Executive Licensing Panel - minutes

Centre 0328 (GCRM - Belfast)

Renewal Inspection Report

Tuesday, 20 August 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Helen Crutcher Dina Halai	Director of Strategy and Corporate Affairs Risk and Business Planning Manager Scientific Policy Manager
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood Victoria Brown	Licensing Manager Inspector (Scientific) - Induction

Declarations of interest

- Members of the panel declared that they had no conflicts of interest in relation to this item.

The panel had before it:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

1.1. The panel considered the papers, which included a completed application form, inspection report and licensing minutes for the last four years.

1.2. The panel noted that GCRM - Belfast has held a treatment and storage licence with the HFEA since November 2013 and provides a full range of fertility services. Other licensed activities at the centre include the storage of gametes and embryos.

1.3. The panel noted that, in the 12 months to 30 April 2019, the centre provided 768 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a medium sized centre.

1.4. The panel noted that HFEA register data, for the period February 2018 to January 2019 show the centre's pregnancy outcomes for IVF and ICSI success rates, in terms of clinical pregnancy outcomes, are in line with the national averages.

1.5. The panel noted that, in 2018, the centre provided 16 cycles of partner inseminations, with two pregnancies, and this is in line with the national average.

1.6. The panel noted that, between February 2018 and January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to produce a multiple live birth rate statistically different from the 10% multiple live birth rate target.

1.7. An inspection was carried out at the centre on the 14 and 15 May 2019.

1.8. The panel noted that at the time of the inspection, there were six major areas of non-compliance concerning transport and satellite arrangements, infection control, medicines management, the Quality Management System (QMS), use of embryos for training staff, alongside obligations and reporting requirements. There were also five 'other' non-compliances regarding the safety and suitability of premises, imports and exports, traceability, equipment and materials, record keeping and document control. Since the inspection visit, the Person Responsible (PR) has given a commitment to implement all the recommendations made in the report, within the prescribed timescales.

1.9. The panel noted that the centre's success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the targets.

1.10. Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the Person Responsible (PR) is encouraged to use it to best effect to monitor and improve the service provided.

1.11. The panel noted that the inspector will continue to monitor the centre's performance and the implementation of the report's recommendations within the required timescales. Failure to implement the recommendations, within the prescribed timescales, will result in the submission of a further report to the Executive Licensing Panel (ELP) with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

1.12. The panel noted that the inspection team recommends the renewal of the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in this report being implemented within the prescribed timescales.

1.13. The panel noted that the centre has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018; these certificates are generally synchronised to the centre's HFEA licence. The inspection team recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

2. Decision

2.1. 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.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel expressed concern regarding the number of non-compliances identified in the report, particularly noting that issues relating to satellite centre agreements were also observed during the interim inspection in June 2017. It hoped to see an improvement in the centre's compliance at the interim inspection.

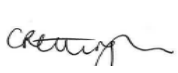
2.5. The panel endorsed the inspectorate's recommendation to renew the centre's treatment and storage licence for a period of four years, without additional conditions, subject to the recommendations made in the report being implemented within the prescribed timescales. The panel agreed that if no representations or any other information is received within 28 days, the final renewal licence should be issued.

2.6. The panel endorsed the inspectorate's recommendation to renew the centre's ITE import certificate, in line with the centre's licence.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

23 August 2019

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Licence Committee (LC) and Executive Licencing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 14 and 15 May 2019

Purpose of inspection: Renewal of a licence to carry out Treatment and Storage

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Grace Lyndon (lead), Andy Leonard, Polly Todd and Victoria Brown (observer).

Date of Executive Licensing Panel: 20 August 2019

Centre name	GCRM - Belfast
Centre number	0328
Licence number	L/0328/2/a
Centre address	Edgewater Business Park, Edgewater House, Edgewater Road, Belfast, BT3 9JQ, United Kingdom
Person Responsible	Dr Peter McFaul
Licence Holder	Ralph Roberts
Date licence issued	25/11/2015
Licence expiry date	24/11/2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

GCRM - Belfast has held a Treatment and Storage licence with the HFEA since November 2013 and provides a full range of fertility services.

The centre provided 768 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2019. In relation to activity levels this is a medium centre.

Other licensed activities at the centre include the storage of gametes and embryos.

GCRM – Belfast is one of the HFEA licensed centre's belonging to the Fertility Partnership corporate group.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the period of February 2018 to January 2019 show the centre's success rates are in line with national averages.

In 2018, the centre reported 16 cycles of partner insemination with 2 pregnancies, a success rate which is consistent with the national average

Multiple births[2]

The single biggest risk of fertility treatment is a multiple pregnancy.

Between February 2018 and January 2019, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 13%. This represents performance that is not likely to be statistically different from the 10% multiple live birth rate target.

[1]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. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.
[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP) and standard licence conditions (SLCs), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16(2)(c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are generally suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including six major and five 'other' areas of non compliance which have resulted in the following recommendations:

Major areas of non compliance:

- The PR should ensure satellite agreements are in place for all satellite clinics and are compliant with General Direction 0010.
- The PR should ensure that infection control guidance is adhered to.
- The PR should ensure compliance with medicines management regulations, best practice guidelines and the centre's standard operating procedures (SOPs).
- The PR should ensure the centre's quality management system (QMS) is compliant with HFEA CoP requirements and guidance.
- The PR should ensure that accurate information is provided to patients prior to them giving consent.
- The PR should ensure that all licensing applications and licensed treatment activity, is reported to the Authority within the required timeframes.

'Other' areas that requires improvement:

- The PR should ensure that the premises are suitable and fit for purpose.
- The PR should ensure that evidence is obtained for the compliance of imports and exports and that the services provided by donor banks are audited against all relevant HFEA requirements.
- The PR should ensure that the centrifuges used for sperm processing are identifiable and documented in the records.
- The PR should ensure that all critical parameters are continually monitored and recorded.
- The PR should ensure the process used to create electronic records is robust.

Recommendation to the Executive Licensing Panel

The centre has six major and five other areas of non compliance or poor practice.

The inspection team notes that the success rates are consistent with the national average and their multiple clinical pregnancy/ live birth rates meet the target. Significant improvement is required in order for the centre to reflect suitable practices. The centre has a QMS and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance and the implementation of this report's recommendations within the required timescales. Failure to implement the recommendations within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends the renewal of the centre's Treatment and Storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Centre 0328 has been issued with an Importing Tissue Establishment (ITE) import certificate by the HFEA, pursuant to the Human Fertilisation and Embryology (Amendment) Regulations 2018. Such certificates are generally synchronised to the centre's HFEA licence. The inspection team therefore recommends the renewal of the centre's ITE import certificate in line with the centre's licence.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements, notwithstanding concerns related to the lack of evidence collected by the centre, for the compliance with HFEA requirements of screening practices at donor banks used by the centre, discussed in 'Imports and Exports'. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Payments for donors (Guidance note 13; General Direction 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes or embryos, notwithstanding concerns related to the lack of evidence collected by the centre, for the compliance with HFEA requirements of donor compensation practices at donor banks used by the centre, discussed in 'Imports and Exports'. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)

It is important that centres use donated gametes or embryos from identifiable donors and keep records of donor characteristics. This is because patients using donated gametes and embryos in treatment and the parents of donor-conceived children, are able to access non identifying information regarding the donor from the clinic. Furthermore, donor-conceived persons are entitled to know non-identifying details about their donor and any donor-conceived genetic siblings they may have at the age of 16 years, and donor identifying information at 18 years.

The centre's procedures are compliant with HFEA requirements which ensure the donor-conceived and their parents will be able to receive all required donor-related information.

What the centre could do better
Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are broadly suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's satellite facilities and laboratories conducting tests that impact on the quality and safety of gametes and embryos (relevant third parties) are suitable, notwithstanding concerns regarding satellite agreements and the audit of satellite services discussed in below in 'Transport and satellite agreements'.

The centre is compliant with HFEA requirements to process gametes and embryos in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)

The centre's laboratories and third party laboratories which undertake the diagnosis and investigation of patients, patients' partners or donors, or their gametes, embryos or any material removed from them, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control (Guidance Note 25)
The centre has systems in place to manage and monitor the prevention and control of infection that are partially compliant with guidance.

Medicines management (Guidance Note 25)
The centre has arrangements in place for obtaining, recording, handling, using, keeping, dispensing, administering and disposing of medicines that are partially compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed to facilitate IVF treatment in a particular subset of women. This centre does not prescribe intralipid therapy therefore requirements related to its use were not relevant at this inspection.

Pre-operative assessment and the surgical pathway (Guidance Note 25)
The centre has policies and procedures in place that are compliant with professional body guidelines for pre-operative assessment and management of the surgical pathway. This is important to ensure that all patients are safely assessed and cared for pre, peri and post operatively.

Multiple births (Guidance note 7; General Direction 0003)
The centre's procedures are compliant with HFEA multiple births minimisation strategy requirements for keeping a summary log of cases in which multiple embryos have been transferred and conducting regular audits and evaluations of the progress and effectiveness of the strategy. The single biggest risk of fertility treatment is a multiple pregnancy.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes (or embryos created with their gametes) in treatment, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)
The centre's procedures for the transport, distribution and recall of gametes and embryos are compliant with HFEA requirements. This is important to ensure that all gametes and embryos sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;

- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes and embryos are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes and embryos from other centres if they are appropriately labelled and are accompanied by enough information to permit them to be stored or used in treatment in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; General Direction 0006)
The centre's procedures for import and export of gametes and embryos are broadly compliant with HFEA requirements.

The Human Fertilisation and Embryology Act 1990 (as amended) was amended on 1 April 2018 by the Human Fertilisation and Embryology (Amendment) Regulations 2018, to incorporate procedures for assuring the quality and safety of gametes and embryos imported into licensed centres in the UK, i.e. 'importing tissue establishments' (ITEs), from tissue establishments outside of the EU, EEA or Gibraltar, i.e. 'third country suppliers' (TCS). UK clinics must apply to the HFEA for an ITE import certificate to allow imports from specified TCSs, a clinic's certificate being synchronised in lifespan with the treatment licence. Centre 0328 has been allocated an ITE import certificate and imports of gametes and embryos from TCSs outside the EU/EEA have been made since the introduction of the ITE import certification scheme on 1 April 2018, only from those TCSs listed on the centre's certificate. The centre is therefore compliant with General Direction 0006.

Traceability (Guidance note 19)
The centre's procedures are broadly compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes and embryos during any step from procurement to use for human application or disposal;
- to identify the donor and recipient of particular gametes or embryos;
- to identify any person who has carried out any activity in relation to particular gametes or embryos; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS that is partially compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements, including those associated with ITE/TCS import certificates, are compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre has systems in place to manage transport and satellite activities that are not compliant with HFEA requirements. This is important to ensure that activities performed by transport and satellite clinics on behalf of the licensed centre are suitable and meet the HFEA requirements.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are broadly compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment. The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes or embryos clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events and reactions) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
The following issues were found on inspection:

- The lamp and extension lead in the men's room had not been subjected to portable electrical appliance testing since December 2016.
- There was no indication to say when the suction machine on the emergency resuscitation trolley had been serviced. Other critical equipment had been service in 2019.
- Blood bottles in one of the consultation rooms had expired in 2017 and 2018.

SLC T17;
Recommendation 7

Infection control (Guidance Note 25)

- Several sharps bins in use were not labelled to show when and by whom the sharps bin was assembled.
- The temporary closure on a number of sharps bins was not routinely used to prevent needle stick injuries.
- The floor in a room used for patient scanning was carpeted so could not be effectively cleaned.

SLC T2, DH Health Building Note 00-09: 'Infection control in the built environment' 2013

(3.82 and 3.109)., Healthcare-associated infections: prevention and control in primary and community care 2017, Section 1.1.4.4; Recommendation 2

Medicines management (Guidance Note 25)

- In one entry in the controlled drug (CD) register the second patient identifier (patient number) had been recorded incorrectly.
- The time of administration of CDs is often not recorded in the CD register or the patient records.
- Some entries in the CD register were illegible.
- One entry in the CD register had been crossed out several times.
- The carry over of stock from one page to another was not recorded or witnessed in a number of instances.
- Some entries in the CD register were in blue rather than black ink.
- These observations are non compliant with best practice guidance as well as the centre's documented procedures, indicating that the centre's audits of medicines management are not robust.

NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management', Misuse of Drugs (Safe Custody) Regulations 2001, Royal Pharmaceutical Society 'Professional Guidance on the Administration of Medicines in Healthcare Settings' 2019; Recommendation 3

Imports and exports (Guidance note 16; General Direction 0006)

Imports of donated sperm have been undertaken under General Direction 0006, but evidence held by the centre for the compliance of donor recruitment with screening and donor compensation requirements, was not robust. The evidence does not include any information of how or when the donor was screened for a pathogen, or the quarantine period applied, only that they were considered 'clear'. It also did not include a statement from the donor bank of the actual expenses incurred by the donor or the amount reimbursed to the donor, as is required by General Direction 0001. Evidence should be available that donor screening is compliant with SLC T52 and T53 and donor compensation with General Direction 0001, paragraphs 12 and 13. The centre has also not audited the services provided by donor banks against the requirements of General Direction 0006 or the relevant third party agreements, when in place.

General Directions 0006 and 0001, SLCs T52, T53, T36 and T112; Recommendation 8

Traceability (Guidance note 19)

The centre has two centrifuges for use in sperm processing and the centrifuge used is not documented in the records (SLC T22). The centre's asset list does not include the code by which each equipment piece is identified in the laboratory records and monitoring system, which may in future make it difficult to identify a specific piece of equipment from the laboratory records, if a traceability issue was to arise (SLC T22).

Recommendation 9

Quality management system (QMS) (Guidance note 23)

The following issues were found on inspection:

- Audit methodology includes observational audit of practice against the documented procedures in some areas but not in others, notably the laboratory processes (SLC T36). In addition, audit of third-party service providers is not undertaken, notably of the courier company used to transport gametes and

embryos.

- The transport of gametes and embryos SOP does not include the need to quarantine recalled materials and to investigate the recall as an adverse incident. The SOP which documents actions to take in the event of equipment failure ('Troubleshooting equipment') does not include the need to add the failure to the non conformance log, so facilitating monitoring of the repair and revalidation of the equipment (SLC T33b).
- The centre has not updated its consent SOP to reflect changes in the CoP related to establishing the relationship between patient couples, early in their treatment pathway, prior to consent for licensed activity and legal parenthood being considered (SLC T33b).

Recommendation 4

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The following issues were identified on inspection:

- GCRM Belfast does not have written agreements with its three satellite clinics at Ballykelly, Letterkenny and Newry (General Direction 0010).
- Of these three satellite clinics, one opened in February 2019; the other two opened prior to 2017 but changed address in January 2019. No details of these satellite clinics have been submitted to the HFEA, contrary to General Direction 0010.
- The services provided in the three satellite clinics have not been audited to assess their ability to comply with HFEA CoP requirements (SLC T36).
- It is not clear what systems are in place to protect the information of patients on the lap tops used during the consultation within the satellite clinics.

The PR considers the satellite clinics as 'outreach clinics', however the inspection team notes that the satellite clinics are advertised on the centre's website as satellite clinics, which can provide registration visits and appointments for initial consultation, tracking scans, for taking bloods to perform the tests required for treatment to progress, and for post-treatment reviews. Drug prescriptions are also generated from the satellite clinics. These clinics are clearly functioning as satellite clinics and it is important that the centre has satellite agreements with them and incorporates them within the centre's clinical governance framework to ensure compliant operation. The lack of governance arrangements is a potential risk to patient care.

The lack of agreements with satellite clinics was a major non compliance at the last interim inspection in 2017 which has not been addressed.

General Direction 0010, SLC T36; Recommendation 1.

Equipment and materials (Guidance note 26)
The quarantine dewar is not connected to the monitoring system and critical parameters in the dewar are therefore not continually monitored or recorded.

SLC T24; Recommendation 10

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has generally complied with HFEA requirements. The inspection team believes the PR's failure to implement satellite agreements after the last inspection in 2017, was due to a misinterpretation of General Direction 0010 and the status of the satellite clinics. Now that this misinterpretation has been clarified, along with the significance of this non compliance, the inspection team expects the PR to comply expeditiously with recommendations related to this area of practice.

The PR has academic qualifications in the field of medicine 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 PR Entry Programme.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better
Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre's procedures to ensure that the centre takes into account before licensed treatment is provided, the welfare of any child who may be born as a result of that treatment and of any other child who may be affected by that birth, are compliant with HFEA requirements.

Safeguarding (Guidance Note 25)
The centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better
Nothing identified at this inspection.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
Preimplantation genetic screening, embryo testing and sex selection are not licensed activities at this centre, therefore requirements related to these areas were not relevant at this inspection.

What the centre could do better
Nothing identified at this inspection.

2. The experience of patients

Patient feedback

What the centre does well

The HFEA website has a facility on its 'Choose a Fertility Clinic' page enabling patients to provide feedback on their experience of their clinic. Only 43 patients have provided feedback (6%) in the last 12 months, giving an average five star rating to the clinic. This suggests that the clinic does not actively seek patient feedback for comparison purposes. For the system to work well, it's important that every patient knows about the rating system. The PR is asked to consider ways to promote the use of this facility; this will be followed up at the next inspection.'

The website also gives the ability for patients to comment on the cost of treatment. The majority of patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting on the friendly supportive staff at the clinic.

The centre's own most recent patient survey responses were also reviewed. Feedback was comparable to that provided to the HFEA.

During the inspection the inspectors spoke to patients (a couple) who also provided positive feedback on their experiences.

On the basis of this feedback and observations made in the course of the inspection it was possible to assess that the centre:

- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- treats patients with empathy and understanding.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg [and sperm] sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)

The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for a conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients and donors are treated fairly and that all licensed activities are conducted in a non discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients and donors providing relevant consent and prior to consenting to legal parenthood.

Egg sharing arrangements (Guidance note 12; General Direction 0001)
The centre provided information on their self-assessment questionnaire (SAQ) to indicate that they provided egg sharing treatments. During the inspection however, one member of staff said that the centre did not provide egg sharing treatments whilst another said that the centre would provide these treatment but had not yet had any patients requesting egg sharing. Therefore this area of practice was not inspected.

Surrogacy (Guidance note 14)
The centre's procedures for treatment involving surrogacy are compliant with HFEA requirements. This is important to protect the surrogate and any children born as a result of the treatment. The centre's SAQ stated they do not undertake surrogacy as it was postponed by the Fertility Partnership at the group level. However, the clinic has two separate cases of surrogacy going through for treatment at the moment, who started on their treatment pathway in 2018 prior to the group postponement.

The records were reviewed and all parties were found to have had an assessment completed for welfare of the child and no issues were identified.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current patients and donors.

What the centre could do better
Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients and donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better
Nothing identified at this inspection.

Consent and disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients and donors have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
Where a couple to be treated with donated gametes or embryos is not married or in a civil partnership, both the woman and her partner must give written consent in order for the partner to become the legal parent of any child born. If this consent is not documented properly or if proper information is not provided or counselling offered prior to both parties giving consent, there may be doubt about the effectiveness of the consent and in some cases it may be necessary for a patient couple to obtain a court declaration to establish legal parenthood.

This centre has been inspected since 2014 and 2015 when significant failings were reported across the sector regarding the collection and documentation of consent to legal parenthood. At the inspection in June 2017, legal parenthood consenting processes were found to be robust.

To provide assurance of the continued compliance and effectiveness of the centre's legal parenthood consenting procedures, the inspection team discussed these procedures with staff and reviewed the results of recent legal parenthood consenting audits. Four sets of records where treatment with donor sperm had recently been provided in circumstances where consent to legal parenthood was required were also audited by the inspection team. These activities enabled the inspection team to conclude that the processes used to collect legal parenthood consent at this centre are compliant with HFEA requirements.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information, to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre's procedures are compliant with the requirements of the HF&E Act 1990 (as amended) and ensure that the special status of the embryo is respected when licensed activities are conducted at the centre because:

- licensed activities only take place on licensed premises;
- only permitted embryos are used in the provision of treatment services;
- embryos are not selected for use in treatment for social reasons;
- embryos are not created by embryo splitting;
- embryos are only created where there is a specific reason to do so which is in connection with the provision of treatment services for a particular woman and
- embryos are only stored if those embryos were created for a woman receiving treatment services or from whom a third party agreement applies.

What the centre could do better

Nothing identified at this inspection.

Screening of patients and Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 15)

The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes and/or embryos.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes and embryos are compliant with HFEA requirements. These measures ensure that the gametes and embryos are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes and embryos in accordance with the consent of the gamete providers. The storage of gametes and embryos is an important service offered by fertility clinics, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. The storage of embryos not required for immediate use also means that women can undergo further fertility treatment without further invasive procedures being performed.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well

Use of embryos for training staff (Guidance note 22)
The centre's procedures for using embryos for training staff are partially compliant with HFEA requirements. Embryos are only used for the purpose of training staff in those activities expressly authorised by the Authority.

What the centre could do better

Use of embryos for training staff (Guidance note 22)
Information is not provided to patients before they consent to the use of their stored embryos in training. Patients will have been provided at the start of their treatment pathway with an information sheet discussing the use of their embryos in training but this may have been some years before when their embryos were first produced. Furthermore, the information sheet provided does not include any content about the training activities the embryos may be used in, contrary to SLC T97a. These observations indicate that consents for the use of embryos in training are not fully informed and robust (HF&E Act 1990 (as amended), Schedule 3.3b).

Recommendation 4

4. Information management

Record keeping and Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are broadly compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are partially compliant with HFEA requirements. This is important to ensure the HFEA can supply accurate information to a donor conceived person and their parents or donors.

The HFEA register audit team found no/some evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Record keeping and document control (Guidance note 31)
In one electronic donor record, the Single European Code (SEC), which is usually on the final page of the paper record, was missing. It is highly likely that it had been omitted during scanning and the creation of the electronic record. This electronic record should not have been cleared by the staff before disposal of the paper record. This failure undermines confidence in the indelibility of information during transfer from paper-based to digital storage within the IDEAS system (SLCs T38, T40).

Recommendation 11

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The PR failed to complete the centre's renewal licence application in advance of this inspection. The absence of the renewal application was discussed during the inspection. The PR confirmed there has not been an IT issue. After a number of reminders, the application was finally submitted on 23 May 2019.

The 2018 IUI data should have been submitted in February 2019 but was submitted on 23 May 2019 after reminders during and after the renewal inspection.

General Direction 0005; Recommendation 6

Section 3: Monitoring of the centre's performance

Following the renewal inspection in 2015, recommendations for improvement were made in relation to five areas of major non compliance and six 'other' areas of non compliance. The PR provided information and evidence that all of the recommendations were fully implemented within the prescribed timescales.

The report of the interim inspection in 2017 cited a lack of satellite agreements as a major non compliance, as satellite activities were started before the HFEA was notified and in receipt of the agreements. This non compliance was seen to be still present at this renewal inspection, as is discussed in recommendation 1. The inspection team believes the PR's failure to implement satellite agreements after the last inspection in 2017, was due to a misinterpretation of General Direction 0010 and the status of the satellite clinics, as well as less than optimal monitoring by the executive. Now that this misinterpretation has been clarified, along with the significance of this non compliance, the inspection team expects the PR to comply expeditiously with recommendations related to this area of practice.

Areas of practice requiring action

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, General 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, or a significant shortcoming from the statutory requirements. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None Identified			

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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. Transport and satellite agreements GCRM Belfast does not have written agreements with its three satellite clinics at Ballykelly, Letterkenny and Newry (General Direction 0010). Of these three satellite clinics, one opened in February 2019; the other two opened prior to 2017 but changed address in January 2019. No details of these satellite clinics have been submitted to the HFEA, contrary to General Direction 0010.	The PR should ensure satellite agreements are in place for all satellite clinics and are compliant with General Direction 0010. The services provided by the satellite clinics should also be audited to ensure their compliance with HFEA CoP requirements. The PR must submit a copy of a satellite agreement and a report of an audit of compliance, for each of the three satellite clinics, to the HFEA by 15 August 2019.	Satellite/Outreach agreements are currently being drafted for each of our outreach clinics and I will forward as soon as they are completed. We have already an agreement with Dr McKernon in and will forward. The description of the services available at our outreach clinics has been wrongly described on our website. This is being corrected. An audit of compliance will be carried out once the agreements have been signed. To have meaningful audits completed by the 15th August 2019 not achievable for us.	The Executive acknowledges the PR's response and commitment to fulfil this non compliance. The Executive acknowledges the PR's suggestion of an extension of the date for the non compliance to be completed. However, on this occasion the executive is not prepared to agree to this request in full. The executive expects this to be fully implemented including all required documentation to be submitted to the centres inspector no later that the 30th

The services provided in these satellite clinics have not been audited to assess their ability to comply with HFEA CoP requirements (SLC T36). It is not clear what systems are in place to protect the information of patients on the lap tops used during the consultation within the satellite clinics. These clinics are clearly functioning as satellite clinics and it is important that the centre has satellite agreements with them and incorporates them within the centre's clinical governance framework to ensure their compliant operation. The lack of governance arrangements is a potential risk to patient care. The lack of agreements with satellite clinics was a major non compliance at the last inspection in 2017 which has not been addressed. General Direction 0010, SLC		We will have these completed by 15th September and forwarded.	August 2019. Consideration was given that this has been a non compliance since 2017 and future non compliances in this area of practice will be upgraded to 'Critical'. Further action required

T36.			
2. Infection control • Several sharps bins in use were not labelled to show when and by whom the sharps bin was assembled. • The temporary closure on a number of sharps bins was not routinely used to prevent needle stick injuries. • The floor in a room used for patient scanning was carpeted so could not be effectively cleaned. SLC T2 DH Health Building Note 00-09: 'Infection control in the built environment' 2013 (3.82 and 3.109).,. Healthcare-associated infections: prevention and control in primary and community care 2017, Section 1.1.4.4.	The PR should ensure compliance with infection control regulations. The PR should provide an action plan with timeframes for implementation to address the infection control issues identified when responding to this report. A summary report of this review, including any corrective actions, with timescales, should be provided to the centre's inspector by 15 November 2019.	Further training with staff will be undertaken in the use and management of sharps bins. This will be actioned by our nurse manager on her return from annual leave on the 22/07/19 and completed by mid August 2019. A report of actions taken will be forwarded before 15 November 2019. All clinic areas where ultrasound scans are carried out will have compliant flooring fitted. A timescale to achieve this will be forwarded.	The Executive acknowledges the PR's response and awaits the timescale for the clinical area flooring to be undertaken as requested when responding to this report. Further action required
3. Medicines Management The following issues were found on inspection: • In one entry in the	The PR should ensure compliance with medicines management regulations, practice guidance and the	A review of our management of medicines will be conducted and will include additional staff training. This will be actioned on the return from annual	The executive acknowledges the PR's response to Medicines management and awaits the outstanding documents.

controlled drug (CD) register the second patient identifier (patient number) had been recorded incorrectly. • The time of administration of CDs is often not recorded in the CD register or the patient records. • Some entries in the CD register were illegible. • One entry in the CD register had been crossed out several times. • The carry over of stock from one page to another was not recorded or witnessed in a number of instances. • Some entries in the CD register were in blue rather than black ink. • These observations are non compliant with best practice guidelines as well as the centre's documented procedures, indicating that the centre's audits of medicines management are not robust.	centre's SOPs The PR should review medicines management practices in the centre including (but not exclusively) staff training requirements (both nursing and medical staff) and provide a summary report of this review to the centre's inspector by 15 August 2019. Three months after this review the PR should audit medicines management practice to ensure that any corrective and/or preventative actions taken have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 15 November 2019.	leave of our nurse manager (22.07.2019) and a report of the review will be forwarded by 15/08/19. The results of an audit of compliance will be forwarded by 15th November 2019.	Further action required

NICE Guideline [NG46] April 2016 'Controlled drugs: safe use and management'. Misuse of Drugs (safe Custody) Regulations 2001. Royal Pharmaceutical Society 'Professional Guidance on the Administration of Medicines in Healthcare Settings' 2019.			
4. Quality Management system (QMS) The following issues were found on inspection: • Audit methodology includes observational audit of practice in some areas but not in others, notably in the lab (SLC T36). In addition, audit of third-party service suppliers is not undertaken, specifically regarding the TPA with the courier company. • The transport of gametes and embryos SOP does not include the need to quarantine recalled materials and to investigate the recall as an adverse incident. • The SOP which documents actions to take in the event	The PR should ensure the centre's QMS is compliant with HFEA CoP requirements and guidance. The PR should address the issues identified in this report and provide a summary report of the corrective actions taken to the centre's inspector by 15 August 2019. Three months after the implementation of any actions, the PR should audit practices to ensure that all corrective actions taken have been effective. A summary report of this audit should be provided to the	The QMS system used in the clinic was introduced by TFP to the whole group. We continually strive to use it to its full potential and to attain full compliance with the HFEA CoP requirements and guidance. An audit of our TPA with the courier will be done, and reported by 15/11/19. Our SOPs governing the following areas of practice will be reviewed with appropriate changes made where necessary: Transport of gametes. Equipment failure. Couples relationships. A report of our actions will be	The Executive notes the PR's commitment to fulfil this non compliance. Further action required

of equipment failure ('Troubleshooting equipment') does not include the need to add the failure to the non conformance log, so facilitating monitoring of the repair and revalidation of failed equipment (SLC T33b). The centre has not updated its consent SOP to reflect changes in the CoP related to establishing the relationship between patient couples, early in their treatment pathway, prior to consent for licensed activity and legal parenthood being considered (SLC T33b).	centre's inspector by 15 November 2019.	forwarded by the 15th August 2019. The outcome of audits of the changes made will be provided before the 15th November 2019.	
5. Use of embryos for training staff Information is not provided to patients before they consent to the use of their stored embryos in training. Patients will have been provided at the start of their treatment pathway with an information sheet discussing the use of their embryos in training but this may have been some years	The PR should ensure that information about the use of embryos in training, compliant with SLC T97, is provided to patients prior to them giving consent to use of embryos (fresh or stored) in training. The PR should provide a summary of changes made to	Our SOP will be changed along with our practice to include the provision of appropriate information to patients before they are asked to consent to the use of embryos in training. A report of the changes will be forwarded by the 15th August 2019.	The Executive acknowledges the PR's response. Further action required

before when their embryos were first produced. The information sheet provided does not include any content about the training activities the embryos may be used in, contrary to SLC T97a. These observations indicate that consents for the use of embryos in training are not fully informed and robust (HF&E Act 1990 (as amended), Schedule 3.3b).	the centre's inspector by 15 August 2019.		
6. Obligations and reporting requirements The PR failed to complete the centre's renewal licence application in advance of this inspection. The centre's annual IUI data submission for 2018 was not submitted in line with General Direction 0005. General Direction 0005	The PR should ensure that all licensing applications and licensed treatment activity is reported to the Authority within the required timeframes. The procedures used to submit licensed treatment data should be reviewed to identify and address the reasons for the non compliances identified here. A report of this review, including corrective actions	We will review our procedures governing the submission of licenced treatment data to ensure that in future all submissions are compliant. A report of actions with timescales will be provided by the 15th November 2019.	The Executive acknowledges the PR's response. Further action required

	with timescales for implementation should be provided to the centre's inspector by 15 November 2019.		

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.

An 'other' area of non compliance is identified in the report by a statement that an area of practice is 'broadly' compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
7. Safety and suitability of premises and facilities The following issues were noted: • The lamp and extension lead in the men's room had not been subjected to portable electrical appliance testing since December 2016. • There was no indication to say when the suction machine on the emergency resuscitation trolley had been serviced. • Blood bottles in one of the consultation rooms had expired in 2017 and 2018. SLC T17	The PR should ensure that the premises are suitable and fit for purpose. The PR should address the issues identified in this report and provide the centre's inspector with confirmation that the actions required have been completed or provide a timeframe for their completion. It is expected that the required actions will have been completed by 15 August 2019.	I can confirm that all portable electric appliances within the clinic have now been tested. We will review our methodology for checking that servicing of all equipment within the clinic is carried out in a timely manner. The procedures employed to check the stock in each clinical area will be reviewed to ensure all stock items are within their use by dates. These actions will be completed by the 15th August 2019.	The Executive acknowledges the PR's response. Further action required
8. Imports and exports Imports of donated sperm	The PR should ensure that	In agreement with the suppliers of imported gametes,	The Executive acknowledges the PR's response and awaits

have been undertaken under General Direction 0006 but evidence held by the centre for the compliance of donor recruitment with screening and donor compensation requirements, was not robust. Evidence should be available that donor screening is compliant with SLC T52 and T53 and donor compensation with General Direction 0001, paragraphs 12 and 13. The centre has also not audited the services provided by donor banks against the requirements of General Direction 0006, licence condition requirements and the relevant third party agreements. General Directions 0006 and 0001, SLCs T52, T53, T36 and T112.	evidence is obtained for the compliance of imports and exports with General Direction 0006 and other HFEA requirements notably, but not exclusively, related to donor screening and compensation, e.g. General Direction 0001, SLC T52 and T53. The PR should also audit the services provided by donor banks against the requirements of General Direction 0006, licence condition requirements and the relevant third party agreements. A summary report of actions taken should be provided to the centre's inspector when replying to this report. Within three months, the centre should carry out an audit of imports and exports to ensure that corrective actions have been effective in ensuring compliance. A summary report of the audit detailing the corrective actions with evidence supporting their	we are currently drafting a new SLA that will require the supplier to provide all relevant data to demonstrate full compliance with the import and export of gametes as set out in the COP (General Direction 0006 and 0001). An audit to confirm compliance will be initiated and a summary report provided before the 15th November 2019.	the required documentation to fulfil this non compliance. Further action required

	implementation should be supplied to the centre's inspector by 15 November 2019.		
9. Traceability The centre has two centrifuges for use in sperm processing but which centrifuge is used is not documented in the records. The centre's asset list does not include the code by which each equipment piece is identified in the laboratory records and monitoring system, which may make it difficult in future to identify a specific piece of equipment from the laboratory records, if a traceability issue was to arise. SLC T22	The PR should ensure that the centrifuges used for sperm processing are identifiable and documented in the centre's records. The PR should ensure that practices and procedures are reviewed to allow for full traceability. Evidence of this should be submitted to the centre's inspector by 15 August 2019.	The SOP has been reviewed to confirm that our practices and procedures allow for full traceability of the centrifuges used in sperm processing. This has been completed, and an audit of the changes will be reported by the 15/09/19.	The Executive acknowledges the PR's response and awaits the evidence supporting this non compliance. Further action required
10. Equipment and materials The quarantine dewar is not connected to the monitoring system so critical parameters within the dewar are not continually monitored or recorded. SLC T24	The PR should ensure that the quarantine dewars have an adequate monitoring system and that critical parameters are continually monitored and recorded. The PR should provide	The quarantine dewar which currently contains no stored material will be connected to the monitoring system to ensure that continuous monitoring and recording is possible. Additional monitoring equipment has been ordered and will be fitted	The PR acknowledges that additional monitoring equipment is on order and awaits confirmation that this non compliance has been fully addressed. Further action required

	evidence of the actions taken to implement this recommendation when responding to this report.	once delivered. The expected delivery is in 6 weeks, we will report when completed.	
11. Record keeping and document control In one electronic donor record, the SEC, which is usually on the final page of the paper record, was missing. It is highly likely that it had been omitted during scanning and the creation of the electronic record. This electronic record should not have been cleared by the staff before disposal of the paper record. This failure undermines confidence in the indelibility of information during transfer from paper-based to digital storage within the IDEAS system. SLC T38, T40	The PR should ensure the process for creating electronic records is robust. The PR should review the process used to create electronic records. A summary of the findings of the review, including corrective actions with timescales for implementation, should be provided to the centre's inspector by 15 August 2019. Within three months of the implementation of corrective actions, the centre should carry out an audit of record keeping, to assess if the corrective actions have been effective. A summary report of the audit should be sent to the centre's inspector by 15 November 2019.	Our processes governing the creation of digital records from scanned documents has been reviewed to ensure a check is made of the digital record that all data from the scanned document is captured and is legible. No changes to the SOP were required. On investigation the non compliance was due to a member of staff not following the instructions as laid down in the SOP. Further training of staff will be completed by the 15/08/19. A report will be forwarded by the 15th August and an audit of future compliance by the 15th November 2019.	The executive acknowledges the PR's response. Further action required

Reponses from the Person Responsible to this inspection report

Page 5 of the draft report refers to one critical area of non-compliance, I was to understand this was graded as major.

The target date of the 15th August 2019 for some of the actions/reports requested in response to the draft inspection report will be challanging for me to respond to due to the short timescale from receipt of this report The report was received on the 10/07/19 (the inspection was carried out on the 14-15/05/19. Following receipt of the report senior members of our team were on annual leave, and have only had sight of the content on their return (22/07/19). I will require significant input from them to complete my reports. I will do my best to meet the deadlines, the 15th November will be achievable but the 15th August will be more challenging.

The various reports and audits will be forwarded separately as they are completed.

Thank you for your response.

The critical area of non compliance has now been graded as a major, as discussed prior to receiving your draft report and is reflected within the report.

The non compliances described in this report were discussed with you and your team member's whilst on inspection and again during feed back, of which many of your team members were present and had taken notes. As you were aware of the non compliances at this point, there were no barriers for you as a centre to commence work on these non compliances before receiving your report. In addition, the time frames for non compliances in the report are in line with the HFEA normal processes.

As your centre's inspector, I wished to keep you informed and up to date on where we were with sending you the draft report. Apologies for the short delay in processing your report which were conveyed to you by email and also a telephone conversation. The delay came about as the Executive were having discussions surrounding the grading of the major non compliance, outstanding from your centres inspection report in 2017. This non compliance required further discussion as you failed to address this from your last inspection.