



Renewal Inspection Report

**Belfast Regional Fertility Centre
0077**

**Date of Inspection: 26 February 2009
Date of Licence Committee: 28 May 2009**

Centre Details

Person Responsible	Mr Peter McFaul
Nominal Licensee	Ms Bernie McNalley
Centre name	Belfast Regional Fertility Centre
Centre number	0077
Centre address	RJMS, Royal Hospitals Grosvenor Rd Belfast BT12 6BB
Type of inspection	Interim
Inspector(s)	Miss Angela Sutherland Dr Andrew Leonard Mrs Gil Walsh
Fee paid	Yes
Licence expiry date	L0077/16/D 28 February 2010
NHS/ Private/ Both	Both

Index

Centre Details	2
About the Inspection:	4
Brief Description of the Centre and Person Responsible	5
Activities of the Centre for the time period from Nov 2006 – Nov 2008	5
Summary for Licence Committee.....	5
Evaluations from the inspection	6
Breaches of the Act, Standard Licence Conditions or Code of Practice:	6
Non-Compliance	7
Recommendations	7
Changes/ improvements since last inspection	8
Report of inspection findings.....	10
1.Organisation.....	10
2. Quality of service.....	12
3. Premises and Equipment	14
4. Information	16
5. Clinical, laboratory and counselling practice	17
Report compiled by:.....	20
Appendix A: Centre staff interviewed.....	Error! Bookmark not defined.
Appendix B: Licence history for previous 3 years	Error! Bookmark not defined.
Appendix C: Response of Person Responsible to the inspection report	Error! Bookmark not defined.

About the Inspection:

This inspection visit was carried out on 26 February 2009 and lasted for 7 hours.

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

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

At the visit the inspection team assesses the effectiveness of the centre through five topics. These are:

How well the centre is organised

The quality of the service for patients and donors

The premises and equipment

Information provided to patients and to the HFEA

The clinical and laboratory processes and competence of staff.

An evaluation is given at the end of each topic and for the overall effectiveness of the centre:

No Improvements Required – given to centres where there are no Code of Practice, legal requirements or conditions that need to be imposed.

Some Improvements Required – given to centres that are generally satisfactory but with areas that need attention. Recommendations will usually be made to help Persons Responsible to improve the service.

Significant Improvements Required – given to centres that have considerable scope for improvement and have unacceptable outcomes in at least one area, causing concern sufficient to necessitate an immediate action plan or conditions put on the Licence.

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

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

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

Brief Description of the Centre and Person Responsible

The centre has been licensed since 1992 and offers treatment to both NHS and privately funded patients, including IVF, ICSI, egg sharing, and egg donation.

The centre is a self-contained unit situated within the Royal Hospital (Belfast) with the patient waiting room situated just outside the entrance. Access to the centre is through doors with controlled access.

The centre is open 6 days a week, including Sundays and the PIQ describes that all treatments can be arranged on any day.

The Person Responsible (PR) is Dr Peter McFaul, who has held this position since February 2005. Dr McFaul is registered with the GMC and is on the specialist register for Obstetrics and Gynaecology.

Activities of the Centre¹ for the time period from Nov 2006 – Nov 2008

In vitro fertilisation (IVF)	1143
Intracytoplasmic sperm injection (ICSI)	810
Donor Insemination	1
Research	No
Storage gametes/embryos	Yes

Summary for Licence Committee

At inspection the centre appeared to be well lead, with a defined management structure, and a cohesive team. The centre management team has been proactive in complying with the recommendations made in relation to the management of resources. The PR has completed the PR entry programme appropriately.

Outcomes are statistically within the range of national averages and patient feedback has generally been very positive.

No areas of improvement were identified in relation to quality of service, premises and equipment and information. Some improvements were identified in the course of the inspection relating to the centres organisation and laboratory and clinical processes.

It is recommended that these areas of practice are addressed in the timescales documented in the report.

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.

Evaluations from the inspection

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

Breaches of the Act, 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
<p>Third party agreements While the QM and PR reported that effort has been made to obtain all third party agreements, some remain outstanding.</p>	<p>The PR should ensure that there are written agreements with all third parties who supply goods or services which influence the quality and safety of gametes and embryos in compliance with standard licence condition A.5.1.</p>	<p>To be assessed at next inspection.</p>
<p>Incident management Inspection of the centre's internal incident log revealed 3 incidents had occurred that had not been reported to the HFEA.</p>	<p>The PR should ensure notification of the HFEA, of adverse incidents and the subsequent provision of a confirmation/conclusion report. Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of the identification of the adverse incident and submit an adverse incident report form within 24 working hours in compliance with A.4.3 and S.9.4.2.</p> <p>The PR should ensure that the centre's SOPs adequately reflect the HFEA reporting requirements and/or that staff awareness of reporting requirements is raised.</p>	<p>This has since been rectified by the PR.</p>
Payment of fees		

The centre is taking on average 50 days to pay HFEA invoices.	The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition A.16.3.	Progress to be monitored at the next inspection.
Procurement, distribution and receipt of gametes and embryos While the laboratory manager reported that all gametes and embryo transportation to date has been carried out in compliance with the HFEA Code of Practice, the centre does not have a documented procedure for the process.	The PR should ensure that there is a system in place that results in clearly defined and effective standard operating procedures (SOPs) for the activities for which a licence has been granted. The system must ensure that work performed is standardised and that all steps are traceable (i.e. coding, transport, distribution) in line with the requirements of A.10.24	SOPs to be established by 01 July 2009.
Validation Validation of laboratory processes has not occurred.	The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.(A.11.11).	Compliance to be assessed at next inspection.

Non-Compliance

Area for improvement	Action required	Time scale
Nil		

Recommendations

Area for improvement	Action required	Time scale
Nil		

Changes/ improvements since last inspection (From previous inspection report 22.01.08)

Recommendations	Action noted at inspection 26.02.09
<p>On 14 April 2008, as a consequence of the failure to implement the recommendation to perform an activity risk assessment on two previous occasions, Licence Committee varied the centre's licence to include the following condition:</p> <p><i>“The Person Responsible must commission an appropriately qualified and experienced independent person to carry out an assessment of the number of treatment cycles that can safely be carried out at the centre. The number of staff, experience of staff and the centre's equipment and premises should all be taken into account. Furthermore, the risk assessment should take into account any risks indicated by the findings of HFEA reports of the most recent inspections of the centre which will be provided to the independent person by the HFEA together with the documentation in relation to accusations of bullying and harassment. The findings of this assessment should then be submitted by the centre to the HFEA not later than 1 August 2008.” (LC Minutes 01.09.08)</i></p>	<p>On 01 September 2008 the Executive reported to Licence Committee that the following actions had been reported by the centre:</p> <p><i>“An independent assessment had taken place on 23 June 2008 and the report of the assessment was received at the HFEA on 16 July 2008. The assessment covered staffing and management, laboratory facilities and contingency arrangements.</i></p> <p><i>An action plan drawn up by the centre to address the issues arising from the HFEA interim inspection and independent assessment was received at the HFEA on 15 August 2008.</i></p> <p><i>An independent analysis of team working at the centre was undertaken on 17 January 2008. This addressed the issues of bullying and intimidation that had been raised at the HFEA interim inspection in August 2007. This was also received 15 August 2008.” (LC Minutes 01.09.08)</i></p> <p>The Committee considered the findings of the independent assessment and decided to impose the recommendation of restricting the centre's activity to 3 cycles per week per experienced member of the embryology team and 2 cycles per experienced locum and trained embryologist. This was based on the finding that a high number of reported incidents were directly attributable to low staffing levels and that activity was considered unsustainable under the staffing levels as they stood.</p> <p>The PR has provided monthly activity reports to the HFEA that indicate compliance with this condition. During inspection the PR, Centre Manager (CM)</p>

	and Laboratory Manager expressed a desire for this restriction to be lifted and for future activity levels to be managed by the centre.
Records shall be kept of meetings and made available to all staff. The inspectorate noted that some meetings were held on an ad hoc basis and were not minuted.	Meeting records were examined during inspection and were found to be compliant with CoP S.6.2.13.
Centres procuring gametes or embryos from donors should maintain a central log of all expenses and compensation paid. The donor expense log was not available on the day.	Not inspected.
Some laboratory staff found it difficult to maintain their CPD as activity levels were high and sometimes this necessitated having to do CPD in own time.	Laboratory and nursing staff CPD records reflected compliance with CoP S.6.2.9. (See detail Pg 18)
Establishing documented evidence that provides a high degree of assurance that a specific Process, SOP, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and Quality attributes. Some older equipment is not validated and none of the processes are validated.	All essential equipment was seen to be validated at inspection but processes are yet to be validated. The laboratory manager reported that it is planned for the company that carried out the equipment validation return to assess key laboratory processes.
The Centre Management shall encourage staff to make suggestions for the improvement of any aspect of the Centre. There is no set process for staff suggestions.	Meeting minutes reflected a high level of staff attendance at multidisciplinary meetings where a variety of issues were discussed and nursing staff interviewed during the inspection reported that they felt able to make suggestions and were involved in decision making at the centre. (See detail Pg 11)
The Centre shall establish Documented Procedures for the resolution of complaints or other feedback received from users. There is no set process for receipt of patient feedback.	The centre utilises patient questionnaires and evidence was seen of analysis of feedback results and complaints and resultant action. (See detail Pg 9/11)
Leadership and management at the centre does not reflect favourably on the centres ability to expedite effective communication at management level.	An appropriate and apparently effective management structure was observed to be place at the time of inspection and all staff interviewed stated that they were content with the support received from senior management at the centre.
Appropriate screening tests are not performed and recorded in surrogacy cases.	An audit of 3 sets of donor records at the time of inspection showed no discrepancies.

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

Leadership and management

The PR has completed the HFEA PR training programme and is considered appropriately qualified and experienced for the role. (CoP S.4.1.5; S.4.1.4) An organisational chart was supplied at inspection that indicates lines of responsibility.

All staff interviewed during the inspection stated that they were content with the support received from senior management at the centre.

Organisation of the centre

The PR and senior staff stated that all members of staff are appropriately qualified and experienced for their roles. This was confirmed by review of staff curriculum vitae and training logs supplied at inspection. (CoP S.4.1.7)

Staff interviewed during the inspection confirmed that they are encouraged to make suggestions and are kept up-to-date regarding changes and developments within the centre. Meeting minutes supplied by the QM suggest regular, well attended multi-disciplinary meetings are held. (CoP S.6.2.13)

Complaints management

At inspection, a comprehensive log was supplied that documented the system used to manage and resolve complaints. Discussion with the QM and CM confirmed that they have identified a trend regarding waiting lists times amongst complaints received and that everything possible is being done to minimise the issue. Complaints information was clearly displayed in the patient waiting area. (CoP S.9.2.2)

Contingency arrangements

The centre has a formal reciprocal contingency arrangement with centre 0200 (CoP S.6.3.4)

(b)). The PR expressed confidence that this arrangement is adequate for the centre's current needs.

Meetings

All staff interviewed confirmed that they felt well informed of developments and issues and felt that they could make suggestions and contribute to the running of the centre. Staff interviewed stated that they were encouraged to attend multidisciplinary and staff group meetings. The most recently recruited member of the nursing team said she felt welcome at such meetings and was encouraged to participate.

Areas for improvement

Third party agreements

While the QM and PR reported that efforts have been made to obtain all third party agreements, some remain outstanding.

Incident management

Inspection of the centre's internal incident log revealed 3 incidents that had not been reported to the HFEA.

The unreported incidents were discussed with the PR during interview and have since been retrospectively reported to the HFEA.

Payment of fees

The centre is taking on average 50 days to pay HFEA invoices.

Areas for consideration

There are no areas for consideration.

Executive recommendations for Licence Committee

The PR should ensure that there are written agreements with all third parties who supply goods or services which influence the quality and safety of gametes and embryos in compliance with standard licence condition A.5.1.

The PR should ensure notification of the HFEA, of adverse incidents and the subsequent provision of a confirmation/conclusion report. Centres must report all adverse incidents to the HFEA by telephone within 12 working hours of the identification of the adverse incident and submit an adverse incident report form within 24 working hours. in compliance with A.4.3 and S.9.4.2.

The PR should review whether there are any barriers to the prompt payment of HFEA fees and take steps to ensure they are paid within 28 days in compliance with standard licence condition A.16.3.

Evaluation

Some improvement required.

Areas not covered on this inspection

Nil

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
- Live birth rates

Live birth rates ¹
In the time period from January 2004 to December 2007, the centre's outcomes were in line with national averages.
Areas of firm compliance
Quality management system The QM has been in post since January 2009 and showed evidence at inspection of extensive quality management experience. Due to the recent nature of her employment she is currently supported by the CM. It was noted at inspection that a comprehensive quality management system is being developed that includes; <ul style="list-style-type: none">• A quality manual that appeared compliant with the requirements of CoP S.5.2.3/4.• Quality objectives and plans for annual review. (CoP S.4.2.4)• Standard operating procedures relevant to key activities and processes (CoP S.5.2.2 (a))
Document control The QM demonstrated an effective document control system and all documents examined at inspection were found to have been controlled in compliance with CoP S.5.2.5.
Feedback/ Quality of service The centre offers different questionnaires to inpatients and outpatients and evidence of analysis of results was provided at inspection (CoP S.4.2.9 (a) and S.9.1.2). It was noted that positive action has taken place in response to feedback analysis. For example; an email system was developed in response to negative patient comments regarding enquiries. In general patient feedback to the HFEA was positive. However 5 of the 13 responses included negative comments regarding the efficiency and general manner of administrative staff. Discussion with the PR, QM and CM revealed that they are aware of this problem and have arranged for all administrative staff to attend a "Customer Care" course and have reviewed the staff induction programme, thus demonstrating compliance with S.4.2.3(c).

Areas for improvement
No areas for improvement.
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
The Executive has no recommendation for the Licence Committee with regard to quality of service.
Evaluation
No improvements required.
Areas not covered on this inspection
Nil

3. Premises and Equipment

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

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

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

Areas of firm compliance

Premises

At inspection staff, clinical and laboratory facilities appeared to be suitable for the activities for which the centre is licensed. (CoP S.6.3.2) The centre as a whole appeared clean and well organised and a cleaning rota was seen on inspection. Cleanliness is monitored with a bi-monthly audit. The centre is entered via the main maternity unit entrance.

The PR reported that a plan is in place to redecorate the clinical areas of the centre and expand the waiting area at the end of April 2009. Any effect on patient safety and/or licensed treatment will be risk assessed and a copy of the results submitted to the HFEA.

Laboratory facilities:

Discussion with staff and observation during the inspection showed that laboratory facilities appear to be appropriate for the activities carried out in them. Storage dewars were alarmed and procedures for responding to emergencies are in place. Inspection of the laboratory confirmed the presence of a low oxygen monitor and extraction fans (CoP S6.3.8) and a documented procedure to deal with liquid nitrogen leaks and dewar non-conformities was seen (CoP S.6.3.8 (d)).

Air quality

Inspection confirmed that air quality is appropriately monitored in the laboratory with monthly settle and contact plates, quarterly airborne bacterial sampling and annual particle counts. Monitoring is performed by an external company and the protocol was seen to be validated. Recent results were compliant with CoP A.10.19.

Management of equipment and materials

Maintenance and service records were available for all laboratory equipment. Several items of equipment sampled on inspection were all within servicing schedules and had been subjected to portable electrical appliance testing

Counselling facilities

Counselling at the centre is conducted by an independent fertility counselling service which has recently relocated to an area out of the city. The counsellor interviewed stated that client

feedback indicated that the relocation of the service has been welcomed by users as there is parking available and the premises are more congenial. The counsellor stated that she would attend the centre should a client request being seen at the centre.

Records storage

The centre was found to store all patient records within appropriately secure facilities accessible to licensed staff (CoP S.6.5.1 (d)).

Areas for improvement

No areas for improvement.

Areas for consideration

No areas for consideration.

Executive recommendations for Licence Committee

The Executive has no recommendations for the Licence Committee with regard to premises and equipment.

Evaluation

No improvement required.

Areas not covered on this inspection

Counselling premises

The premises in which counselling takes place were not inspected.

4. Information

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

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

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

Areas of firm compliance
Information for service users: All patient information sheets were submitted to the HFEA at inspection and appeared to contain required information in an appropriate format. Analysis of patient information leaflets confirmed that all service users are provided with comprehensive treatment information. Satisfaction surveys consistently noted that patients felt adequately informed and staff interviews confirmed that patients are given sufficient time to contemplate and ask questions before signing consent to treatment (CoP S.7.4.1). The in-date HFEA licence and information regarding how to make a complaint were clearly displayed in the patient waiting/reception area.
Consent/Welfare of the Child The HFEA Compliance Audit team visited the centre on the 17 March 2009. 17 sets of patient records were audited for accuracy and completeness of consent forms and the Welfare of the Child assessment. No discrepancies were found (CoP S.7.1.4 and CoP D2006/05).
Areas for improvement
No areas for improvement.
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
The Executive has no recommendations for the Licence Committee with regard to information.
Evaluation
No improvement required.
Areas not covered on this inspection
Provision of information to the HFEA register. Access to health records.

5. Clinical, laboratory and counselling practice

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

Summary of findings from inspection:

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

Full time equivalent staff

Based on information provided with the pre-inspection questionnaire.

GMC registered doctors	3.75
NMC registered nurses	9.48
Non NMC registered clinical staff	0
HPC registered scientists	2
Scientists working towards registration	2
Support staff (receptionists, record managers, quality and risk managers etc)	7.95
Counsellors	3

Summary of laboratory audit

Information provided with the pre-inspection information confirms that the centre last audited stored material on 04 November 2008. Approximately 8500 samples were checked and one "consent related" discrepancy was found. This has since been resolved.

Summary of spot check of stored material

No discrepancies noted.

Areas of firm compliance

Staff training and competency

During inspection the training logs, competency assessments and professional development records for the centre's most senior and most recently employed nurses were examined. Both appeared comprehensive, containing records of mandatory and voluntary education and training (CoP S.6.2.9). A programme of competency assessment has been initiated for laboratory staff and their training and CPD logs were observed, which indicated compliance in these areas.

Screening of donors

Three sets of patient records related to treatment involving donor gametes were audited during inspection all required screening had been conducted.

Three embryo transfer

The centre's multiple birth minimisation strategy and patient information related to elective single embryo transfer were supplied to the inspection team in compliance with D.2008/5 and a log of three embryo transfers was seen to be maintained (CH(08)03). Based on HFEA data for the year December 2007 to November 2008 the centre's multiple birth rate was 19.05%.

Traceability and coding

A protocol for recording the lot numbers of materials that come into contact with, and could potentially affect the safety and quality of gametes and embryos, was provided with the pre-inspection information. This was verified during inspection as demonstrative of compliance with CoP S.7.3.1.

Witnessing

It was observed on the day of inspection that the centre has a reviewed and document controlled witnessing policy. Inspection of the training records confirmed that all staff have been trained in witnessing procedures (G.13.6.2).

The manual witnessing process has been risk assessed since the last inspection and five sets of patient records examined contained evidence of documentation of witnessing in compliance with requirements.

Counselling practice

Interviews with centre staff confirmed that all patients are offered counselling which, where taken up, is provided independent of clinical decision making.

All counselling is provided free to service users who may be referred by the centre or can contact the counselling centre directly. The service is provided separately from the activities of the centre and employs two counsellors. The qualifications for both counsellors were seen to be appropriate and both counsellors participate in regular independent supervision in line with BACP ethical framework recommendations.

Both counsellors are members of BICA and are founder members of the Irish Fertility Counsellors' Association and regularly attend clinical meetings at the centre.

An audit of counselling was made available on inspection. In the year January to December 2008, 532 counselling sessions were arranged, approximately 50% of which were self referred.

The counsellor interviewed was able to describe appropriate management of welfare of the child concerns and stated that clients requiring their case to be considered by the centre's ethic committee are fully informed about the process at all times.

The counsellor interviewed confirmed that counselling records are stored securely at the counselling centre, access to which is controlled.

All patients attending counselling are offered a satisfaction questionnaire to fill out.

Areas for improvement
<p>Procurement, distribution and receipt of gametes and embryos While the laboratory manager reported that all gametes and embryo transportation to date has been carried out in compliance with the HFEA Code of Practice, the centre does not have a documented procedure to ensure this.</p> <p>Validation While inspection revealed compliance with the validation of key equipment, the validation of laboratory processes has not occurred. The laboratory manager reported that it is intended that the external company that carried out the equipment validation will return to assess processes.</p>
Areas for consideration
No areas for consideration.
Executive recommendations for Licence Committee
<p>The PR should ensure that there is a system in place that results in clearly defined and effective standard operating procedures (SOPs) for the activities for which a licence has been granted. The system must ensure that work performed is standardised and that all steps are traceable (i.e. coding, transport, distribution) in line with the requirements of A.10.24.</p> <p>The critical processing procedures must be validated and must not render the gametes or embryos clinically ineffective or harmful to the recipient. This validation may be based on studies performed by the establishment itself, or on data from published studies or from well-established processing procedures, by retrospective evaluation of the clinical results of tissues provided by the establishment.(A.11.11).</p>
Evaluation
Some improvement required.
Areas not covered on this inspection
Nil

Report compiled by:

Name: Angela Sutherland.....

Designation: Inspector.....

Date 27 April 2009.....

Appendix C: Response of Person Responsible to the inspection report

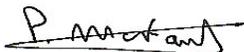
Centre Number.....077.....

Name of PR... DR PETER McFAUL.....

Date of Inspection.....26 Feb 2009.....

Date of Response.....17 April 2009.....

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

Signed..... 

Name.....Dr P McFaul.....

Date..... 2009-04-17.....

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.

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

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