Renewal Inspection Report

Date of Inspection: 14 January 2010
Length of inspection: 5 hours
Inspectors: Angela Sutherland (lead) Paula Nolan and Sara Parlett (observing)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 15 January 2009 and 14 January 2010.

Date of Licence Committee:

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 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 Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Epsom and St Helier NHS Trust Assisted Conception Unit
Centre Number	0259
Licence Number	E0259/2/b
Centre Address	St Helier Hospital Wrythe Lane Carshalton S Surrey London SM5 1AA
Telephone Number	020 829 62101
Person Responsible	Dr Elizabeth Sherriff
Licence Holder	Dr Rim Elrifai
Licence expiry date	30 June 2010
Additional conditions applied to this licence	Nil

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Report to Licence Committee / Executive Licensing Panel

Brief description of the centre and its licensing history:

The Assisted Conception Unit (ACU) at Epsom and St Helier University Hospital provides intrauterine insemination (IUI) treatment to NHS patients and has been licensed since 05 July 2007. The centre operates from premises within the Women's Health Services Department of St Helier Hospital and shares some facilities with the Gynaecology outpatient's department.

Dr Elizabeth Sherriff has been Person Responsible (PR) since inception and has completed her HFEA Person Responsible Entry Programme (PREP). She has been registered with the General Medical Council since1981 and has been a member of the Royal College of Obstetricians and Gynaecologists since 1997. A new Licence Holder; Dr Rim Elrifai was appointed on 16 December 2009.

The centre provides transport services for The Bridge (0070) and ACU Kings College (0109) centres, performing approximately 130 cycles of transport IVF per year.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period
IUI partner services for the year 2008	9 cycles

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

*These data were extracted from the HFEA register for the year 2008. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Summary for licensing decision:

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

- The PR is suitable and has discharged her duty under section 17 of the HF&E Act 1990 (as amended).
- The premises are suitable.
- The practices are suitable.
- The centre has submitted appropriately completed documentation in application for renewal of their licence.

- The centre has submitted an application fee to the HFEA in accordance with requirements.

Recommendation to the Executive Licensing Panel:

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

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

The PR should provide evidence that all major recommendations have been met within the specified timeframes including:

- The PR should implement a programme to validate all critical equipment and processes at the centre.

- The PR should carry out an audit of witnessing documentation within patient records with the aim of identifying any further discrepancies. The PR should use the findings of this audit to identify any areas where the SOP or staff training could be amended to minimise the risk of recurrence. The results of this audit should be submitted to the HFEA.

- The PR should ensure that all third party agreements contain such detail as required by T113 and T114.

- The PR should facilitate the validation of the air quality monitoring programme including the interval for repeat monitoring.

- The PR should commence a programme to review and assess the competence of all staff at the centre.

- The PR should provide quarterly reports on the progress of validation and the assessment of staff competence until each programme is complete.

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).
- **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:
    - Traceability.
    - Validation.
    - Witnessing.
    - Third Party Agreements.
    - Staff competence assessment.
    - Air quality monitoring.
    - Participation in inter-laboratory comparisons.

▶ 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 (guidance note 8):** The centre has a dedicated welfare of the child standard operating procedure (SOP) (T33). Five sets of patient records that were audited during the inspection and all were found to contain appropriate welfare of the child documentation (T56).
What the centre does well.
What they could do better.

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

Evidence of how the centre demonstrates compliance with this principle

Procurement and processing (guidance note 15):

The centre has a dedicated IUI SOP that was provided before the inspection. It appears to adequately cover all steps in the IUI process from sample verification to patient identification at the time of IUI and includes a list of trained staff authorised to perform IUI and all witnessing steps (G15.1).

Quality management (guidance note 23):
Before and during the inspection the Quality Manager (QM) provided evidence of a quality management system (T33) that included:

- SOPs including (but not limited to); prescribing fertility drugs; classifying OHSS; positive screening results and egg collection (T33).
- An audit plan including (but not limited to); patient satisfaction; staff satisfaction; IUI; and HFEA reporting (T36).

The QM described an annual review programme for the quality management system that she conducts with the PR. Minutes for this review were provided and it was seen to include; the new HFEA code of practice; issues regarding patient satisfaction questionnaires; inter laboratory comparisons and staff training. The QM expressed confidence that all members of the centre team have input into quality issues and information can be disseminated with ease (T32).

The QM provided a copy of the quality action plan which was seen to contain varied items including; progress with a staff satisfaction questionnaire; discussion regarding the centre's emergency contingency plan with centres for which they provide transport services, sperm preparation training and a plan to conduct security spot checks (T32).

The centre takes part in the NEQAS for inter-laboratory comparisons (G23.23).

What the centre does well.

What they could do better.

Procurement and processing (guidance note 15):
While evidence that steps had been taken to commence validation of the IUI process was seen this was not complete at the time of inspection (T72).

Quality management (guidance note 23):

The centre does not have any quality indicators to measure the required standards of quality and safety of licensed activities (T35).

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

Evidence of how the centre demonstrates compliance with this principle.

Traceability (guidance note 19):
The requirements for traceability appear to be adequately built into the IUI SOP (T99). A comprehensive IUI traceability checklist was provided before the inspection and audit of five sets of patient records provided evidence that this had been thoroughly completed in all cases (T102).The PR reported that only traceable items are used at the centre and this was evidenced through a random sample of consumables (T101).

Premises and facilities (guidance note 25):
All activities at the centre are carried out on licensed premises that appear fit for the intended purpose (T17). The centre is somewhat restricted in size due to it's location within (and sharing some facilities with) the gynaecology outpatient department but centre staff appear able to provide treatment to patients with an acceptable level of efficiency and privacy.

Equipment and materials (guidance note 26):
A random check of stored consumables during the inspection indicated that none had expired and all were stored in such a way that their expiry date and batch number could be identified.

An equipment maintenance log and SOP that facilitates the service and repair of key equipment as per the manufacturer's specifications was seen during the inspection.

A microscope was randomly checked and was found to have been serviced within timeframes specified in the log (T26).

What the centre does well.

What they could do better.

Procurement and processing (guidance note 15):
A programme for validation was reported by the PR to have been commenced. Evidence during the inspection suggested that to date no equipment had been validated and the only critical process to have been commenced was IUI, this being in the beginning stages of the validation process (T72). This was discussed with the PR and QM who expressed willingness to commence and complete this programme but reported that they had both been unable to negotiate to increase the time spent in their respective roles and this is inhibiting their ability to take on large projects. The QM requested advice regarding the implementation of a validation programme and expressed her intention to refer to the Association of Clinical Embryologists validation information and templates.

This was an issue raised at the last inspection on 15 February 2009.

Witnessing (guidance note 18):
During the inspection five sets of patient records were audited for compliance with witnessing requirements. Two sets were found not to include a space to record the times of all witnessing steps. This was discussed with the PR who confirmed that this has previously been recognised as a potential risk and the form recently updated to include the times for all steps. Three sets of patient records were seen for which treatment had commenced after the implementation of the new documentation and space to record each time was included. Of the five sets of records audited the sperm preparation witnessing step appeared to have been omitted in one case (T71). This was discussed with the PR but as the staff member in question was on long term leave the reason for this omission

could not be obtained.

The witnessing form seen at inspection did not include a treatment date which would provide evidence that the checks included had taken place at the time of the relevant process or procedure (T71). During the inspection the PR and QM agreed that this date would be added to the documentation.

Third party agreements (guidance note 24):
While at inspection it was observed that all Third Party Agreements are now in place (T111), these did not appear to contain sufficient detail as to the terms of the relationship and responsibilities between the parties and the protocols to be followed to meet the required performance specification (T113/T114). This was discussed with the PR who expressed willingness to update the agreements to include more detail.

Premises and Facilities: (guidance note 25):
The sperm processing room and hood have been assessed once for air quality and were found to be compliant with the requirements of T20, evidence of these results were provided by the QM during the inspection. However, this process has not been validated and the PR was unable to provide justification for opting not to test for fluctuations when the monitoring programme was commenced or for the choice to monitor air quality at annual intervals. (T72).

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

Evidence of how the centre demonstrates compliance with this principle

Person responsible (guidance note 1):
Dr Sherriff has completed the HFEA PR Entry Programme (T8). Information provided before and during the inspection and an interview conducted on the day confirm that she has a clear understanding of the responsibilities outlined in T9 of the HFEA Code of Practice and demonstrated a positive approach to developing and improving services provided by the centre.

Staff (guidance note 2):
The centre has a small nursing, medical and management team that appeared functional and cohesive. A clear organisational chart was provided before the inspection (T11) and analysis of staff professional development files during the inspection confirmed that they are appropriately qualified and competent for the tasks they perform (T12.)

What the centre does well.

What they could do better.

Staff (guidance note 2):
Both the PR and QM expressed that they are increasingly challenged by the limitations of the time allocated to their roles and have both attempted previously to expand them within the Trust structure. They reported that large projects like validation have repeatedly been postponed in the past due to the lack of time, within their limited roles to dedicate to them (T12).

While staff appeared to be qualified to perform designated tasks at the centre records of ongoing evaluation or review of their key competencies were incomplete. The professional development folders of the most senior and the most recently employed nurses were provided at inspection and while one nurse had been assessed for IUI and scanning and the other for consenting, other key competencies including witnessing, sperm preparation and emergency procedures did not appear to have been assessed at regular intervals (T12/T15).

This was an issue raised at the last inspection on 15 February 2009.

▶ Report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11).

Evidence of how the centre demonstrates compliance with this principle

Incidents (guidance note 27):
The centre has a low reporting rate (one incident since 15 February 2009) consistent with the provision of less than ten cycles in the past year. The QM described an incident reporting and management SOP (T118) and was able to verbalise the HFEA requirements regarding timeframes for reporting and investigating adverse incidents.

Complaints (guidance note 28):
The HFEA has not received any complaints regarding this centre since the last inspection on 15 February 2009. The QM described a complaints management SOP and provided evidence that complaints reported to the centre were investigated and resolved in line with it (G28).

What the centre does well.

What they could do better.

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

NB: These themes are not directly relevant to an IUI centre providing partner only services to NHS patients.

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:

- There were no specific areas of concern with regard to the "Patient Experience" identified before the inspection.

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1).
Evidence of how the centre demonstrates compliance with this principle **Fair treatment (guidance note 29):** The centre operates within the Epsom and St Helier NHS Trust and is therefore guided by the Trust wide Equal Opportunities and Managing Diversity Policy (2008). **Counselling (guidance note 3):** Although it is not a mandatory requirement the centre offers counselling to all IUI patients.
What the centre does well.
What they could do better.
▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2).
Evidence of how the centre demonstrates compliance with this principle A tour of the centre confirmed that patients are provided with an acceptable level of privacy and comfort within the limited size of the facilities. An alternative waiting area is available when required and all treatment rooms were seen to have curtains to protect from opening doors and obscured windows where necessary (G25.7). Before the inspection a copy of an SOP guiding the use of chaperones for intimate examinations was provided. The use of a chaperone is mandatory if the clinician/nurse is of opposite gender to the patient in line with Epsom and St Helier Trust Policy. **Confidentiality (guidance note 30):** Inspection of the centre and discussion with the PR and QM confirmed that records at the centre are stored in an appropriately secure environment and there is an SOP in place to ensue that information is only disclosed in circumstances permitted by law. The PR confirmed that she has personally visited the site where the counsellor stores records and is satisfied that they are appropriately secure. (T43).
What the centre does well.

What they could do better.

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

Evidence of how the centre demonstrates compliance with this principle

Patient information (guidance note 4):
Before the inspection patient information sheets were provided which covered:

- Ovulation induction and/or Intrauterine insemination.
- OHSS.
- Information on infertility websites.
- Self injecting.
- Counselling and emotional support
- Chaperoning during intimate examinations.
- Welfare of the child.
- Information following IUI treatment.
- Information for the production of semen samples for IUI
- HIV and Hepatitis screening (T58).

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

What the centre does well.

What they could do better.

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

Evidence of how the centre demonstrates compliance with this principle

Consenting (guidance note 5):
The centre has an SOP in place for the taking of effective consent (G5.3) and audit of the consent forms in five sets of patient records found no discrepancies (T57/G5.1). Discussion with the PR and QM confirmed that patients are provided with appropriate information before signing consent as recommended in G5.4. (See also guidance note 4 above).

What the centre does well.

What they could do better.

4. Good governance and record keeping

Focus

- **Where gametes or embryos are used complete and accurate information should be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers
- **Ensuring gametes and embryos are only stored in accordance with effective consent and within the statutory timeframe**
- **Ensuring identifying information is only disclosed in accordance with consent**
- **Inspection theme 2010 - 2012** – for this period, this should include the following:
  - Patient consent to the disclosure of information, held on the HFEA register, for use in research
  - Consent issues in relation to the storage of embryos (including cooling off period)
- **Areas of concern** – The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.
  - There were no specific areas of concern with regard to the "Good Governance and Record Keeping" identified before the inspection.

▶ Maintain accurate records and information about all licensed activities (Principle 10).
Evidence of how the centre demonstrates compliance with this principle **Records (guidance note 31):** The centre has an established document control procedure (T34) and all documents provided to the HFEA were seen to include identifiers and identification information as recommended by G31.4.
What the centre does well.
What they could do better. **Records (guidance note 31):** While all documents provided to the HFEA before the inspection and observed on the day were noted to be within their document control review dates, the period for review in most cases appeared to be two years rather than annually, as recommended by G31.6.
▶ 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

What the centre does well.
What they could do better.

5. Changes / improvements since the last inspection on 15 February 2009

Breach noted at previous inspection 15 January 2009	Action required	Changes noted at inspection 14 January 2010
The centre does not have a documented third party agreement with Hunter Scientific, suppliers of their centrifuge.	The PR should obtain and maintain third party agreements with suppliers of all external products that have the potential to influence the quality and safety of gametes processed and/or procured at the centre in compliance with standard licence condition A.5.1.	At inspection it was observed that all Third Party Agreements are now in place.
Sperm processing currently takes place in a flow hood cabinet in the same room that inseminations are performed. There has been no previous testing of air quality, within the hood or in the surrounding room. The room opens directly onto a corridor that is at times busy with pedestrian traffic. Temperature is controlled with an air conditioning unit vented to the exterior of the building.	The failure to monitor air quality is a breach of standard licence condition A.10.19. The PR should arrange for the testing of air quality in the area where sperm is being processed, document a plan for the ongoing maintenance and monitoring of air quality and act upon the results of testing in order to ensure that sperm is being processed in an environment compliant with the requirement of standard licence condition A.10.19.	A programme for air quality monitoring has now been implemented and air quality has been assessed as compliant once. During the inspection it was discussed with the Quality manager (QM) and PR that validation of the air quality process is required and should include justification for the proposed annual interval for testing.
At inspection several items were observed to have passed the manufacturers recommended expiry date and other items were stored in such a way that their expiry date and batch number could not be identified. For example sperm tubes from different batches are stored loose in a drawer out of their original	This is a breach of CoP S.6.4.1.The PR should ensure that all equipment and materials (including disposables, reagents, calibration and control materials) shall meet the requirements of the relevant EU Directives, 93/42/EC Medical Devices and 98/79/EC In vitro Diagnostic Medical Devices guidelines.	A random check of stored consumables during the inspection indicated that none had expired and all were stored in such a way that their expiry date and batch number could be identified.

boxes.	This should include storing materials in such a way that staff can be assured of compliance with CoP S.6.4.1 before use.	
At inspection a service/repair log was provided by the Quality Manager (QM) that documented items of equipment that had not been serviced within the timeframes specified by the manufacturer or supplier.	This is a breach of CoP S.6.4.2(c). The PR should assess which items of equipment have not been serviced as recommended by the manufacturer and take steps to ensure that servicing takes place and results are acted upon.	An equipment maintenance log and SOP that facilitates the service and repair of key equipment as per the manufacturer's specifications was seen during the inspection. A microscope was randomly checked and was found to have been serviced within timeframes specified in the log.
While it is reported by the QM that all staff are subject to regular assessment of their competence and take part in continuous education and professional development but in most cases, this is not documented. This includes nurse IUI, scanning and sperm preparation training.	This is a breach of CoP A.10.11. It is recommended that the PR take steps to ensure that the competence of each person to perform designated activities is evaluated at intervals specified in the Quality Management System. Re-training should be undertaken when required and competence reviews and assessments documented and regularly updated The PR should ensure that any training programme ensures and documents that each individual: has demonstrated confidence in the performance of their designed tasks in compliance with the requirements of A.10.11.	A programme for the assessment of staff competence was seen to have been commenced but had not been completed for all staff interviewed at the inspection. One senior nurse was able to provide evidence that she had been assessed as competent for scanning, IUI and sperm preparation but a second nurse could only provide evidence of he competence to take patient consent. There was no evidence that medical staff had been assessed as competent to perform any key skills or activities.
The centre has not participated in inter-centre or inter-laboratory comparisons.	The centre should participate in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality assessment schemes) and by other	The PR confirmed that the centre now participates in NEQAS.

	external bodies. The results of these comparisons should be evaluated and documented and relevant findings be used to improve the service in compliance with the requirements of CoP S.9.2.6 and S.4.2.9 (e).	
The centre was found to have no traceability procedures. Materials and consumables are not traced and in some instances were stored in such a way that they could not be matched with their batch numbers and/or expiry dates. For example sperm tubes from different batches are stored loose in a drawer out of their original boxes.	The Centre should establish documented procedures for the management of equipment and materials that include traceability of any materials that come into contact with gametes or embryos in compliance with CoP S.6.4.3 (d)	An SOP for traceability was observed and evidence of thorough traceability was seen in five sets of patient records.
The centre was found to have no documented procedures for validation of key equipment and processes and no validation has taken place to date.	This is a breach of CoP S.7.8.3. The PR should ensure that procedures are validated in accordance with professional guidelines, based on previously published studies or retrospective evaluation of the centre's own data.	A programme for validation was reported by the PR to have been commenced. Evidence during the inspection suggested that to date no equipment had been validated and the only process to have been started was IUI, this being in the beginning stages of the validation process.

Non-Compliance

Area for improvement	**Action required**	
While verbal accounts of witnessing by staff during inspection suggest that procedures are compliant with CoP S.7.8.15 this is not reflected in the documentation which is designed in such a way that there is no obvious space for staff to record the date and time of each witnessing	This is a breach of CoP G.13.1.1(c) The PR should arrange for the review of the witnessing documentation in consideration of the HFEA guidance.	During the inspection five sets of patient records were audited for compliance with witnessing requirements. Two sets were found not to include a space to record the times of all witnessing steps. This was discussed with the PR who confirmed that this has been recognised as a potential risk and the form

step.		recently updated to include the times for all steps. Three sets of patient records were seen for which treatment had commenced after the implementation of the new documentation and space to record each time was included. Of the five sets of records audited the sperm preparation witnessing step appeared to have been omitted in one case (T71). The witnessing form seen at inspection did not include a treatment date which would provide evidence that the checks included had taken place at the time of the relevant process or procedure (T71).

Assessment of compliance with statutory requirements

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

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

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

Licence Condition	Assessment
Licensing	
T1	Fully compliant
T2	Fully compliant
T3	Fully compliant
T4	Fully compliant
T5	Fully complaint
T6	Fully compliant
T7	NA
Person Responsible	
T8	Fully compliant

T9	Fully compliant
T10	NA
Staff	
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	NA
T20	Fully compliant
T21	NA
Licence Condition	**Assessment**
Equipment and Materials	
T22	Fully compliant
T23	Fully compliant
T24	Partially compliant
T25	Not compliant
T26	Fully compliant
T27	x
T28	Partially compliant
T29	Not compliant
T30	Fully compliant
T31	X
Quality Management	
T32	Fully compliant
T33	Fully compliant
T34	Fully compliant
T35	Not compliant
T36	Fully compliant
Records and Information	
T37	Fully compliant
T38	Fully compliant
T39	Fully compliant
T40	x
T41	Fully compliant
T42	NA
Data protection and Confidentiality	
T43	Fully compliant
T44	Fully compliant
T45	x
Patient Records	
T46	Fully compliant
T47	Fully compliant
T48	x
Patient Selection Criteria and Laboratory Tests	
T49	x
T50	NA

T51	NA
Donor Selection Criteria and Laboratory Tests	
T52	NA
T53	NA
T54	NA
T55	NA
Licence Condition	**Assessment**
Welfare of the Child, Provision of Information, Counselling and Consent	
T56	Fully compliant
T57	Fully compliant
T58	Fully compliant
T59	X
T60	NA
T61	NA
T62	NA
T63	NA
T64	NA
T65	NA
Procurement of Gametes and Embryos	
T66	NA
T67	NA
T68	X
T69	NA
T70	Fully compliant
Processing and Use of Gametes and Embryos	
T71	Not compliant
T72	Not compliant
T73	Not compliant
T74	NA
Storage of Gametes and Embryos	
T75	NA
T76	NA
T77	NA
T78	NA
T79	NA
T80	NA
T81	NA
T82	NA
T83	NA
T84	NA
T85	NA
Embryo testing	
T86	NA
T87	NA
T88	NA
T89	NA
T90	NA
T91	NA
Licence Condition	**Assessment**
Use of Embryos in Training Staff	

T92	NA
T93	NA
T94	NA
T96	NA
T97	NA
T98	NA
Licence Condition	**Assessment**
Traceability and Coding	
T99	Fully compliant
T100	Fully compliant
T101	Fully compliant
T102	Fully compliant
T103	x
T104	x
Import, Export and Transportation / Distribution of Gametes and Embryos	
T105	NA
T106	NA
T107	NA
T108	NA
Receipt of gametes and/or embryos	
T109	NA
T110	NA
Third Party Agreements	
T111	Fully compliant
T112	x
T113	Not compliant
T114	Not compliant
T115	Fully compliant
T116	Fully compliant
T117	NA
Identification, investigation, reporting, recording and notification of serious adverse events and reactions	
T118	Fully compliant
T119	Fully compliant
T120	NA
T121	NA
T122	NA

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

HFEA Directions	
HFEA Directions	**Assessment**
0001 Gamete and embryo donation	NA
0003 multiple births	NA
0005 Collecting and recording information for the HFEA	NA
0006 Import and export of gametes and embryos	NA
0007 Consent	Fully compliant
0008 Form and content of applications	Fully compliant

0009 Keeping gametes and embryos in the course of carriage between premises	NA
0010 Satellite and transport IVF	Fully compliant
0011 Reporting adverse incidents and near misses	Fully compliant
0012 Time periods for retention of records	Fully compliant

Areas of practice that require the attention of the Person Responsible

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

Critical area of non compliance

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review

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	Ref	Action required	Timescale for action	PR Response	Executive Review
Procurement and processing (guidance note 15): A programme for validation was reported by the PR to have been commenced. Evidence during the inspection suggested that to date no equipment had been validated and the only critical process to have been commenced was IUI, this being in the beginning stages of the validation process (T72). This was discussed with the PR and QM who expressed willingness to commence and complete this programme but reported that they had both been unable to negotiate to increase the time spent in their respective roles and this is inhibiting their ability to take on large projects. The QM requested advice regarding the implementation of a validation programme and expressed her intention to refer to the Association of Clinical Embryologists validation information and templates. **This was an issue raised at the last inspection on 15 February 2009.**	T72	The PR should implement a programme to validate all critical equipment and processes at the centre. The PR should submit to the HFEA a quarterly report on the progress of this programme until it is complete.	To commence immediately.	ACE templates downloaded and ready for use, QM visiting other centres and has sort advice from other centres. Attending BFS Quality management study day 11/06/10. Date to set master plan 01/04/10. Agree to submit to HFEA quarterly report as requested.	
Quality management The centre does not have any quality indicators to measure the required standards of quality and safety of licensed activities as required by T35.	T35	The PR should develop quality indicators to measure the required standards of quality and safety of licenced activities.	To be completed by 14 May 2010		

Witnessing (guidance note 18): During the inspection five sets of patient records were audited for compliance with witnessing requirements. Two sets were found not to include a space to record the times of all witnessing steps. This was discussed with the PR who confirmed that this has previously been recognised as a potential risk and the form recently updated to include the times for all steps. Three sets of patient records were seen for which treatment had commenced after the implementation of the new documentation and space to record each time was included. Of the five sets of records audited the sperm preparation witnessing step appeared to have been omitted in one case (T71). This was discussed with the PR but as the staff member in question was on long term leave a reason for the omission could not be obtained. The form seen at inspection did not include a treatment date which would provide evidence that the checks included had taken place at the time of the relevant process or procedure (T71). During the inspection the PR and QM agreed that this date would be added to the documentation.	T71	The PR should carry out an audit of witnessing documentation within patient records with the aim of identifying any further discrepancies. She should use the findings of this audit to identify any areas where the SOP or staff training could be amended to minimise the risk of recurrence. The results of this audit should be submitted to the HFEA.	To be completed by 14 May 2010	KPIs from SAQ established. Monitoring system in draft form. Audit of all IUI cycles in 2009 performed in Dec 09 with further audit planned for July 10. Result of Dec 09 audit confirms current SOPs are appropriate. Since inspection each IUI form now requires a date this has now been completed	
Third party agreements (guidance note 24): While at inspection it was observed that all Third Party Agreements are now in place (T111), these did not appear to contain sufficient detail as to the terms of the relationship and responsibilities between the parties and the protocols to be followed to meet the required performance specification (T113/T114). This was discussed with the PR who expressed willingness to update	T111 T113 T114	The PR should ensure that all third party agreements contain such detail as required by T113 and T114.	By 14 January 2011	A third party mandatory information form has now been devised and all TPA are to be audited in order to comply with HFEA	

the agreements to include more detail.				regulations.	
Premises and Facilities: (guidance note 25): The sperm processing room and hood have been assessed for air quality once and was found to be compliant with the requirements of T20, evidence of these results was provided by the QM during the inspection. However, this process has not been validated and the PR was unable to provide justification for opting not to test for fluctuations when the monitoring programme was commenced or for the choice to monitor air quality at annual intervals. (T72).	T72	The PR should facilitate the validation of the air quality monitoring programme including the interval for repeat monitoring.	By 14 May 2010	Next test 23/04/10 Advice sort from other units and air quality testing providers for validation.	
Staff (guidance note 2): While staff appeared to be qualified to perform designated tasks at the centre records of ongoing evaluation or review of their key competencies were incomplete. The professional development folders of the most senior and the most recently employed nurses were provided at inspection and while one nurse had been assessed for IUI and scanning and the other for consenting, other key competencies including witnessing, sperm preparation and emergency procedures did not appear to have been assessed at regular intervals (T12/T15). **This was an issue raised at the last inspection on 15 February 2009.**	T12 T15	The PR should commence a programme to review and assess the competence of all staff at the centre.	By 14 May 2010	Programme already commenced. Copy of Trust consultant appraisal documentation and certificates to be kept by the QM. Timetable established to review and assess competencies in key areas	

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	Ref	Action required	Timescale for action	PR Response	Executive Review
Records (guidance note 31): While all documents provided to the HFEA before the inspection and observed on the day were noted to be within their document control review dates, the period for review in most cases appeared to be two years rather than annually, as recommended by G31.6.	G31.6	The PR should consider amending the centre's document control procedure to include annual review of all documents.	By 14 May 2010.	Periods of review is infact annually as recommended and is recorded electronically following inspection 'last review date' will now be added to each document footer.	

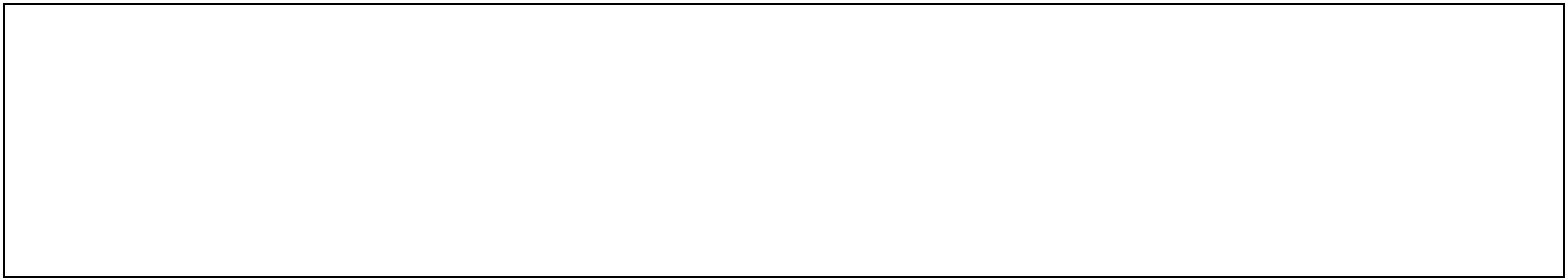
Additional information from the Person Responsible

Minor Corrections

Dr Sherriff has been registered with the GMC since 1981
The title for the licence holder is Dr not Mr Rim Elrifai
The unit undertook 256 cycles of transport IVF in 2009.

Copy of our action plan is attached.

These factual errors have been amended within the body of the report.



HFEA Executive Licensing Panel Meeting

23 March 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 1

Epsom & St Helier NHS Trust (0259) Renewal Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Hannah Darby – 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 Committee:

- papers for Licence Committee (52 pages)
- no papers were tabled for this item

The Committee also had before it:

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

1. The Panel considered the papers which included a renewal inspection report and application for the renewal of licence, as well as the previous licence committee minutes.

2. The Panel noted that the centre's inspection took place on 14 January 2010 and lasted for five hours.

3. The Panel noted the centre provides intrauterine insemination (IUI) treatment to NHS patients and has been licensed since 05 July 2007.

4. The Panel noted that the centre operates from premises within the Women's Health Services Department of St Helier Hospital and shares some facilities with the Gynaecology outpatients department.

5. The Panel noted that the Person Responsible Dr Elizabeth Sherriff has been in this post since inception and has completed her HFEA Person Responsible Entry Programme (PREP).

6. In addition the Panel noted that the Person Responsible is registered with the General Medical Council since1981 and has been a member of the Royal College of Obstetricians and Gynaecologists since 1997.

7. The Panel noted that a new Licence Holder; Dr Rim Elrifai, was appointed on 16 December 2009.

8. The Panel noted that the centre provides transport services for The Bridge (0070) and ACU Kings College (0109) centres, performing approximately 130 cycles of transport IVF per year.

9. The Panel noted the inspectorate's recommendation that the licence should continue without any additional conditions.

10. The Panel noted that the centre had submitted an action plan on page 29 of the report, and noted that the PR had already begun taking steps to address these outstanding issues. The Panel noted that some of these issues were also identified in the previous Licence Committee minutes, which had awarded a one year licence.

11. The Panel noted that the inspectorate has asked for quarterly reports from the centre addressing the outstanding issues.

12. The Panel noted that there are no issues regarding the character, qualifications or experience of the PR or her ability to discharge the necessary duties under section 17 of the HFE Act 1990 (as amended). On the basis of the information provided, the Panel agreed that it was satisfied of the suitability of the Person Responsible and the premises.

13. The Panel agreed that it was satisfied it had sufficient and satisfactory information on which to make a determination, and were in receipt of a complete application and the relevant fee had been paid.

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

14. The Panel noted the inspectorate's recommendation to renew the licence for a period of 4 years. However, the Panel decided that the significance of the areas for improvement identified in the report in combination with matters still outstanding from the previous licence committee minutes meant that the centre should be licensed for 2 years with no additional conditions. As the previous licence was for one year, the Panel considered a two year licence also reflected the improvements made, and gave due recognition to the commitments

provided, by the centre. The Panel endorsed the inspectorate's recommendations highlighted within the report.

Signed..... Date.....

Peter Thompson (Chair)