Renewal Inspection Report

Louis Hughes
0011

Date of Inspection: 23rd October 2008
Date of Licence Committee: 11th February 2009

Centre Details

Centre name	Louis Hughes
Centre number	0011
Person Responsible	Dr Louis Hughes
Nominal Licensee	Miss Linda Sheahan
Centre address	99, Harley Street, London, W1G 6AQ
Type of inspection	Renewal
Inspector(s)	Ellie Suthers, Andy Glew, Jim Monach
Fee paid	Yes
Licence expiry date	31st March 2009
NHS/ Private/ Both	Private Storage

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About the Inspection:

This inspection visit was carried out on Thursday 23rd of October 2008 and lasted for approximately 5 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

Louis Hughes, centre 0011, has been licensed since 1992 and supplies donor sperm to fertility clinics throughout the UK.

The centre is located in the basement of 99 Harley Street, London. The premises consist of a semen preparation laboratory, three semen production rooms, an office, a staff kitchen and a large room doubling as a cryostore and administration room.

The centre is open Monday to Friday 08:00 to 16:00. Donors can visit the centre between 08:00 and 14:30 and do not require appointments.

The Person Responsible (PR) is Dr Louis Hughes who has completed Unit 1 of the Person Responsible Entry Programme (PREP), is registered with the General Medical Council and has extensive experience in the field of assisted reproductive therapy.

The centre has two other staff members who perform all the laboratory, administrative and donor care activity and the support of a receptionist in the main building.

Number of donors[1]

Donation and storage of gametes only	2005	23
	2006	28
	2007	7
	2008 to the date of inspection	8

Summary for Licence Committee

All members of the Louis Hughes team attended the inspection and were available for interview. The premises remain unchanged from the last inspection.

Following inspection the inspection team is concerned that the cumulative effect of issues discovered at the time of inspection calls into question the robustness of the quality management systems and processes that underpin the sperm preparation process.

The inspection team have particular concerns relating to:

- The development of quality management systems and processes;
- The lack of development and measurement of quality objectives and quality indicators;
- The lack of air quality measurement and documentation;
- The use of locally prepared cryo preservant without evidence of quality control;

[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.

A number of improvements are required relating to the following aspects of the centres practice.

- Completion of PREP by the PR as required by Directions 2008/1a;
- Paying invoices within the time requirements of licence conditions;
- The complaints procedure is not prominently displayed nor written information given to the donor;
- The communication of information, standard operating procedures and in particular HFEA Alerts should be improved upon;
- Training, continued professional development and competency assessments of staff;
- Qualifications of the centre's counsellor and status of the independent counsellor;
- Validation and maintenance records of critical equipment and procedures;

The licence committee is asked to note that three recommendations from the last inspection have not been acted upon and remain in breach this inspection;

- The complaints procedure is not prominently displayed nor written information given to donors: required immediately from the time of the last inspection.
- The provision of independent counselling is not included in written donor information: required by the 31st of December 2007.
- There is no documented evidence of air quality monitoring or outcomes: required by the 31st of December 2007.

The licence committee is asked to review the content and recommendations in this report in the context of the low level of complexity of the organisational structure and service provided by the centre.

The licence committee is asked to consider what, if any, regulatory sanctions are warranted in consideration of the breaches and areas of non-compliance documented in this report. The inspectorate recommends that the licence is renewed for a period of one year contingent on the production, submission to the HFEA and implementation of an action plan to remedy the breaches and non compliances defined in this report by January 31st 2009. The action plan and any supporting documentation submitted by the Louis Hughes centre will be presented to for licence committee for their consideration.

Evaluations from the inspection

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

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
The PR has not completed or submitted Unit 2 of the Person Responsible Entry Programme (PREP).	The PR should complete the HFEA's PR assessment process. *(CoP S. 4.1.5 & Directions on completion of Persons Responsible Entry Programme (PREP) Assessments Ref. D 2008/1a)*	Jan 31st 2009
A complaints procedure was supplied to the inspectorate prior to the inspection as requested. The documented complaints procedure is very brief, does not describe the acknowledgement or investigation process and is not considered compliant with the requirements of the Code of Practice 7th Edition	The PR should ensure that written procedures are in place for acknowledging and investigating complaints and that staff who deal with complaints have received appropriate training. *(CoP G.11.2.1)*	Immediately
One invoice has been sent to centre 0011 this financial year 08/09. The centre took 50 days to pay the invoice.	The PR should review payment processes to ensure that there are no barriers to the payment of fees within 28 days of the date of the notice of such additional fees. The PR should ensure that invoices are paid according to the requirements of Standard Licence Conditions A.16.3	Jan 31st 2009
A member of staff interviewed during the inspection informed the inspectorate that she is not informed of HFEA Alerts but was aware that they are sent to the PR of the centre. She was unaware of the recently issued Alert 24 regarding the restrictions of reimbursements to sperm donors.	The PR should ensure that the Centre has an effective means for communicating information to staff in particular Alerts issued by the HFEA *(CoP S.6.2.13)*	Immediately

An interviewed member of staff said that they were not aware of Standard Operating Procedures for laboratory procedures but thought that if there were any they would be on the laboratory computer.	The PR should ensure that the centre shall have an effective means for communicating information to staff and receiving suggestions from staff. *(CoP 6.2.13)*	Jan 31st 2008
The inspectorate was informed that the centre does not have any documented measurable quality objectives or internal audits of elements of the donation and storage process.	The inspectorate recommends that the PR should: - establish an effective system for monitoring and assessing laboratory, clinical and counselling practice, and be able to demonstrate that procedures and outcomes are satisfactory judged by the highest standards of professional colleagues in relevant disciplines elsewhere. *(CoP S.9.5.3)* - establish quality indicators for systematically monitoring and evaluating the centre's performance and when this programme identifies opportunities for improvement these should be addressed (*CoP S.9.5.2);* - establish an internal audit process and a documented procedure for audit in compliance with CoP S.9.2.4:S.9.2.5; - conduct a regular review of the Centre's quality management system and all its services. The review should assess the need for changes to the quality management system and opportunities for improvement. The maximum interval between management reviews should be twelve months but shorter intervals should be adopted when a quality management system is being established. (*S.4.2.8., S.4.2.9*)	By the time of the next inspection.
The centre does not participate in inter-centre or inter laboratory comparisons.	The PR should consider participating in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external Quality assessment schemes) and by other external bodies. *(CoP S.9.2.6)*	By the time of the next inspection

At the time of inspection there was no evidence that the air quality is being monitored or that documentation regarding air quality is maintained. There was no evidence made available to demonstrate compliance with air quality requirements. (Grade C in the critical work area and grade D in the background environment) This was required by 31st December 2007 from the last inspection.	The PR should monitor the quality of the air immediately. Should it seem likely that the environmental air quality has dropped below grade D in the course of a procedure involving the manipulation of gametes the PR should assess whether there is any additional risk from the use of the gametes to a woman being treated or to any resulting child. The PR should advise the HFEA of the outcome of the monitoring and assessment and ensure that all centres that have purchased donor sperm are made aware of any risks and where relevant that the quality requirements of any third party agreements may have been breached *(CoP A.10.20: S.6.3.6 (b): G 9.4.6 G.9.4.5. G 9.4.7: HFEA Summary of air quality information 2006)* Where the licensed activities include storage of gametes the storage conditions necessary to maintain the gametes including relevant parameters such as temperature, humidity or air quality should be defined. The PR should ensure that an air quality monitoring programme is developed and results documented. *(CoP A.10.20: S.6.3.6 (b): G 9.4.6 G9.4.7: HFEA Summary of air quality information 2006)* The PR should submit a plan to the HFEA outlining how the requirements of standard licence condition A.10.19 can be accommodated to ensure that processing of gametes and embryos while exposed to the environment takes place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality.	Immediately Jan 31st 2009 Jan 31st 2009
At the time of inspection the centre did not provide evidence of validation or maintenance records or maintenance contracts for critical equipment.	The PR should ensure that all critical equipment is identified and validated, regularly inspected and preventatively maintained. Test results must be documented. Maintenance, servicing, cleaning. Disinfection and sanitation of all equipment must be performed regularly and recorded accordingly. (CoP S.6.4.2: S.6.4.2 (c)	Jan 31st 2009

At the time of inspection there was no evidence of ongoing training or continued professional development provided by any of the staff. The laboratory manager informed that inspectorate that competency assessments are not performed.	Staff at the centre should take part in regular professional development programmes that include audit of practice. Following initial/ basic training the competence of each person to perform designated activities shall be evaluated at intervals and retraining undertaken when required. *(CoP S.6.2.11:S.6.2.9)* Training should be documented in compliance with A.10.11	By the time of the next inspection
The laboratory manager has many years of experience in providing information to sperm donors but does not have qualifications as required by the Code of Practice for counselling. No evidence was provided of continued professional development (CPD) or membership of a recognised professional counselling body.	The PR should ensure that counselling is provided only by qualified counsellors. Evidence of continued professional development and membership of a recognised professional counselling body should be documented *(CoP S.7.6.3: G.1.4.2: G.7.1.1) BICA Guidelines for Good Practice in Infertility Counselling (2006)*	March 31st 2009
The independent counsellor informed the inspectorate that she is not a member of British Infertility Counselling Association: has not attended any of their training or study days: does not have counselling or psychotherapy qualifications within those terms.	The PR should ensure that the centre has access to an appropriately qualified independent counsellor. *(CoP S.7.6.3: G.1.4.2))*	March 31st 2009
The centre does not use a commercially prepared cryo protectant for the storage of sperm. The centre has a protocol for the preparation of locally prepared preservation media (CPM) including the ingredient of egg yolk. No evidence was seen at the time of inspection of validation, or recording of quality measures in the manufacture or use of	The PR should ensure that cryo protectants and other media used in sperm processing and freezing must be validated and batch numbers recorded. Home made media should not be used unless there is documented evidence supporting its manufacture according to good manufacturing practice (GMP) *(Association of Medical Andrologists: Laboratory Andrology: Guidelines for Good Practice March 2004)* (CoP A.6.5 (a))	Jan 31st 2009

locally prepared preservation media following procedures that minimise bacterial or other contamination.	No documented evidence was made available to the inspection team therefore the use of home made cryo preservant should cease immediately until the PR can provide evidence that *g*ametes are being handled in a way which protects those properties that are required for ultimate clinical use, while minimising the risk of bacterial and other contamination. (A.8.8: S.7.8.5 (b))	Immediately
It was noted at the time of inspection that there was no evidence that the scales used for measuring the constituents of the preservation media had been calibrated.	The PR should ensure that the centre has documented procedures for the management of equipment and materials: including detailed specification for all critical materials and reagents. (CoP S.6.4.3)	Jan 31st 2009
At the time of inspection there was no evidence of validation of laboratory procedures in accordance with professional guidelines, previously published studies or retrospective evaluation of the centres own data.	The PR should ensure that the laboratory procedures are validated in accordance with professional body guidelines, previously published studies or retrospective evaluation of the centres won data. The PR should ensure that records of all validations are kept. *(CoP S.7.8.3 paragraph 2)*	By the time of the next inspection
There was no evidence that laboratory procedures are evaluated or risk assessed for hazards to laboratory staff.	The PR should ensure that procedures are evaluated or risk assessed for hazards to laboratory staff.*(CoP S.7.8.3 paragraph 4)*	March 31st 2009

Non-Compliance

Area for improvement	Action required	Time scale
A small, hand written, card with the, very brief, complaints contact number was located inside a closed small cupboard inside the sperm production room.	The centre should consider the display of notices prominently in reception areas explaining the complaints procedure and the provision of his information to the donor. *(CoP G.11.3.2)*	Jan 31st 2009
At the time of inspection no witnessing records were observed for removing samples for transportation or destruction.	Centres should have witnessing protocols in place for the removal, disposal and transport of gametes at the point of release *(CoP G.13.1 (j) and transporting of gametes CoP G.13.1 (k) S.7.8.10 (d)*	Jan 31st 2009

Recommendations

Area for improvement	Action required	Time scale
There are no contingency arrangements in place in case of equipment or service failure. There are no arrangements with any other licensed premises to transfer or store dewars containing stored sperm.	The PR should consider whether there is any advantage in reaching an arrangement with other licensed facilities which would avoid allowing the stored sperm to perish in the case of equipment or service failure.	By the time of the next inspection

Changes/ improvements since last inspection

Issue	Action required	Action
The adverse incident procedure is not compliant with the Code of Practice, 7th edition, S.9.4 as it does not include reporting to the HFEA.	The adverse incident procedure should be re-written to comply with the Code of Practice, 7th edition, S.9.4.	The adverse incident policy has been re written to include the requirements of reporting to the HFEA within Code of Practice timescales
The complaints procedure is not openly displayed in the centre, and complaints are not all logged in the complaints' log, contrary to the Code of Practice, 7th Edition (G.11.3.1 – G.11.3.3).	The complaints procedure should be openly displayed in the centre and all complaints logged to ensure compliance with the Code of Practice, 7th Edition	A small card with the complaints procedure was located in a small cupboard in the sperm production room. The complaints procedure is not prominently displayed in the centre. Written information is not given to donors: remains non compliant *(CoP G.11.3.2)*
Written donor information is not provided to all donors, contrary to the Code of Practice, 7th edition, S.7.4.1. The donor information written by the centre, which could be used, does not contain details of counselling provision, as required by the Code of Practice, 7th edition, G.5.2.1.	The centre should provide all donors with written donor information. Provision of counselling should be included in the written donor information.	The provision of independent counselling is not included in written donor information: remains non compliant *(CoP G.5.2.1)*
The centre does not have an air quality monitoring programme at present and air quality in the sperm processing laboratory is unknown, contrary to the air quality requirements in Code of Practice, 7th edition, G.9.4.1 – G.9.4.7 and with Licence Condition A10.19.	An air quality monitoring programme should be developed. If risk assessment of the air quality requires it, air purification methods should be sourced to bring the air in the sperm preparation laboratory to Grade D or better, as required by Code of Practice, 7th edition, G.9.4.1 – G.9.4.7 and Licence Condition A10.19.	An air quality monitoring programme has not been developed. The centre offered no documented evidence of air quality monitoring or outcomes: remains non compliant *(CoP A10.19)*
The centre does not validate and verify fridge and freezer temperatures, contrary to the Code of Practice, 7th edition, S.6.4.2.	The centre should develop a method of validating and logging fridge and freezer temperatures, on a schedule determined as	The centre has developed a method of measuring and logging fridge and freezer temperatures

The storage dewars are not fitted with low nitrogen alarms nor with temperature monitoring devices, thus monitoring of storage temperatures is not performed. This is potentially contrary to Code of Practice, 7th edition, S.6.3.7, and Licence Conditions A.10.20 – A.10.21, which require critical parameters related to the storage conditions of gametes and embryos (temperature; humidity; air quality) to be defined, controlled, monitored and recorded.	reasonable by the centre. To risk assess the lack of monitoring on the storage dewars. To cost and consider fitting the storage dewars with low nitrogen alarms and temperature monitoring devices if risk assessment indicates such control measures are required.	Consideration has been given to the use of alarms on the storage dewars. As there are no patient/oncology or sibling samples in the dewars the centre has decided not to fit them.

Additional licence conditions and actions taken by centre since last inspection

No additional licence conditions or actions since the last inspection

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
Centre 0011 is located in the basement of a house which hosts several other private medical practices in Harley Street, London. Access is by the ground floor front door to a staffed shared reception desk with adjacent waiting room. Donors are directed from here down a staircase into the centre administrative/dewar storage room in the basement. This route is used by donors on their initial visit. Alternative access for donors is also provided by a lockable gate in railings at street level (open 08:00 – 14:30) via steps to basement level and through a robust door fitted with a key pad lock and a dead lock into the administrative/dewar storage room. The key pad lock code is provided to donors so they can use this access during their donation course. The security of the centre appeared appropriate at the time of inspection. *(CoP S.6.3.8)* **Leadership and management:** The Person Responsible (PR) is Dr Louis Hughes is registered with the General Medical Council (GMC) and has experience in the field of assisted reproductive therapy. *(CoP S.4.1.4)* The laboratory manager also has the role of Nominal Licensee (NL) and has experience of andrology and sperm storage centre management experience. All employed members of staff appeared clear about the roles and responsibilities of each member of the team. The PR reported that he is available for consultation to address any issues via telephone and attends the centre each week. **Organisation of the centre:** The centre does not have a printed organisational chart as there are only three people employed; during interview each member of staff demonstrated their understanding of roles and responsibilities within the centre. Staff informed the inspectorate that the organisational structure creates an environment in which all staff are fully involved in the activities of the organisation. *(CoP S.4.1.3)*

Resource management:
There are three individuals: PR, laboratory manager and laboratory technician, employed by the centre who work together to deliver the service. The management and coordination is overseen by the PR and the daily running of the centre is supervised by the laboratory manager.
The inspectorate was informed that the centre has sufficient staff and equipment to perform the tasks required of them. This was confirmed at the time of inspection.*(CoP S.6.2.1)*

Incident management:
An incident protocol was seen as part of the quality management system. The protocol has been amended following recommendations from the last inspection to include the requirement for notification of the HFEA by the PR of incidents in a timely and effective manner*. (CoP S.9.4.2 (c))*

Complaints management:
The PR is the designated complaints manager and the laboratory manager deputises when required *(CoP G.11.3.1)*
The laboratory manager informed the inspectorate that they had not received any complaints from donors about the service since the last inspection and therefore there was no evidence of a completed complaints log.

Meetings / dissemination of information:
The laboratory manager and PR reported that as there are only three people in the centre that talking to each other on a day to day basis is adequate to ensure communication and dissemination of information. The quality manual describes meetings to be held when needed and at least quarterly to allow discussion of regulatory issues and any other issues related to the effective running of the centre.

Areas for improvement

Leadership and management:
The PR has completed Unit 1 of the PREP assessment. During discussions with the inspector the PR acknowledged that his submission of Unit 1 may have been rather brief and sparsely populated and welcomed an opportunity to resubmit a document which more readily evidenced his understanding and expertise in the field of reproductive therapy. *(CoP S. 4.1.5)*

The PR has not completed or submitted Unit 2 of PREP. The PR should complete the HFEA's PR assessment process. *(CoP S. 4.1.5 & Directions on completion of Persons Responsible Entry Programme (PREP) Assessments Ref. D 2008/1a)*

The named independent counsellor does not attend training in infertility counselling issues or meet with colleagues or receive briefings related to current HFEA policies or issues.

Risk Management;
At the time of inspection the laboratory manager informed the inspectorate that no risk assessments had been undertaken since the last inspection and that there are no plans to do so.

Complaints:
A complaints procedure was supplied to the inspectorate prior to the inspection as requested. The documented complaints procedure is very brief, does not describe the acknowledgement or investigation process and is not considered compliant with the guidelines outlined in the Code of Practice 7th Edition *(CoP G.11.2.1)*
A small, hand written, card with the, very brief, complaints contact number was located inside a small closed cupboard inside the sperm production room. No notices were observed in the centre regarding how donors could make complaints. The centre should consider displaying notices prominently in reception areas explaining the complaints procedure and giving the name and contact information for the complaints officer.

Payment of licence/treatment fees:
One invoice was sent to the centre in the financial year 08/09. The centre took 50 days to pay the invoice. The Person Responsible should review payment processes to ensure that there are no barriers to the payment of fees within 28 days of the date of the notice of such additional fees according to the requirements of Standard Licence Condition A.16.3

Alert management:
A member of staff interviewed during the inspection informed the inspectorate that she is not informed of HFEA Alerts but was aware that they are sent to the PR of the centre. She was unaware of the recently issued Alert 24 regarding the restrictions of reimbursements to sperm donors. The PR should ensure that the Centre has an effective means for communicating information to staff in particular Alerts issued by the HFEA (CoP S.6.2.13)

Meetings / dissemination of information/Communication:
The named independent counsellor is not invited nor attends meetings with other members of staff

An interviewed member of staff said that they were not aware of Standard Operating Procedures for laboratory procedures but thought that if there were any they would be on the laboratories computer. The PR should ensure that the centre shall have an effective means for communicating information to staff and receiving suggestions from staff. *(CoP 6.2.13)*

Areas for consideration

Contingency arrangements:
There are no contingency arrangements in place in case of equipment or service failure. There are no arrangements with any other licensed premises to transfer or store dewars containing stored sperm. The PR should consider an arrangement which would avoid allowing the stored sperm to perish in the case of equipment or service failure.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:

- Leadership and management. The PR should complete his PREP in the time specified;
- Complaints;
- Payment of licence/treatment fee;
- Alert management;
- Communication within the centre;
- Contingency arrangements.

Evaluation
Some improvements required
Areas not covered on this inspection
None

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
- Reimbursement of reasonable expenses

Areas of firm compliance

Quality management system:

Implementation of the quality management system appears to be at the same stage as at the last inspection. Given the limited complexity of the centres activities the inspectorate considered it to be generally compliant.

A quality manual was made available to the inspectorate that included a brief description of the centre and the scope of the services provided. The procedures included in the quality manual were seen to be document controlled and within review dates. It appeared at the time of inspection that the quality manual provided the register of current versions of policies and procedures. *(CoP S.5.2.5)*

There are three people employed at the centre so communication is largely verbal and informal: the laboratory manager informed the inspectorate that meetings are convened when necessary and minutes taken when required. Please see other sections of this report regarding communications and the relating recommendations.

Feedback:

The inspectorate were informed that centre staff communicate well with potential and actual sperm donors and this ensures that any issues with satisfaction are dealt with at the time the donor attends the centre.

Reimbursement of reasonable expenses:

The PR and laboratory manager informed the inspectorate that individuals considering donation are informed that the donation of gametes is voluntary and unpaid, compensation being restricted to expenses and inconveniences *(CoP S.7.6.6)*

The inspectorate observed a central log of expenses and compensation paid to donors which contained information about the date, amount, recipient and reasons for payments *(CoP G.4.11.1)*

Prior to inspection it was observed that the centre was offering, via a recruitment website, a single amount in payment for sperm donors. At the time of inspection it was brought to the notice of the PR that this was in contravention of CoP S.7.6.6: CH (06)01 Implementation of the outcomes of the SEED review. The PR agreed to remove the amount of payment from

recruitment material. The inspectorate can confirm that this has been done and, of recruitment material reviewed by the inspectorate, there is no offer of payment.

Areas for improvement

Quality objectives and plans:
The laboratory staff informed the inspectorate that the limited complexity of the centres activities and that laboratory practices have changed very little, if at all. Therefore they believe that there is no need for a designated quality manager, stated quality objectives or audit of practice, including review of the quality management service.

The inspectorate were informed that the centre does not have any documented measurable quality objectives*: (CoP S.4.2.4)*

The inspectorate recommends that the PR should:

- establish an effective system for monitoring and assessing laboratory, clinical and counselling practice, and be able to demonstrate that procedures and outcomes are satisfactory judged by the highest standards of professional colleagues in relevant disciplines elsewhere. (CoP S.9.5.3)

- establish quality indicators for systematically monitoring and evaluating the centre's performance and when this programme identifies opportunities for improvement these should be addressed (*CoP S.9.5.2);*

- establish an internal audit process and a documented procedure for audit in compliance with CoP S.9.2.4:S.9.2.5;

- conduct a regular review of the Centre's quality management system and all its services. The review should assess the need for changes to the quality management system and opportunities for improvement. The maximum interval between management reviews should be twelve months but shorter intervals should be adopted when a quality management system is being established. (*S.4.2.8., S.4.2.9*);

The PR should establish an effective system for monitoring and assessing laboratory, clinical and counselling practice, and be able to demonstrate that procedures and outcomes are satisfactory judged by the highest standards of professional colleagues in relevant disciplines elsewhere. (CoP S.9.5.3)

The centre does not participate in inter-centre or inter laboratory comparisons. The PR should consider participating in inter-centre comparisons such as those organised by professional bodies and inter-laboratory comparisons (e.g. external quality assessment schemes) and by other external bodies. *(CoP S.9.2.6)*

Areas for consideration

No areas for consideration

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to: ➢ Quality objectives, quality indicators, audit and quality management review; ➢ Inter centre and inter laboratory comparisons;
Evaluation
Significant improvements required
Areas not covered on this inspection
None

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
- 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
Premises: The premises consist of a central administrative/dewar storage area, a semen preparation laboratory, three small sperm production rooms, an office and a staff kitchen. Premises remain unchanged since the last inspection and remain suitable for licensable activity. *(CoP S.6.3.2)* **Counselling facilities:** Information sessions for donors are carried out in a small office off the main administrative/ storage area. The room is quiet and provides confidential surroundings for a private discussion. If a donor were to request counselling it would be provided in the nearby private consulting room of the independent counsellor. (*CoP S.6.3.5)* **Storage facilities for gametes and embryos:** Donor sperm is stored in a secure area with restricted access to authorised individuals only. Donors at the centre are supervised at all times in the administrative and storage areas. The area is appropriate for the volume and activities conducted within it. *(CoP S.6.3.8)* **Staff facilities:** It was observed during inspection that staff facilities including toilet accommodation, basic catering facilities, changing area and secure storage are readily available. *(CoP 6.3.9: S.6.3.10)* **Storage of records:** Active donor paper records and laboratory records are stored in locked filing cabinets in the main administrative/dewar storage room. Electronic donor data is stored on a computer in the locked administrative/dewar storage room. The PR informed the inspectorate that old donor records are securely stored at his home. *(CoP S.7.2.1)*

Areas for improvement

Air quality:

At the time of inspection there was no evidence that the air quality is being monitored or that documentation regarding air quality is maintained. There was no evidence made available to demonstrate compliance with air quality requirements. (Grade C in the critical work area and grade D in the background environment)

The PR should monitor the quality of the air immediately. Should it seem likely that the environmental air quality has dropped below grade D in the course of a procedure involving the manipulation of gametes the PR should assess whether there is any additional risk from the use of the gametes to a woman being treated or to any resulting child. The PR should advise the HFEA of the outcome of the monitoring and assessment and ensure that all centres that have purchased donor sperm are made aware of any risks and where relevant that the quality requirements of any third party agreements may have been breached *(CoP A.10.20: S.6.3.6 (b): G 9.4.6 G.9.4.5. G 9.4.7: HFEA Summary of air quality information 2006)*

Where the licensed activities include storage of gametes the storage conditions necessary to maintain the gametes including relevant parameters such as temperature, humidity or air quality should be defined. The PR should ensure that an air quality monitoring programme is developed and results documented.
(CoP A.10.20: S.6.3.6 (b): G 9.4.6 G9.4.7: HFEA Summary of air quality information 2006)

The PR should submit a plan to the HFEA outlining how the requirements of standard licence condition A.10.19 can be accommodated to ensure that processing of gametes and embryos while exposed to the environment takes place in an environment of at least Grade C air quality with a background environment of at least Grade D air quality.

Management of equipment and materials:

At the time of inspection the centre did not provide evidence of validation or maintenance records or maintenance contracts for critical equipment. (CoP S.6.4.2: S.6.4.2 (c))
The inspectorate was informed during discussions that the only evidence that a machine had been serviced was through payment records. No other documents were available. The equipment which had been serviced (but not witnessed) was the O_2 monitor and microscopes.

The PR should ensure that all critical equipment is identified and validated, regularly inspected and preventatively maintained. Test results must be documented. Maintenance, servicing, cleaning. Disinfection and sanitation of all equipment must be performed regularly and recorded accordingly.

Areas for consideration

No areas for consideration

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:

- Air quality (repeated breach);
- Management of equipment and material;

Evaluation
Significant improvements required
Areas not covered on this inspection
None

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
- Access to health records
- Provision of information to the HFEA register

Areas of firm compliance
Information for service users: Verbal information is given to donors at the time of their first attendance at the centre. The laboratory manager informed the inspectorate that donors are informed of: lack of anonymity of donors; the importance of keeping the HFEA up to date with any change of address; donor screening tests, results and any consequences; access to a counsellor prior to the taking and recording of consent. The information giving sessions takes on average 30 minutes. The donor is also informed of the availability if information on the HFEA web site. A new donor is given a leaflet: '*Important information for semen donors'* that outlines the process prior to giving consent to storage. **Consent:** It was observed at the time of inspection that all consents forms reviewed (six sets of donor records) were completed accurately. The laboratory manager described in detail the process for taking consent from sperm donors that included: verification of the donor's identity via a passport; appropriate verbal information given to the donor; opportunity for the donor to ask questions and the accurate completion of consent forms. *(CoP S.7.5.3)* **Access to donor (health) records:** The inspectorate were informed that donors can have access to their donor records: there is a procedure in place to facilitate this which is outlined in a protocol in the quality management manual. *(CoP S.7.2.2)*
Areas for improvement
Provision of information to the HFEA register: The centre provides regular information to the HFEA as required. There are a few outstanding errors which are being addressed by the laboratory manager and the quality assurance officer at the HFEA. It is recommended that the PR address and amend these errors prior to the next inspection.
Areas for consideration
No areas for consideration
Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to: ➢ The provision of information to the HFEA register
Evaluation
Some improvements required
Areas not covered on this inspection
None

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
- Screening of donors
- 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

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	0
Non NMC registered clinical staff	0
HPC registered scientists	0
Scientists working towards registration	0
Support staff (receptionists, record managers, quality and risk managers, support scientist etc)	2
Counsellors	1 available

Summary of laboratory audit
The laboratory manager provided confirmation of a laboratory audit in the form of a letter: *This is to confirm between 12-15th of May 2008 we carried out an audit of all the dewars. No errors were found. We did decide to keep a record of donors that were nearing their expiry in order to make things simpler for the disposal of said samples*
Summary of spot check of stored material
There was no spot check of stored material carried out on the day of inspection
Areas of firm compliance
Staff training and competency: The three members of staff have all been working at the centre for a number of years: there has been no staff turn-over for five years. The laboratory manager and PR informed the inspectorate that all three members of staff have considerable experience in the field of sperm donation and storage.

Screening of donors:
It was observed at the time of inspection during a review of six sets if donor records that donors had undergone appropriate screening tests and samples are not stored without screening. *(CoP S.7.8.12 (a))*The requirements for donor screening are detailed in donor information and the laboratory manager informed the inspectorate that implications of donor screening are discussed with prospective donors along with a clinical and risk assessment of donor suitability. *(CoP S.7.6.7)*

Traceability and coding:
It was observed at the time of inspection that the centre uses an identification code for the traceability of all gametes. There are documented procedures in place to ensure that all gametes are traceable from procurement to the point of storage: including accurate identification of the donor and registers of received, processed and stored gametes. A log of was seen to record the receipt of batches of consumables.*(CoP S.7.3.1)*

Witnessing:
The centre has a laboratory witnessing procedure in place which states that all stages of freezing must be witnessed and a secondary confirmatory signature is required. *(CoP G.13.1.1)*
Documented evidence was observed at the time of inspection of the witnessing procedures for transferring samples during the preparation and cryo preservation process.

Counselling practice:
Donor information is provided by the laboratory manager who is also the centres Nominal Licensee. During interview the laboratory manager stated that all donors are made aware of the availability of independent counselling when they visit the centre for their initial discussions about the implications of their deciding to become donors. The laboratory manager informed the inspectorate that this discussion covers all the issues related to donation including: procedures to be adopted; parental responsibility; implications of tests undertaken; availability of information to any donor-conceived children once adult and; the nature of reimbursements. The centre attempts to create an open and relaxed relationship with their donors which means that they can, and do, telephone at any time to discuss any matters of concern as well as when attending to donate *(G.4.4: G.4.6).*

Areas for improvement

Training and competencies:
At the time of inspection there was no evidence of ongoing training or continued professional development being provided for any of the staff. The laboratory manager informed the inspectorate that competency assessments are not performed.

Staff at the centre should take part in regular professional development programmes that include audit of practice. Following initial/ basic training the competence of each person to perform designated activities shall be evaluated at intervals and retraining undertaken when required. *(CoP S.6.2.11:S.6.2.9).* Training should be documented in compliance with A.10.11.

Counselling practice:
Donor guidance is provided by the laboratory manager who is also the centre's Nominal Licensee. At the time of inspection she informed the inspectorate that she is attending substantive training in counselling skills as part of her commitment to youth work outside her employment which she sees as relevant to her role in advising donors. She does not claim to

be a counsellor herself. The laboratory manager has many years of experience in guidance of sperm donors but does not have qualifications as required by the Code of Practice to assume the role of counsellor.
(CoP S.7.6.3: G.1.4.2: G.7.1.1) BICA Guidelines for Good Practice in Infertility Counselling (2006)

Independent Counsellor:
The centre does have a designated independent counsellor who provided her curriculum vitae as part of the inspection. The cv provided evidence of the counsellor being a well qualified and highly respected medical specialist in Psychosexual Medicine. She informed the inspectorate during interview that the agreement with the centre for providing independent counselling services had been made many years ago but she had never received any referrals for sperm donors requiring counselling. She is a member of the British Association for Counselling and Psychotherapy, which is open to non-counsellors but is not an accredited member.

The independent counsellor informed the inspectorate that she is not a member of British Infertility Counselling Association: has not attended any of their training or study days: does not have counselling or psychotherapy qualifications within those terms. Her qualifications do not meet the requirements of the HFE Code of Practice Ed 7. *(CoP S.7.6.3: G.1.4.2)*
The PR should establish documented procedures for obtaining consent to the storage or use of gametes to ensure that before people give consent they must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, in compliance with the requirements of schedule 3(1)(a) of the 1990 Human Fertilisation and Embryology Act .

The PR should ensure that where required, counselling is provided only by qualified counsellors. *(CoP S.7.6.3: G.1.4.2: G.7.1.1) BICA Guidelines for Good Practice in Infertility Counselling (2006)*

Sperm storage and cryo-protectant:
The centre does not use a commercially prepared cryo protectant for the storage of sperm. The centre has a protocol for the preparation of locally prepared preservation media which includes egg yolk. No evidence was seen at the time of inspection of validation, or recording of quality measures undertaken in the course of the manufacture or use of locally prepared preservation media or the use of procedures to minimise bacterial or other contamination. *(CoP A.6.5(a))*

Cryoprotectants and other media used in sperm processing and freezing must be validated and batch numbers recorded. Home made media should not be used unless there is documented evidence supporting its manufacture according to good manufacturing practice (GMP) *(Association of Medical Andrologists: Laboratory Andrology: Guidelines for Good Practice March 2004).*

The PR should provide evidence that gametes are being handled in a way which protects those properties that are required for ultimate clinical use, while minimising the risk of bacterial and other contamination. *(A8.8: S.7.8.5 (b))*

No documented evidence was made available to the inspection team therefore the use of home made cryo preservant should cease immediately until the PR can provide evidence that *g*ametes are being handled in a way which protects those properties that are required for ultimate clinical use, while minimising the risk of bacterial and other contamination. (A.8.8: S.7.8.5 (b))

It was noted at the time of inspection that there was no evidence that the scales used for measuring the constituents of the preservation media had been calibrated. The centre should have documented procedures for the management of equipment and materials: including detailed specification for all critical materials and reagents. *(CoP S.6.4.3)*

Selection and validation of laboratory procedures:
At the time of inspection there was no evidence of validation of laboratory procedures in accordance with professional body guidelines, previously published studies or retrospective evaluation of the centres own data.
The PR should ensure that the laboratory procedures are validated in accordance with professional body guidelines, previously published studies or retrospective evaluation of the centres own data. The PR should ensure that records of all validations are kept. (CoP S.7.8.3 paragraph 2)

There was no evidence that laboratory procedures are evaluated or risk assessed for hazards to laboratory staff. The PR should ensure that procedures are evaluated or risk assessed for hazards to laboratory staff.*(CoP 7.8.3 paragraph 4)*

Areas for consideration

Witnessing:
At the time of inspection no documentation of witnessing was observed when placing gametes into cryo preservation or removing gametes from cryo preservation, transporting gametes or at the time of disposal of gametes. The PR should review the procedures for witnessing in consideration of the requirements of *G.13.1.1 (j) (k))*

Donor information forms: ('green forms'): The inspectorate was shown a box of donor information forms: it was noted during an audit of 100 forms (2006) that only three donors had completed questions 22 and 23. These are the sections a donor conceived person may wish to access for non identifying details of their donor. The laboratory manager informed the inspectorate that the donors are offered the opportunity to complete these sections but very few accepted. She emphasized that that the donors are never pressurized to complete the forms but are offered the choice. The interviewing inspector asked the laboratory manager to consider whether more encouragement to complete this form may help prospective donor conceived children. The laboratory manager agreed to add a line on the form to make it clear that the donor had been offered the choice of giving information and had chosen to accept or decline.

Executive recommendations for Licence Committee

The Licence Committee is asked to endorse the recommendations made in relation to:

- Training and competencies;
- Counselling practice;
- Independent counsellor;
- Sperm storage and cry protectant;
- Selection and validation of laboratory procedures;
- Witnessing;
- Donor information forms.

Evaluation
Significant improvement required
Areas not covered on this inspection
None

Report compiled by:

Name	Ellie Suthers
Designation	Inspector
Date	27th November 2008

Appendix A: Centre staff interviewed

Dr Louis Hughes, 2 members of staff and 1 independent counsellor.

Appendix B: Licence history for previous 3 years

05/07/2007 – 31/03/2009
L0011/16/a
Storage only
Active licence with no conditions

01/09/2005 – 31/03/2006
L0011/14/a
Storage only
Expired licence

01/04/2004 – 31/03/2005
L0011/12/a
Storage only
Expired licence

Appendix C: Response of Person Responsible to the inspection report

Centre Number……011……

Name of PR……Dr Louis Hughes

Date of Inspection……

Date of Response……26 January 2009

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

Signed……

Name……

Date……

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.

Factual inaccuracies already discussed and documented by the HFEA following both emails and face to face meeting.

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

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

-Alterations have already been made to the QM to incorporate the necessary amendments to our complaints procedures. -Relevant Alerts received by email have been distributed. - In order to comply with centre having 'documented measurable quality objectives' etc, we intend to develop a questionnaire for our donors to complete on how they have 'enjoyed the experience' here, specifically asking about information given, counselling opportunities, the importance of the pen sketch, any thing we can have done differently to have improved their experience, and would they either recommend us or be willing to return if asked to. - Various centres will also be asked to supply us with the counts they record with our

ampoules so that we can cross reference these with our own records to inform us of accuracy etc.
- Settle plates were used to monitor the air quality in the laboratory and flow hood on 23rd January –both showed no bacterial growth after 48 hours. The laboratory we use is fully accredited and will be forwarding us further details in near future.
-Contract in place for microscope, service chased as they are running behind, have been promised this will occur in February. Balance calibrated using known weights.
-Details of disinfection/sanitation procedures already present in our GM.
-Although staff do not attend any conferences or training days they do keep abreast of journals received from the BFS, ACE and ABA. LS has attended training days (all be it in a different capacity) on being a leader in charge, health and safety and mental health all of which are also of direct benefit in her role at the clinic.
-As this centre employs less than five people it does not need to have procedures for H&S or COSHH forms, this can be confirmed by looking at the documents 'Leading Health and Safety at Work' and 'A brief guide to the COSHH regulations'.
-The complaints cards are already placed where every donor sees it on each and every visit therefore no need to move it is thought necessary just to please non-donors.
-Witnessing of ampoules transported to a third party now occurs. However when discarding samples we respectfully suggest this is not needed as these samples are NOT assigned to any patient, are only discarded if of insufficient quality or past expiry date. The worst that can happen is that the wrong samples are discarded which would only impact the financial aspects of the business rather than a patient.
- Contingency arrangements are being looked into, but spare dewars are already kept. If the premises flooded all would have been lost by the time we could get in anyway.
-Regarding CPM we intend to continue making our own, any changes in constituents will be documented as will when a new batch is used. Each batch will be tested to ensure equivalent levels of post thaw recovery have been maintained and will be sent off for culture. Until after the licence committee a version without egg yolk will be used but this is known to have a lower post thaw recovery (similar to commercial preparations), but this will result in few donors being accepted and more ejaculates being rejected, so clarification over the use of egg yolks will be eagerly awaited.

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

HFEA Licence Committee Meeting
11 February 2009

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Licence Renewal, Louis Hughes (0011)

Members of the Committee:	
Anna Carragher, Lay Member (Chair)	Committee Secretary:
Emily Jackson, Lay Member	Claudia Lally
Richard Harries, Lay Member	
William Ledger, Professor of Obstetrics and Gynaecology at the University of Sheffield	Legal Adviser: Stephen Hocking, Beachcroft LLP
	Observers:
Attending via video conference link:	Mair Crouch
Rebekah Dundas, Lay Member	Gemma Hobcraft

Declarations 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 (55 pages)
- one tabled paper: email from Elaine Suthers dated 11 February.

The Committee also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings and Hearings
- 7th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- HFEA (Licence Committees and Appeals) Regulations 1991 (SI 1991/1889)
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence; and

- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21st January 2009.

1. The Committee noted that this centre has been licensed since 1992 and recruits sperm donors, supplying donor sperm to fertility clinics throughout the UK. The Committee also noted the centre's very low level of activity: 7 donors were recruited in 2007 and 8 in 2008 up to the date of the inspection. The Committee considered the centre's licence renewal application, the licence renewal inspection report dated 23 October 2008, and the tabled email.

2. The Committee noted Mrs Suthers' statement to the effect that the Person Responsible has now completed, and posted to the Executive, his Person Responsible Entry Programme (PREP) assessment. Taking into account that he had completed this assessment, and taking into account the fact that he had been in post for some time, the Committee agreed that they were satisfied as to the suitability of the Person Responsible.

3. The Committee agreed that on the basis of the inspection report they were satisfied as to the suitability of the centre premises. The Committee considered the areas for improvement identified at the inspection, and also the Person Responsible's action plan for addressing these and the update from Mrs Suthers in the form of an email to the Committee Secretary. The Committee considered the breaches which were identified in the report and asked the Legal Adviser to advise them how much they should take into account the individual circumstances of the centre when deciding how much weight to give to these.

4. The Legal Adviser advised the Committee that the requirements of the Act and the Code of Practice applied equally to all centres regardless of their circumstances, but that any decisions made as to sanction or follow up action as a result of any breaches identified in the report should be proportionate to the breach, and to the objective of securing compliance. In that context it was necessary to have regard to the circumstances of the centre. The degree to which those circumstances might cause the committee to take a more or less severe view of a breach would be a matter for it, provided it acted within reasonable margins.

5. The Committee noted the relatively high number of breaches identified in the inspection report. However, on the basis of the work being done to address these concerns and also taking into account the fact that this centre is a small donor

recruitment centre with a very low level of activity, the Committee agreed that they were satisfied as to the use of suitable practices at the centre.

6. The Committee noted that a signed renewal application had been received and the renewal fee had been paid. The Committee agreed that it was satisfied that it had sufficient and satisfactory information on which to make a determination and decided to grant a licence for a period of one year. This time period accorded with the Executive recommendation (although the committee was mindful that it was not bound by this) and reflected the relatively high number of breaches described in the inspection report, and the need to ensure compliance henceforth.

7. The Committee considered whether it wanted to give any advice or recommendations to the centre and agreed that it did. In particular, it noted that a number of areas for improvement identified at the inspection remain unaddressed, or without a commitment by the Person Responsible to address them. These included the requirements that:

- written procedures are in place for acknowledging and investigating complaints
- the centre has an effective means of communicating information to staff
- the Person Responsible establishes an effective system for monitoring and assessing laboratory, clinical and counselling practice
- the centre participates in inter-centre or inter-laboratory comparisons
- staff take part in regular professional development
- the centre has documented procedures for the management of equipment and materials, including a more robust process for the calibration of the scales; and
- laboratory procedures are validated in accordance with professional body guidelines

8. The Committee asked that the above list of actions be addressed by the centre in accordance with the time lines stated in the report. They asked that the Executive works with the centre to ensure that the actions be addressed. The Committee also noted that the establishment of a Quality Management System would be a focus of the next inspection.

9. The Committee noted the response by the Person Responsible on the issue of cryopreservation material. Mr Hocking advised the Committee that standard licence condition 8.8 states that “procurement procedures must protect those

properties of the gamete or embryo that are required for their ultimate clinical use, and at the same time minimise the risk of microbiological contamination during the process". Other provisions of the Code of Practice are to the same effect. There was no express requirement that home-made media could not be used under any circumstances, but it would be a matter for the Committee's judgement as to whether it had sufficient evidence and felt sufficiently confident in any case that such media met the requirement of "minimising" the risk of microbiological contamination. This was noted by the Committee.

10. The Committee also noted the comments at page 51 of the report that the use of home-made preservation media introduces the likelihood of batch variability, and that no quality control documentation or certification could be offered by the centre for their home-made cryoprotectent. The Committee concluded that the current practice of use of home-made preservation media by this centre would not be consistent with standard licence conditions. The Committee agreed that they would therefore expect the centre to move immediately to using commercial cryoprotectent, and asked the Executive to monitor this issue.

11. The Committee asked Mr Hocking to explain what the Code of Practice says about the requirement to display complaints procedures. Mr Hocking advised the Committee that at G.11.3.2 the Code states that "the centre should display notices prominently in reception areas explaining the complaints procedure, and giving the name and contact information for the complaints officer."

12. The Committee agreed that the centre should comply with the Code of Practice by erecting a prominent notice to this effect in its reception area.

13. The Committee noted the low level of completion of pen portraits by donors. The Committee suggested that the centre may want to take steps to address this, possibly by providing written information to donors to explain why this information may be important for any children born following the donation.

Signed…… … Date……..
Anna Carragher (Chair)