Interim Inspection Report

Louis Hughes
0011

Date of Inspection: 16th October 2007

Date of Licence Committee: 28th January 2008

CENTRE DETAILS

Centre Address	99 Harley Street, London W1G 6AQ
Telephone Number	020 7935 9004
Type of Inspection	Interim
Person Responsible	Dr Louis Hughes
Nominal Licensee	Miss Linda Sheahan
Licence Number	L0011/16/a
Inspector(s)	Dr Andrew Leonard Parvez Qureshi
Fee Paid - date	Not applicable
Licence expiry date	31st March 2009

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About the Inspection:

This inspection visit was carried out on the 16th October 2007 and lasted for 5 hours. The report covers the pre-inspection analysis, the visit and information received between January 2007 and October 2007.

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

The report summarises the findings of the interim inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Licence Committee who make the decision about the centre's licence renewal application. The report is also available to patients and the public following the Licence Committee meeting.

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

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

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

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

Brief Description of the Centre and Person Responsible

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

The unit is located in the basement of 99 Harley Street, London. The premise consists 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 visit the centre between 08:00 to 14.30.

The Person Responsible (PR) has considerable experience of the field of assisted reproduction and has been PR of centre 0011 since 1992.

The centre has two other staff members who perform all the laboratory and administrative work required.

Activities of the Centre

Licensed treatment cycles	N/A	
Donor Insemination cycles	N/A	
Unlicensed Treatments	N/A	
Research	N/A	
Storage	✓	Storage of sperm (all donor)

Summary for Licence Committee

Some improvements are required but the Inspectorate were satisfied with the key areas of service provided by the centre and recommend continuation of the centre's licence without additional conditions. The weight to be attached to potential breaches and areas of non-compliance highlighted within this report is a matter for the consideration of the Licence Committee.

Risk Assessment

Current general risk assessment on the risk matrix is 11%, i.e. LOW, with no active incidents. This compares with the 2006 EUTD risk assessment of 9%.

General risk increased slightly this year due to centre 0011 being involved in two breaches of the 10 family limit in the last 3 years. Both incidents were however due to patients reporting outcomes back late to their centres, who in turn were very late in reporting births back to centre 0011 who had supplied their donor sperm.

Overall judgement of the effectiveness of the centre

No Improvements required	Some Improvement required	Significant Improvement required
	X	

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		

Issues which in the view of the inspectorate constitute breaches of the HFE Act (1990) and/or HFEA Code of Practice, 7th edition.

Issue	Action required	Time scale
●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.	31st Dec 2007
●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 (G.11.3.1 – G.11.3.3).	Immediate
●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.	31st Dec 2007

● 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.	31st Dec 2007
● The centre do 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 reasonable by the centre.	31st Dec 2007
●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.	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.	31st Dec 2007

Non-Compliance

Area for improvement	Action required	Time scale
None		

Recommendations	Time scale
●The inspectorate recommend that the centre risk assess lone working and staff safety when donors are visiting, and deploy appropriate control measures (e.g. personal attack alarms) if required to ensure compliance with Code of Practice, 7th edition, S.6.3.2.	31st Dec 2007

●The centre Quality Manual did not contain the procedure for dealing with positive screening tests, which had been written and supplied to HFEA in response to the previous inspection. This should be included in the Quality Manual.	31st Dec 2007

Proposed licence variations

N/A
N/A

Changes/ improvements since last inspection

Recommendation from last inspection	Action taken
No documented procedure for dealing with positive screening results	Documented procedure submitted to HFEA in 2006.
To ensure there are written standard operating procedures for all laboratory processes	Documented procedure submitted to HFEA in 2006.
To ensure relevant written information covering all the implications of donation and the counselling service is prepared	Documented procedure submitted to HFEA in 2006.
To ensure a record supplying relevant written information to the donors is kept	Documented procedure submitted to HFEA in 2006.
To have a written procedure in place for dealing with complaints	Documented procedure submitted to HFEA in 2006.

Additional licence conditions and actions taken by centre since last inspection

NONE

Report of Inspection findings

1. Organisation

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

Summary of findings from inspection
Evidence is drawn from:

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

Summary
Centre 0011 is located in the basement of house which hosts several other private medical practices in Harley Street, London. Access is by the ground floor front door to a manned shared reception desk with adjacent waiting room, and then when instructed by reception, via a staircase and locked door to the centre's administrative/dewar storage room in the basement. This route is used by donors on their first few visits to the centre. Alternative access is 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 key pad lock and a dead lock (the latter open 08:00 – 14:30) 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 was considered appropriate by the inspectorate. Paper donor records are stored securely in the central administrative/dewar storage area and are only accessible to staff on the licence. Electronic records are on computer in the office which was considered secure. Equipment present in the laboratory and the rest of the centre was appropriate for the centre activities. The centre is staffed by the PR and two staff members. Given the average number of donors supplying per week (ca. 6/week in the previous month), the inspectorate considered facilities and staffing were appropriate. The management and co-ordination of resources is overseen by the PR while the daily running of the unit is supervised by the Nominal Licensee (NL). Evidence indicated the centre organisation and resource management was compliant with the requirements of the Code of Practice, 7th edition. Implementation of a Quality Management system is in progress and given the limited complexity of the centre's activities, the quality management system was considered by the inspectorate to be generally appropriate. There are only three member of staff, thus meetings are held as required. Discussions at the meetings include HFEA communications, incidents, complaints, training, quality and governance issues. Meetings are minuted, as required by the last inspection team, and the minutes of the previous inspection were made available. The PR and NL were aware of the HFEA incident alert system. The PR receives the alerts via

email and circulates them to staff and, if relevant, discusses them in unit meetings.

The PR and NL were clear about the roles and responsibilities of each member of the team. Due to external issues the PR attends the centre approximately monthly at present. The NL and other staff member stated they felt well supported and managed as the PR is in daily telephone contact and responds to any issues raised; the inspectorate considered centre management was robust.

The PR is the incident and complaints manager and oversees their investigation and resolution. This is delegated to the NL if the PR is absent. An adverse incident log was evidenced by the inspectorate, as required after the last inspection, and an SOP for incident reporting is present. This was though not compliant with the Code of Practice, 7th edition, S.9.4, in that it does not include, for example, reporting of adverse incidents immediately to the PR then to the HFEA within 12 working hours by phone and 24 working hours in writing. The NL stated that due to the nature of their activities incidents were very rare. Indeed no incidents had occurred since the log's inception.

A contingency plan was evidenced in the quality manual for retrieving 'retired' donor notes from the PR's house and providing medical cover at the centre in case of a disaster.

Business planning involves placing adverts in magazines to attract a diverse range of donors. Third party agreements and robust conditions of supply are in place with all centres in receipt of donated samples from centre 0011.

One aspect of concern was that the staff could sometimes be working alone when a donor arrives. This could constitute a risk to staff safety if a donor becomes unruly, contrary to Code of Practice, 7th edition, S.6.3.2. The centre staff do not consider this to be the case as one aspect of donor screening is that they filter potential donors whose demeanour they are uncomfortable with. They also pointed out that the reception staff are within shouting range if they wish to summon assistance. The inspectorate recommend that the centre risk assess lone working and staff safety when donors are visiting, and deploy appropriate control measures (e.g. personal attack alarms).

Areas for improvement

●The adverse incident procedure is not compliant with the Code of Practice, 7th edition, S.9.4, and should be re-written with reference to these standards.

●The inspectorate recommend that the centre risk assess lone working and staff safety when donors are visiting, and deploy appropriate control measures if required to ensure compliance with Code of Practice, 7th edition, S.6.3.2.

Executive recommendations for Licence Committee

NONE

Areas not covered on this inspection

N/A

Evaluation

SOME IMPROVEMENT REQUIRED

2. Quality of service

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

Summary of findings from inspection:

- Confidentiality (including safe storage of donors' records)
- Privacy and dignity of donors
- Complaint handling
- Donor feedback and satisfaction
- Counselling facilities and services
- Donor selection

Summary
Donor data is stored on a computer in a lockable office and is only accessible to staff on the licence. Paper and laboratory records for active donors are kept in locked cupboards in the administration/dewar storage area. Old donor records are said by the PR to be securely stored at his home. The inspectorate considered donor confidentiality to be maintained Once donors are cleared of viral pathogens and donation commences, they attend the centre on days they, not the centre, select. Entry is via the basement door to which the donors are provided with the key pad access code. The PR and NL stated that donors prefer this system over the more regulated appointment schedules operated by other centres. Donors log in with the staff on duty and are provided with a labelled sample pot and are shown to a production room. Once produced, their sample is handed over to the staff on duty. In discussion with the staff it was clear that they talk socially with donors who wish to do so and are quiet with those who do not. Staff are very positive about the service they provide. The inspectorate consider that the arrangements for donors are sensitive to their dignity and privacy. After inspection of the premise and information for donors, it was noted that the centre do not make clear a method by which complaints can be made, though a complaints' log and procedure were evidenced by the inspectorate. The NL said this was because they consider it inappropriate to provide the complaints procedure to all donors and that donors normally complain verbally to staff, in the vast majority of cases about the literature available in the production rooms. The NL also described receiving a verbal complaint which the inspectorate found was not entered in the complaints log. The inspectorate pointed out that it was a requirement of the Code of Practice, 7th Edition (G.11.3.1 – G.11.3.3) that the centre's complaints procedure was openly displayed and the complaints log was maintained. Further, while the staff appeared amenable to verbal complaints, it was possible that some donors would not voice complaints which, if acted upon, could improve the service level. The NL agreed that some donors may not reattend if there were issues which concern them which they failed to complain about. The inspectorate recommend that the complaints procedure is openly displayed in the centre, providing a mechanism for making verbal and written complaints, and that all complaints are logged in the complaints log, to ensure compliance with the Code of Practice, 7th Edition (G.11.3.1 – G.11.3.3). The centre gains verbal feedback about the service from the donors. The NL stated comments from the donors are always positive.

Counselling is available without charge and is routinely verbally offered to all donors at their first two consultations. The NL stated that most potential donors had already thought through their course of action and were dismissive of counselling. A few are more uncertain and the offer of counselling is emphasised in these cases and they are asked to reattend when they have considered their course of action and are comfortable with it. It was suggested by the inspectorate that written donor information should be provided to all donors (see Section 4, Information), and it should contain details of counselling to ensure counselling is consistently offered in writing to all donors, especially when informed consent is an issue, as required by the Code of Practice, 7th edition, G.5.2.1.

The independent counsellor is registered with the British Association for Counselling and Psychotherapy and counselling is provided on their premises. A counselling audit was not provided with the pre-inspection paperwork. On inspection, the NL stated this was because no donor has used the service in the last year. The NL provides counselling to donors who test positive for viral pathogens in screening and has many years of experience in this activity. The NL stated that appointments with the professional counsellor are also offered in these circumstances.

Donors are only paid expenses, not fees, at £20 per donation. Donors sign that the £20 constitutes reasonable reimbursement of their expenses in travel and time off work, however the centre do not collect receipts as proof. When this was discussed the centre said their donors often forget receipts and are frightened away by the requirement to collect and present them. They feel the expenses system they use is within the spirit of the payment recommendations of the SEED review and does not reward donors; it merely provides reasonable recompense for time off work and travel costs, within a workable administrative system which does not discourage donors from attending

Areas for improvement

●The inspectorate recommended that the complaints procedure is openly displayed in the centre, providing a mechanism for making verbal and written complaints, and that all complaints are logged in the complaints' log to ensure compliance with the Code of Practice, 7th Edition (G.11.3.1 – G.11.3.3).

●Written donor information should contain details of counselling to ensure counselling is consistently offered in writing to all donors, especially when informed consent is an issue, as required by the Code of Practice, 7th edition, G.5.2.1.

Executive recommendations for Licence Committee to consider

●The Licence Committee should consider the method of donor reimbursement (£20 expenses per donation) and that centre 0011 do not currently require receipts from their donors to justify expenses, though donors sign that the £20 constitutes reasonable reimbursement of their expenses in travel and time off work.

Areas not covered on this inspection

N/A

Evaluation

SOME IMPROVEMENT REQUIRED

3. Premises and Equipment

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

Summary of findings from inspection:

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

Summary

The premise consists of the central administrative/dewar storage area, a semen preparation laboratory with three semen production rooms off of it, an office and a staff kitchen. Premises were unchanged since the last inspection and were considered appropriate for the centre activities.

In order to meet the requirements of the EUTD, a new air flow cabinet has been procured and sited in the sperm processing laboratory. This is specified by the manufacturer to produce Grade C air quality or better. This is currently under a two year guarantee period and will be placed on a maintenance contract thereafter. The centre does not have an air quality monitoring programme at present and the air quality of the laboratory is unknown. The inspectorate recommend the development of an air quality monitoring programme to ensure compliance with the air quality requirements in Code of Practice, 7th edition, G.9.4.1 – G.9.4.7 and with Licence Condition A10.19.

The central administrative/dewar storage area is fitted with a low oxygen monitor and alarm and a procedure is in place for responding to it. The storage dewars are filled, as required, from a 240 litre liquid nitrogen reservoir which is stored outside the centre and is filled every two weeks. A spare storage dewar is available in case of emergency. The exterior doors are always opened when storage dewars are topped up, which is done on a regular schedule according to an evidenced standard operating procedure.

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. The centre consider that low nitrogen alarms and temperature monitoring are not needed on their dewars as the sperm samples stored are commercial donor stock only. Centres purchase 10 ampoules of sperm per donor slot, which centre 0011 considers provides enough for the centre to store sibling stock if a first pregnancy results.

Key pieces of laboratory equipment were seen to be serviced regularly. Documented evidence was seen of monitoring temperatures of the liquefaction incubator, and of the filling of dewars with liquid nitrogen. The centre do not validate fridge and freezer temperatures. To ensure compliance with the Code of Practice, 7th edition, S.6.4.2, the inspectorate recommend that an external temperature probe is purchased and used to validate the fridge

and freezer temperatures on a schedule determined as reasonable by the centre; the results should be logged.

The centre is an effective reporter of incidents to HFEA, and HFEA Alert bulletins are disseminated back to staff by the PR.

Areas for improvement

● The centre does not have an air quality monitoring programme at present and air quality in the sperm processing laboratory is unknown. The inspectorate recommend the development of an air quality monitoring programme to ensure compliance with the air quality requirements in Code of Practice, 7th edition, G.9.4.1 – G.9.4.7 and with Licence Condition A10.19.

● The centre do not validate and verify fridge and freezer temperatures. To ensure compliance with the Code of Practice, 7th edition, S.6.4.2, the inspectorate recommend that the fridge and freezer temperatures are validated, and that this testing is logged, on a schedule determined as reasonable by the centre.

Executive recommendations for Licence Committee to consider

●The storage dewars are not fit with low nitrogen alarms nor with temperature monitoring devices, thus monitoring of storage conditions 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.

Areas not covered on this inspection

N/A

Evaluation

SOME IMPROVEMENT REQUIRED

4. Information

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

Summary of findings from inspection:

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

Summary
Documents within the centre are effectively controlled. The document control officer, the NL, oversees their issue, change, review and destruction and communicates these changes to the staff. This was evidenced from the controlled documents. Potential donors are verbally provided with information covering all the relevant aspects of sperm donation. A checklist is used by one staff member while the NL has years of experience and is confident all information required is discussed by her with donors. The centre has written donor information which was considered by the inspectorate as suitable. The centre said however that no written information is provided to donors unless requested, because donors leave it behind at the centre. The inspectorate recommend that all donors are given written donor information, as required by the Code of Practice, 7th edition, S.7.4.1. The HFEA Registry Department considered that 35 donor registrations were incorrectly reported by centre 0011. Centre 0011 disputed 8 of these cases because they considered other centres were responsible for the registration; this seemed to be true. All other cases involved incomplete donor personal data entry, just the donor town of birth being absent in nearly all cases. The centre explained that some donors did not know their town of birth. These registration conflicts have been referred back to HFEA Registry for future discussion with the centre. The centre agreed to collect all required donor details in the future. Donors complete HFEA consent forms at a second consultation, after having been verbally advised about screening, non-anonymity, counselling and other aspects of the donation process. Signed HFEA consent forms are stored securely with the donor records. Supplied centres are sent an anonymised consent form with the centre donor number and the use by date, along with the donor registration (again anonymised), the donor characteristics, the terms and conditions of supply and a copy of the top sheet of centre 0011's HFEA licence. Donor records were inspected on the day of the inspection. The records were found to be well organised and complete. Evidence of appropriate consent, assessment and screening certification were found in all files. The supply of samples to other centres was clearly logged. The centre Quality Manual contains all their standard operating procedures and donor information. It was reviewed and found to be satisfactory, except for issues raised in other areas of this report. It also did not contain the procedure for dealing with positive screening tests, which had been written and supplied to HFEA in response to the previous inspection.

Areas for improvement
●Written donor information is not provided to all donors, even though effective donor information has been written by the centre. The inspectorate recommend that donors are all given written donor information, as required by the Code of Practice, 7th edition, S.7.4.1. This donor information should include details of counselling to ensure counselling is consistently offered to all donors. It should also include details about the complaints procedure. ●The centre Quality Manual did not contain the procedure for dealing with positive screening tests, which had been written and supplied to HFEA in response to the previous inspection. This should be included in the Quality Manual.
Executive recommendations for Licence Committee
To note that the centre say they inspect the donor passport as proof of identity yet HFEA registry report that a number of donor registrations do not contain the town or city of birth. In the view of the inspectorate this suggests inadequate collection and submission to the HFEA of relevant donor information.
Areas not covered on this inspection
N/A
Evaluation
SOME IMPROVEMENT REQUIRED

5. Laboratory and Clinical Practice

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

Summary of findings from inspection:

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

Full time equivalent staff

GMC registered doctors	1
NMC registered nurses	0
HPC registered scientists	0
Scientists	2
Support staff (receptionists, record managers, quality and risk managers etc)	0

Summary of laboratory audit
The unit carried out an audit of stored sperm in December 2006. A brief report of this was supplied to the inspectorate at the premises, in which the NL stated to the PR that no discrepancies were found.
Summary of spot check of stored material
Two sperm samples were tracked from the records to the tank, no discrepancies were noted. Two sperm samples were tracked from the tank to the records, no discrepancies were noted.
Areas of firm compliance
Potential donors telephone the centre in response to advertisements and, after discussing the donation process, are asked to attend for a consultation and blood test if still interested. At this first consultation, a blood test is taken to test for Tay Sachs, Cytomegalovirus, beta-thalassaemia and sickle cell trait and information pertaining to donation is discussed, which includes the requirement for donor registration and that donation is no longer anonymous. All potential donors are also told they must supply their passport as proof of identification and complete a self assessment form covering lifestyle, medical and family history and physical characteristics. This was surprising to the inspectorate as town of birth is normally provided in a passport yet was missing from some patient registrations, as described in Section 4 above. Donors attend 1 – 4 weeks later for screening results and, if negative, another blood sample is taken and tested for cytomegalovirus, Hepatitis B and C, HIV and syphilis. Genetic analysis is also performed for karyotype and for cystic fibrosis carrier status. A urine sample is taken for Chlamydia and gonorrhoea screening. The donor also completes the HFEA donor registration form and consent and provides a semen sample. An aliquot is analysed for concentration, morphology and motility and the remainder is stored segregated until the

screening results come through. The centre consider their screening protocol to be in accordance with national guidelines and the inspectorate agree with this view.

If screened positive, sperm samples are perished and disposed of as clinical waste, while counselling is offered to the donor, according to the NL. If negative, the ampoules are moved to a main storage dewar and the donor completes a donation course during which 120 ampoules are collected and stored in the same dewar. The donor is tested periodically during the course of donation and six months after the course of donation is completed, for Cytomegalovirus, Hepatitis B and C, HIV, syphilis, chlamydia and gonorrhoea. If the final screen is clear the semen samples are released for use and the donors are paid their expenses. If any donor tests positive during their donation programme, all aliquots of sperm stored in that dewar are discarded.

The centre have instigated a new system of sample supply in the last year to minimise the risk of breaches of the 10 family limit. This involves selling 'a donor slot' consisting of 10 ampoules of a donor's sperm guaranteed to contain at least 5 million motile sperm, for use on a named patient in a specified year period. Centre 0011 said that centres supplied were in favour of this new arrangement as they have enough sperm for repeat use and/or storage as sibling stock. Centre 0011 now initially supply 12 slots simultaneously from each donor. The centre said that a recent meeting of the HFEA Licensed Centres Panel had agreed that this practice was compliant with the HFE Act (1990) and was unlikely to lead to a breach of the 10 family limit. Centre 0011 made clear to the inspectorate that, as part of their contract of supply and third party agreement with centres supplied, they demand that outcomes are rapidly reported back to them; centre 0011 refuse to supply further orders to centres which fail to do so. Donors who are approaching their 10 family limits are not supplied to new centres until all outcomes have been reported back to avoid a breach of the 10 families limit. The PR considers the 10 family rule in the UK to be excessively restrictive and notes that in Denmark, which has a population 20% of that in the UK, they allow a donor to contribute to 25 families. He also notes that centre 0011 conscientiously reports incidents in which other centres, through failing to report outcomes to centre 0011 in reasonable time, risk a breach of the 10 family limit. He would like it noted that these incidents are not their 'fault' and that they have introduced their 10 ampoule/year donor slot system to minimise the risk even further.

The double witnessing in the laboratory was evidenced in laboratory notes. The laboratory manager was able to find all paperwork requested. This indicated a well organised documentation system. Laboratory protocols and the experience of the laboratory staff (current staff have been in place for over 7 years) support a conclusion that donor sperm is safely handled. An air flow cabinet has also been recently installed in the laboratory which the manufacturers assure supplies Grade C air or cleaner. The inspectorate note however that laboratory background air is not cleaned and that air quality monitoring is not yet performed. The inspectorate recommend that a programme of air quality monitoring is instigated throughout the laboratory and that risk assessment of the effects on the donor gametes of the background and critical work area air qualities should be performed.

Staff are well qualified and retention is very good (all staff in post more than 7 years). All staff were happy with their opportunities for training and CPD.

Areas for improvement
NONE
Executive recommendations for Licence Committee
NONE
Areas not covered on this inspection
N/A
Evaluation
SOME IMPROVEMENT REQUIRED

Report compiled by:

Name: Dr Andy Leonard

Designation: Inspector

Date: 12th November 2007

Appendix A: Centre Staff interviewed

Dr Louis Hughes (PR), the Nominal Licensee and on other staff member

Appendix B: Licence history for previous 3 years

Licensing History

Centre: Louis Hughes

Number: 0011

Licence	Status	Type	Active From	Expiry Date
L0011/15/a	Active	Storage only	01/04/2006	31/03/2009
L0011/14/a	Expired	Storage only	01/09/2005	31/03/2006
L0011/13/b	Replaced by New Version	Storage only	03/10/2005	28/02/2006
L0011/13/a	Replaced by New Version	Storage only	01/04/2005	31/03/2006
L0011/12/a	Expired	Storage only	01/04/2004	31/03/2006
L0011/B/b	Expired	Storage with Treatment	16/09/2003	31/03/2004

Appendix C: Response of the Person Responsible to the Report

Centre Number……0011

Name of PR……Dr Louis Hughes

Date of Inspection……16th October 2007

Date of Response……20th December 2007

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

Reply by e-mail on 20th December 2007:

I write in response to the recent inspection report.

1. No alarms on storage dewars.

This has been the subject of numerous discussions over a two to three year period. The HFEA have advised us that as the samples stored are not patients but donor samples that alarms are not necessary as the only potential loss is to ourselves. The inspector said he would check our records on this –he obviously has not done so.

2. We have never asked for receipts from donors. They are only paid expenses. We give them £20 towards taxi fares receipts are not asked for as it is down to the individual as to whether he wants to use a taxi. The conversation mentioned in the report never even took place.

3. Incubators and heated blocks.

The inspector is confusing us with a totally different centre, as we do not have incubators in the traditional sense; rather one used to aid in the liquefaction of samples, and we have never possessed a heated block. This is like a clock striking thirteen –not only inaccurate in itself but casts a doubt on all that went before.

4. Third Party Agreements.

Firstly, we would like to know what the outrageous charge of £250 is actually for. If we take this at face value it would add up to £1,750 per annum. All our third party suppliers use CE approved products apart from two. The Doctor's laboratory being a licensed laboratory conform to a high quality standard and have provided us with evidence of this, and the only other one is Kynisi Couriers. Our previous inspector had informed us that by using CE approved products this requirement would be negated. Hence we would like to have a justification for this charge.

Dr Louis Hughes

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

Signed……

Name……..

Date……

2. Correction of factual inaccuracies

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

See 2) and 3) in response above

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

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