Executive Licensing Panel Minutes

Centre 0307 (Complete Fertility Centre Southampton)

Interim Inspection Report

Variation to Change Person Responsible (PR)

Date:	15 June 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Joanne Anton Dan Howard	Director of Strategy and Corporate Affairs Head of Regulatory Policy Chief Information Officer
Executive:	Bernice Ash	Secretary
Observers	Catherine Burwood	Licensing Manager

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 noted that Complete Fertility Centre Southampton is located within the Princess Anne Hospital and has held a licence with the HFEA since 2008. The centre provides a full range of fertility services including the storage of gametes and embryos.

1.2. The panel noted that the centre previously procured ovarian tissue for storage at a Human Tissue Authority (HTA) licensed unit. However, following meetings with the HTA and HFEA in 2020, which concluded that a HTA licence was required for the activities being carried out in this area of practice, the Person Responsible (PR) has ceased the service until alternative licensing arrangements can be made.

1.3. The panel noted that the centre had submitted an application to change the Person Responsible (PR) and this would also be for consideration at this meeting.

1.4. The panel noted that, in the 12 months to 30 April 2021, the centre had provided 817 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels, this is a medium sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.

1.5. The panel noted that, HFEA register data, for the year ending 31 October 2021, show the centre's success rates for IVF and ICSI are in line with the national averages.

1.6. The panel noted that, in 2020, the centre reported 28 cycles of partner insemination, with four pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.7. The panel noted that, HFEA register data, for the year ending 31 January 2021, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be statistically lower than 10% multiple live birth rate target for this period.

1.8. The panel noted that, due to the Covid-19 pandemic, a Desk Based Assessment and Risk Based Approach (DBA/RBA), was initially conducted for the centre's interim inspection. This process identified some potential areas of concern which the assessors considered were associated with significant enough risk, to merit further review during an on-site inspection. Therefore, a shorter than normal on-site visit to the centre, with a smaller inspection team, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. This onsite inspection allowed for potential non-compliances to be appropriately reviewed.

1.9. The panel noted that the DBA was conducted, followed by an onsite inspection on 15 April. This process included videoconferencing with key members of centre staff. The centre's own assessment of its service, the progress made in implementing the actions identified at the last inspection and on-going monitoring of the centre's performance was also taken into account.

1.10. The panel noted that at the time of the inspection, there were three major areas of non-compliance identified concerning the Quality Management System (QMS), equipment and materials and suitable premises. Since the inspection, the PR has provided evidence that actions have been taken to implement the recommendation surrounding suitable premises and has committed, where required, to audit the effectiveness of those actions within the required timescales. The PR has given a commitment to fully implementing the non-compliances regarding the QMS and equipment and materials.

1.11. The panel noted the centre is well led and provides a good level of patient support. The inspectorate particularly noted the positive comments, made by patients, in relation to their experiences at the centre.

1.12. The panel noted that the inspection team recommends the continuation of the centre's treatment and storage licence.

2. Decision

2.1. The panel was satisfied the centre was fit to have its treatment and storage licence continued, noting the outstanding audits and summary reports, were due for submission in July and October 2021.

2.2. The panel expressed particular concern that non-compliance regarding the centre's QMS, which had been identified at a previous inspection and had been resolved, were now found to be recurring.

2.3. Due to the nature of non-compliances identified in the report, the panel requested that, should the centre fail to submit the necessary audits and summary reports, within the prescribed timescales, or if these are not to the satisfaction of the inspectorate, especially with regards to the QMS, a further report should be submitted for the panel's consideration.

3. Change of Person Responsible - Consideration of Application

3.1. The panel considered the papers, which included a completed application form, an executive summary, previous licensing minutes, a CV and confirmation of acceptance from the proposed PR.

3.2. The panel noted that an application to change the PR for Complete Fertility Centre Southampton has been received by the HFEA on 12 April 2021 and it is requested to be considered by the Executive Licensing Panel (ELP).

3.3. The panel noted that the proposed PR, Ms Victoria Ryder, has academic qualifications in the field of biological sciences and has more than two years of practical experience which are directly relevant to the activities to be authorised by the licence. The proposed PR has successfully completed the HFEA PR Entry Programme (T/1376/82).

3.4. The panel noted the outstanding issues from centre's interim inspection. The report has been reviewed by the current and the proposed PR; the proposed PR is aware of, and has agreed, to take responsibility for these outstanding issues.

3.5. The panel noted that, from the information provided, the character, qualifications and experience of the proposed PR, Ms Victoria Ryder, are suitable to carry out a PR's duties under section 17 of the HFE Act 1990 (as amended).

3.6. The panel noted the inspectorate's recommendation to vary the centre's licence to Ms Victoria Ryder as the PR.

3.7. The panel noted that, as a result of the UK's departure from the EU, a relicensing exercise is currently in progress. This follows approval by the Licence Committee (LC) of a variation without application on 4 March 2021, meaning that new offer licences are being sent to all clinics, incorporating changes to some of the standard licence conditions. The varied licences will all come into effect on 1 July 2021, after the transition period ends on 30 June 2021.

3.8. Due to the relicensing exercise, the panel is asked to approve this change of PR for the centre's current licence, and also for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence (if approved) for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, also reflecting the variation of PR, as requested.

4. Decision

4.1. The panel agreed that it was in receipt of the appropriate documentation as required by the HFE Act 1990 (as amended) in relation to Section 16(2), which sets out the requirements with regard to the role of Licence Holder and Person Responsible.

4.2. The panel noted that the proposed PR was aware of the outstanding actions, with regards to the non-compliances identified at the centre's interim inspection, agreeing to take responsibility for them.

4.3. The panel endorsed the inspectorate's recommendation and agreed to vary the licence of Complete Fertility Centre Southampton (centre 0307) with immediate effect to reflect the change of Person Responsible to Ms Victoria Ryder in accordance with Section 18A of the HFE Act 1990 (as amended), also approving this change for the new, varied, licence that will supersede it on 1 July 2021. The Licensing team will send the centre a varied licence for immediate use until 30 June 2021, and an updated offer licence for 1 July 2021 onwards, also reflecting the approved variation of PR.

5. Chair's signature

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

Signature

Name

Clare Ettinghausen

Date

21 June 2021

Interim Licensing Report

Centre name: Complete Fertility Centre Southampton
Centre number: 0307
Date licence issued: 1 November 2019
Licence expiry date: 31 October 2023
Additional conditions applied to this licence: None
Date of inspection: 15 April 2021
Inspectors: Sarah Stedman (Lead), Polly Todd (onsite inspection); Lesley Brown, Karen Campbell (virtual inspection)
Date of Executive Licensing Panel: 15 June 2021

Purpose of the report

The Human Fertilisation and Embryology Authority (HFEA) is the UK's independent regulator of the fertility sector. The HFEA licenses centres providing in vitro fertilisation (IVF) and other fertility treatments and those carrying out human embryo research.

Licensed centres usually receive a licence to operate for up to four years, although some centres have had their licence extended to five years due to the Covid-19 pandemic (five years being the maximum length of a treatment licence permitted by law). The full inspection prior to a licence being granted or renewed assesses a centre's compliance with the law and the HFEA's Code of Practice (CoP) and Standard Licence Conditions (SLC).

This is a report of an interim inspection, at the mid-point of the licence period.

In March 2020, the World Health Organisation declared a world-wide pandemic of Coronavirus (Covid-19). In response to UK measures to contain and mitigate the spread of the virus, new inspection methodologies were developed and implemented.

These methods enable compliance to be reviewed through desk based assessment (DBA) and the use of virtual technology where available and appropriate. A risk based approach (RBA) can then be applied, balancing the risks of on-site inspection during the Covid-19 pandemic against those resulting from potential non compliances, identified during DBA, if not adequately investigated.

For this centre, the DBA/RBA process identified some potential areas of concern which the assessors considered were associated with significant enough risk, to merit further review during an onsite inspection. Therefore, a shorter than normal on-site visit to the centre, with a smaller inspection team, was undertaken, thereby reducing the risks of travel and close contact during the pandemic. This on-site inspection allowed for potential non compliances to be appropriately reviewed.

This inspection was therefore carried out by a combination approach including desk based assessment, onsite inspection and virtual inspection, which included videoconferencing with key members of centre staff.

The current foci for an interim inspection are:

- **Quality of care:** the quality of care provided by a centre is defined by positive healthcare outcomes and a positive patient experience delivered via safe and effective care.
- **Patient safety:** patient safety is a fundamental and essential attribute to quality healthcare: without safety there cannot be high quality. Improving safety is an ethical imperative for healthcare providers, and the individuals who deliver that care.
- **Patient experience:** understanding what matters to patients and improving the patient experience is crucial in delivering high quality care.

We also take into account the centre's own assessment of its service; the progress made in implementing the actions identified at the last inspection; and our on-going monitoring of the centre's performance.

The report represents a mid-term evaluation of a centre's performance based on the above. The aim is to provide the Authority's Executive Licensing Panel (ELP) with information on which to make a decision about the continuation of the licence.

The centre is also applying to vary the licence to change the Person Responsible (PR) and the ELP is asked to consider this variation in conjunction with this report.

Summary for the Executive Licensing Panel

Summary for licensing decision

The inspection team recommends the continuation of the centre's licence.

In particular we note the positive comments made by patients in relation to their experiences.

The centre is well led and provides a good level of patient support.

The ELP is asked to note that this report makes recommendations for improvement in relation to three major area of non compliance or poor practice.

Since the inspection visit, the PR has provided evidence that actions have been taken to implement the following recommendations and has committed, where required, to audit the effectiveness of those actions within the required timescales:

Major areas of non compliance:

- The PR should ensure that the premises are safe and suitable equipment is used.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- The PR should ensure that the quality management system (QMS) is effective and fit for purpose.
- The PR should ensure that only CE marked medical devices are used wherever possible.

Information about the centre

The Complete Fertility Centre Southampton is located within the Princess Anne Hospital and has held a licence with the HFEA since 2008.

The centre provides a full range of fertility services including the storage of gametes and embryos.

The centre previously procured ovarian tissue for storage at a Human Tissue Authority (HTA) licensed unit. However, following meetings with the HTA and HFEA in 2020 which concluded that a HTA licence was required for the activities being carried out in this area of practice, the PR has ceased the service until alternative licensing arrangements can be made.

The centre provided 817 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 30 April 2021. In relation to activity levels this is a medium centre**.** The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom may have had an impact on treatment numbers.

The centre followed professional body guidance to suspend all non-essential treatments in response to Covid-19 and is compliant with GD0014 Version 2 for resuming treatment services.

Details of Inspection findings

Quality of Service

Each interim inspection focuses on the following themes: they are important indicators of a centre's ability to provide high quality patient care and to meet the requirements of the law.

Pregnancy outcomes[1]

For IVF and ICSI, HFEA held register data for the year ending 31 October 2021 show the centre's success rates are in line with national averages.

In 2020, the centre reported 28 cycles of partner insemination with four pregnancies. Which is in line with the national average.

Multiple births[2]

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

HFEA held register data for the year ending 31 January 2021 show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 4%. This represents performance that is likely to be statistically lower than 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%.

Witnessing

Good witnessing processes are vital to ensure there are no mismatches of gametes or embryos and that identification errors do not occur. During the virtual inspection, the inspection team was not able to observe any laboratory activities but was able to discuss witnessing with staff and had performed a desk-based review of the centre's own audit of witnessing practice. These activities indicated that witnessing procedures are compliant with HFEA requirements, with the exception of the issues noted in the quality management system (QMS) section of this report.

Consent: To the storage of cryopreserved material

The storage of gametes and embryos is an important service offered by fertility clinics. It enables patients to undergo further fertility treatment without additional invasive procedures and to preserve their fertility prior to undergoing other medical treatment such as radiotherapy. It is important that the centre has measures in place to ensure that gametes and embryos are stored in accordance with the consent of the gamete providers.

During the inspection process, reports of audits of all stored gametes and embryos and of the accuracy of storage logs and consent records were reviewed. The 'bring-forward' system was discussed with staff and storage records were reviewed. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective, with the exception of the issues noted in the quality management system (QMS) section of this report.

Staffing

Having the right numbers of staff, competent to carry out highly technical work in a non-pressured environment is important in infertility services.

The inspection team considered that staffing levels in the clinic appeared suitable for the activities being carried out; the atmosphere in the clinic appeared calm at all times.

Quality Management System (QMS)

It is important that centres audit all of their practices at least every two years to ensure they are delivering the expected quality of service, that staff are following standard operating procedures and that the centre's processes meet the HFEA's regulatory requirements. It is also important that these audits are robust and that any necessary changes that are identified are made, as this supports continuous improvement.

The effectiveness of the centre's QMS was assessed by reviewing the reports of the following audits: medicines management; infection control; legal parenthood; witnessing; consent to storage.

The centre's procedures for auditing and acting on the findings of audits are partially compliant with requirements because:

- For some of the incidents reviewed, the investigation lacked robustness, in determining a root cause analysis (RCA) and the inspection team are concerned that this lack of analysis may have contributed to these incidents reoccurring. This was a non-compliance at the licence renewal inspection in 2019.
- As part of the DBA process and virtual inspection, the inspection team reviewed audits of storage and witnessing performed by the centre. It was noted that audit findings were recorded as either 'observations' or, 'non-conformances' and it was

unclear how these were graded. On discussion with the laboratory manager, she believed that several of the 'observations' should have been graded as 'non-conformances'. She explained that when a non conformance is recorded in 'QPulse' (an electronic incident management system), this triggers a series of actions required to be completed before the non-conformance is closed. If an 'observation' is recorded on the system, it does not trigger further actions. Therefore, there is a risk that corrective actions may not have been identified and/or implemented when an issue has been noted on an audit. Furthermore, many findings were recorded as "no action required". In most cases reviewed, where 'no action required' was recorded, the laboratory manager was able to demonstrate that actions had indeed been taken and concluded that the audit documentation was badly worded. However, in a witnessing audit, in one recorded 'observation' (where the person's identity had not been checked following sperm being produced at home), there was no evidence that further actions had been taken, nor alerted for via the QPulse system. The laboratory manager was therefore uncertain if this case was a witnessing error or not (as the sample in question may not have been related to fertility treatment).

- The centre's legal parenthood audit lacked robustness in that it did not document pregnancy outcomes; correct completion of the WP (Your consent to your partner being the legal parent) and PP (Your consent to being the legal parent) consent forms; whether there had been any withdrawal of consent to legal parenthood or whether counselling had been offered prior to obtaining consent.

(See Recommendation 1).

We also considered whether the clinic's processes for implementing learning are effective. If a clinic is to achieve continuous improvement and encourage a learning culture, then it is important that they act to review their practices when guidance is issued by the HFEA or other bodies. The clinic's procedures for acting on guidance from the HFEA were evaluated with reference to the following:

- leadership
- patient support
- extension of storage consent
- consent
- imports of gametes and embryos from outside the EU/EEA
- data submission to the HFEA
- the use of CE marked medical devices

The centre has been effective in ensuring compliance with guidance issued by the HFEA with the exception of the issues noted in the quality management system (QMS) section of this report.

Medicines management

It is important that clinics follow best practice for medicines management both to protect patients and ensure that medicines are stored, administered, and disposed of in the correct way.

Documentation provided as part of the DBA indicate that the clinic's processes for medicines management and the safe storage, disposal and administration of medicines are compliant with guidance.

Prescription of intralipid 'off label'
Intralipid is an intravenous nutritional supplement sometimes prescribed during 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.

Infection Control
It is important that clinics have suitable arrangements in place so that patients experience care in a clean environment and to prevent patients and staff acquiring infections.

Documentation provided as part of the DBA and discussions during the virtual inspection indicate that the clinic's infection control practices are compliant with guidance.

Equipment and Materials
It is important that products (known as medical devices) that come into contact with gametes and/or embryos are approved for the provision of fertility treatment, to ensure the safety of gametes, embryos and patients. The approval of such products is denoted by the issue of a 'CE mark'.

As part of the DBA, the inspection team reviewed the centre's own audit of CE marked equipment. We found the centre to be partially compliant with HFEA requirements to use CE marked medical devices wherever possible because 50ml flasks in use at the centre are not CE marked. This was a non-compliance at the interim inspection 2017 when the centre had given assurances that a suitable product would be in use at the clinic within the specified timescales.

(See recommendation 2).

Patient experience

Patient support
New HFEA guidance strengthens support provided by staff at all levels to patients, so as to improve their emotional experience of care. All clinics should have a policy outlining how appropriate psychosocial support from all staff is provided to patients, donors and their partners, before, during and after treatment. All staff should understand their responsibilities and be provided with appropriate training, information and functional aids to assist them. Patient feedback should be collected to enhance the patient support procedures.

The centre's patient support procedures are compliant with HFEA guidance.

Patient feedback
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 six patients have provided feedback in the last 12 months, giving an average 4.5 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 is 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 centre's own most recent patient survey responses were therefore reviewed. The feedback for the first two months of 2021 provided 203 responses from patients. The centre's feedback was comparable to that provided to the HFEA. Patients

specifically made comment about feeling well supported during their treatments. 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.

During the onsite inspection, the inspectors spoke to two patients who also provided positive feedback on their experiences, stating they were very happy with the care they had received and would recommend the clinic to friends and family.

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

- treats patients with privacy and dignity;
- provides a clean and well organised environment for patient treatment;
- has staff who are supportive and professional;
- gives patients sufficient, accessible and up-to-date information to enable them to make informed decisions.
- treats patients with empathy and understanding.

Monitoring of the centre's performance

In addition to commenting on evidence gathered on the inspection it is important to report on the centre's performance since the granting of the licence based on other evidence available to us.

Compliance with HFEA standard licence conditions

Information submitted by the centre in their self-assessment questionnaire, the pre-inspection assessment, and observations during the visit to the centre, indicate that the centre is partially compliant with HFEA requirements because:

- In a photograph provided by the clinic pre-inspection, two oxygen cylinders in the procedure room were positioned in front of a radiator and not appropriately secured.
- On the emergency resuscitation trolley an ambu-bag (a handheld device used to provide positive pressure ventilation to patients that are not breathing), had a sticker on it stating it should not be used beyond January 2021. This was immediately replaced by the PR during the inspection.

(See recommendation 3).

Compliance with recommendations made at the time of the last inspection

Following the licence renewal inspection in 2019, recommendations for improvement were made in relation to one critical, five major and five 'other' areas of non compliance.

The PR subsequently provided information and evidence that all the recommendations were fully implemented within the required timescales however the recommendation relating the QMS has reoccurred.

On-going monitoring of centre success rates

Since the last licence renewal inspection in May 2019 the centre has not received any performance related risk tool alerts.

Provision of information to the HFEA

Clinics are required by law to provide information to the HFEA about all licensed fertility treatments they carry out. This information is held in the HFEA Register.

The clinic is compliant with requirements to submit information to the HFEA.

Legal parenthood

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 last inspection in May 2019, 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. Five 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 with the exception noted in the QMS section of this report.

Leadership

The centre is compliant with HFEA guidance regarding effective leadership.

Good leadership improves patient care and is encouraged by the HFEA. A PR should have the necessary authority and autonomy to carry out the role. The PR should ensure that staff understand their legal obligations, are competent, have access to appropriate training and development, and can contribute to discussions and decisions about patient care. The PR is legally accountable for the overall performance of the centre and should establish clear responsibilities, roles and systems of accountability to support good governance, including ensuring that appropriate action is taken following all forms of feedback from the HFEA or patients.

Annex 1

Areas of practice that require the attention of the Person Responsible

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

Critical areas 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 child who may be born as a result of treatment services. A critical 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			

‘Major’ areas 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 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;
- which can comprise 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. QMS There were several issues found in the QMS which are detailed in the main body of the report. SLC T12 and T36. CE (14)01.	The PR should ensure that the quality management system (QMS) is effective and fit for purpose. The PR should review the findings of all audits completed within the last audit cycle to ensure that findings have been graded appropriately. Where audit findings have been recorded as ‘observations’ (as opposed to	The review of audit findings will take place and the report will be provided to the HFEA by the deadline. Staff requiring audit training will be identified and training organised. The RCA's will be reviewed and a report provided. I confirm that Complete Fertility will be compliant with	The executive acknowledges the PR’s response and commitment to implementing this recommendation. Further action required.

	‘non-conformances’), the PR should ensure that appropriate corrective actions have been identified and implemented. This should include a full review of the witnessing ‘observation’ cited in this report. A report of this review should be provided to the centre’s inspector by 15 July 2021. The PR should ensure that all staff involved with the audit process are appropriately trained. Confirmation that this training has taken place should be provided by 15 October 2021. The PR should ensure that there are processes in place to ensure the accuracy of records when data is both entered and/or amended. The PR should ensure that effective analysis of incidents is conducted to limit the risk of similar incidents re-occurring.	the CE letter 14(01) regarding legal parenthood audit methodology.	

	The PR should review the RCAs of all incidents in the past 12 months and determine what further root causes (if any) there may be, so that effective corrective actions can be implemented. The PR should provide a summary report of this review including any corrective actions and timeframes for implementation to the centre's inspector by 15 July 2021. Three months after this review, the PR should audit the RCA of any incident that has occurred since the inspection, to ensure that any corrective actions taken have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 15 October 2021. The PR should review the scope of the legal parenthood audit methodology and ensure		

	compliance with the requirements of HFEA Chief Executive letter (CE(14)01). The PR should confirm that going forward the centre will be compliant with requirements of the CE letter when responding to this report.		
2.Equipment and Materials The following issue was noted: • 50ml flasks in use by the centre are not CE marked medical devices. This was a non compliance at the interim inspection in 2017. SLC T30.	The PR should ensure that only CE marked medical devices are used wherever possible. The PR should investigate why non compliant equipment continues to be used by the centre when appropriately CE marked alternatives are available and the PR has previously given an undertaking to use the alternative products. The PR should provide a summary report of this investigation to the centre's inspector when responding to this report.	An investigation will take place and the summary report provided. I confirm that as of 17 May 2021, where available, only appropriately CE marked products are in use in the lab.	The executive acknowledges the PR's response and commitment to implementing this recommendation. Await summary report due by 21 July 2021. Further action required.

	We would not recommend precipitous changes that might impact on the quality of treatment, but the PR should ensure that a plan is developed and implemented so that CE marked medical devices are used. It is expected that the appropriately CE marked products are in use by 21 July 2021 and the PR should provide confirmation by this date to the centre's inspector.		
3. Suitable premises: The following issues were noted: • In a photograph provided by the clinic pre-inspection, two oxygen cylinders in the procedure room were positioned in front of a radiator and not appropriately secured. • On the emergency resuscitation trolley an ambu-bag (a handheld device used to provide positive pressure ventilation to patients that are not breathing)	The PR should ensure that the premises are safe and suitable equipment is used. The PR should ensure that compressed gas cylinders are stored in accordance with cylinder storage regulations and that the appropriate storage containers are used at all times. The PR should review arrangements for the safe storage of compressed gas cylinders and provide a summary report of the review with corrective actions	A canniser holder for the smaller bottle has been ordered for the smaller cannister and should be delivered shortly. 2 cannister trollies for the larger bottles have now been delivered and are in place. All staff are aware that the gas should not be near any radiator. All staff are renewing their medical gas training. A report will be provided. The process will be audited 3 months later and will also be provided.	The executive acknowledges the PR's response and commitment to implementing this recommendation. The executive confirms that no further actions beyond submission of the audit of gas storage processes due by 15 October 2021 and summary review of emergency resuscitation equipment checking processes due by 31 July 2021.

had a sticker on it saying it should not be used beyond January 2021. This was immediately replaced by the PR during the inspection. SLC T17. DH Health Technical Memorandum 02-01: Medical gas pipeline systems; Operational management (2006).	implemented to the centre's inspector by 15 July 2021. Three months after this review the PR should audit processes for the storage of compressed gas cylinders to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 15 October 2021. The PR should review the processes for checking emergency resuscitation equipment. A summary report of this review and actions taken to address this non-compliance should be provided to the centre's inspector when responding to this report. Three months after this review the PR should review the processes for checking	The ambu bag has been added to RI witness, so that its expiry date will be an alert. The process for checking emergency equipment will b e reviewed and a report on this will be provided. Three months later the centre will audit this process and will provide a report by 15 October 2021 (I believe there is a typo in the column to the left as it says July 2021 for this.)	

	emergency resuscitation equipment to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this audit should be provided to the centre's inspector by 31 July 2021.		

'Other' areas of practice that require improvement

'Other' areas of practice that require improvement are any areas of practice in which failings occur, which cannot be classified as either a critical or major area of non-compliance, but which indicate 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
None		n/a	

Additional information from the Person Responsible
All requested actions will take place and reports will be provided to the HFEA.