Inspection Report

Date of Inspection: 28 March 2012
Purpose of inspection: Renewal of Treatment Licence
Length of inspection: 7 hours
Inspectors Parvez Qureshi
Stephanie Gadd

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 10 January 2010 and 1 June 2012.

Date of Executive Licensing Panel: 15 June 2012

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. 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 Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Craigavon Area Hospital
Centre number	0294
Licence number	L/0294/d/2
Centre address	Lurgan Road, Portadown, Craigavon, BT63 5QQ,
Person Responsible	Dr Timothy McCormick
Licence Holder	---
Date licence issued	01/09/2009
Licence expiry date	31/08/2012
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Brief description of the centre and its licensing history:
This centre is set within the general gynaecology service of Craigavon Area Hospital, Co. Armagh, Northern Ireland and is part of the Southern Health and Social Care Trust. The centre shares resources with the general gynaecology and maternity outpatient department.

The centre has been licensed since September 2007 and provides services for the investigation and diagnosis of sub fertility and treatment for couples who may benefit from stimulated and un-stimulated cycles of partner sperm intrauterine insemination (IUI).

Semen analysis and preparation for insemination is conducted in a laboratory within the hospital, but is located in another building.

Since the last inspection in January 2010, the premises have not undergone any major changes.

A variation of the centre's licence to change the Person Responsible (PR) from Dr Richard Noel Heasley to Dr Timothy McCormick was granted by an Executive Licensing Panel in February 2012. The new PR is a consultant gynaecologist and obstetrician and is registered with the General Medical Council (GMC). He is also a member of the Royal College of Obstetricians and Gynaecologists.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period I January 2010 – 31 December 2010*
Intra uterine insemination (IUI)	263

Other licensable activities	Not applicable

Outcomes*

For the year 2010 the centre reported 263 cycles of partner insemination with 22 pregnancies. This equates to an 8% pregnancy rate.

*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.

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR is suitable and has, with the exception of the areas of non-compliance identified in this report, discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with General Direction 0008, in application for renewal of their licence
- the centre has submitted an application fee to the HFEA in accordance with requirements

The Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including one major area of non-compliance and two other areas of non-compliance or areas of poor practice.

Since the inspection visit on 28 March 2012 the PR has provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance:

- The PR should establish quality indicators (QIs) or objectives relevant to all activities and conduct regular audits for them.

Other areas of practice that require improvement:

- The PR should ensure that centre's organisational chart is updated to reflect current staffing relationships and reporting lines.
- The PR should ensure that identification of persons responsible for managing arrangement between the centre and the third party is included in any third party agreement.

The inspection team recommend the renewal of the centre's licence for a period of four years without additional conditions.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned.

▶ **Witnessing and assuring patient and donor identification** (Guidance Note 18)
What the centre does well. **Witnessing – Guidance Note 18** The centre has a standard operating procedure (SOP) in place for the process to be followed when carrying out witnessing (Standard Licence Condition (SLC) T33b)). A review of the witnessing SOP and discussions with laboratory staff demonstrated that processes are in place to double check the identification of samples and the patients to whom they relate at all critical points of the clinical and laboratory processes. The scientific inspector noted in patients' medical records that the witnessing checks are carried out and documented appropriately at the time the procedure takes place (SLC T71). Five sets of patients' notes were audited for witnessing during the inspection. All were found to contain a record of all required witnessing checks which included the names, status and signatures of staff performing the checks (Code of Practice (CoP) Guidance 18.8). The centre has established (QIs) relevant to witnessing. A six monthly audit of witnessing practice is undertaken by the centre staff and evidence of this for November 2011 was reviewed during the inspection, no corrective action was required (SLC T36). Staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing. (SLC T15 (a)).
What the centre could do better. Nothing noted at the time of inspection.

Patient selection criteria and laboratory tests

- Procuring, processing and transporting gametes and embryos (Guidance Note 15)

What the centre does well.

Justification for the use of gametes in treatment, based on the patient's medical history and therapeutic indications was seen to be documented in patient notes reviewed on inspection (SLC T49). Evidence was provided by staff to show that laboratory tests for patients are undertaken in a laboratory which has been accredited by Clinical Pathology Accreditation (CPA) UK Ltd (SLC T21).

What the centre could do better.

Nothing noted at the time of inspection.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

The quality management system – Guidance Note 23
The centre has a quality management system (QMS) in place. There is a process in place for the annual review of the performance of the QMS to ensure continuous and systematic improvement. Evidence of this was submitted as part of the renewal application for an annual review conducted in March 2011.

The QMS consists of a quality manual, SOPs and training and reference manuals, as required by SLC T33. Evidence of audits for consent, welfare of the child (WoC), provision of information and witnessing were seen. The findings of the audits and, where required, the corrective actions taken were also seen (SLC T36).

The centre has a document control procedure in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed during the course of the inspection.

Traceability - (Guidance Note 19)
The centre has a procedure in place to ensure all gametes are traceable from procurement to patient treatment. All relevant data relating to anything coming into contact with those gametes is traceable. Consumable log were observed during the inspection (SLC T99).

Containers are, at all stages of procurement and processing, labelled with the patient's full name, date of birth and partner's clinic number. A barcode label system is in use (SLC T101). Staff reported that the centre has a procedure in place to ensure data necessary for traceability is stored for at least 30 years (SLC T103).

The centre has a SOP which documents the procedures to ensure traceability. Also, documented evidence of ensuring traceability was seen in the competency and training matrix for laboratory staff (SLC T33(b)).

Process Validation - (Guidance Note 15)
Laboratory staff provided evidence of validation, of critical procurement and processing procedures which influence the quality and safety of gametes (SLC T72).

Equipment and materials - (Guidance Note 26)
Laboratory staff provided documented evidence of the regular cleaning, disinfection, maintenance and regular inspection of equipment in accordance with manufacturer's instructions. Records of servicing of the flow hood and centrifuge were provided in evidence (SLCs T23 and T26).

Critical equipment has been validated and documented evidence of this was seen on the centre's database. All equipment that affects critical processing parameters is subject to monitoring and alarms. Evidence of this was seen for an incubator and a fridge which had independent digital thermometers checked on daily basis and once every two weeks checked using a calibrated thermometer. The incubator is also linked to the haematology alarm system (SLC T24).

Laboratory staff reported that instruments or devices used for the procurement of gametes are validated or specifically certified and regularly maintained. Also, where possible the centre uses CE marked consumables. (SLCs T28, and T30).

Premises – suitability of the premises and air quality (Guidance Note 25)
The activities authorised by the licence are carried out in the premises specified in the licence (SLC T1). All licensed premises are located within the same building but semen analysis and preparation for insemination is conducted in a laboratory which is located in another building.

Review of documents submitted for the inspection and discussions with the laboratory staff showed that the critical work area where gametes are processed achieves Grade C air quality, with a background within the laboratory of Grade D air quality. The critical work area is subject to checks on air quality twice yearly (SLC T20).

Adverse incidents - (Guidance Notes 27)
Centre staff demonstrated that there were documented procedures in place for the reporting of serious adverse events and reactions that may occur (SLC T118). These procedures are part of a Trust-wide policy. Since the last inspection in January 2010, no adverse incidents have been reported to the HFEA and no evidence of an adverse incident having occurred was seen during the inspection.

Third party agreements (Guidance Note 24)
A list of all agreements established with third parties who provide goods and services that influence the quality and safety of gametes was made available for the inspection (SLCs T111 and T115).

Staff reported that no issues have arisen with regard to the ability of third parties to meet the required standards (SLC T112). A review of third party agreements showed that their content was compliant with requirements with one exception detailed below (SLC T114).

What the centre could do better.

Traceability - (Guidance Note 19)
The centre has not established QIs relevant to traceability and procedures for traceability have not been audited (SLCs T35 and T36).

Third party agreements (Guidance Note 24)
One third party agreement did not include identification of persons responsible for managing the arrangement between the centre and the third party (SLC T114b).

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible (Guidance Note 1)
The PR has academic qualifications in the field of medicine as required by the HF&E Act 1990 (as amended) section 16(2)(c)(i) and (ii) and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence.

The PR has successfully completed the HFEA Person Responsible Entry Programme (PREP number T1205/8).

Staff - (Guidance Note 2)
The centre has an organisation chart is in place which defines accountability and reporting relationships (SLC T11). The centre has access to a registered medical practitioner who is able to advise on and oversee the medical activities (SLC T16). The PR confirmed that staff working under the auspices of the licence are qualified and suitable persons to participate in the activities authorised by the licence (HF&E Act Schedule 17 (1) (a)).

The PR reported that the centre has assessed the workforce requirements within the last year and confirmed that currently they are operating with a full staff complement. The PR considered that the number of staff is adequate for the current volume of work being undertaken by the centre (SLC T12).

There is a formal Trust induction training programme in place for all staff, evidence of this was seen in the training records for nursing and laboratory staff. The PR confirmed that all staff are competent in their designated tasks. From documentation reviewed at inspection, staff were able to demonstrate evidence of the assessment of their competence to perform

designated tasks and participation in relevant professional development by attending training courses and meetings including attendance of laboratory staff at European Society of Human Reproduction and Embryology (ESHRE) and nursing staff at fertility conferences (SLC T15).

Medical, nursing and scientific staff are appropriately registered with their respective professional bodies (SLC T14).

What the centre could do better.

The centre's organisational chart does not reflect current staffing accountability and reporting relationships (SLC T11).

Welfare of the Child (Guidance Note 8)

What the centre does well.

Welfare of the Child
The centre has a SOP in place for the process to be followed when carrying out a welfare of the child ((WoC) assessment (SLC T33(b)). The nursing staff reported that prior to any patient being provided with treatment services the welfare of any child who may be born as a result of the treatment and of any other child who may be affected by that birth is considered. Evidence of this was seen from a review of five patients' notes which contained WoC forms completed and signed by both partners (SLC T56).

The centre has established QIs relevant to the assessment of WoC and these were audited in January 2012. Where required, corrective actions are documented and implemented (SLCs T35 and T36). Staff who conduct WoC assessments were able to demonstrate their competence in this process (SLC T15(a)).

What the centre could do better.

Nothing noted at the time of inspection.

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)

What the centre does well.

Treating patients fairly - (Guidance Note 29)
The centre follows Trust-wide policies on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner.

Confidentiality and privacy - (Guidance Note 30)
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicated that the privacy and confidentiality of all patients is maintained.

There is a Trust policy in place to ensure that all information is kept confidential and only disclosed in circumstances permitted by law (SLC T43). All patient records at the centre are kept confidential and stored in secure areas with only staff on the centre‘s licence having access to confidential information. (SLC T44).

The PR reported that as part of the Trust policy all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during the inspection (SLC T15(a)).

Complaints (Guidance Note 28)
There is a Trust wide complaints procedure in place and staff were able to demonstrate their understanding of how they would resolve a complaint in a timely manner. Since the last inspection in January 2010, no complaints have been made to the HFEA.

What the centre could do better.

Nothing noted at the time of inspection.

Information

- Information to be provided prior to consent (Guidance Note 4)

What the centre does well.

Information (Guidance Note 4)
Staff reported that all relevant patient information is discussed with patients during the consultation stage and a record of this is kept in the notes. Evidence of this was seen during a review of patients' notes.

There is a SOP for the process to be followed when providing information to patients prior to consenting to treatment (SLC T33(b)).

Information provided at the time of inspection, including an audit of patient records; an audit of patient information material submitted for the inspection; discussions with staff showed that relevant information is provided to patients prior to treatment.

The centre has conducted an audit of the provision of information for 2011. Where required, corrective actions have been documented and implemented (SLC T36). Staff were able to provide documented evidence of their competence to provide information for those consenting to treatment (SLC T15(a)).

As the centre does not have a website of its own therefore its compliance with Chair's letter CH (11)02 and the CoP was not assessed for this inspection.

What the centre could do better.

Nothing noted at the time of inspection.

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

What the centre does well.

Consent (Guidance Note 5)
The centre has a SOP in place for the staff to follow when taking consent to treatment (SLC T33(b)). During the inspection five sets of patient notes were reviewed and appropriately completed consents seen to be in place (SLC T57). When consents are taken, the identity of the person giving consent is verified and cross-referenced to patient notes.

Evidence was provided by staff showing that the centre has established QIs relevant to obtaining consent and these are audited and where required corrective actions are documented and implemented (SLCs T35 and T36). A report of the consent audit conducted in December 2011 was made available on inspection. Staff were able to provide documented evidence of their competence to take consent (SLC T15(a)).

What the centre could do better.

Nothing noted at the time of inspection.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Legal Requirements [Human Fertilisation and Embryology Act 1990 (as amended)] • Licensed activities only take place on licensed premises
What the centre does well. From a tour of the licensed premises, review of documentation provided by the centre and discussions with staff, the inspection team consider that they have sufficient information to determine that all activities for which the centre is licensed are conducted within premises to which the licence applies. Also all gametes are procured and used in a lawful manner, with appropriate consent.
What the centre could do better. Nothing noted at time of inspection.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date awareness and understanding of legal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping • Record keeping and document control (Guidance Note 31)
What the centre does well. **Record keeping and document control: Guidance Note 31** All patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patient's notes also included details of the service provided to them, a medical history, relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).
What the centre could do better. Nothing noted at time of inspection.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)] • Obligations and reporting requirements of centres (Guidance Note 32)
What the centre does well. The PR provided all information required by the application process prior to inspection. Centre staff co-operated fully with the inspection team and all further information requested for the inspection was provided in a timely manner (SLC T9(c) and (f)).
What the centre could do better. Nothing noted at time of inspection.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that all information is kept confidential and only disclosed in circumstances permitted by law. The centre has processes in place to ensure that access to the centre's health data and records is kept secure at all times and is only available to centre staff named on the centre's licence or authorised by the PR (SLCs T43; T44 & T45).

What the centre could do better.

Nothing noted at time of inspection.

5. Changes / improvements since the previous inspection on 10 January 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
Audit processes Procurement and processing procedures have not been audited. SLC T36	Audit of procurement processes against the centre's own QIs and regulatory requirements to be conducted. The SOP for the preparation of semen for therapeutic use should be audited against compliance and best practice and validated accordingly.	The centre has conducted an audit of procurement and processing procedures for the preparation of semen for therapeutic use, this was evidenced during the inspection. No further action required.
Air Quality monitoring Validation SLC T20 and Guidance15.16/18 and 25.9	The centre should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.	The centre has conducted validation of air quality using settle plates and particle count. Validation document was observed during the inspection. No further action required.
Formulation and review of SOPs SLC T33	Overall the quality of the centre's document control and SOPs were considered to be very good. However, a small number of SOPs required formulation to reflect practice or review and to reflect current best practice, namely: Validation of new or repaired equipment (T25) and to document the traceability process being conducted (T99) SOP for sperm procurement requires amendment to reflect all steps in the process undertaken for transporting prepared samples from the laboratory to the clinical area.	SOPs are reviewed every two years and this is documented in the centre's database. No further action required.

Access to appropriate clinical professional development SLC T15	The PR should review any barriers to staff being able to participate in appropriate clinical professional development and make adjustments to facilitate this accordingly.	Evidence of staff being able to participate in appropriate clinical professional was seen. A member of laboratory staff attended ESHRE in 2011. No further action required.
The LED display on one incubator in use was found to be faulty and did not accurately reflect the actual working temperature of the incubator. However the centre is testing and recording the actual working temperature of the incubator which indicates that it is working within acceptable temperature parameters. This incubator and one centrifuge (not currently in use) are not part of the scheduled maintenance programme. Reports were seen for the maintenance schedules and maintenance having been conducted for all other equipment observed. SLC T26	The centre should ensure that all critical equipment in use or available for use is regularly maintained or if no longer required should be decommissioned.	The centre's services manager reported that class II hood and all incubators are on service contract which is managed by NHS procurement. No further action required.
Organisational chart SLC T11	Requires minor updating to reflect current staffing and reporting lines.	Due to recent staff changes at the centre, the organisational chart needs to be updated to reflect this. Further action required.
Quality Management - joint working re lab and clinical	The responsibility for quality management is currently divided between laboratory and clinical personnel. Both areas are demonstrating significant commitment to the	The PR reported that meetings are taking place between clinical and laboratory staff to address this issue and the plan is to continue with these meetings

	quality management process but it appeared that the two areas were not working in partnership. The centre may wish to consider how the two areas may be more closely aligned in the management of the quality system.	on a regular basis. Last meeting took place in early March 2011 No further action required.

Areas of practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of non compliance. These have been classified into critical, major and others. Each area of non-compliance is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services. A critical area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None identified at the time of this inspection.			

Major area of non compliance

A major area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or to a child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several “other” areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre has not established QIs or objectives relevant to traceability or has conducted regular audits for them. SLC T35 and T36	The PR should establish QIs or objectives relevant to all activities and conduct regular audits for them. An action plan to be submitted to the lead inspector by the time the PR responds to this report.	My understanding is that the failure of compliance, referred to in the HFEA Inspection report, relates to auditing of consumables and plastics used in laboratory processes for the evaluation and preparation of semen samples for licensed activities. The centre has introduced a regular 6 monthly audit of consumables utilising the laboratory Q-Pulse computer system. Lot numbers and expiry dates of reagents and consumables are recorded on this system and on laboratory logs. All consumables are CE marked in compliance with NHS standards and procurement processes. A reagents log is maintained to record lot numbers of reagents along with expiry dates. We also record the date of opening of each batch of reagents and solutions. Plastic consumables lot numbers and expiry dates are recorded. The lot numbers of consumables	Following review of the audit report submitted by the PR, The inspectorate considers this to be an acceptable response.

		utilised in the treatment process for each individual patient are recorded as part of the clinical record for the purposes of traceability. The laboratory has already performed an audit of consumables to ensure that lot numbers and expiry dates have been accurately recorded on Laboratory data storage systems, and to ensure that all consumables stored or utilised in current treatment processes have not exceeded their expiry dates. This audit can be forwarded electronically to the HFEA for evaluation on request. The centre has initiated plans to perform regular audits to evaluate the robustness of traceability pathways for reagents and consumables utilised in treatment processes. This audit process will examine individual patient records to ensure that the data recorded therein which defines the consumables utilised in the treatment process, correlates with data held separately on Q-Pulse and laboratory logs. This will include an assessment of the accuracy of the recording of Lot numbers, expiry dates and utilisation dates. Our	

		standard will be 100% correlation. These audits and standards will be added to the fertility clinic's quality manual.	

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
The centre's organisational chart does not reflect current staffing and reporting lines. SLC T11	The PR should ensure that centre's organisational chart is updated to reflect current staffing relationship and reporting lines Evidence of compliance to be forwarded to the lead inspector by the time the PR responds to this report.	The organisational chart has been updated to include new andrology staff members who have been employed since the last Centre Inspection. In addition, in compliance with Inspectorate suggestions, it includes other members of the laboratory team who accept semen samples at the laboratory reception and check client identification and consent. The director of the Laboratory and Cancer directorate has also been added as the named manager with Southern Trust HSCNI responsibility	Following review of the supporting information submitted by the PR, The inspectorate considers this to be an acceptable response.

		for processes and performance in the laboratory.	
A third party agreement did not include identification of persons responsible for managing arrangement between the centre and the third party SLC T114b	The PR should ensure that identification of persons responsible for managing arrangement between the centre and the third party is included in any third party agreement. Evidence of compliance to be forwarded to the inspector by 28 June 2012.	The third party arrangement between the centre and the Southern Trust HSCNI (CAH) supplies department regarding the procurement and supply of consumables utilised in the fertility centre and its processes, has been amended to include the names and signatures of the PR and the Supplies and Distribution Manager .	Following review of the third party agreement submitted by the PR, The inspectorate considers this to be an acceptable response.

Additional information from the Person Responsible

HFEA Executive Licensing Panel Meeting

15 June 2012

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0294 – (Craigavon Area Hospital) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Juliet Tizzard, Head of Policy & Communications (Chair) Rachel Hopkins, Head of Human Resources Hannah Darby, Senior Policy Manager	Joanne McAlpine

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

The Panel also had before it:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration of Application

1. The Panel noted that this centre has been licensed since September 2007 and provides services for the investigation and diagnosis of sub fertility and treatment for couples who may benefit from stimulated and un-stimulated cycles of partner sperm intrauterine insemination (IUI).

2. The Panel noted that the centre carried out 263 cycles of partner insemination with 22 pregnancies, which equates to a 8% pregnancy rate for the year 2010.

3. The Panel noted that, at the time of the inspection, the Inspectorate identified one major area of non-compliance and two other areas that required improvement.

4. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence that these non-compliances or areas of practice that required improvement have now been addressed.

5. The Panel noted that the centre had implemented most of the recommendations made during the previous inspection, apart from the organisational chart which the PR has given a commitment to implement within the appropriate timescales

6. The Panel noted that the Inspectorate recommended the renewal of the centre's licence for a period of four years with no additional conditions.

Decision

7. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

8. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act.

9. The Panel was satisfied that the licence renewal application concerns treatment or non-medical fertility services which relate to gametes intended for human application.

10. The Panel was satisfied that the premises to be licensed were suitable for the conduct of licensed activities based on the evidence provided within the report.

11. The Panel noted that the application does not involve the use of embryos for training purposes.

12. The Panel had regard to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in paragraph 4.3 and noted paragraph 4.4 of the guidance which states that the Executive Licensing Panel will normally grant a renewal licence for treatment/storage/non-medical fertility services licences for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

13. The Panel endorsed the recommendations made by the Inspectorate within the report. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions.

Signed: [signature] Date: 25 June 2012
Juliet Tizzard (Chair)