THE REGULATION AND QUALITY IMPROVEMENT AUTHORITY
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ANNOUNCED ESTATES INSPECTION

Inspection No:	20303
Establishment ID No:	10635
Name of Establishment:	Origin Fertility Care Clinic, Belfast
Date of Inspection:	30 July 2014
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:	Mrs. Jennifer Eliza McLaughlin, Registered Manager
Other person(s) present during inspection:	Mr. Paul Whitcombe, Facilities Officer Dr. Richard Fawthrop, 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:	14 December 2011
Date and time of inspection:	30 July 2014 (10:40am. – 1:40pm.)
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
- Draft Independent Health Care Minimum Standards HOSPITALS AND CLINICS (DHSSPS, March 2005)

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. Richard Fawthrop, Embryology Manager (brief discussion regarding environmental monitoring)

2. A review of the premises

3. 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. Richard Fawthrop, 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 Draft Independent Health Care Minimum Standards HOSPITALS AND CLINICS. This inspection focused specifically on a review of the premises. A brief review of the documentation in relation to the ongoing management of the ventilation installations was also completed.

Standards inspected:

- Standard C.18. Premises and Grounds,

- Standard C.24 Fire Safety

7.0 SUMMARY

Following this Estates Inspection of the Origin Fertility Care Clinic in Belfast on 30 July 2014, improvements are required to comply with The Independent Health Care Regulations (Northern Ireland) 2005 and the criteria outlined in the following draft minimum standards:

- Standard C.18. Premises And Grounds,
- Standard C.24 Fire Safety

This resulted in four requirements and four recommendations. 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. Richard Fawthrop, Embryology Manager (brief discussion regarding environmental monitoring) throughout the inspection process.

8.0 INSPECTION FINDINGS

8.1 Recommendations and requirements from previous Estates inspection 14 December 2011

8.1.1 The following should be noted in relation to the issues included in the Quality Improvement Plan for the previous Estates inspection to this clinic on 14 December 2011:

8.1.2 Mr. Whitcombe confirmed that the since the previous Estates inspection the fire risk assessment had been reviewed with a specific focus on the protection of the critical areas of the premises. Enhancements had been made to the physical fire protection measures for these critical areas. These improvements included the upgrading of the ceiling to the cryro room and the installation of an additional fire door. The Northern Ireland Fire and Rescue Service had also visited the premises so that they would be aware of the specific risks associated with the premises including the importance of protecting the critical areas.

8.1.3 A specialist company is engaged to provide pest control services for the premises. The most recent inspection visit was carried out on 27 June 2014 with a satisfactory outcome.

8.1.4 The uninterrupted power supply (UPS) equipment (2No.units) was serviced on 16 May 2014. The report for this service recommended that the batteries should be replaced. This was completed on 04 June 2014.

8.0 INSPECTION FINDINGS CONTINUED

8.1 Recommendations and requirements from previous Estates inspection 14 December 2011 continued

8.1.5 The legionella risk assessment was reviewed and updated on 01 July 2014. Alterations had been carried out to the plumbing installation to facilitate the twice weekly flushing of any 'dead legs'. Refer also to section 9.2.4 below which deals with the current position in relation to the legionella bacteria controls.

8.1.6 The current position in relation to the arrangements in place for the ongoing management of the gas installations and the ventilation installations is detailed in section 8.2.9 of this report.

8.1.7 The current risk assessment in relation to the delivery, storage and use of liquid nitrogen was not reviewed during this Estates inspection. Subsequent to this Estates inspection a copy of the current risk assessment in relation to this issue was forwarded to RQIA. This risk assessment was completed on 06 December 2104 with a review date of 07 December 2014. The record of the significant findings for this risk assessment identified that the residual risks in relation to a range of hazards associated with liquid nitrogen had been evaluated as 'Low'.

8.2 Standard C18: Premises and Grounds

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

8.2.1 The facilities management arrangements for the premises had been revised recently. A specialist company has been engaged to assist with the management of water safety, asbestos and general health and safety. It is intended to achieve certification to BS OHSAS 18001 Occupational Health and Safety Management. This will integrate with the other quality systems in the clinic for environmental management (ISO 14001) and quality management (ISO 9001). In addition to these developments a new response maintenance system had also been introduced for the clinic at the beginning of 2014. This new electronic system provides a comprehensive process for reporting and following up ongoing premises and equipment issues. Redecoration had been carried out to the premises since the previous Estates inspection.

8.0 INSPECTION FINDINGS CONTINUED

8.2 Standard C18: Premises and Grounds Continued

8.2.2 The following issues were identified for attention during this Estates inspection in relation to this standard:

8.2.3 The door to the Andrology Laboratory required attention to close properly. Remedial works should be carried out to this door. Reference should be made to item 1 in the attached Quality Improvement Plan.

8.2.4 A water risk assessment had been carried out on 01 July 2014. Water samples had been tested on 14 May 2014 with satisfactory results. Mr. Whitcombe also confirmed that the hot and cold water system temperatures at the sentinel outlets had been checked the week previous to this Estates inspection. The results for these checks had not yet been received by the clinic although the new electronic recording system employed by the specialist company engaged to carry out the water management controls includes an alert facility for highlighting any issues that require attention. The controls also include a procedure for the twice weekly flushing of the 'dead legs' in the plumbing pipework and the quarterly descaling and disinfection of the showers. The most recent decaling and disinfection of the showers was completed on 10 June 2014. The risk assessment that was completed on 01 July 2014 identified some issues that required attention. Mr. Whitcombe confirmed that arrangements had been made for a plumber to carry out the remedial works required. Subsequent to this Estates inspection RQIA received confirmation that these remedial works had been completed.

8.2.5 A new electronic register is being established for all of the equipment in the clinic. This register will include a picture of each item of equipment. The register will have a filter facility to highlight all of the equipment that the clinic considers to be critical. This will also include all of the critical equipment prescribed by the Human Fertilisation and Embryology Authority (HFEA). Subsequent to this Estates inspection RQIA received copies of the validation reports for the IVF workstations. This validation was completed on 28 February 2014.

8.0 INSPECTION FINDINGS CONTINUED

8.2 Standard C18: Premises and Grounds Continued

8.2.6 A policy had been drawn up in relation to the ongoing management of the electrical installation. An Authorising Engineer (Low Voltage) had been appointed. The generator was serviced on 06 May 2014 and Mr. Whitcombe also confirmed that the generator was tested 'on-load' every month. The electrical equipment was inspected and tested in October 2013 and the mains power failure alarm system is tested on a quarterly basis with the most recent tests having been carried out on 07 March 2014 and 06 June 2014. The fixed wiring installation was inspected and tested on 21 March 2011. This inspection and test identified a number of issues for attention which Mr. Whitcombe confirmed had been addressed. It was 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. Reference should be made to item 4 in the attached Quality Improvement Plan.

8.2.7 The clinic has in place a monitored alarm system for fire alarm activation, power failure, intruder alarm activation, oxygen depletion alarm activation for the liquid nitrogen and incubator failure. This system is tested on a quarterly basis with the most recent tests having been carried out on 07 March 2014 and 06 June 2014. The oxygen depletion monitors for the liquid nitrogen dewars were serviced on 25 November 2013. In addition the three fixed room oxygen depletion monitors and the repeater panel at the front door of the premises were serviced on 15 May 2013 and again on 12 November 2013. It is recommended that the individual rooms where each of these fixed monitors are installed should be identified against each unit on the service reports. Reference should be made to item 5 in the attached Quality Improvement Plan.

8.2.8 The annual gas safety inspection to the heating boilers was carried out on 12 August 2013 with a satisfactory outcome. The policy for managing the gases in the premises was discussed briefly during this Estates inspection. It was highlighted that the details in relation to the Authorising Engineer (Medical Gas Pipeline Systems) and a schematic for the gas installations should be added to this policy. An independent pharmacy test to the carbon dioxide gases for the incubators was completed on 1 May 2014 with a satisfactory outcome. Subsequent to this Estates inspection RQIA received a copy of the schematic for the gas installations in the premises. It was recommended that routine audits should be carried out by the Authorising Engineer (Medical Gas Pipeline Systems) to provide independent assurance in relation to the ongoing safe management of the gas installations. Reference should be made to item 6 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.2 Standard C18: Premises and Grounds Continued

8.2.9 An Authorising Engineer (Ventilation) had been appointed. The independent air conditioning units were serviced and checked on 14 April 2014. A full service of the main ventilation system for the embryology laboratory and the procedure room was completed on 11 April 2014 and a further inspection was completed on 29 July 2014. 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 was 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 installations. A schematic drawing for the ventilation installations in the premises should also be provided. Reference should be made to item 7 in the attached Quality Improvement Plan.

8.2.10 The most recent environmental monitoring (particulate, pressure differential and air change rates) was completed on 09 May 2014 for the embryology laboratory and on 06 June 2014 for the sperm laboratory. Microbiological monitoring was also carried out for these areas on 12 March 2014 and again on 03 June 2014. New pressure differential monitors had been installed on 20 July 2014. The readings on the new pressure differential monitors noted during this Estates inspection indicated that the pressure differential between the procedure room and the main processing laboratory was 7Pa. This should be reviewed with the 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. Reference should be made to item 2 in the attached Quality Improvement Plan.

8.0 INSPECTION FINDINGS CONTINUED

8.2 Standard C18: Premises and Grounds Continued

8.2.11 At present the environmental monitoring is carried out in the 'At rest' condition. The need to also carry out 'In operation' environmental monitoring should be reviewed. The HFEA, the lead embryologist and the Authorising Engineer (Ventilation) should be consulted as part of this review. The outcome of this review should be confirmed to RQIA. Reference should be made to item 3 in the attached Quality Improvement Plan.

8.2.12 The above issues where applicable are detailed in the section of the Quality Improvement entitled 'Standard C18 – Premises and Grounds.

8.3 Standard C24: Fire safety

Fire safety precautions are in place that reduce the risk of fire and protect patients, staff and visitors in the event of fire.

8.3.1 The following issues should be noted in relation to this standard:

8.3.2 Fire training had been provided for the staff on 02 July 2014 and a fire drill with a satisfactory outcome had been completed on 21 July 2014. Mr. Whitcombe confirmed that all of the staff with the exception of a Consultant had attended fire training. Arrangements should be made for the Consultant to attend a fire training session. Reference should be made to item 8 in the attached Quality Improvement Plan.

8.3.3 A fire risk assessment was completed on 30 July 2013. Mr. Whitcombe also confirmed that the fire risk assessment had been reviewed again the week previous to this Estates inspection and no issues had been identified for attention during this review. The fire detection and alarm system was inspected and tested on 03 July 2014 with a satisfactory outcome. In addition the fire alarm is checked each week.

8.3.4 The emergency lights were inspected and tested on 25 July 2013. A number of issues were identified for attention during this inspection and test. Subsequent to this Estates inspection RQIA received confirmation that the remedial works to the emergency lighting were completed on 08 August 2014.

8.3.5 The above issues where applicable are detailed in the section of the Quality Improvement entitled 'Standard C24: Fire safety'.

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 draft minimum standards for registration and inspection, 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 Sign Off Sheet for Estates Inspectors

Name of Home	Origin Fertility Clinic, Belfast RQIA ID 10635
Date of Inspection	30 July 2014
Estates Inspector	Kieran Monaghan

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	13 October 2014

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 Draft minimum standards for registration and inspection, 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 should be signed below 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	
NAME OF RESPONSIBLE PERSON / IDENTIFIED RESPONSIBLE PERSON APPROVING QIP	

The following requirements and recommendations should be noted for action in relation to Standard C18: 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 25(2)(a)	Remedial works should be carried out to the door to the Andrology Laboratory to ensure that this door closes properly. Reference should be made to item 8.2.3 in the report.	1 Month	
2.	Regulations 15(7) 25(2)(c) 25(2)(d)	The pressure differentials between the embryology laboratory and the procedure room should be reviewed with the 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. Reference should be made to item 8.2.10 in the report.	1 Month	
3.	Regulations 15(7) 25(2)(c) 25(2)(d)	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. Reference should be made to item 8.2.11 in the report.	1 Month	

The following requirements and recommendations should be noted for action in relation to Standard C18: 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)**
4.	Standard C18	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. Reference should be made to item 8.2.6 in the report.	1 Month & Ongoing	
5.	Standard C18	It is recommended that the individual rooms where each of these fixed monitors is installed should be identified against each unit on the service reports. Reference should be made to item 8.2.7 in the report.	1 Month	
6.	Standard C18	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. Reference should be made to item 8.2.8 in the report.	1 Month	

The following requirements and recommendations should be noted for action in relation to Standard C18: 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)
7.	Standard C18	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. Reference should be made to item 8.2.9 in the report.	1 Month	

The following requirements and recommendations should be noted for action in relation to Standard C24: Fire safety				
ITEM	**STANDARD REF/ REGULATION**	**REQUIREMENTS ACTION TO BE TAKEN BY REGISTERED PROVIDER/ MANAGER**	**TIMESCALE**	**DETAILS OF ACTION TAKEN BY REGISTERED PERSON (S)**
8.	Regulation 25(4)(a) 25(4)(c) 25(4)(d)	Arrangements should be made for the Consultant to attend a fire training session. Reference should be made to item 8.3.2 in the report.	1 Month	