographic identity documentation having been requested to do so in the pre-appointment information pack. The patient couple or donor are photographed and this photograph and the stated names are verified against the identity documentation presented. The centre member performing this check signs for it in the patient or donor records and inserts there copies of the photographic identity documentation and the centre's photograph of the patient couple or donor. This identification process is documented in procedures and must be performed before anyone is seen for consultation. When patients subsequently attend for consultation or treatment, staff were said to always check the patients against the centre's photograph to confirm their identity.	The inspectorate have no regulatory concerns regarding this issue

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are 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-1	Action required/timescale	PR Response	Executive Review
The centre currently has a set of embryos in storage for which storage has been consented by letter, in the opinion of the LM, but not by a valid HFEA storage consent form, contrary to Direction 0007, paragraph 1.	The PR should *immediately* ensure the letter of consent satisfies all consenting requirements under Schedule 3, paragraph 2 (2a,b,c) of the HF&E Act 1990 (as amended). The PR should also *immediately* ensure the patient completes a HFEA storage consent form for these embryos, to comply with Direction 0007. The PR should keep the Executive updated regarding the consenting process. If the letter of consent does not satisfy all requirements of the HF&E Act and the patient fails within a reasonable time to provide a completed HFEA storage consent form, the PR should recognise the storage is in breach of the Act, Schedule 3, paragraph 8(1) and take appropriate actions.	Since the inspection, this has been followed up with the couple and the legal situation made clear. In light of the discussion with the HFEA inspector and with no signed HFEA consent forms being completed by the couple, the embryos have now been allowed to perish as it was felt that all reasonable effort had been made to obtain these	The Executive note the efforts taken by the centre to obtain appropriate completed HFEA consent for storage for these embryos. The patient couple have not provided consents for storage and therefore the embryos have been allowed to perish. There is therefore no longer a regulatory concern regarding this matter and no further action need be taken.

Area of practice-2	Action required/timescale	PR Response	Executive Review
According to HFEA registry data, the multiple pregnancy rate at the centre in all patients increased from 24 to 27% between 2008 and 2009. It is possible that the 27% multiple pregnancy rate will lead to a multiple birth rate above the 24% target for 2009, non-compliant with Direction 0003 (version 1).	The inspectorate recommends that the PR continues to monitor the centre's MBMS and how it is applied, as planned, to ensure that the 20% MBR target for 2010/2011 is achieved. This action will be monitored at the time of the next inspection	The multiple birth rate for all ages so far this year has recently been reviewed and is 18.6% which is compliant with the MBR target for 2010/2011. The centre altered its MBMS at the start of 2010 in recognition that it needed to widen the criteria for eSET and this would appear to have been effective. The MBR will continue to be monitored on a regular basis	A MBMS review for Jan-May 2010 was provided on 20 July 2010. It indicates, relative to 2009, a decline in the multiple pregnancy rate (from 29 to 19%) and an increase in eSET (from 10 to 32% of total ETs). These positive results have been produced while maintaining the overall pregnancy and implantation rates, relative to 2009 data, at 34% and ca. 27%, respectively. No further specific action is necessary in this area besides the monitoring and review of the MBMS normally performed by the centre.

Area of practice-3	Action required/timescale	PR Response	Executive Review
Competency assessments have been performed in multiple actvities, however to ensure full compliance with Licence Conditions T12 and T15a, competency assessments need to be completed and documented for all relevant staff for witnessing, donor selection and recruitment, cryostorage and for the submission of data to the HFEA.	The PR should ensure the competency assessment programme is completed, as required by Licence Conditions T12 and T15a. This action should be completed by 1 October 2010.	This will be completed by October 1 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 October 2010 and will monitor the situation accordingly.

Area of practice-4	Action required/timescale	PR Response	Executive Review
The centre has a procedure to ensure traceability of consumables in the laboratory, however this does not discuss the recording of which equipment is used in gamete and embryo processing, non-compliant with CoP Guidance 19.1c.	To ensure compliance with CoP Guidance 19.1c, the PR must ensure that a traceability procedure documents that each item of equipment which could impact on gamete and embryo quality and safety, is documented in patient records. The PR should ensure that such records are maintained for traceability purposes. This action should be completed by 1 September 2010.	There is a procedure in place to ensure traceability of consumables in the laboratory as well as equipment used in embryo processing. It is unclear therefore what the concern was here and since Licence Condition T87 relates to embryo testing and sex selection we are unable to clarify this any further.	The inspectorate apologise for the incorrect regulatory reference (T87) – it should read CoP Guidance 19.1c - and this has now been modified accordingly in the report. The LM on 30 July 2010 provided evidence that key equipment is documented on the patient's laboratory work sheet and that a procedure is now in place which documents the equipment traceability practices at the centre. The centre is now compliant regarding this matter and no further action needs to be taken.

Area of practice-5	Action required/timescale	PR Response	Executive Review
In the SAQ, the PR indicated that the centre was not fully compliant with Licence Condition T21; i.e. with the requirement that all diagnostic services used in support of patient treatment are appropriately accredited.	The PR should ensure that all diagnostic services used by the centre are provided by suppliers who are appropriately accredited, as required by Licence Condition T21. This should be accomplished by 1 October 2010.	This will be accomplished by 1 October 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 October 2010 and will monitor the situation accordingly.

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-A	Action required/timescale	PR Response	Executive Review
On inspection it was observed that health and safety signage was absent in several areas. Thus it is questionable that the PR has complied with his responsibilities under Licence Condition T9b, i.e. that the premises are suitable for the licensed activities which are undertaken there.	The PR said that health and safety management had recently changed, and an external consultancy would now provide a Health and Safety service which would include a review of signage at the centre. This review needs to be performed, to ensure that appropriate health and safety signage is displayed for risk control purposes within the centre. It should be completed by 1 September 2010	This will be completed by 1 September 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 September 2010 and will monitor the situation accordingly.

Area of practice-B	Action required/timescale	PR Response	Executive Review
The SAQ indicated, and evidence on inspection confirmed, that third party agreements (TPAs) were not in place with all suppliers required by Licence Condition T111. Third parties have also not all been evaluated for their compliance with HFEA requirements, as required by Licence Condition T112	The PR should ensure the final two TPAs are developed to comply with Licence Condition T111. The PR should also ensure that all service providers are regularly evaluated for their compliance with HFEA Licence Conditions and other requirements, to comply with Licence Condition T112. These actions should be completed by the 1 October 2010	These actions will be completed by 1 October 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 October 2010 and will monitor the situation accordingly.

Area of practice-C	Action required/timescale	PR Response	Executive Review
The sperm donor screening SOP is detailed and compliant with Licence Condition T52. It differs however from professional body guidelines (PBG; Human Fertility (2008) 11; 201-210) in two ways and is thus non-compliant with CoP Guidance 11.15: 1) The procedure allows the recruitment of sperm donors up to and including 45 years of age (PBG states 40 years) 2) HTLV testing is only provided in persons considered at high risk. PBG states HTLV 1 and 2 testing should be applied in all potential donors.	The PR should consider modifying the donor selection procedure to bring it into line with PBG, compliant with CoP Guidance 11.15, or document the rationale for any deviations from PBG. This action should be taken by 1 September 2010.	Age of donor: HFEA CoP 11.2 states: Unless there are exceptional reasons, sperm for the treatment of others should not be taken from donors aged 46 or over. We are therefore compliant with the Code. HTLV testing: HFEA CoP T52 g states: HTLV-1 antibody testing must be performed for donors living in or originating from high incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas. We are therefore compliant with the Code. I would contend that there is currently some ambiguity regarding guidance from the HFEA. We are compliant with the CoP as detailed above. We have discussed HTLV testing with our local microbioligists whose view is that our local UK donors are not from 'high incidence areas'.	The inspectorate notes the centre is compliant with Licence Condition T52 regarding donor screening, including age, but is not compliant with the more rigorous PBG and thus with CoP Guidance 11.15. The justification for not testing for HTLV 1 and 2 in all potential donors has been documented by the centre and is stated here. The inspectorate notes that several other donor recruitment centres also accept donors up to the age of 45 years, like this centre. This practice is still however non-compliant with PBG and thus Guidance 11.15, but is compliant with Licence Condition T52.

Area of practice-D	Action required/timescale	PR Response	Executive Review
Given the QI audits performed, the centre needs to develop quality indicator monitoring and audit for HFEA data submission, counselling provision and patient confidentiality and privacy, to be compliant with Licence Condition T35.	The PR should ensure these QI audits are developed to comply with Licence Condition T35. The PR should also ensure that the monitoring mechanisms, audit frequencies and responsibilities for all quality indicators, as well as associated quality objectives, are documented in procedures, to comply with CoP guidance 23.19 – 23.22. This action should be taken by 1 September 2010.	This will be actioned by 1 September 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 September 2010 and will monitor the situation accordingly.

Area of practice-E	Action required/timescale	PR Response	Executive Review
The procedures associated with counselling provision; donor recruitment and selection, patient confidentiality and the submission of data to the HFEA, have not been recently audited against HFEA regulatory requirements. This is a breach of licence condition T36.	To comply with licence condition T36, the PR should have the counselling; donor recruitment and selection, patient confidentiality and the submission of data procedures audited against HFEA regulatory requirements to ensure compliance. Non-conformities and corrective actions should be documented. This should be completed by 1 September 2010	This will be actioned by 1 September 2010.	The inspectorate accepts the PR's assurance that the action will be completed by 1 September 2010 and will monitor the situation accordingly.

Area of practice-F	Action required/timescale	PR Response	Executive Review
All equipment failures are brought to the LM's attention and after repair, equipment is re-validated before re-entering service. These common practices are not documented in procedures, non-compliant with Licence Conditions T25 and T27	The PR should ensure the update of procedures to include the actions to be taken in response to suspicion of failure. The equipment maintenance and repair procedure should detail that all equipment returned to the centre after repair is revalidated before being used in licensed activities, to ensure compliance with Licence Condition T25. These procedural changes should be made by 1 September 2010	SOPs will be amended according within the time frame	The inspectorate accepts the PR's assurance that the action will be completed by 1 September 2010 and will monitor the situation accordingly.

Area of practice-G	Action required/timescale	PR Response	Executive Review
HFEA Finance reported before inspection that invoices in the year to 6th March 2010 had been paid in an average of 31 days (range 8 – 53 days). Since the invoice in July 2009 which took 53 days to be paid, the centre has taken under 37 days to pay each invoice.	The PR should note that Chair's Letter CH(10)02 requires payment of HFEA invoices within 28 days of their issue. The PR is obliged under Licence Condition T9d to ensure fees are paid within the written specified timescale. The PR should therefore take appropriate actions to attempt to meet the 28 day payment deadline.	I confirm we will attempt to meet the 28 day deadline.	The inspectorate accepts the PR's assurance that the centre will attempt to be compliant with the 28 day deadline for invoice payment, and note that invoices in the year to 6th March 2010 had been paid in an average of 31 days. The inspectorate will monitor the situation accordingly.

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

12 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0035 (Oxford Fertility Unit) - Interim Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy and Information (Chair) Mark Bennett, Director of Finance & Facilities Danielle Hamm, Policy Manager	Terence Dourado

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

The following papers were considered by the Panel:

- Interim inspection report, 18 May 2010, an PR response
- Licence Committee Minutes 11 Sept 2008, Last renewal inspection report
- Licence Committee Minutes 13 November 2008, PGS treatment variation
- Licence Committee Minutes 13 November 2008, Change of PGS-related Licence Conditions
- Licence Committee Minutes 30 July 2009, Interim inspection report
- Licence Committee Minutes 21 September 2009, New Licence Application, Change of PR and NL.
- ELP Minutes 23 October 2009, PGD treatment variation
- ELP Minutes 23 October 2009, Change of Licence Holder

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance

- HFEA Directions 0000 – 0012
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Tabled Document

- Revised 'Brief Description of the Centre and its Licensing History' (Interim Inspection Report, page 5 of 56)

Consideration of Application

1. The Panel noted that the Centre's first licence was granted in 1992. However, it had since re-located to new premises where it was granted a new treatment and storage licence on 21 September 2009. The Panel noted that the Centre conducted 1452 treatment cycles from 1 February 2009 – 31 January 2010.

2. The Panel noted that the Person Responsible (PR) is accredited with the General Medical Council (GMC) as a Consultant Obstetrician and Gynaecologist and as a sub-specialist in Reproductive Medicine. The Panel also noted that the he has sufficiently completed the PR Entry Programme (PREP).

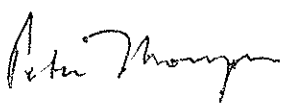
3. The Panel considered the Interim Inspection Report and was satisfied that the Centre was broadly compliant. The Panel was satisfied that the PR had made a clear effort to address areas of non-compliance raised by the Inspector. The Panel noted that the PR input to the SAQ appeared frank and possibly too self-critical.

4. The Panel commended the work the PR had done to improve the Centre's clinical practices and reduce its multiple birth rates.

5. The Panel noted the rigour with which the Centre had introduced an electronic witnessing system. The Panel commended the Centre for testing the electronic system in parallel with its manual witnessing system to ensure the robustness of the procedure.

Decision

6. The Panel agreed to the continuation of the Centre's licence without any conditions. The Panel endorsed the Inspectorate's recommendations and associated timeframes set out in the report.

Signed:  Date: 3/9/10

Peter Thompson (Chair)