Renewal Inspection Report

Date of Inspection: 20 January 2010
Length of inspection: 9.5 hours
Inspectors: Mr W Lenton (lead)
Dr A Leonard
Ms J Kirkland

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between December 2008 and January 2010 and the PR response received on 31 March 2010

Date of Executive Licensing Panel: 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 Code of Practice 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 Licence Committee/ Executive Licensing Panel which make the decision about the centre's licence renewal application.

Centre details

Centre Name	St Mary's Hospital, Manchester
Centre Number	0067
Licence Number	L0067-15-a
Centre Address	Department of Reproductive Medicine Old St Mary's Hospital, Oxford Rd, Manchester M13 9WL
Telephone Number	0161 276 6340
Person Responsible	Dr Cheryl Fitzgerald
Licence Holder	Dr Mike Deegan
Date Licence issued	1st August 2007
Licence expiry date	31st July 2010
Additional conditions applied to this licence	None

Version: 0

Trim:

Contents

Report to Licence Committee / Executive Licensing Panel

Brief description of the centre:
St Mary's Manchester has been licensed by the HFEA since 1992. It currently provides over 1000 licensed treatment cycles to NHS only patients from Greater Manchester and surrounding areas. It is part of the Department of Health's initiative to promote single embryo transfer (SET) and does not perform any 3 embryo transfers. The senior management team has produced a multiple births minimisation plan, in order to reduce the incidence of multiple births, in line with recent professional body guidelines.

The centre successfully moved into new 'state-of-the art' laboratories and theatre facilities during February 2008 and refurbished theatre and recovery facilities between July and November 2009.

The Person Responsible (PR) has been in post since August 2006 and is appropriately qualified to discharge her duties as outlined in Guidance Note 1 of Code of Practice (CoP) 8. She has successfully completed the PR entry programme and is familiar with all aspects of the service provided such as, clinical, nursing, laboratory, administrative and managerial responsibilities as she was previously the accredited consultant at the centre.

Licensing history:

Date	Committee	Outcome
Feb 11 2009	Licence Committee	Licence variation to include storage of oocytes
Jan 12 2009	Licence Committee	Interim inspection undertaken 17 October 2008. Licence Committee (LC) concerned that live birth rates remain significantly below the national average. Endorse Executive recommendation of need for external review of clinical service.
July 7 2008	Licence Committee	New premises inspection. New laboratory, theatre and recovery facilities within existing curtilage.
November 21 2007	Licence Committee	Interim inspection undertaken 26 September 2007. The LC noted that the centre is continuing to address the issue of success rates and asked the Executive to continue to monitor the rates on an on-going basis. The Committee suggested that to facilitate this monitoring the centre should have another interim inspection in the following year.
June 7 2007	Representations hearing	Dr Fitzgerald presented evidence of measures put in place by the centre which have lead to improvements in success rates. Also noted that one piece of data presented to LC in Jan 2007 inaccurate – Additional licence condition removed. Licence approved for 3 years.
April 26 2007	Licence Committee	EUTD Licence variation
March 8 2007	Licence Committee	Following revisit to centre additional data presented to LC by Executive. LC still not convinced that measures put in place effective. Additional condition imposed concerning need for external review of service.
January 18 2007	Licence Committee	Renewal inspection undertaken 19 September 2006. LC not satisfied that primary focus of inspection (success rates) had been addressed. Asked Executive to revisit centre to collect more evidence of improvements.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period Jan-Dec 2007 (HFEA verified data)
IVF/ICSI (Fresh)	547
IVF/ICSI (Frozen)	367
DI	101
IUI (2008 data)	29

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

*These data were extracted from the HFEA register for the period [Jan-Dec 2007]. 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 20 January 2010

The PR responded to the inspection report on 31 March 2010.

The documents supplied by the PR in response to the inspection report are comprehensive and, to facilitate assimilation of the information provided, have been submitted by the inspectorate separate to the report, but will be published alongside the report at the appropriate time.

The information provided suggests that many issues have been resolved and others are being appropriately addressed by the centre.

The response included;

1. Action Plan in response to areas of non compliance including a final person responsible comment. (TRIM 2010/000003376)

2. Report of the person responsible in response to the issues raised. (TRIM 2010/000003377)

3. The proposed audit calendar for 2010/11 (TRIM 2010/000003378)

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 suitably qualified and has generally attempted to discharge her duties under section 17 of the HF&E Act 1990 (as amended). However there are issues from the previous inspection in October 2008 which remain unresolved, such as the submission of data to the Authority, continuing poor success rates, nursing staff resourcing/training and emergency trolley failures, together with an incident concerning the continued storage of embryos beyond the statutory period, which bring into question the ability of the PR to discharge her duties effectively.

- centre staff acting under the supervision of the PR are suitably qualified for their designated roles. However it was noted that staff competencies are not currently being assessed and recorded as required.

- the Inspectorate considers that the premises and facilities inspected are generally suitable for the treatment activities for which the centre is licensed

- the Inspectorate is satisfied that the centre generally demonstrates appropriate practices in respect of laboratory, clinical and administrative procedures. However issues were identified relating to the records store door, the emergency trolleys, the site of the key required to mute the cryostore alarm, electrical testing of critical equipment and keys being left in a drugs cabinet together with unattended patient notes, which need to be addressed.

- the centre has submitted appropriately completed documentation in application for renewal of its licence in accordance with paragraph 16 of General Direction 0008 and as detailed on page 14 of the licence renewal application form.

- the centre had not submitted a licence renewal application fee, prior to the inspection taking place, but subsequently did so on 25 March 2010, in accordance with requirements.

The Inspectorate considers that information received from the PR subsequent to the inspection has provided reassurance that some of the issues identified above have been resolved and others will be appropriately addressed within the given timeframes.

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 *2 years.*

The Inspectorate also recommends that the Licence Committee requires that the PR complies with the following recommendations within the prescribed timeframes set out in the inspection report:

RECOMMENDATIONS

- The PR must resolve regulatory issues concerning the accurate and timely submission of data to the Authority as a matter of urgency. (HF&E Act S17 (1) (d)(e); D0005; T2; T9(e); (f); T39)

- Submission of an incident report concerning the continued storage of an embryo beyond statutory storage period, which involved the loss of patient records (HF&E Act S17(1); D0011; T120; HF&E Act S14(1)(c) – schedule 3 S8(1); T79)

- A report to be submitted to the Executive, within 3 months of the Licence Committee minutes being published, detailing the proposed implementation of recommendations from recent external reviews. This should address all areas of present practice such as: the senior management structure; nursing resources and training; delivery of the service and strategies to improve live birth rates.

- Revision of nursing staff management and training practices which would prevent the recurrence of drug cabinets keys being left in situ and patients notes being left unattended during the inspection (HF& E Act S17 (1) (a); (d); S33A; T2; T12; T15; T33b; T43)

- Revision of staff practices when using the new patient records store to prevent the door from being left open with the potential for a breach of confidentiality (HF& E Act S17 (1) (a); (d); S33A; T2; T15; T33b; T43)

- Revision of nurse management, training and practices in order to prevent further failures concerning the emergency crash trolleys (HF& E Act S17 (1) (a); (d); T2; T12; T15; T17; T23; T33b)

- Revision of staff policy and practices when storing and accessing the key used to mute the low oxygen cryo-alarm (HF& E Act S17 (1) (a); (d); T2; T15;)

- Review of the management of nursing staff, to include resourcing and training issues (HF& E Act S17 (1) (a); (d); T12; T15)

- Review and implementation of periodic staff competency assessment and recording (T12; T15a)

- Immediate implementation of electrical safety (PAT) testing of critical equipment which is currently not being performed (HF& E Act S17 (1) (a); (b); (d); T24)

- Review of the quality management system to assess areas where quality indicators are not currently in place and audits not being performed (HF& E Act S17 (1) (a); (d); T32; T35; T36)

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:

    - Establishment of quality indicators relevant to welfare of the child (WoC) and other processes
    - Lack of audit of processes
    - Lack of assessment/recording of staff competencies
    - Formalisation of third party agreements

▶ 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) Guidance Note 8*** Prior to any woman/couple being provided with treatment services at the centre, WoC issues are considered. There is a standard operating procedure (SOP) in place for assessing this issue and evidence of this procedure being performed was observed in patient records reviewed on the day of inspection. (T56) ***Donor recruitment, assessment and screening Guidance Note 11*** As evidenced from the self assessment questionnaire (SAQ) and discussions with staff on the day of inspection, there are written SOPs in place for the recruitment, assessment and screening of gamete/embryo donors. (T52)
What the centre does well.
What they could do better. The SAQ stated that no quality indicators or objectives relevant to assessing WoC have been established. (T35)

▶ 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

Person Responsible Guidance Note1

The PR oversees the running of the unit and allocates one fifth of her time, within her present job plan, to the role. She has designated senior management 'leads' within each discipline. The departmental leads then ensure that appropriately qualified, trained and competent staff undertake the various licensed activities. Regular, minuted departmental and unit meetings take place in order to discuss various aspects of departmental/unit practice, provide feedback from patients and to receive updates from departmental leads. Minutes from such meetings were made available to the inspection team on the day of inspection.

Staff Guidance Note 2

There is an organisational chart in place which was supplied prior to inspection, which clearly defines accountability and reporting relationships (T11). There is an induction policy in place and staff are provided with initial/basic training and have access to ongoing training. Where appropriate staff such as the Scientific Director (Health Professions Council - HPC), Laboratory Manager (HPC), embryologists (HPC or Association of Clinical Embryologist - ACE), nurses (Nursing and Midwifery Council – NMC) are registered with the appropriate professional and/or statutory bodies. (T14)

QMS Guidance Note 23

There is a quality management system (QMS) in place, which is maintained by a Quality Manager. (T32) (T33). The Quality Manager was able to demonstrate the various aspects of the QMS electronically to the Inspectorate via the Q-Pulse database system. It had been noted by the inspection team that some of the documentation supplied to the Executive prior to inspection had included items that were out of date and not the current version (T34). The Quality Manager stated that this had occurred due to the fact that another staff member had collated pre-inspection documentation to be sent to the Authority, whilst she had been on maternity leave. The Quality Manager was able to demonstrate that updated versions of the relevant documentation were actually in place and in use.

What the centre does well.

What they could do better.

Lack of quality indicators in place and audits not performed

As evidenced throughout the SAQ, some of the QMS quality indicators & audit procedures have not been either established, recorded or reviewed on a regular basis. (T35; T36). This relates to areas including;

- data submission
- confidentiality & privacy
- third party agreements
- QMS
- traceability
- witnessing
- consent taking
- provision of information

Lack of assessment and/or recording of staff competencies

As evidenced by the SAQ and following staff interviews on the day of inspection, staff competency assessments have not been regularly undertaken and recorded for all staff

groups (laboratory; clinical or administration). (HF& E Act S17 (1) a; d; T12; T15a)

These important aspects relating to the establishment, recording and review of the above mentioned quality indicators, the regular audit of these procedures, together with the lack of assessment/recording of staff competency, could, if left unattended lead to senior management having very little insight into how the staff are performing their duties and how the unit is performing as a whole in delivering patient services.

This could account for the inability of the PR and/or senior management to resolve the significant issue relating to data submission to the Authority (D0005; T39), as there appeared to be no firm coordinated management lead on this issue and there appeared to be no staff 'ownership' or responsibility for the process.

More worryingly, there appears to be a lack of urgency or ability on the part of the PR to resolve such important issues that have been identified within the unit from various external reviews. Ultimately it is the PR that is responsible for all licensable activities which take place at the centre [HF&E Act 1990 S17(1) a-g] and it is incumbent upon the PR to implement whatever actions are necessary in order to resolve any presently unresolved issues within the unit.

These issues may be due to a lack of time available to the present PR to perform the required PR duties and responsibilities and may indicate that there is a need for a separation of roles between Medical Director and a full-time regulatory PR. The latter should have the authority to manage the centre effectively in order to ensure regulatory compliance.

▶ 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

Premises/facilities Guidance Note 25

The current treatment and storage licence was seen to be displayed along the clinical corridor adjacent to the nurses' office. (T5)

Presently there is a great deal of building work taking place around the centre with the delivery of a £500M private finance initiative (PFI) project which began in 2004.
New laboratory facilities were introduced in February 2008, with refurbishment to theatre and recovery facilities taking place between July and November 2009. The PR informed the Inspectorates of these changes to the facilities which were within the curtilage of the centre.

(T18)

Generally the premises and facilities for both staff and patients were seen to be good and the new theatre and recovery suite has added to the functionality of the unit. (T17)

The diagnostic andrology laboratory is accredited by the Clinical Pathology Association (CPA). The Laboratory Manager stated that the last CPA inspection had taken place in November 2009 after which the laboratories had been accredited as compliant. (T21)

Equipment/materials Guidance Note 26
The licensed activities are carried out using equipment/materials designed for purpose and maintained to suit the intended purpose. (T23)

All critical use equipment has servicing/maintenance contracts in place as evidenced from the SAQ and discussions with staff on the day of inspection. (T26)

Validation of critical use laboratory equipment was undertaken at the time of the new laboratory build in 2008. (T24)

As stated in the SAQ and discussed on the day of inspection, CE marked equipment is used wherever possible. (T30)

Procuring/processing Guidance Note 15
As evidenced by documentation provided prior to the inspection, the SAQ response and from discussions with staff on the day of inspection, there are SOPs in place for the procurement and processing of gametes and embryos. (T33b)

From the SAQ response and documentation seen on the day of inspection, the centre has an on-going air-quality monitoring and recording system in place, to ensure that the air-quality, within which gametes/embryos are processed, is compliant with current regulatory requirements. (T20)

Witnessing Guidance Note 18
A witnessing SOP was provided prior to the inspection and seen to be in place via a record review undertaken on the day of inspection. This procedure facilitated the recording of information when any gametes/embryos were procured/processed. An electronic witnessing system had recently been validated and was in use.

Traceability Guidance Note 19
A traceability SOP was provided prior to the inspection and seen to be in place via a records review undertaken during the inspection. This process ensured the recording of all equipment and materials which came into contact with gametes and embryos (T22)

Third Party Agreements Guidance Note 24
The quality manager was able to provide details of the third party agreements in place with

different companies via the NHS Trust procurement department. This list identified equipment and consumable suppliers, critical equipment maintenance suppliers, a courier company and satellite centre. (T111; T115)

What they could do better.

Gaining access to the centre
Initially gaining access to the centre was time-consuming, due to the aforementioned PFI development work and the lack of appropriate signage from the new St Mary's building central reception. Fortunately a reception staff member was able to redirect us around the building works and out on to the Oxford Road, where access to the centre was gained.
This was discussed with the centre senior management team on the day of inspection and it was stated that they had not had any major problems with this issue as they had given specific details concerning centre access during this period of building work to prospective patients via appointment correspondence. This issue was due to be resolved in the very near future, as new kerb-stones were to be laid which would allow direct access to centre reception via the Oxford road.

Records store door left open: potential breach of confidentiality
During the tour of the premises it was observed that the door of the new records store was not kept closed whilst records were being sought by staff. This could potentially lead to a breach of confidentiality as patients and other members of the public use the corridor on which the store is based to gain access to other parts of the hospital. (HF& E Act S17 (1) a; d; S33A; T2; T15; T33b; T43)

PAT testing of electrical equipment not being preformed
A significant amount of electrical equipment was found to have date expired electrical testing stickers on it. If this electrical equipment is not appropriately serviced/maintained then it could potentially lead to the equipment being non-functional or a danger to staff in the future. (HF& E Act S17 (1) a; b; d; T24)

Keys left in drugs cabinet together with patient notes in unattended treatment room
During the tour of the premises it was observed that within one of the new treatment rooms, patients notes had been left unattended and keys left in a drugs cabinet whilst the room was left unoccupied by staff, with patients waiting outside in the corridor.
(HF& E Act S17 (1) a; d; S33A; T2; T12; T15; T33b T43)

Access to low O_2 monitor alarm mute key
During discussions with staff on the tour of the premises it was stated that the key required to mute the low oxygen alarm outside of the cryo-room was actually sited within the cryo-room itself. Obviously this arrangement needs to be revised as staff should not enter the cryo-room if the alarm is sounding, as it could potentially lead to asphyxiation. (HF& E Act S17 (1) a; d; T2; T15; T33b)

Emergency trolleys
During the tour of the premises it was noticed that there were problems associated with all three of the emergency trolleys observed. Two of the trolleys had no log-books when first encountered. These books should remain with the trolley and be signed daily in order to assure that staff have examined the equipment and found it to be satisfactory for use in an emergency. The other equipment had an un-signed log-book. One of the logs identified that an oxygen

cylinder had not been available for several days. Also of concern was that emergency drugs associated with the trolleys were left in an un-secured case at the side of the trolley. These drugs could easily be removed by patients or other members of the public using the corridors. This issue is of greater concern as it was highlighted as a problem in the previous report, to which the PR had replied in response to the report finding that, 'The nurses acknowledge that the emergency trolley needs to be checked regularly and this is now being done. We recognise the importance of the emergency trolley, but would also like to add that if a patient collapsed within the unit, the emergency crash team for the hospital would also be called, in line with Trust policy.' (HF& E Act S17 (1) a; d; T2; T12; T15; T17;T23)

▶ 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 Guidance Note 2*** An organisational chart was supplied prior to inspection, which clearly defines accountability and reporting relationships (T11). There is an induction policy in place and staff are provided with initial/basic training and have access to ongoing training. Where appropriate staff such as the Scientific Director (Health Professions Council - HPC), Laboratory Manager (HPC), embryologists (HPC or Association of Clinical Embryologist - ACE), nurses (Nursing and Midwifery Council – NMC) are registered with the appropriate professional and/or statutory bodies. (T14)
What the centre does well.
What they could do better. ***Person Responsible Guidance Note 1*** From discussions with staff on the day of inspection, it was established that the nursing staff thought that they lacked a nurse manager, were under-resourced, insufficiently-trained and generally over-stretched due to workload pressures. It is important that the PR assesses both the number, training and competence of staff providing licensed treatment services (HF& E Act S17 (1) a; d; T12; T15) ***Quality management systems Guidance Note 23*** An annual management review for 2009 had not taken place and therefore the assessment of whether there were adequate staff in place to provide the licensed treatment services had not been undertaken. An annual review should be instigated as soon as possible in order to address the perceived lack of resources. (HF& E Act S17 (1) a; d; T12) ***Staff Guidance Note 2*** From SAQ responses and discussions with centre staff on the day of inspection it was established that few if any staff competency assessments were taking place or being recorded. (HF& E Act S17 (1) a; d; T12; T15a) ***Management of nursing staff, resourcing and training issues*** As outlined above nursing staff, stated that they felt poorly managed, under-resourced and lacked appropriate training in order to safely deliver the licensed treatment services. There is an urgent need to review this vital part of the clinical service as nurses are involved in so many of the day-to-day patient services. This present situation could also account for the problem highlighted elsewhere in the report, such as; • emergency trolley issues • Keys left in drugs cabinet in treatment room • Data submission to the authority This area was also highlighted as an issue in one of the external reviews undertaken in late 2009, by a respected clinical practitioner. (HF& E Act S17 (1) a; d; 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 ***Adverse incidents/reporting Guidance Note 27*** As evidenced from the SAQ response and during staff interviews on the day of inspection, the centre has documented procedures in place through which any serious adverse event or reaction can be reported. (T118) ***Complaints Guidance Note 28*** As evidenced on the day of inspection there is a complaints procedure in place at the unit. Notices describing the process were observed throughout the unit and it is also mentioned in the information booklet provided to patients.
What the centre does well.
What they could do better. ***Embryo storage issue involving loss of patient records*** During the course of the inspection it was revealed to the Inspectorate by centre staff that an embryo had been kept in storage after the expiry of its consent period. This had occurred due to the loss of the patient's notes and the subsequent inability of staff to contact the patient. This is a serious non-compliance relating both to a potential breach of confidentiality and non-compliant with statutory storage conditions. This should have been reported as an incident as soon as the patient's notes could not be successfully located. (HFE Act S17(1); D0011; T120; HFE Act S14(1)(c) – schedule 3 S8(1); T79)

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:
    - Improvement of outcomes for patients

▶ 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 ***Treating people fairly Guidance Note 29*** The inspection team was informed that as the centre is part of a large NHS Trust, which has its own policies relating to the fair treatment of patients, then all staff are mindful to abide by these Trust policies at all times when dealing with patients. ***Counselling Guidance Note 3*** The access to counselling services is described in the patient information booklet. Further information about the counselling service was seen to be available to patients throughout the centre. (T60; T61) ***Legal parenthood Guidance Note 6*** As evidenced from the SAQ and observed during the review of patient notes, the centre has established a written procedure to provide appropriate information and obtain the relevant records of consent to parenthood prior to treating a woman with donor sperm or embryos. (T61) ***Costed treatment plans*** There are no self-funding patients attending the centre. All patients treated are NHS patients referred via local primary care trust (PCT) funding arrangements.
What the centre does well.

What they could do better.

Nothing noted on inspection.

▶ 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

Confidentiality and privacy Guidance Note 30
The centre has an SOP in place to ensure that all staff are aware that all information concerning patients and their treatment at the centre is to be kept confidential. This is brought to the attention of all new staff as part of the induction policy and is part of the Trust policy. (T43)

The centre's patient information booklet has a section which informs patients about the obligation of any person who deals with centre patient information to respect patient confidentiality.

Premises/facilities Guidance Note 25
The premises and facilities at the centre were seen to be comfortable and able to provide privacy for patients and/or donors during their treatment. (T17)

What the centre does well.

What they could do better.

Nothing noted on inspection.

▶ 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

Information Guidance Note 4

A patient information booklet, which is sent out to all prospective patients, was provided prior to the inspection and seen to contain information on;

- Types of fertility treatment available
- Numbers of treatment cycles available
- Screening
- Possible complications
- Research
- Starting treatment
- Prescription charges
- Counselling
- Support groups
- HFEA (including confidentiality/consent to disclosure/donor issues)
- Suggestions and complaints
- Emergency contact numbers
- Useful books on fertility issues
- Useful organisations

Counselling Guidance Note 3

The access to counselling services is described in the patient information booklet mentioned above. Further information about the counselling service was seen to be available to patients throughout the centre. There was also information available concerning open patient support group meetings which were scheduled to occur outside normal working hours, (18-00 to 19-00) on a monthly basis. (T58)

What the centre does well.

What they could do better.

Information Guidance Note 4

Although the 'information for patients undergoing fertility treatment' booklet was being made available to patients prior to treatment, it was initially introduced in 2007 and there is a need to update the information in order to take into account the changes brought about by the introduction of the new HF&E Act in October 2009. (It does state at the back of the booklet, 'To be reviewed April 2009') (Guidance 31.6)

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

Consents Guidance Note 5
As evidenced from the SAQ, there is an SOP in place for taking effective consent from patients. As discussed with staff during the inspection, consent is taken by clinicians after discussion with the patients and/or donors concerning issues and implications. (HF&E Act Schedule 3(3); T58; T59)

What the centre does well.

What they could do better.

Consents Guidance Note 5
As evidenced from the SAQ, the process of consent taking has not been audited within the last 2 years. It was therefore not possible to ascertain how compliant the procedure is with respect to approved protocols, regulatory requirements and quality indicators. This was confirmed with discussions with the Quality Manager on the day of inspection. (HF& E Act S17 (1) a; d; T36)

Also as evidenced from the SAQ and from discussions with staff on the day of inspection, the competency of staff who take consent has not been assessed/recorded. (HF& E Act S17 (1) a; d; T15a)

Live Birth Rates

Relative live birth success rates HFEA held register data [Jan 01, 2005 to Dec 31, 2007] show:

Age Group	DI		FET		IVF/ICSI	
Below 35	14.907%	No difference	13.473%	Significantly below	17.984%	Significantly below
35 - 37	14.545%	No difference	13.279%	No difference	12.673%	Significantly below
38 - 39	15.385%	No difference	12.069%	No difference	11.053%	No difference
40 - 42	-		6.944%	No difference	17.647%	No difference
Over 42	-		18.182%	No difference	-	

The centre's success rates are in line with national averages with the following exceptions:

1. IVF/ICSI: below 35 years age group
2. IVF/ICSI: 35 to 37 years age group
3. FET: below 35 years age group

This has been an on-going issue for this centre over the last three years. At the last Licence Committee on January 12th 2009 a recommendation was made for the centre to undertake an external review of its clinical service. Three independent external reviews were undertaken over the period, July to December 2009. External reviewers acknowledged that results have been below the national average with some outcome measures showing a decline in success from 2007 to 2008. Another observation was that even more recent outcomes (between February 2008 and February 2009) were inconsistent month on month.

The PR stated that the senior management team was due to consider all the recommendations suggested as part of the recent review process, and would instigate any changes to practice that they felt were necessary, in order to improve the outcome for patients.

As this issue has been a concern for recent Licence Committees, the Inspectorate felt that the PR should produce a report discussing which recommendations were to be instigated by the centre and on what basis. This issue should be followed up within 3 months of the Licence Committee minutes being published.

As stated above this is an issue that has been on-going for a number of years and is another issue that calls into question the ability of the PR in being able to bring about effective change to the centre.

With respect to the PR response the following data can be found on the HFEA website:

(See Tables below)

1. live birth rate data for 1st quarter 2008 (shown below)

HFEA live births per treatment cycle started for 1st quarter 2008

Female Age (yrs)	Live births per treatment cycle	% Live births per treatment cycle (LBR/Cycle)	National average % (LBR/Cycle)
< 35	73/357	20.4	32.3 (below)
35-37	23/142	16.2	27.3 (below)
38-39	4/79	5.1	19.1 (below)
40-42	0/6	0	11.9 (consistent)

And

2. clinical pregnancy data for the first quarter 2009 (shown below)

Female Age (yrs)	Pregnancies & live births per embryo transferred	Predicted % chance of an average patient having a live birth	Comparison to national average %
< 35	92/545	16.9	22.9 (below)
35-37	32/241	13.3	19.2 (consistent)
38-39	14/141	9.9	14.6 (consistent)
40-42	3/13	23.1	9.4 (consistent)

NB this is clinical pregnancy data, which may translate to lower figures for final live birth rates due to pregnancy loss etc.

These data were not published on the website until after the inspection visit.

Multiple Births

Evidence of how the centre improves its live birth rates and reduces the number of multiple births:

The centre was part of the initial Department of Health initiative for single embryo transfer and does not perform any 3-embryo transfers under any circumstances. Senior management put a multiple births minimisation strategy (MBMS) into place during September 2008 and their multiple birth rate for 2009 was in line with professional body guidelines at 24%.
During 2009 the centre undertook a review of its single embryo transfer policy, which was made available to the Executive prior to the inspection, and is in the process of evaluating the review prior to implementing any changes to its MBMS.

What the centre does well

The centre has been at the forefront of implementing the eSET initiative in order to reduce the incidence of multiple births.

The table below illustrates that the centre has consistently been replacing only one embryo in approximately one third of all fresh IVF/ICSI cycles between 2004 to 2007 (with the exception of 2005 which was 25.6%) and in over fifty percent of frozen embryo transfers within the same timeframe, which is an excellent effort by the whole team.

Embryo Transfer Rates (for the past four years)

Type: FET				Type: ICSI/IVF			
Year	Single	Double	Triple	Year	Single	Double	Triple
2004	278 (58.65%)	196 (41.35%)	(0%)	2004	119 (31.07%)	264 (68.93%)	(0%)
2005	228 (52.29%)	208 (47.71%)	(0%)	2005	96 (25.6%)	279 (74.4%)	(0%)
2006	195 (59.63%)	132 (40.37%)	(0%)	2006	132 (33.85%)	258 (66.15%)	(0%)
2007	171 (52.94%)	152 (47.06%)	(0%)	2007	138 (30.07%)	321 (69.93%)	(0%)

What the centre could better

Nothing noted on inspection.

3. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos must only be procured, processed, used, stored and disposed off in accordance with the law
- **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.
  - Staff competency assessment/recording
  - Establishment of quality indicators for the witnessing procedure

▶ Have respect for the special status of the embryo when conducting licensed activities (Principle 3).
Evidence of how the centre demonstrates compliance with this principle ***Staff Guidance Note 2*** The centre has an SOP in place for staff induction training where there is reference to the HFEA and its regulatory function. As laboratory staff undertake ACE training there is reference to the HFEA and ethics which covers topics such as the special status of the embryo. (T15) ***Witnessing Guidance Note 18*** As evidenced from the SAQ and provided to the Executive prior to the inspection, the centre has an SOP in place for witnessing, which ensures that gametes/embryos are identifiable from procurement to disposal. ***Traceability Guidance Note 19*** As evidenced from the SAQ and provided to the Executive prior to the inspection, the centre has an SOP in place for traceability, which ensures that gametes/embryos are traceable from procurement to disposal. (T99) ***Premises/facilities Guidance Note 25*** From the SAQ response and documentation seen on the day of inspection, the centre has an on-going air-quality monitoring and recording system in place, to ensure that the air-quality, within which gametes/embryos are processed, is compliant with current regulatory requirements. (T20) The cryostore contained dewars which were seen to be secure and fitted with low liquid nitrogen alarms, connected to an auto-dialler system for out-of-hours incidents. A written protocol was in place to cover such situations. A low Oxygen monitor was in place within the cryostorage area, with an external audio/visual alarm. (T17)
What the centre does well.
What they could do better. ***Staff Guidance Note 2***

From SAQ responses and discussions with centre staff on the day of inspection it was established that few if any staff competency assessments were taking place or being recorded. (HF& E Act S17 (1) a; d; T12; T15a)

Witnessing Guidance Note 18

As evidenced from the SAQ response and discussions with staff on the day of inspection there are no quality indicators developed for witnessing. (HF& E Act S17 (1) a; d; T35)

4. Good governance and record keeping

Focus

Version: 0

Trim:

- **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.
  - Submission of accurate/timely information to the Authority

▶ Maintain accurate records and information about all licensed activities (Principle 10).
Evidence of how the centre demonstrates compliance with this principle ***Record keeping and document control Guidance Note 31*** The Quality Manager was able to demonstrate the database on the Q-Pulse system which illustrated when documents were created, when they were reviewed and which version was currently in use. (T34) ***Traceability Guidance Note 19*** As evidenced from the SAQ and provided to the Executive prior to the inspection, the centre has an SOP in place for traceability, which ensures that gametes/embryos are traceable from procurement to disposal. (T99) ***Witnessing Guidance Note 18*** As evidenced from the SAQ and provided to the Executive prior to the inspection, the centre has an SOP in place for witnessing, which ensures that gametes/embryos are identifiable from procurement to disposal. ***Premises/facilities Guidance Note 25*** A new records store on the ground floor of the centre was seen during the tour of the premises and found to be adequate for its intended purpose. (T17)
What the centre does well.
What they could do better. Nothing noted on inspection.
▶ Conduct all licensed activities with regard for the regulatory framework governing

treatment and research involving gametes or embryos within the UK, including: maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13).
Evidence of how the centre demonstrates compliance with this principle **Obligations and reporting requirements of centres – Guidance Note 32** The PR and centre staff interviewed during the inspection demonstrated an awareness and understanding of legal obligations and recent changes to the CoP. Staff cooperated fully during the inspection and made all documents and records available to the inspection team. (T3)
What the centre does well.
What they could do better. ***Submission of data to the Authority*** Unfortunately, as was the case at the previous inspection in October 2008, the accurate and timely submission of data to the Authority is still problematic. The problems seem to centre around three issues; 1. there is an interface problem between the centre's database (ACUbase) and the EDI equipment supplied (technical issue) 2. there is no management or staff ownership of the problem (management issue) 3. there is no SOP in place which describes the process of data entry at the centre. Consequently staff have not been trained to perform specific roles as part of this process (procedural issue). As there is no ownership of the problem by management or staff, the issue remains unresolved. The last error report submitted to the centre by the Authority's quality assurance team consisted of 16-pages. The centre now has the worst error report of any licensed centre. When discussed with the PR it was acknowledged that there were ongoing problems as identified above in relation to the technical, management and procedural issues. She said that the Trust's IT department had been attempting to resolve the electronic interface problem and that a new procedure for the data entry had been formulated. This is another example of the inability of the PR to adequately manage the situation. Ultimately the PR has to resolve this issue as she is responsible for all licensed and unlicensed activities that are undertaken at the centre. As of the date of writing this report the data entry issue(s) remain unresolved for the second consecutive inspection. The Inspectorate considers that this is unacceptable. (HF&E Act S12 (1)g; S17 (1)(d)(e); D0005; T2; T9(e)(f); T39;)

5. Changes / improvements since the last inspection on 17 October 2008

Area for improvement	Action required	Action taken as evidenced during this inspection
Verified data has not been forwarded to the Authority within given timeframes	Verified data to be forwarded to the Authority within required timeframes	***No improvement evidenced at present inspection.*** There have been no improvements in this area of practice as evidenced during the present inspection. The centre now has the worst error report of any licensed centre.
The emergency trolley within the department was found to have equipment missing and had only been checked twice during October (up to the day of inspection – October 17th)	The emergency trolley should be checked as required by HFEA Standards	***No improvement evidenced at present inspection***. There were still significant failures associated with this critical equipment observed during the present inspection.
Present nursing staffing levels may not be adequate to provide a good quality of service	Risk assessment of present nursing staffing levels to be undertaken	***No improvement evidenced at present inspection***. Although there have been more nursing staff recruited since the last inspection, there remain unresolved issues relating to the management, training and competency of staff as evidenced during the present inspection.
Payment of fees to the Authority takes 58 days on average.	Payment of fees to the Authority to comply with standard licence conditions	Generally there has been an improvement in this area, concerning the timely payment of invoices, but presently the licence renewal fee remains outstanding.

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	Not compliant
T3	Fully Compliant
T4	Fully Compliant
T5	Fully Compliant
T6	Fully Compliant
T7	N/A
Person Responsible	
T8	Fully Compliant
T9	Not 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	Fully Compliant
T19	N/A
T20	Fully Compliant
T21	N/A

Licence Condition	Assessment
Equipment and Materials	
T22	Fully Compliant
T23	Not compliant
T24	Not compliant
T25	N/A
T26	Not compliant
T27	Fully Compliant
T28	Fully Compliant
T29	Fully Compliant
T30	Fully Compliant
T31	Fully Compliant
Quality Management	
T32	Not compliant
T33	Not compliant
T34	Fully Compliant
T35	Not compliant
T36	Not compliant
Records and Information	
T37	Fully Compliant
T38	Fully Compliant
T39	Not compliant
T40	Fully Compliant
T41	Not compliant
T42	Fully Compliant
Data protection and Confidentiality	
T43	Not compliant
T44	Not compliant
T45	Fully Compliant
Patient Records	
T46	Fully Compliant
T47	Fully Compliant
T48	Fully Compliant
Patient Selection Criteria and Laboratory Tests	
T49	Fully Compliant
T50	Fully Compliant
T51	Fully Compliant
Donor Selection Criteria and Laboratory Tests	
T52	Fully Compliant
T53	Fully Compliant
T54	Fully Compliant
T55	Fully Compliant

Licence Condition	Assessment
Welfare of the Child, Provision of Information, Counselling and Consent	
T55	Fully Compliant
T56	Fully Compliant
T57	Fully Compliant
T58	Fully Compliant
T59	Fully Compliant
T60	Fully Compliant
T61	Fully Compliant
T62	Fully Compliant
T63	Fully Compliant
T64	Fully Compliant
T65	Fully Compliant
Procurement of Gametes and Embryos	
T66	Fully Compliant
T67	Fully Compliant
T68	Fully Compliant
T69	Fully Compliant
T70	Fully Compliant
Processing and Use of Gametes and Embryos	
T71	Fully Compliant
T72	Fully Compliant
T73	Fully Compliant
T74	Fully Compliant
Storage of Gametes and Embryos	
T75	Fully Compliant
T76	Fully Compliant
T77	Fully Compliant
T78	Fully Compliant
T79	Not compliant
T80	Fully Compliant
T81	Not compliant
T82	N/A
T83	Fully Compliant
T84	Fully Compliant
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	Fully Compliant
T93	Fully Compliant
T94	Fully Compliant
T96	Fully Compliant
T97	Fully Compliant
T98	Fully Compliant
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	Fully Compliant
T106	Fully Compliant
T107	Fully Compliant
T108	Fully Compliant
Receipt of Gametes and / or Embryos	
T109	Fully Compliant
T110	Fully Compliant
Third Party Agreements	
T111	Fully Compliant
T112	Fully Compliant
T113	Fully Compliant
T114	Fully Compliant
T115	Fully Compliant
T116	Fully Compliant
T117	N/A
Identification, investigation, reporting, recording and notification of serious adverse events and reactions	
T118	Not compliant
T119	Not compliant
T120	Not compliant
T121	Not compliant
T122	Fully Compliant

Additional Licence Conditions	
Licence Condition	**Assessment**
N/A	

HFEA Directions	
HFEA Directions	**Assessment**
0001 Gamete and embryo donation	X
0003 multiple births	Fully Compliant
0005 Collecting and recording information for the HFEA	Not compliant
0006 Import and export of gametes and embryos	Fully Compliant
0007 Consent	Not compliant
0008 Form and content of applications	Not compliant
0009 Keeping gametes and embryos in the course of carriage between premises	Fully Compliant
0010 Satellite and transport IVF	Fully Compliant
0011 Reporting adverse incidents and near misses	Not compliant
0012 Time periods for retention of records	Fully Compliant

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 staff, 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
Failure to maintain emergency crash trolleys in line with professional body guidelines	(HF& E Act S17 (1) (a); (d); T2; T12; T15; T33b;)	Revision of nurse management, training and practices in order to prevent further failures concerning the emergency crash trolleys	Immediately	31 March 2010 Action implemented. See PR action plan	**PR actions noted.** **To be followed up at next inspection**
The present practice of storing the low oxygen cryo-alarm mute key within the cryostore is potentially lethal.	(HF& E Act S17 (1) (a); (d); T2; T15; T33b)	Revision of staff policy and practices when storing and accessing the low oxygen cryo-alarm mute key.	Immediately	31 March 2010 Resolved immediately See PR action plan	**Issue resolved.** **To be followed up at next inspection**

requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
The continued storage of an embryo beyond the statutory storage period, which involved the loss of patient records	(HF&E Act S17(1); D0011; T120; HFE Act S14(1)(c) – schedule 3 S8(1); T79)	Submission of an incident report concerning the continued storage of an embryo beyond statutory storage period, which involved the loss of patient records	Immediately	31 March 2010 This issue is resolved Incident has been reported See PR action plan	**PR actions noted.**

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
Accurate and timely submission of data to the Authority.	(HFE Act S17 (1)(d)(e); D0005; T9(e)(f); T2; T39)	The PR must resolve regulatory issues concerning the accurate and timely submission of data to the Authority as a matter of urgency.	Within 3 months of the LC minutes being published	31 March 2010 Issue being actioned See PR action plan	**PR actions noted.** **Update from PR required on this crucial issue to be forwarded to Executive within given timeframe**
Observed practice of drugs cabinet keys being left in situ and patient notes left unattended within a patient treatment room.	(HF& E Act S17 (1) (a); (d); S33A;T2; T12; T15; T33b; T43)	Revision of nursing staff training practices which would prevent the recurrence of drug cabinets keys being left in situ during the inspection	Immediately	31 March 2010 Resolved immediately See PR action plan	**PR actions noted.** **To be followed up at next inspection**
Potential for breach of patient confidentiality due to the practice of the records store door being left open.	(HF& E Act S17 (1) (a); (d); S33A; T2; T15; T33b; T43)	Revision of staff practices when using the new patient records store to prevent the door from being left open with the potential for a breach of	Immediately	31 March 2010 Resolved immediately See PR action plan	**PR actions noted.** **To be followed up at next inspection**

through the procurement, use, storage or distribution of gametes and yos, 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
Lack of the management, training and competency assessment within the nursing department	(HF& E Act S17 (1) (a); (d); T12; T15)	Review of the management of nursing staff, to include resourcing, training and competency issues	Within 3 months of the LC minutes being published	31 March 2010 Lead Nurse for Gynaecology has been based within Unit with immediate effect Permanent Nurse Manager position to be advertised. See PR action plan	**PR actions noted.** **Updated information on progress made to be provided by PR.**
There was a lack of both assessment and recording of staff competency throughout the centre	(HF& E Act S17 (1) (a); (d); T12; T15a)	Review and implementation of periodic staff competency assessment and recording	Within 3 months of the LC minutes being published	31 March 2010 Competencies to be assessed as per PR action plan	**PR actions noted.**
The quality management system had not been maintained	(HF& E Act S17 (1) (a); (d); T32; T35; T36)	Review of the quality management system to assess areas where	Within 6 months of the LC minutes being	31 March 2010 Quality management system to be reviewed over	**PR actions noted.**

not been reviewed/ audited. There had been no annual review.					

- which poses an indirect risk to the safety of staff, 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
Electrical safety (PAT) testing of some critical equipment is presently not being undertaken	(HF& E Act S17 (1) (a); (b) (d); T24)	Implementation of electrical safety (PAT) testing of all critical equipment	Immediately	31 March 2010 Immediately resolved All outstanding PAT testing has been undertaken.	**Issue resolved**

departure from good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Implementation of recommendations from recent external reviews.		A report to be submitted to the Executive detailing the proposed implementation of recommendations from recent external reviews. This should address all areas of practice such as: the senior management structure; nursing resources and training; delivery of the service and strategies to improve live birth rates.	Within 3 months of the Licence Committee minutes being published	31 March 2010 The department will submit an action plan within the timescales specified by HFEA.	**Action plan to be submitted by PR within given timeframe**

addressing all issues raised.

The documents supplied by the PR in response to the inspection report are comprehensive and, to facilitate assimilation of the information provided, have been submitted by the inspectorate separate to the report, but will be published alongside the report.

The response included;

4. Action Plan in response to areas of non compliance including a final person responsible comment. (TRIM 2010/000003376)

5. Report of the person responsible in response to the issues raised. (TRIM 2010/000003377)

6. The proposed audit calendar for 2010/11 (TRIM 2010/000003378)

The PR also commented:

- As the report states, some of the issues raised cannot be addressed by the PR and these have been escalated to the Nominal Licensee for resolution. *(Noted)*

- It is inappropriate to discuss poor pregnancy rates over the preceding three years without reference to any data from that time, although such data is publically available. *(This point has been addressed)*

- The inclusion of a section “What the unit does well”. This section was left blank throughout suggesting that there is nothing that the unit does well. This gives an unbalanced slant to any inspection report and is not in keeping with recent recommendations for better regulation. *(This point has been addressed)*

HFEA Executive Licensing Panel Meeting

6 May 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 3

St Mary's Manchester (0067) 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 they had no conflicts of interest in relation to this item.

The following papers were considered by the Panel:

- papers for Licence Committee (104 pages)
- no tabled papers for this item

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 incorporating the PR's response, renewal application form, action plan, audit calendar, and previous Licence Committee minutes.

2. The Panel noted that this inspection took place on the 20 January 2010 and lasted for nine and half hours.

3. The Panel noted that this centre has been licensed since 1992, and currently provides over 1000 treatment cycles to NHS patients from Greater Manchester and the surrounding areas. The Panel also noted that the centre's live birth rates are below the national average with some outcome measures showing a decline in success from 2007 to 2008.

4. The Panel noted that the centre has produced a multiple births minimisation strategy in order to reduce the incidence of multiple births, in line with recent professional body guidelines. The Panel also noted that the centre's multiple birth rate is in line with the professional body guidelines at 24%.

5. The Panel noted that the PR has been in post since August 2006 and is appropriately qualified to discharge her duties as outlined in Guidance note 1 of the Code of Practice 8.

6. The Panel noted that the centre has a large number of areas to address identified on the inspection, listed on page 7 of the report. However, it has taken steps to address some of these areas, documented on page 6 of the report and set out in the PR response on page 47.

7. The Panel noted that among the outstanding issues which the centre needs to address were the submission of incident reporting, revision of nursing staff management and training practices to address issues such as keys being left in the drugs cabinet and patient notes being left unattended.

8. The Panel noted that the inspectorate identified that the reporting of accurate and timely data to the Authority as particularly problematic and endorsed the inspectorate's recommendation that this should be resolved as a matter of urgency.

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 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.

12. The Panel noted the PR's willingness to address the outstanding areas within the report. However, given the licensing history and the outstanding areas that the centre still needed to address, the Panel endorsed the inspectorate's recommendation to issue a licence for two years with no additional conditions.

13. The Panel noted that the premises and practices are suitable as stated in the inspection report.

The Panel's Decision

14. The Panel agreed to renew the licence for a period of two years with no additional conditions as per the inspectorate's recommendation. The Panel agreed that the areas for improvement on page 31 of the inspection report still need to be addressed, with the exception to the payment of fees to the Authority.

15. The Panel recognised that the centre has addressed a large number of areas and is compliant with a majority of the licence conditions as indicated on pages 35 – 37 of the inspection report.

16. The Panel noted the detailed response from the PR and acknowledged that she has taken steps to, or is in the process of, addressing these outstanding areas. The Panel encouraged the inspectorate to work in collaboration with the PR to address these areas in the action plan within the timescales indicated.

Signed.....Date...12/5/10
Mark Bennett (Chair)