Interim Inspection Report

The Royal Surrey County Hospital
0159

Date of Inspection: 3rd October 2007
Date of Licence Committee: 17th December 2007

CENTRE DETAILS

Centre Address	Department of Cytopathology, Royal Surrey County Hospital, Egerton Road Guildford Surrey, GU2 7XX
Telephone Number	01483 571 122
Type of Inspection	Interim
Person Responsible	Mrs Barbara Sayer
Nominal Licensee	Dr Stephen Whitaker
Licence Number	L0159/9/a
Inspector(s)	Ms Allison Cummings
	Dr Andrew Leonard
Licence expiry date	31st March 2011

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About the Inspection:
This inspection visit was carried out on Wednesday 3rd October and lasted for approximately 7 hours. The report covers the pre-inspection analysis, the visit and information received between January 2006 and September 2007.

The purpose of the inspection is to ensure that centres are providing a quality service for patients in compliance with the HF&E Act 1990, Code of Practice and to ensure that centres are working towards compliance with the EU Tissue and Cells Directive 2004/23/EC. Inspections are always carried out when a licence is due for renewal although other visits can be made in between.

The report summarises the findings of the 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 Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:
How well the centre is organised
The quality of the service for patients and donors
The premises and equipment
Information provided to patients and to the HFEA
The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:
No Improvements Required – given to centres where there are no Code of Practice, legal requirements, recommendations or conditions that need to be imposed.
Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.
Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

The report includes a response form for the Person Responsible to complete following the inspection.

The HFEA welcomes comments from patients and donors, past and present, on the quality of the service received. A questionnaire for patients can be found on the HFEA website www.hfea.gov.uk .

Brief Description of the Centre and Person Responsible

The centre is a part of the Royal Surrey County Hospital operating within the NHS Trust. It is situated within the Department of Cytology and Histopathology. The centre has been active since 1994 and provides a sperm storage service for both private and NHS patients. The most common reason for storing sperm at the centre is because of possible fertility compromise due to forthcoming urological surgical procedures or chemo/radiotherapy treatment.

The Person Responsible (PR) reported that plans to refurbish the Department of Cytology and Histopathology are slow moving and currently undecided at Trust level and higher. This has interfered with plans to implement the appropriate air quality.

The PR has other responsibilities besides that of PR. She reported that she is also the director of the training school at the hospital; the hospital based co-ordinator for the cervical screening programme and has clinical responsibility for all seminology. The nominal licensee could not be present on the day of inspection.

Activities of the Centre

The centre is licensed for storage only.

Summary for Licence Committee

Some improvements are required in all areas except for premises and equipment, for which the inspectorate considered that significant requirements are needed.

Please note that some breaches and non-compliance raised in the report are due to the implementation of the EUTD in July 2007. The weight to be attached to these reported breaches is a matter for the Licence Committee to determine.

The inspectorate recommends the continuation of the centre's licence.

Risk Assessment

Prior to the inspection, the centre scored a green risk rating of 0%. Following this inspection, the risk score increased to 18% although the score is still considered in the low range.

Upon assessment of the centre's application to vary their licence with the implementation of the EUTD, the centre scored a low risk rating of 10%.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	✓	

Evaluations from the inspection

Topic	No Improvements required	Some Improvement required	Significant Improvement required
1. Organisation		✓	
2. Quality of the service		✓	
3. Premises and Equipment			✓
4. Information		✓	
5. Laboratory and clinical processes		✓	

Breaches of the Act or Code of Practice

Breach	Action required	Time scale
Organisation 1. All-staff meetings occur infrequently therefore records are not kept of these meetings and made available to staff.	In accordance with S.6.2.13, the centre shall establish an effective means for communicating to staff. Records are to be kept of meetings and made available to staff.	From the next centre meeting.
2. The CV provided to the inspectorate for the proposed staff member to take on a second NHS nurse counsellor role does not appear to have formal qualifications, training, CPD or experience in the field.	The PR should ensure that the person appointed for this role is equipped with the training, continuing education and professional development as outlined in S.6.2.7 and S.6.2.11.	Before the staff member is appointed to the role.
3. Agreements with third parties who supply products or services that have potential to affect the quality and safety of gametes or embryos have not been formalised. This is a breach of Standard 4.2.10.	The PR should ensure that: (a) Third parties are identified and a list of these submitted to the HFEA. (b) Agreements with third parties are formalised.	(a) 30 November 2007 (b) 28 February 2008
Quality of Service 4. A counselling protocol was provided on the day of inspection in place of a counselling audit which had been requested in the pre-inspection questionnaire and as per S.4.2.9(d).	An audit of the counselling service should be supplied to the HFEA.	30 November 2007
Premises 5. The inspectorate found that the laboratory is not locked during the day (even when it is not occupied) therefore potentially compromising the security of gametes stored in the laboratory.	In accordance with S.6.3.8, gametes should be stored in a designated security area with controlled access.	Immediately.

6. The air quality in the laboratory has not been tested.	The air quality will be tested and monitored to make sure it complies with Standard licence condition A.10.19	Initial test of air quality by 31December 2007.
7. The microscopes were lasted tested for their electrical safety in 2002.	In accordance with S.6.3.6, the microscopes will be appropriately maintained.	31 December 2007.
Clinical and Laboratory Practice 8. Two patient sperm samples mentioned in the laboratory audit report were exported to other countries without following General Direction 1991/8.	The PR should ensure that the information listed in the Directions is provided to the HFEA as a matter of urgency. For all future exports, the Directions should be followed.	31 December 2007.
9. Not all products that come into contact with gametes and embryos are traceable.	In accordance with S.7.3.1, traceability should be extended to plasticware and other consumables that impact on the quality of the sperm.	30 November 2007.
10. The training and CPD records for the NHS nurse counsellor were deemed inadequate.	The nurse counsellor should be supported by her employer to meet the level of education and CPD as set out in S.6.2.7 and S.6.2.11.	This will be reviewed at the next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
Organisation 11. A complaints register has not been established.	In accordance with G.11.3.4, records should be kept of all complaints and their investigations, together with the corrective actions.	Immediately.
Premises and equipment 12. Since the last inspection the centre has acquired two more holding dewars and a	The inspectorate recommends that the PR risk assess this situation to	30 November 2007

small dewar in which hepatitis C positive samples are held; all of which were found not to be connected to an alarm.	determine whether control measures are required.	
<u>Clinical and laboratory practice</u> 13. The form signed by a patient when a sample is produced does not explicitly ask for declaration that the sperm has been produced by that man and that the sample has not been tampered with.	In accordance with G.2.3.1, the centre should review the existing form to include these requirements.	31 December 2007.
14. A number of witnessing steps were seen to be omitted, contrary to the Code of Practice, 7th Edition, G13	The witnessing practice should be reviewed with respect to the witnessing guidance outlined in G.13, when the revised version of the Code of Practice, 7th edition is released on the 30 November 2007.	The reviewed witnessing procedure should be in place by 31 December 2007.

Recommendations	**Time scale**
15. The PR re-submits a detailed project plan outlining current areas of non-compliance and action plans for their correction with timescales.	This should be submitted to the HFEA by 31 December 2007.
16. The patient feedback questionnaire should be reviewed to ensure it captures the user's perception as to whether all aspects of the HFEA licensed service meet their needs and requirements, as per S.9.2.1.	31 January 2008.
17. The 'cryopreservation of semen preparation' protocol should be updated to incorporate the technical steps that were discussed with the inspectorate.	31 December 2007.

Proposed licence variations

None.

Changes/ improvements since last inspection

Recommendation	Action taken
It is important that the centre has low level-nitrogen alarms for all the storage dewars, and also an autodial facility for every dewar. Until the alarms are fitted an on call rota should be implemented and a copy be made available to HFEA.	For those dewars that were acquired at the time of the renewal inspection in 2005, a local alarm system and auto-dialler facility have been installed. A protocol for responding to ineffective dewars, including an on-call rota, was seen by the inspectorate.
The oxygen alarm outside the laboratory needs to be repaired and when repairs are completed, the completion report should be submitted to the HFEA.	The biomedical scientist confirmed this has been repaired. It was seen to be in operation on the day of inspection.
The consent forms must be completed carefully and routinely with the help of the nurse so that no signatures are missing and incomplete forms are not filed.	A number of errors were also noted on the interim inspection. The PR noted these and plans to carry out another internal audit if necessary.
Patient information leaflets do not fully comply with all the requirements of the Code of Practice. A small number of omissions were discussed and the centre should submit the revised information leaflet to the HFEA.	These were submitted and reviewed for compliance by the executive. No further issues have been noted.
The nominal licensee, also a consultant oncologist, was interviewed and it was recommended to him that he visits the laboratory at regular intervals for holding / attending departmental meetings.	Evidence of meetings held were not seen by the inspectorate. The nominal licensee was not present on the day of inspection.

Additional licence conditions and actions taken by centre since last inspection

C	
A	**Complied Y/N**
C	
A	**Complied Y/N**
C	
A	**Complied Y/N**

Report of Inspection findings

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection
Evidence is drawn from:

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident management
- Contingency arrangements
- Business planning
- Clinical governance
- Payment of treatment fees

Areas of firm compliance
The centre appeared to be well organised including the referral pathway for patients. For the small amount of HFEA licensed activity that is carried out on the premises, there appeared to be adequate staff to do the job.
Areas for improvement
The Person Responsible Entry Programme, a study package to ensure suitability of the PR, was due for submission to the HFEA on the 30th April 2007. This was received by the HFEA on the 23rd August 2007, prior to the inspection. The PR explained that due to her multiple roles within the hospital, she found it difficult to complete this within the deadline. The PR's responses were discussed on the day of the inspection and appeared to be suitable. It was found that all-staff meetings occurred infrequently however the PR stated that most communication occurred via email. When this issue was raised by the inspectorate, the PR was concerned that some members would not attend due to work commitments in other departments of the hospital. The inspectorate recommended that regular meetings should be held anyway and the minutes should be kept and made available to staff. The centre plans to recruit another nurse counsellor for NHS patients. The inspectorate reviewed the curriculum vitae of the proposed candidate to take on this role. It was noted that although the nurse's professional qualifications and work history were clinically based, counselling qualifications were not apparent. The PR is reminded that they are responsible for ensuring the qualifications and experience of those carrying out HFEA licensed activities are suited to the work they are carrying out at the centre. The PR should also ensure that the person appointed for this role is equipped with the training, continuing education and professional development they need to effectively fulfil the role. The centre's project plan for the implementation of the EUTCD was discussed with the PR. The project plan was limited because at the time of submission, it was unknown what the

future plans were for the centre. Now that there are definite plans to refurbish the existing premises, the inspectorate recommend the PR re-submits a detailed project plan outlining current areas of non-compliance and action plans for their correction with timescales.

A third party agreement was seen for the supply of liquid nitrogen. Agreements should be extended to all third parties who supply products that have the potential to affect the quality and safety of gametes. To do this effectively, the PR should review their processes to identify where third party agreements are required. As this is now a requirement, the PR should ensure these have been formalised as soon as possible.

Executive recommendations for Licence Committee
The issues raised above, in the opinion of the inspector, constitute breaches of the following sections of the Code of Practice and guidance: • S.6.2.13 regarding meetings and communication. • S.6.2.7 and S.6.2.11 regarding training, continuing education and professional development. • S.4.2.10 regarding third party agreements.
Areas not covered on this inspection
Risk management; incident management; contingency arrangements; payment of treatment fees.

Evaluation
Some improvement required.

2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection:

- Live birth rates
- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services
- Donor selection
- Egg sharing and surrogacy
- Protection of children arrangements (for patients under 18yrs)

Areas of firm compliance
Interviews held with key staff on the day were indicative that the staff were dedicated to the service. The counselling facilities for both private and NHS patients were deemed adequate by the inspectorate. The notes held by each counsellor were seen to be held under lock and key with restricted access. The NHS counsellor was formally interviewed on the day of the inspection. The complexities of her role were discussed including the limited time to counsel patients before starting treatment such as chemotherapy. Elements of audit were seen to be in place which should lead to improvements in the quality management system; these include a vertical process audit with provision for updating SOP gaps highlighted and an internal quality assurance protocol, the results of which were seen by the inspectorate. Additionally, the biomedical scientist stated they participate in inter-laboratory comparisons through their participation in the external quality assessment schemes administered by UK NEQAS.
Areas for improvement
The PR stated that few complaints were received and that records of them were kept in the patient's records. A complaints register was therefore not available for inspection; it was recommended a register be established for this purpose. The assessment of user satisfaction is conducted through a patient feedback questionnaire that was developed for the Department of Cytology and Histopathology as a whole rather than being specific to the licensed storage centre. The inspectorate recommended the questionnaire is reviewed to ensure it captures the user's perception as to whether all aspects of the service meet their needs and requirements, as per S.9.2.1. A counselling protocol was provided in place of a counselling audit on the day of inspection. A verbal report from the NHS counsellor suggested that approximately 36 sessions have been provided since 1st September 2006. She stated this does not take into account the sessions

provided by the private counsellor. The PR should supply an audit of the service as requested in the pre-inspection questionnaire, demonstrating they meet S.4.2.9(d) which requires internal audit of all elements of the QMS including the assisted conception processes.

Executive recommendations for Licence Committee
The issues raised above, in the opinion of the inspector, constitute breaches and non-compliance of the following sections of the Code of Practice and guidance: • G.11.3.4 regarding a complaint register. • S.4.2.9(d) regarding internal audit of assisted conception services.

Areas not covered on this inspection
Live birth rates, 'Welfare of the Child' arrangements; choice of treatments; donor selection; egg sharing and surrogacy. These areas are not applicable to this centre.

Evaluation
Some improvements required.

3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection:

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

Areas of firm compliance
The premises were seen to be clean and comfortable for patients. An inspector was shown the two sperm production rooms that were located in another wing of the hospital close to where the oncology service takes place. Although most men produce samples at home, the facilities on site were considered by the inspector to provide adequate privacy. The centre has responded positively to the outcome of the Licence Committee meeting in February 2006 through the installation of a local alarm system and an auto-dialler facility for the storage dewars. These were seen to be monitored on a computer system and the biomedical scientist reported that logs are reviewed on a weekly basis for unexplained variations from normal levels. On the day of inspection, an error message had been noted by the staff and it will be dealt with next week by the supplying company. The auto-dialler call out system appeared to be robust and an SOP was seen for this. A spare dewar was seen to be available for use in the event another dewar fails. A folder was seen to contain the most recent alerts although responses to these were not discussed in detail on the day of inspection.
Areas for improvement
The inspectorate found that the cryostore is not locked during the day, even when it is not occupied. It is potentially accessible to non-licensed staff and the general public as access to the building is not restricted. The biomedical scientist stated that not all cytologists and seminologists are on the licence, yet they all have access to the semen processing lab which is also the cryostore. The staff were reminded that gametes should be stored in a designated security area with controlled access. Since the last inspection, the centre has acquired two more holding dewars and a small dewar in which hepatitis C positive samples are held. These three dewars were found not to be connected to an alarm system. The biomedical scientist stated this was because the samples are held for no longer than three days in the holding dewars and the hepatitis C dewar contains one patient's samples only. This is not in accordance with CH (04) 03. The inspectorate recommended to the PR that if they decide not to act on this, their decision for this should be risk assessed. The dewars are stored in the same room where the processing of sperm takes place.

Ventilation to the room was seen to be provided by an open window only. The inspectorate were informed that that the window must be either left open at night to ensure ventilation, producing a security hazard to the stored sperm and the building itself, or closed to ensure security, but causing a potential asphyxiation hazard for staff in the morning. It was recommended that the method of ventilation be reviewed.

Additionally, the PR stated that the air quality has not yet been tested. The inspectorate noted that this is, in part, due to the lack of development of the refurbishment plan with which the air quality issue has become intertwined. The PR reported that a class II cabinet will be made available to them by another hospital. There are no plans for air quality monitoring although options were discussed, including the use of settle plates. The inspectorate re-iterated the importance of have the air quality in the laboratory tested and monitored.

Electrical safety testing on equipment was found to be not up to date. It was noted by the inspectorate that the microscopes were last tested in 2002. The health and safety hazards were highlighted by the inspectorate to the staff at the inspection feedback. The PR should ensure that equipment is maintained to minimise hazards to recipients and/or staff.

The centre equipment maintenance and servicing is all organised by the cytology unit manager. Maintenance logs are stored by him and were not available on the day of inspection as he was out of the office.

Executive recommendations for Licence Committee

The issues raised above, in the opinion of the inspector, constitute breaches and non-compliance of the following sections of the Code of Practice and guidance:

- S.6.3.8 regarding controlled access to ensure the security of gametes and embryos.
- Chair's Letter (04)03 outlining the expectation that all centres storing patients' gametes to have effective alarms and monitoring systems in place to ensure the safety of cryopreserved gametes.
- Standard licence condition A.10.19 regarding air quality.
- S.6.3.6 regarding the maintenance of equipment and the environment expected for processing gametes in the laboratory.

Areas not covered on this inspection

None.

Evaluation

Significant improvements required.

4. Information

Desired outcome: Information is relevant, clear and up to date for patients and the HFEA

Summary of findings from inspection:

- Information management
- Information to patients and donors
- Information to the HFEA registry and updates
- Consent
- Protocols
- Record keeping

Outcome of audit of records
Five records were randomly selected by the Inspectorate and reviewed for completeness. Of these, three had discrepancies: 1) In one set of patient records, the storage periods conflicted: the HFEA Male Storage (MS) consent form stated a 5 year storage request whilst the HFEA Male Treatment (MT) consent form stated a 10 year storage period. A HFEA Male Treatment (MT) form was not completed accurately in one patient record. 2) In one set of patient records, the HFEA 'consent to disclosure' form did not contain important identifying patient information, including the patient's hospital number and their date of birth. 3) In one set of patient records, the patient requested to store his samples for 30 years. The PR stated that the centre's storage policy is initially 10 years and that they would extend this if the patient wanted to, therefore they needed to contact the patient to seek consent to correct this in accordance with their policy. PR stated that an audit had recently been undertaken but that she would review the issues raised on the day of inspection and carry out another audit if necessary. The inspectorate recommended that the patient records where storage periods were seen to be conflicting, should be followed up with the patient.
Areas of firm compliance
Hard copy patient records were seen to be kept in locked cabinets within the PR's office. Standard Operating Procedures were seen for both semen disposal and the release of semen to another centre. These included the provision for witnessing although a record audit on witnessing was not performed on this inspection. In response to the last inspection, protocols for responding to dewar alarms (oxygen and nitrogen) were seen to be well written, and designed and displayed so that all relevant staff could sign to say that they had read it.
Areas for improvement
Adequate document control was apparent in many of the SOPs seen on the day of inspection and the biomedical scientist stated they were updating the remaining few to achieve compliance.

Review of the ‘cryopreservation of semen preparation’ protocol showed that it referenced witnessing steps only. The procedure should be updated to incorporate the technical steps, as discussed with the inspectorate.
Executive recommendations for Licence Committee
None.
Areas not covered on this inspection
Information to patients and donors; information to the HFEA registry and updates.

Evaluation
Some improvements required.

5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection:

- Assessment of patients and donors
- Safe handling systems
- Procedures in practice
- Laboratory processes and practice
- Clinical practice
- PGD/ PGS
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

Full time equivalent staff

GMC registered doctors	< 0.1
NMC registered nurses	< 0.1
HPC registered scientists	< 0.6
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	<0.1

Summary of laboratory audit
The centre had last performed a dewar audit on the 10th November 2006 in which all samples stored concurred with the information in the dewar record books and on the pink request cards for each patient stored in their patient records. The laboratory audit was provided prior to the inspection and stated that two patient samples were exported to other countries. On the day of inspection the PR was unsure if the HFEA General Directions on exports had been followed for these. The PR has since confirmed that General Direction 1991/8 has not been complied with and that she will provide the HFEA with the information as per the Directions. The inspector has suggested to the PR that she review the Directions as applicable to her centre.
Summary of spot check of stored material
No discrepancies were noted during the inspectorate's spot check of stored material. One patient's sperm samples were tracked from dewar to paperwork and two patient's sperm samples were tracked from paperwork to the dewars.
Areas of firm compliance
The laboratory is CPA accredited and is next due for inspection in March 2008. A sample of Continued Professional Development (CPD) and training records were reviewed by the inspectorate. The records were deemed appropriate for the scientific staff.

Areas for improvement

The centre's procurement and witnessing practices were reviewed in detail. They should be reviewed so that they meet the requirements of the Code of Practice:

1. Upon receipt of a sperm sample, it was found that the patient declares the place of producing his sample, i.e. on-site or at home, however it was found that the declaration form does not explicitly request the patient to confirm that the sample was produced by him and that it has not in any way been tampered with.

2. Some of the witnessing steps were omitted. It was noted that the receipt of the sample when delivered by the patient is not witnessed. This omission was mentioned in the centre's vertical process audit which was evidenced by the inspectorate. It should be noted that the requirement for this step has now been embedded into the 'cryopreservation of semen preparation' protocol. It was also observed that sperm processing was seen to be witnessed in its entirety with a single witnessing signature on the form. The inspectorate were informed that the centre only process one sample at a time. Thus witnessing of all required processes (i.e. tube to tube transfers) is not carried out, contrary to the Witnessing Guidelines in Code of Practice, 7th edition, G.13. A recent meeting of the HFEA Regulation Committee on 3rd October 2007, agreed that the practice of witnessing the entire sperm processing procedure by reviewing the labelling on all tubes and the final collection tube at the beginning and end of the process, is compliant as long as risk assessment is performed and only one sperm sample is processed at a time. This will be included in the Code of Practice revision due at the end of November 2007. The witnessing practice currently adopted by the centre is still not compliant under this revised guidance, as only one witnessing signature is collected at the end of the process. The inspectorate recommended that witnessing practices are reviewed in line with the model guidelines in G.13 of the Code of Practice when the updated version is sent out to the centre. The witnessing laboratory sheet and protocol should be updated to reflect those requirements. These changes should be communicated with all staff involved in the witnessing practice.

The system for traceability was reviewed by the inspectorate. It was found that the biomedical scientist records batch numbers of liquid reagents that are used and interact with gametes. This should be extended to plasticware and other consumables that may impact on the quality of the sperm.

During the record audit, it was noted that a number of young men (one as young as 18 years) consented their young female partners to the posthumous use of their sperm. The PR commented that the counselling sessions are often conducted quickly as the patient needs to undergo chemotherapy within one week of being diagnosed. These situations raised concerns for the inspectorate about the effectiveness of the implications counselling for NHS patients and whether the nominated partners took part in counselling sessions. The work of the nurse counsellor is acknowledged by the inspectorate however it was felt that in the best interest of the patients and the NHS nurse counsellor, she should be appropriately skilled to handle the complexities of the cases presented to her. The evidence of counselling experience and training presented to the inspectorate for the NHS nurse counsellor was not deemed adequate. The inspectorate therefore recommended the counsellor is supported by her employer to meet the level of education and CPD for this critical post, as set out in the HFEA code of practice, 7th edition.

Executive recommendations for Licence Committee
The issues raised above, in the opinion of the inspectorate, constitute breaches and non-compliance of the following sections of the Code of Practice and guidance: • D.1991/8 regarding export of gametes • G.2.3.1 regarding patients producing sperm at home. • G.13 regarding witnessing procedures. • S.7.3.1 regarding traceability. • S.6.2.7 and S.6.2.11 regarding training, continuing education and professional development.
Areas not covered on this inspection
Assessment of patients and donors; clinical practice; safe handling systems.

Evaluation
Some improvements needed.

Report compiled by:

Name: Ms Allison Cummings

Designation Inspector

Date 11 November 2007

Appendix A: Centre Staff interviewed

The PR and three other staff.

Appendix B: Licence history for previous 3 years

2007

14th May 2007: Variation of Licence under the EUTCD Legislation

The Committee agreed to vary the licence to incorporate the requirements of the EUTCD.

2005/06

27th February 2006: Consideration of renewal inspection report

A renewal inspection was carried out on 16th November 2005. In response to the inspection findings, the Committee agreed that the centre should ensure that dewar alarms are installed within three months of receipt of the minutes. The Committee decided to renew the centre's licence with no additional conditions for a period of five years.

2004

13th December 2004: Consideration of interim inspection report

An interim inspection was carried out on 2nd September 2004. The Committee noted that the centre had acquired new storage tanks and low nitrogen level alarms have now been fitted to some tanks and an auto-dialler facility is expected to be in place by the end of June 2005. The Committee agreed that the consent forms submitted by the centre were not suitable for long-term storage for oncology patients. They asked that copies of the forms be passed to the Policy team for consideration as part of their review of consent forms. The Committee had no recommendations to make to the centre.

Appendix C:

RESPONSE OF PERSON RESPONSIBLE TO THE INSPECTION REPORT

Centre Number 0159

Name of PR Mrs Barbara Sayer

Date of Inspection 3rd October 2007

Date of Response 28th November 2007

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

1. Minutes to be distributed from this morning's meeting. Next scheduled for 10 January to discuss progress and forms. After that 3 monthly.

2. We are looking into a suitable short counselling course for Clare. In the meantime she is supported by Val and Gail. We are training her for the role in-house.

3. In the process of setting up 3rd party agreements with help of operational manager. Formalised agreements should be in place by 28 February 2008.

4. We have discussed audit of counselling. The counsellors do not formally audit but we do ask all patients to complete a form to say that the procedure has been explained to them. The person doing the counselling is named on the form.
Clare is in the process of producing an audit form for each patient to complete.

5. The telephone has been removed from the semenology room in order that it can be locked during the day.

6. We shall from 1 January 2008 keep a record of all products trhat come in to contact with the sperm.

7. I am sending certificates that you requested for Val.

8. We are monitoring all complaints and will set them out in a register.

9. We have had agreement to alarm the small tanks.

10. A disclaimer label is to be added to the request form for the patient to sign and will be in place by 1 January 2008.

11. Cryopreservation protocol to be reviewed to take account of witnessing procedures.

12. I shall endeavour to submit an action plan by 1 January 2008.

13. A patient feedback questionnaire will be drawn up for 1 February 2008.

14. See 11.

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

Signed……

Name Mrs Barbara Sayer

Date 28th November 2007

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

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

Please return Appendix C of the report to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

17 December 2007
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 7

Royal Surrey County Hospital (0159)
Interim Inspection

Members of the Committee:	In Attendance:
Jennifer Hunt, Lay Member – Chair	Trish Davies, Director of Regulation / Deputy Chief Executive
David Archard, Lay Member	Claudia Lally, Committee Secretary
Sally Cheshire, Lay Member	
Hossam Abdalla, Director of Lister Fertility Centre	Providing Legal Advice to the Committee: Sarah Ellson, Field Fisher Waterhouse Solicitors

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

The following papers were considered by the Committee:

- papers for Licence Committee (29 pages)
- no papers were tabled.

1. The papers for this item were presented by Allison Cummings, HFEA Inspector. Ms Cummings informed the Committee that this centre is a small sperm storage centre which had been granted an inspection holiday in 2006 and therefore had not been inspected since 2005. Ms Cummings further informed the Committee that a number of areas for improvement which had been identified at the inspection visit are yet to be resolved. Ms Cummings summarised for the Committee the breaches, areas of non compliance and recommendations identified at pages 7 to 9 of the report.

2. Ms Cummings stated that the Person Responsible had been cooperative with the inspection and had responded at page 24 of the report with a list of actions being undertaken following receipt of the inspection report.

3. The Committee endorsed the recommendations of the inspection report and agreed that they expected the concerns of the inspection team to be addressed

in the time frames specified. The Committee requested that compliance be monitored by the Executive, and that the Executive arrange a further interim inspection to the centre next year.

4. The Committee agreed that it was content for the centre's licence to continue.

Signed…… … Date……..
Jennifer Hunt (Chair)