THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
9th floor Riverside Tower, 5 Lanyon Place, Belfast, BT1 3BT
Tel: 028 9051 7500 Fax: 028 9051 7501

ANNOUNCED ESTATES INSPECTION

Inspection No:	IN021297
Establishment ID No:	10635
Name of Establishment:	Origin Fertility Care Clinic, Belfast
Date of Inspection:	10 February 2015
Inspector's Names:	K. Monaghan

1.0 GENERAL INFORMATION

Name of Clinic:	Origin Fertility Care Clinic
Address:	380 Belmont Road Belfast BT4 2NF
Telephone Number:	028 90 76 17 13
Registered Responsible Person:	Dr. Richard Noel Heasley, Origin Fertility Care Limited
Registered Manager:	Mrs. Jennifer Eliza McLaughlin
Person in Charge of the Hospital at the time of Inspection:	Dr Steve Green, Embryology Manager
Other person(s) present during inspection:	Mr. Paul Whitcombe, Facilities Officer Dr Steve Green, Embryology Manager (for brief discussion regarding environmental monitoring)
Type of establishment:	Independent Hospital
Categories of Care:	PT (IVF), PD
Number of Registered Places:	N/A
Conditions of Registration:	PT (IVF) - Prescribed techniques or prescribed technology: establishments providing in vitro fertilisation. PD - Private doctors (other)
Date of previous inspection:	30 July 2014
Date and time of inspection:	10 February 2015 (2:00pm. – 3:45pm.)
Name of Inspectors:	K. Monaghan

2.0 INTRODUCTION

The Regulation and Quality Improvement Authority (RQIA) is empowered under The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to inspect independent health care establishments.

This is a report of an announced inspection to assess the quality of the premises and grounds in which the service is being provided including the upkeep of the building and engineering services and equipment. The report details the extent to which the standards measured during inspection were met.

3.0 PURPOSE OF THE INSPECTION

The purpose of this inspection was to consider whether the premises and grounds were safe, well maintained and remain suitable for their stated purpose in compliance with legislative requirements and current draft minimum standards. This was achieved through a process of evaluation of the available evidence.

The Regulation and Quality Improvement Authority aims to use inspection to support providers in improving the quality of services, rather than only seeking compliance with regulations and standards.

The aims of the inspection were to examine the estates related policies, practices and monitoring arrangements for the provision of independent health care establishments, and to determine the provider's compliance with the following:

- The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003,
- The Independent Health Care Regulations (Northern Ireland) 2005
- The Minimum Care Standards for Independent Healthcare Establishments – July 2014

Other published standards which guide best practice may also be referenced during the inspection process.

4.0 METHODS/PROCESS

Specific methods/processes used in this inspection include the following:

1. Discussions with Mr. Paul Whitcombe, Facilities Officer and Dr. Steve Green, Embryology Manager (brief discussion regarding environmental monitoring)

2. Evaluation and feedback.

Any other information received by RQIA about this regulated establishment has also been considered by the Inspectors in preparing for this inspection.

5.0 CONSULTATION PROCESS

During the course of the inspection, the Inspector spoke to Mr. Paul Whitcombe, Facilities Officer and Dr. Steve Green, Embryology Manager (brief discussion regarding environmental monitoring).

6.0 INSPECTION FOCUS

This inspection sought to establish the level of compliance achieved with respect to the following DHSSPS Minimum Care Standards for Independent Healthcare Establishments – July 2014.

Standards inspected:

- Standard 22 Premises and Grounds;

This inspection focused specifically on the issues included in the Quality Improvement Plan for the previous Estates inspection to the clinic that was carried out on 30 July 2014.

7.0 SUMMARY

Following this Estates Inspection of the Origin Fertility Care Clinic in Belfast on 10 February 2015, improvements are required to comply with The Independent Health Care Regulations (Northern Ireland) 2005 and the criteria outlined in the following Minimum Care Standards for Independent Healthcare Establishments - July 2014:

- Standard 22. Premises and Grounds,

This resulted in two requirements and one recommendation. These are outlined in the Quality Improvement Plan appended to this report.

The Estates Inspector would like to acknowledge the assistance of Mr. Paul Whitcombe, Facilities Officer and Dr. Steve Green, Embryology Manager (brief discussion regarding environmental monitoring) throughout the inspection process.

8.0 INSPECTION FINDINGS

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

The following issues should be noted with regard to the issues identified for attention during the previous Estates inspection to this clinic on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.1	Regulations 25(2)(a)	**Previous QIP Item 1** Remedial works should be carried out to the door to the Andrology Laboratory to ensure that this door closes properly.	This issue was not reviewed during this Estates inspection.	Confirmation that this issue had been addressed was provided in the completed Quality Improvement Plan that was returned to RQIA for the previous Estates inspection. Mr. Whitcombe also confirmed during this inspection that this door was operating satisfactorily.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.2	Regulations 15(7) 25(2)(c) 25(2)(d)	**Previous QIP Item 2** The pressure differentials between the embryology laboratory and the procedure room should be reviewed with an Authorising Engineer (Ventilation) in relation to the guidance contained in the Guide to Good Manufacturing Practice, ie 10 Pa. In addition the values for the pressure differentials and the air change rates for the sperm lab should be confirmed to RQIA.	The pressure differentials had been reviewed by the Authorising Engineer (Ventilation). Further adjustment to the ventilation installation was however required to achieve the 10 Pa Standard.	Mr. Whitcombe confirmed that plans were in hand to install a new ventilation system for the embryology laboratory and the procedure room. The details for this new installation should be confirmed to RQIA. Refer also to section 8.1.7. Reference should be made to item 1 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.3	Regulations 15(7) 25(2)(c) 25(2)(d)	**Previous QIP Item 3** The need to carry out 'in operation' environmental monitoring should be reviewed. The HFEA, the lead embryologist and the Authorised Engineer (Ventilation) should be consulted as part of this review. The outcome of this review should be confirmed to RQIA.	The need to carry out 'in operation' environmental monitoring had been reviewed and this was now being carried out in relation to microbial activity.	The need to carry out 'in operation' environmental monitoring in relation to particulates should be reviewed again. Dr. Green advised that it would be difficult to carry out 'in-operation' particulate monitoring. This issue should be reviewed again with reference to the guidance contained in the Guide to Good Manufacturing Practice and current best practice in this sector of health care. The outcome of this review should be confirmed to RQIA. Reference should be made to item 2 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.4	Standard C18	**Previous QIP Item 4** It is recommended that routine audits should be carried out by the Authorising Engineer (Low Voltage) to provide independent assurance in relation to the ongoing safe management of the electrical installation.	It is good to report that an audit had been carried out by the Authorising Engineer in January 2015. A copy of the report for this audit was provided to RQIA during this Estates inspection.	The report for this audit included a number of recommendations. These issues should be addressed within the timescales set out in the Authorising Engineer's report. Reference should be made to item 3 in the attached Quality Improvement Plan.
8.1.5	Standard C18	**Previous QIP Item 5** It is recommended that the individual rooms where each of the fixed monitors is installed should be identified against each unit on the service reports.	The location for the fixed oxygen depletion monitors had been identified.	N/A

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.6	Standard C18	**Previous QIP Item 6** It is recommended that the details in relation to the Authorising Engineer (Medical Gas Pipeline Systems) for the gas installations should be added to the policy for managing the gases in the premises. It is also recommended that routine audits should also be carried out by the Authorising Engineer (Medical Gas Pipeline Systems) to provide independent assurance in relation to the ongoing safe management of the gases installation.	An audit had been carried out by the clinic's Authorising Engineer in January 2015 in relation to the gases being used in the clinic. A copy of the report for this audit was provided to RQIA during this Estates inspection.	The report for the audit carried out by the Authorising Engineer identified a small number of issues for attention. These issues should be addressed within the timescales set out in the Authorising Engineer's report. Reference should be made to item 3 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.7	Standard C18	**Previous QIP Item 7** The method of recording the outcomes for the servicing and inspections to the main ventilation system should be reviewed with the Authorising Engineer (Ventilation) to establish if quarterly inspection reports and annual verification reports in accordance with the guidance contained in Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises should be issued. The outcome of this review should be confirmed to RQIA. It is also recommended that routine audits should be carried out by the Authorising Engineer (Ventilation) to provide independent assurance in relation to the ongoing safe management of the ventilation installation. A schematic drawing for the ventilation installations in the premises should also be provided.	Mr. Whitcombe confirmed during this Estates inspection that it had been decided to replace the existing ventilation installation for the procedure room and the embryology laboratory. Approval had been given for this work and arrangements were currently being made for the completion of same. The new system will be installed, commissioned and maintained in accordance with the guidance contained in Health Technical Memorandum 03-01: Specialised ventilation for healthcare premises	RQIA should be kept up to date with progress in relation to the new ventilation installation. Reference should be made to item 1 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from the previous Estates inspection on 30 July 2014:

Standard 35 - Safe and healthy working practices				
No	**Regulation**	**Requirements**	**Action taken - As confirmed during this inspection**	**Inspector's Comments**
8.1.8	Regulation 25(4)(a) 25(4)(c) 25(4)(d)	**Previous QIP Item 8** Arrangements should be made for the Consultant to attend a fire training session.	This issue was not reviewed during this Estates inspection.	Confirmation that this issue had been addressed was provided in the completed Quality Improvement Plan that was returned to RQIA for the previous Estates inspection.

8.0 INSPECTION FINDINGS CONTINUED

8.2 Standard 22: Premises and Grounds

The premises and grounds are safe, well maintained and remain suitable for their stated purpose

8.2.1 The following issue was identified for attention during this Estates inspection in relation to this standard:

8.2.2 The policy in relation to environmental monitoring in the critical areas should be reviewed and updated to ensure that it fully reflects current good practice in this area of health care. In addition a copy of the Guide to Good Manufacturing Practice should be printed and retained in the clinic as a benchmark reference source. Reference should be made to item 2 in the attached Quality Improvement Plan.

8.2.3 The above issue is detailed in the section of the Quality Improvement Plan entitled ‘Standard 22 – Premises and Grounds.

9.0 QUALITY IMPROVEMENT PLAN

The details of the Quality Improvement Plan appended to this report were discussed Mr. Paul Whitcombe, Facilities Officer as part of the inspection process.

The timescales commence from the date of inspection.

Requirements are based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 and The Independent Health Care Regulations (Northern Ireland) 2005 and must be met.

Recommendations are based on the Department of Health, Social Services and Public Safety's Minimum Care Standards for Independent Healthcare Establishments – July 2014, promote current good practice and should be considered by the management of the hospital to improve the quality of service experienced by patients.

The registered provider is required to record comments on the Quality Improvement Plan.

10.0 ENQUIRIES

Enquiries relating to this report should be addressed to:

Regulation and Quality Improvement Authority
9th Floor
Riverside Tower
5 Lanyon Place
BELFAST BT1 3BT

QUALITY IMPROVEMENT PLAN
- for –

ANNOUNCED ESTATES INSPECTION IN021297
- to –

ORIGIN FERTILITY CARE CLINIC, BELFAST RQIA ID 10635
- on –

10 FEBRUARY 2015

QIP Position Based on Comments from Registered Persons			QIP Closed		Estates Officer	Date
			Yes	No		
A.	All items confirmed as addressed.	–	–	–	–	–
B.	All items either confirmed as addressed or arrangements confirmed to address within stated timescales.	–	–	–	–	–
C.	Clarification or follow up required on some items.	√	–	√	K. Monaghan	08 April 2015

NOTES:

The details of this Quality Improvement plan were discussed with Mr. Paul Whitcombe, Facilities Officer, as part of the inspection process.

The timescales commence from the date of inspection.

The Requirements are based on The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003, and The Independent Health Care Regulations (Northern Ireland) 2005 and must be met.

Recommendations are based on the Department of Health, Social Services and Public Safety's Minimum Care Standards for Independent Healthcare Establishments – July 2014, promote current good practice and should be considered by the management of the Clinic to improve the quality of the service being provided.

The Registered Provider is required to record comments on the Quality Improvement Plan.

The quality improvement plan is to be completed by the registered provider and registered manager and returned to estates@rqia.org.uk.

Please complete the following table to demonstrate that this Quality Improvement Plan has been completed by the registered manager and approved by the responsible person / identified responsible person:

NAME OF REGISTERED MANAGER COMPLETING QIP	J. McLaughlin
NAME OF RESPONSIBLE PERSON / IDENTIFIED RESPONSIBLE PERSON APPROVING QIP	

The following requirements and recommendations should be noted for action in relation to Standard 22: Premises and Grounds:

ITEM	STANDARD REF/ REGULATION	REQUIRMENTS ACTION TO BE TAKEN BY REGISTERED PROVIDER/ MANAGER	TIMESCALE	DETAILS OF ACTION TAKEN BY REGISTERED PERSON (S)
1.	Regulations 15(7) 25(2)(c) 25(2)(d)	The details for the new ventilation installation for the embryology laboratory and the procedure room should be confirmed to RQIA. Reference should be made to item 8.1.2 in the report.	Two months	See attached contract. Install due 15/6/15 → 6/7/15
2.	Regulations 15(7) 25(2)(c) 25(2)(d)	The arrangement for ongoing environmental monitoring in the critical areas should be reviewed again with reference to the guidance contained in the Guide to Good Manufacturing Practice and current best practice in this sector of health care. The outcome of this review should be confirmed to RQIA. The policy in relation to environmental monitoring in the critical areas should be reviewed and updated to ensure that it fully reflects current good practice in this area of health care. In addition a copy of the Guide to Good Manufacturing Practice should be printed and retained in the clinic as a benchmark reference source. Reference should be made to items 8.1.3 and 8.2.2 in the report.	Two months	Dr. Green has revisited the environmental monitoring and carried out a risk assessment of the same, this will be included in the environmental monitoring policy which will reference the Guide to Good Manufacturing Practice.

The following requirements and recommendations should be noted for action in relation to Standard 22: Premises and Grounds:				
ITEM	**STANDARD REF/ REGULATION**	**RECOMMENDATIONS ACTION TO BE TAKEN BY REGISTERED PROVIDER/ MANAGER**	**TIMESCALE**	**DETAILS OF ACTION TAKEN BY REGISTERED PERSON (S)**
3.	Standard 22	The recommendations in the Authorising Engineer's audit report of January 2015 should be addressed within the timescales set out in the report. Reference should be made to items 8.1.4 and 8.1.6 in the report.	Ongoing	This is ongoing and will be fulfilled within the given timescales.