Interim Inspection Report

Royal Surrey County Hospital
Centre 0159

Date of Inspection: 2 October 2008
Date of Licence Committee: 26 November 2008

Centre Details

Person Responsible	Mrs Barbara Sayer
Nominal Licensee	Dr Stephen Whitaker
Centre name	Royal Surrey County Hospital
Centre number	0159
Centre address	Department of Cytopathology Royal Surrey County Hospital Egerton Road Guildford Surrey, GU2 7XX
Type of inspection	Interim
Inspector(s)	Ms Allison Cummings
	Mr David Gibbon
Fee paid	Not applicable
Licence expiry date	31 March 2011
NHS/ Private/ Both	NHS

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About the Inspection:

This inspection visit was carried out on 2 October 2008 and lasted for six hours.

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 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 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 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.

Where recommendations are made the HFEA will provide details of what needs to be addressed but not how they should be carried out as this is the responsibility of the Person Responsible.

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), Mrs Barbara Sayer, is a Clinical Scientist Grade C and is registered with the Health Professions Council. 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 (NL), Dr Stephen Whitaker, is a consultant oncologist, regularly referring male patients to the centre for semen analysis and storage.

Refurbishment plans to the Department of Cytology and Histopathology were discussed at the October 2007 inspection but were slow moving at the time. On this inspection, the PR provided building plans which will involve extending the existing building so that there will be three levels instead of two. The extension is due for completion by the end of the 2008/09 financial year. The centre will be subject to a new premises inspection by the HFEA prior to re-locating to the third floor.

Activities of the Centre[1] for the time period from October 2007-08

Research	No
Storage gametes	Yes

Summary for Licence Committee

At this inspection, the staff at Royal Surrey County Hospital demonstrated that they had largely complied with the recommendations made at the previous inspection. However, the two major concerns (also highlighted at the centre's 2007 inspection) remain:

- The air quality within the laboratory and processing areas remains untested
- The provision of counselling for NHS patients considering storage of their sperm does not meet HFEA requirements or professional guidelines.

Aside from this issue other improvements should be considered relating to the following aspects of the centre's practice:

- Establishment of one third party agreement;
- Control of documentation;
- Validation of the flow hood cabinet;

[1] This data is supplied to the HFEA by individual clinics who are responsible for its accuracy and for verifying it. The data published by the HFEA is a snapshot of the state of the Register at a particular time. 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.

- Establishment of documented procedures for the receipt of gametes;
- Revision of patient information;
- Revision of witnessing documentation;
- Revision of documented procedures for the release of samples.

The inspection team would recommend that progress in addressing the issues outlined should be made within the timescales specified in the tables below.. The executive recommends the continuation of the centre's licence.

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, clinical and counselling practice			✓

Breaches of the Act, Standard Licence Conditions or Code of Practice:
The table below sets out matters which the Inspection Team considers may constitute breaches of the Act, Standard Licence Conditions and/or the Code of Practice, and their recommended improvement actions and timescales. The weight to be attached to any breach of the Act, Standard Licence Conditions or Code of Practice is a matter for the Licence Committee;-

Breach	Action required	Time scale
One third party agreement for the supply of pipettes remains outstanding.	The centre should establish a written agreement with third parties for external activities which influence the quality and safety of gametes and embryos procured or processed and in particular where: (b) A third party provides goods or services that affect gamete or embryo quality and safety assurance, including the process of distribution (Standard License Condition A.5.1).	This will be monitored at the next inspection.
Samples of documents reviewed during the course of the inspection were version controlled except for the counselling protocol.	The procedure to control all documents should be followed to ensure that the counselling protocol is also version controlled (CoP Standard 5.2.5 (a)).	This will be monitored at the next inspection.
The air quality within the	The PR should ensure that gametes	21 November 2008

laboratory has not been tested and monitored.	are processed in an environment of at least Grade C air quality with a background environment of at least Grade D air quality to comply with standard licence condition A.10.19. The PR agreed gave her assurances that testing would occur as the earliest possible opportunity and that these results would be submitted to the HFEA prior to the Licence Committee date.	
The recently installed flow hood cabinet used to process sperm samples has not been validated.	The PR should arrange for the immediate validation of the new air flow cabinet to ensure the safety and quality of gametes processed within this piece of equipment. (CoP Standard 6.4.2(a))	21 November 2008
The centre does not have documented procedures for the receipt of gametes from another HFEA licensed centre.	The PR should establish documented procedures for the receipt of gametes in accordance with CoP Standard 7.7.15 and 7.7.16 and the recommendations outlined in Alert 21 for transporting gametes and embryos.	This will be monitored at the next inspection.
NHS patients considering the storage of their sperm are not given a suitable opportunity to receive proper counselling, from an independent counsellor, about the implications of giving consent to treatment or to the storage of their gametes. This is a breach of Schedule 3 paragraph 3(1)(a) of the HFE Act 1990 and Standard 7.5.4(a) of the CoP.	The PR should comply with this breach, ensuring that before people give consent to the storage of gametes they are given a suitable opportunity to receive proper counselling, from an independent counsellor, about the implications of giving consent to the storage of gametes.	The PR should update the HFEA of the centre's progress by 21 November 2008 (prior to the Licence Committee 26 November 2008).
An annual audit of the counselling work was not supplied to the HFEA prior to the centre's inspection. This was also the case at the 2007 inspection.	The PR should supply an annual audit of counselling work as requested by the HFEA within 28 days before any future inspection in compliance with standard licence condition A.13.2. The PR should refer to 8.10 (ii) of	To be supplied prior to the centre's next scheduled inspection.

	BICA Guidelines for Good Practice 2007 which outlines the level of detail and scope needed to adequately compile an annual audit of counselling work.	

Non-Compliance

Area for improvement	Action required	Time scale
The written information given to patients before consenting to the storage of gametes does not fully comply with CoP guidance.	The PR should ensure information outlined in CoP Guidance 5.2.1(e), (f) and 5.10.1(a) is provided to patients. It is acknowledged that this information may be provided verbally or in another form. If this is the case, the PR should communicate this to the HFEA. A written record should be kept of all relevant information provided to patients in accordance with CoP Guidance 5.1.2.	21 November 2008
The documentation of witnessing does not provide a space for two individuals to sign, date and time when labels on cryopreservation tubes are cross-referenced against source documentation or when the location of storage is witnessed.	The PR should revise witnessing documentation so that it complies with CoP Guidance G.13.1.1 (h) and G.13.2.1.	21 November 2008
The nurses providing counselling to NHS considering the storage of their sperm are not qualified counsellors.	To comply with CoP Guidance G.1.4.2, the member of staff appointed to fulfil the counsellor role should: (a) hold either a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above; or (b) hold an Infertility Counselling Award; or (c) hold a professional social work qualification recognised by one of the UK social care councils; or (d) be able to provide evidence of	The PR should update the HFEA of the centre's progress by 21 November 2008 (prior to the Licence Committee 26 November 2008).

In this arrangement, the provision of counselling is not clearly distinguished from clinical care.	working towards accreditation through the British Infertility Counselling Association/ British Fertility Society Infertility Counselling Award. The PR should comply with CoP Guidance G.7.1.1. ensuring that the provision of counselling is clearly distinguished from the clinical assessment of a person's suitability for storage, the provision of information prior to obtaining consent and the normal relationship between clinical staff and patients.	

Recommendations

Area for improvement	Action required	Time scale
The centre's documented procedures for the release of samples do not specify the requirement for: ➢ Communication with the receiving centre to agree arrangements with the before the release of samples. The scientific inspector was informed that although not documented, the PR communicates with the receiving centre and/or courier. ➢ Requirements for labelling transport packages. ➢ The information that should be communicated to patients about the risks associated with transporting the gametes.	The PR should amend the documented procedures for the release of samples to incorporate the recommendations outlined in Alert 21 for transporting gametes and embryos.	31 December 2008

Changes/ improvements since last inspection (October 2007)

Breach	Action required	Action taken
<u>Organisation</u> 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.	Meetings are now held every three months. Minutes are recorded and disseminated via email to the staff on the licence.

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.	The arrangements for the provision of counselling are changing. See *section 5: Clinical, laboratory and counselling practice*.
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.	One agreement remains outstanding. See *section 1: organisation*.
<u>Quality of Service</u> 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.	A counselling audit report was never submitted to the HFEA.
<u>Premises</u> 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.	The door to the laboratory is now fitted with a key-pad entry lock.
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	The air quality within the laboratory remained untested at the time of the inspection.
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.	The microscopes were tested for their electrical safety on 31 March 2008.
<u>Clinical and Laboratory Practice</u> 8. Two patient sperm	The PR should ensure that	There have been no exports of

samples mentioned in the laboratory audit report were exported to other countries without following General Direction 1991/8.	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.	stored material since the last inspection. The PR reported that she has familiarised herself with the HFEA General Directions for exporting gametes/embryos released 2008.
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.	A system for tracking materials has been implemented. However, this should be extended to include pipettes. See *section 5: Clinical, laboratory and counselling practice.*
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.	The nurse counselling service has been reviewed since the last inspection. See *section 5: Clinical, laboratory and counselling practice*.

Non-Compliance

Area for improvement	Action required	Action taken
<u>Organisation</u> 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.	A register was reviewed on inspection.
<u>Premises and equipment</u> 12. Since the last inspection the centre has acquired two more holding dewars and a small dewar in which hepatitis C positive samples are held; all of which were found not to be connected to an alarm.	The inspectorate recommends that the PR risk assess this situation to determine whether control measures are required.	All dewars in use are alarmed.
<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.	This recommendation has now been complied with.

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 steps are now accounted for although the document used to capture the necessary steps needs improvement. See *section 5: Clinical, laboratory and counselling practice.*

Recommendations

Area for improvement	Action required	Action taken
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.	The PR supplied this in 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.	A draft questionnaire was produced during the course of inspection. It had been reviewed by the audit department although a date for implementation had not been confirmed.
17. The 'cryopreservation of semen preparation' protocol should be updated to incorporate the technical steps that were discussed with the inspectorate.	31 December 2007.	The protocol was updated and submitted prior to the inspection.

Additional licence conditions and actions taken by centre since last inspection

The centre has no additional conditions placed on the centre's licence.

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 the findings from the inspection of the following areas of practice:

- Leadership and management
- Organisation of the centre
- Resource management
- Clinical governance
- Risk management
- Incident management
- Alert management
- Complaints management
- Contingency arrangements
- Establishment of third party agreements
- Meetings / dissemination of information
- Payment of licence/treatment fees

Areas of firm compliance
Organisation of the centre The centre's quality manual contains an organisational chart with clear lines of responsibility and communication. The PR is in overall control of licensed activity but delegates authority to experienced departmental clinical and nursing leads. Scientific matters are dealt with by the PR. **Complaints management** Since the October 2007 inspection, a complaints register has been compiled to keep all complaints and their investigation together with the corrective action in a central location. The inspection team confirmed that no complaints had been received since 2006. **Meetings / dissemination of information** To improve communication amongst staff involved in the cryopreservation of semen, the PR began holding quarterly meetings following recommendations made at the October 2007 inspection. These meetings are used to discuss HFEA updates, complicated cases and as a forum for discussing difficulties. The PR reported that it is difficult getting staff to attend but that she will review the current arrangements so that more staff can attend. These meetings are recorded and circulated via email to the appropriate staff. Those interviewed during the course of inspection responded positively to the implementation of these meetings. The inspection team noted a marked improvement on the dissemination of information since the last inspection.
Areas for improvement
Establishment of third party agreements All third party agreements have been established except for one with the supplier of pipettes.
Areas for consideration

Executive recommendations for Licence Committee
The PR should establish a written agreement with the third party who supplies pipettes to comply with Standard Licence Condition A.5.1.
Evaluation
Some improvements required
Areas not covered on this inspection
Leadership and management Organisation of the centre Resource management Clinical governance Risk management Incident management Alert management Contingency arrangements Payment of licence/treatment fees

2. Quality of service

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

Summary of the findings from the inspection of the following areas of practice:

- Quality management system
- Quality policy
- Quality manual
- Quality objectives and plans
- Quality management review/evaluation
- Feedback
- Document control

Areas of firm compliance
Feedback A draft questionnaire for obtaining feedback from service users was provided during the course of inspection. The PR stated that it has been reviewed by the audit department although a date for its implementation has not been decided.
Areas for improvement
Document control The inspection team noted a marked improvement in the control of documents since the October 2007 inspection. Samples of documents reviewed during the course of the inspection were version controlled except for the counselling protocol.
Areas for consideration
Executive recommendations for Licence Committee
The procedure to control all documents should be followed to ensure that the counselling protocol is also version controlled (CoP Standard 5.2.5 (a)).
Evaluation
Some improvements required
Areas not covered on this inspection
Quality management system Quality policy Quality manual Quality objectives and plans Quality management review/evaluation

3. Premises and Equipment

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

Summary of the findings from the inspection of the following areas of practice:

- Premises
- Clinical facilities
- Counselling facilities
- Laboratory facilities
- Air quality
- Management of equipment and materials
- Storage facilities for gametes and embryos
- Staff facilities
- Storage of records

Areas of firm compliance
Laboratory facilities In response to the October 2007 inspection findings, the PR has organised the installation of a coded entry system to the door leading into the laboratory. This provides increased security and controlled access to the area where gametes are stored. **Management of equipment and materials** The PR has complied with the recommendation for the electrical safety testing of the microscopes made at the October 2007. Additionally, the inspection team found a sample of other key equipment within the laboratory had recently been tested. **Storage facilities for gametes and embryos** The centre has recently acquired a large dewar for emergency use. The inspection team noted that all dewars in use were alarmed, including the three dewars (two quarantine dewars and one for hepatitis C positive samples) that were not connected to an alarm system at the October 2007 inspection. **Storage of records** Health records are kept in locked cabinets within the PR's office.
Areas for improvement
Air quality At the October 2007 inspection, the air quality within the laboratory or processing areas had not been tested and/or monitored contrary to standard licence condition A.10.19. At the October 2008 inspection the air quality remained untested despite the recommendation that it is tested by 31December 2007. Although this is in part due to the imminent move to a new laboratory, the inspection team strongly recommended the air quality is tested and monitored as soon as the PR could arrange for this to be done. The PR agreed and gave her assurances that testing would occur as the earliest possible opportunity and that these results would be submitted to the HFEA prior to the Licence Committee date. The open windows providing ventilation to the laboratory may impact on air quality and should be considered at the time of monitoring.

Management of equipment and materials
Additional factors impacting on the grade of air quality include the recent installation (three weeks prior to the inspection) of a new flow hood cabinet used to process sperm samples. This cabinet has not yet been validated contrary to the requirements of CoP Standard 6.4.2(a).

Areas for consideration

Executive recommendations for Licence Committee

The PR should ensure that gametes are processed in an environment of at least Grade C air quality with a background environment of at least Grade D air quality to comply with standard licence condition A.10.19.

The PR should arrange for the immediate validation of the new air flow cabinet to ensure the safety and quality of gametes processed within this piece of equipment. (CoP Standard 6.4.2(a)).

Evaluation

Some improvements required.

Areas not covered on this inspection

Clinical facilities
Counselling facilities
Staff facilities

4. Information

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

Summary of the findings from the inspection of the following areas of practice:

- Information for service users
- Consent
- Welfare of the child
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance

Consent

Documented procedures for taking consent were not reviewed during this inspection. However, the nurse counsellor stated that this process starts with provision of information (verbal and written) about the semen cryopreservation service, including information on the risks and benefits so that the patient can make an informed decision. If the patient wishes to proceed, the nurse counsellor would then explain to the patient how to complete the HFEA male treatment (MT) and male storage (MS) consent form. The patient then takes these forms away to complete them in their own time. The nurse counsellor stated that each patient is given a contact number so that there is the option of discussing the implications of storage in further detail. The nurse counsellor said that the forms are checked for completeness when they are returned to the laboratory on the same day that the sample is produced for processing and cryopreservation (patients have the option of producing on site or at home).

Two health records were audited for compliance with consent taking. Consents were present, complete and compatible with the treatment/service provided. The records were kept in an organised manner.

Areas for improvement

Information for service users

A patient information leaflet: *Storage of Sperm including the Collection & Delivery of Semen Samples for Cryopreservation* was provided during the course of inspection. The information leaflet does not contain information on:

1. Costs, fees or reimbursements relevant to counselling or storage of gametes;
2. Options available in the event of death or mental incapacity and the requirements for consent necessary to fulfil the individual's wishes.

Information for those seeking to store gametes does not contain information about:

3. The possible deterioration or loss of viability of gametes or embryos as a consequence of storage and the potential risk of cross contamination between samples.

It is acknowledged that this information could be provided verbally in the course of discussions.

Areas for consideration

Executive recommendations for Licence Committee

The PR should ensure information outlined in CoP Guidance 5.2.1(e), (f) and 5.10.1(a) is provided to patients. It is acknowledged that this information may be provided verbally or in another form. If this is the case, the PR should communicate this to the HFEA. A written record should be kept of all relevant information provided to patients in accordance with CoP Guidance 5.1.2.
Evaluation
Some improvements required.
Areas not covered on this inspection
Welfare of the child – this assessment is not applicable as the centre is a storage only facility. Access to health records Provision of information to the HFEA register – not applicable as the centre is a storage only facility.

5. Clinical, laboratory and counselling practice

Desired outcome: Clinical, counselling and laboratory practices are suitable and are provided by competent staff.

Summary of findings from inspection:

- Staff training and competency
- Clinical practice
  - Screening of donors
  - Three embryo transfer
- Laboratory practice
  - Procurement, distribution and receipt of gametes and embryos
  - Traceability and coding
  - Selection and validation of laboratory procedures
  - Coding/ identification of samples
  - Witnessing
- Counselling practice
  - Counselling audit
- Storage of gametes and embryos

Full time equivalent staff

GMC registered doctors	<0.1
NMC registered nurses	<0.1
Non NMC registered clinical staff	0
HPC registered scientists	1.0
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers etc)	0
Counsellors	<0.1

Summary of laboratory audit
In November 2007, an audit of stored gametes indicated that all documentation was complete and accurate. The report was provided to the HFEA along with the pre-inspection questionnaire. Another audit of all stored material was in progress at the time of the inspection. The PR confirmed that she will submit the report to the HFEA once it is complete.
Summary of spot check of stored material
Two patient's samples were tracked by the scientific inspector from the dewars to the laboratory workbook and to the relevant consent forms. In reverse of this, another two samples were tracked from the patient's consent forms to the laboratory workbook and to the dewars. All documentation was complete and accurate.
Areas of firm compliance
Staff training and competency The lead nurse has identified a number of external one day training courses that focus on cancer, infertility and counselling. Plans are in place for the nursing team to attend these courses before the end of the 2008 calendar year. In addition to this external training, the lead nurse has developed a 'competence framework

for those chemotherapy nurses trained in semen cryopreservation'. A comprehensive training program has been established and one element includes an internal training day. The sessions will focus on issues such as cancer and male infertility, counselling skills, HFEA Code of Practice, consent issues and clinical competency. The inspection team was informed that the first training session is scheduled for November 2008. These documents were provided during the course of inspection.

The biomedical scientist reported that all laboratory staff participate in the UK National External Quality Assessment Service scheme to review performance in semen diagnostics.

Areas for improvement

Laboratory practice

Procurement, distribution and receipt of gametes and embryos

An audit tool was used by the inspection team to check compliance with recommendations made in Alert 21 for transporting gametes and embryos. The audit revealed that the centre's documented procedures for the release of samples do not specify:

- Communication with the receiving centre to agree arrangements with the before the release of samples. The scientific inspector was informed that although not documented, the PR communicates with the receiving centre and/or courier.
- Requirements for labelling transport packages.
- The information that should be communicated to patients about the risks associated with transporting the gametes. The biomedical scientist reported that this information is verbally communicated.

Although the centre has only ever received one sample from another centre, there are no documented procedures for their receipt.

Witnessing

The centre's protocols reference witnessing requirements at the time of receipt of the sperm sample and at freezing. The centre does not perform any sperm sample processing. The protocol for the removal of cryopreserved material from storage was not reviewed.

Procedures for the documentation of witnessing do not comply with G.13.1.1 (h) and G.13.2.1. The documentation of witnessing does not provide a space for two individuals to sign, date and time when labels on cryopreservation tubes are cross-referenced against source documentation or when the location of storage is witnessed.

Counselling practice

To date, private patients are referred to a qualified counsellor and NHS patients see a nurse from the cancer centre for the provision of counselling, information and the consent process prior to agreeing to the storage for gametes. The counsellor for private patients was not available for this inspection. The nurses are not qualified counsellors to the standard recommended in Guidance 1.4.2. nor is the provision of counselling independent to the clinical assessment of a person's suitability for storage, the provision of information prior to obtaining consent, and the normal relationship between clinical staff and patients. The centre does not comply with Schedule 3 paragraph 3(1)(a) of the HFE Act 1990 and Standard 7.5.4(a) of the CoP in that NHS patients are not given a suitable opportunity to receive proper counselling, from an independent counsellor, about the implications of giving consent to treatment or to the storage of their gametes.

The PR and the nominal licensee informed the inspection team that the centre has been approved funding to refer patients to a qualified counsellor specialising in fertility issues at The Woking Nuffield Hospital (0144) if a patient requests counselling.

The inspection team noted that the PR has not complied with the HFEA's recommendation to supply an annual audit of the counselling work, data required for the HFEA to effectively plan for the centre's inspection. This was also the case at the 2007 inspection. BICA Guidelines for Good Practice 2007 8.10 (ii) expects that data on the counselling service is maintained and presented in the form of an annual audit.

Areas for consideration

Executive recommendations for Licence Committee

The PR should amend the documented procedures for the release of samples to incorporate the recommendations outlined in Alert 21 for transporting gametes and embryos.

The PR should establish documented procedures for the receipt of gametes from another HFEA licensed centre in accordance with CoP Standard 7.7.15 and 7.7.16 and the recommendations outlined in Alert 21 for transporting gametes and embryos.

The PR should revise witnessing documentation so that it complies with CoP Guidance G.13.1.1 (h) and G.13.2.1.

The PR should comply with Schedule 3 paragraph 3(1)(a) of the HFE Act 1990 and CoP Standard 7.5.4 (a) ensuring that before people give consent to the storage of gametes they are given a suitable opportunity to receive proper counselling, from an independent counsellor, about the implications of giving consent to the storage of gametes.

The PR should ensure that counselling is provided only by qualified counsellors to comply with G.7.1.1. Incorporated into this guidance is the requirement for the centre to ensure that provision of counselling is clearly distinguished from the clinical assessment of a person's suitability for storage, the provision of information prior to obtaining consent and the normal relationship between clinical staff and patients.

To comply with CoP Guidance G.1.4.2, the member of staff appointed to fulfil the role counsellor should:
(a) hold either a recognised counselling, clinical psychology, counselling psychology or psychotherapy qualification to diploma of higher education level or above; or
(b) hold an Infertility Counselling Award; or
(c) hold a professional social work qualification recognised by one of the UK social care councils; or
(d) be able to provide evidence of working towards accreditation through the British Infertility Counselling Association/ British Fertility Society Infertility Counselling Award.

The PR should supply an annual audit of counselling work as requested by the HFEA within 28 days before any future inspection in compliance with standard licence condition A.13.2.

The PR should refer to 8.10 (ii) of BICA Guidelines for Good Practice 2007 which outlines the level of detail and scope needed to adequately compile an annual audit of counselling work.

Evaluation
Significant improvements required.
Areas not covered on this inspection
Screening of donors and three embryo transfers - not applicable as the centre is a storage only facility. Traceability and coding

Report compiled by:

Name	Allison Cummings
Designation	Inspector
Date	21 October 2008

Appendix A: Centre staff interviewed

The person responsible, nominal licensee and two other staff.

Appendix B: Licence history for previous 3 years

2007

17 December 2007: Consideration of interim inspection report

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

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.

Appendix C: Response of Person Responsible to the inspection report

Centre Number 0159

Name of PR Mrs Barbara Sawyer

Date of Inspection 2nd Ocotber 2008

Date of Response 2nd December 2008

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

Signed Received via email from the PR.

Name Barbara Sayer

Date 2nd December 2008

1. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made. We will make alterations to the report where there are factual inaccuracies.

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Person Responsible (PR) Mrs Barbara Sayer is a Clinical Scientist Grade C

2. Please use the space below to document any comments or additional information that you would like to be considered by a Licence Committee.

Page 5

PR requested the help of Mr Phillip Gent from the QA reference centre at St George's hospital. He advised liaising with Caroline May from pharmacy here at RSCH. Caroline organised Settle plates and testing was carried out on 16 October. The report was received back 4 November 2008. Phillip visited the department 24 November and advised PR on ways of improving air quality in current room. He is devising a plan for monitoring which will include particle testing, microbiological testing and air flow readings. It is envisaged that testing will take place monthly and quarterly.

Plans have been drawn up for a clean room in the new build and Phillip has advised us to submit the plans to Richard Bateman (Regional QC at Guys hospital) to approve the plans using the MHRA criteria. Our operational manager is to do this. The plans are going out to tender on 15 December.

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Please find attached 3 party agreement with Woking Nuffield for provision of counselling.

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The flow hood cabinet has now been validated.

Page 8

PR will ensure that patients receive all information outlined in Code of Practice Guidance 5.1.2. This will be done verbally.

Page 8

A new witnessing document has been drawn up and is now in use.

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

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

Please return Appendix C of the report electronically to your inspector or in hard copy to:
Regulation Department
Human Fertilisation & Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF