Executive Licensing Panel Minutes

Centre 0015 (Sussex Downs Fertility Centre)

Interim Inspection Report and Variation to Change of Person Responsible (PR)

Date:	26 January 2021	
Venue:	HFEA Teleconference Meeting	
Attendees:	Clare Ettinghausen (Chair) Yvonne Akinmodun Kathleen Sarsfield-Watson	Director of Strategy and Corporate Affairs Head of Human Resources Communications Manager
Executive:	Bernice Ash	Secretary
Observers:	Catherine Burwood Sarah Stedman Karen Campbell	Licensing Manager Clinical Inspector (Induction) Inspector (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 noted that the Sussex Downs Fertility Centre is located in Eastbourne and has held a treatment and storage licence with the HFEA since 1992. The centre provides a full range of fertility services for NHS and private patients. Other licensed activities at the centre include storage of gametes and embryos. The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

1.2. The panel noted that, in 2019, the centre changed ownership, becoming part of the Hospital Fertility Group (HFG) and relocated to new premises.

1.3. The panel noted that, in the 12 months to 31 October 2020, the centre had provided 265 cycles of treatment (excluding partner intrauterine insemination treatments). In relation to activity levels this is a small sized centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom has impacted on treatment numbers.

1.4. The panel noted that, for IVF and ICSI, HFEA register data, for the period August 2019 to July 2020, show the centre's success rates are in line with the national averages.

1.5. The panel noted that, in 2019, the centre reported 14 cycles of partner insemination, with two pregnancies. This represents a clinical pregnancy rate which is comparable to the national average.

1.6. The panel noted that, HFEA register data, between August 2019 and July 2020, show the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 0%. This represents performance that is significantly less than the 10% multiple live birth rate target for this period.

1.7. The panel noted, following the centre's renewal inspection in November 2019, recommendations for improvement were made in relation to two critical, seven major and four 'other' areas of non-compliance. The Person Responsible (PR) has provided information and evidence that most the recommendations, made in the renewal report, have been fully implemented, within the required timescales, with the exception of compliance with CD management, supervision and use of regulations and practice guidelines; this has been delayed due to the Covid-19 pandemic. The PR has agreed to implement this outstanding recommendation.

1.8. The panel noted that, due to the number and complexity of non-compliances, observed at the interim inspection, the 5 March 2020 Licence Committee (LC) issued the centre a three year licence, instead of the standard four year licence.

1.9. The panel noted that a virtual inspection, due to the Covid-19 pandemic, was conducted on 4 November 2020. This inspection was conducted via a Desk Based Assessment and Risk Based Approach (DBA/RBA) combined with virtual technology. The executive determined that a virtual approach for this inspection was appropriate and was in keeping with the requirements of the HF&E Act 1990 (as amended). The centre was last inspected on 3 March 2020, when a variation to licensed premises inspection was conducted. Photographic evidence and documents had been supplied by the centre in support of this inspection and video conference calls with key staff have been conducted.

1.10. The panel noted that at the time of the virtual inspection, there was one major area of non-compliance concerning medicines management. There was also one 'other' non-compliance regarding the quality management system (QMS). Since the virtual inspection, the PR has

provided evidence that actions have been taken to implement the recommendations concerning medicines management and the QMS and, where required, the necessary root cause analysis and summary reports will be submitted within the timescales provided.

1.11. 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.

3. Variation of Change of Person Responsible

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 Sussex Downs Fertility Centre has been received by the HFEA on 19 November 2020 and it is requested to be considered by the Executive Licensing Panel (ELP).

3.3. The panel noted that the proposed PR, Ms Sarah Pallett, is Clinical Lead for The Hospital Fertility Group which includes Sussex Downs Fertility Centre as well as Chelsfield Park ACU (for which Sarah Pallett is the current PR). The proposed PR has academic qualifications in the field of nursing and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The proposed PR has successfully completed the HFEA PR Entry Programme ((T/1090/7).

3.4. The panel noted that, before joining The Hospital Fertility Group in November 2020, Ms Sarah Pallett had previously been a PR at other HFEA licensed centres.

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

3.6. The panel noted that the report from the virtual interim inspection, conducted on 4 November 2020, had also been considered at this meeting; two recommendations for improvement were made and the proposed PR has agreed to take responsibility for the outstanding issues.

3.7. The panel noted that all the information required under General Directions 0008 has been provided.

3.8. The panel noted that inspectorate's recommendation to vary the centre's licence to Ms Sarah Pallett as the PR.

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.

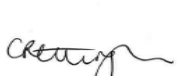
4.2. The panel endorsed the inspectorate's recommendation and agreed to vary the licence of Sussex Downs Fertility Centre (centre 0015) with immediate effect to reflect the change of

Person Responsible to Ms Sarah Pallett, in accordance with Section 18A of the HFE Act 1990 (as amended).

5. Chairs signature

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

Signature



Name

Clare Ettinghausen

Date

1 February 2021

Interim Licensing Report

Centre name: Sussex Downs Fertility Centre
Centre number: 0015
Date licence issued: 1 July 2020
Licence expiry date: 30 June 2023
Additional conditions applied to this licence: None
Date of the virtual inspection: 4 November 2020
Inspectors: Sandrine Oakes (lead), Louise Winstone
Date of Executive Licensing Panel: 26 January 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 and must, by law, be inspected every two years. 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 a short notice interim inspection together with our assessment of the centre's performance based on other information. We do this at the mid-point of the licence period. The current focus 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.

This inspection was conducted via a Desk Based Assessment and Risk Based Approach (DBA/RBA) combined with virtual technology. The executive determined that a virtual approach for this inspection was appropriate and was in keeping with the requirements of the HF&E Act 1990 (as amended). The centre was last inspected on 3 March 2020, when a

variation to licensed premises inspection was conducted. Photographic evidence and documents have been supplied by the centre in support of this inspection and video conference calls with key staff have been conducted using Microsoft Teams.

Summary for the Executive Licensing Panel

Summary for licensing decision

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

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 one major and one 'other' area of non-compliance or poor practice.

The Person Responsible (PR) has committed to fully implementing the following recommendations:

Major areas of non-compliance:

- The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements.

Other areas of non-compliance:

- The PR should ensure that audits have documented clear methodology and corrective and preventative actions (CAPA) including dates for implementation and closure.

Information about the centre

The Sussex Downs Fertility Centre is located in Eastbourne and has held a Treatment and Storage licence with the HFEA since 1992. The centre provides a full range of fertility services for NHS and private patients. Other licensed activities at the centre include storage of gametes and embryos.

In October 2019, the centre changed ownership and became part of the Hospital Fertility Group (HFG) and in April 2020, they relocated to new premises. The current licence was also varied in October 2020 to reflect a change of Licence Holder.

This ELP is also considering a change of PR application for this clinic. The proposed PR is aware of this inspection report and has agreed to take responsibility for these outstanding issues, should the application be successful.

The centre has a satellite arrangement with BMI Goring Hall Hospital, Sussex.

The centre provided 265 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 October 2020. In relation to activity levels, this is a small centre. The Covid-19 pandemic and suspension of fertility treatments across the United Kingdom will have had an impact on treatment numbers.

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 period August 2019 to July 2020 show the centre's success rates are in line with national averages.

In 2019, the centre reported 14 cycles of partner insemination with two pregnancies, which is in line with the national average.

Multiple births[2]

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

Between August 2019 to July 2020, the centre's multiple pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 0%. This represents a performance that is significantly less than the 10% multiple live birth rate target for this period.

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 course of the inspection, an embryo thaw was observed in the laboratory via a video camera. The procedure observed was witnessed using a manual witnessing system and in accordance with HFEA requirements.

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.

On inspection, the centre's report of the audit for all cryopreserved gametes and embryos, the accuracy of storage logs and consent records were reviewed and the 'bring-forward' system was discussed with staff. These activities indicate that the centre's processes for storing gametes and embryos in line with the consent of the gamete providers are effective.

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: due to the Covid-19 pandemic, patients are currently offered virtual consultations whenever possible and there were no patients at the clinic when this inspection was conducted; the atmosphere in the clinic appeared calm at all times; staff in the laboratory were able to carry out their activities without distraction and were available to carry out witnessing activities when required.

[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] Multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$.

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: legal parenthood; witnessing; consent to storage; medicines management and infection control.

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

- The methodology of the audits reviewed was not clear; and audits conducted by the centre that identified non-conformances did not all detail CAPA and/or have due dates and closure dates for the CAPA. Recommendation 2.

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
- implications of treatment and consent
- extension of storage consent
- consent
- the use of CE marked medical devices
- the content of the centre's website
- the centre's audit of legal parenthood

The centre has been effective in ensuring compliance with guidance issued by the HFEA.

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.

During the inspection, the clinic's processes for medicines management and the safe storage, disposal and administration of medicines were reviewed and were found to be partially compliant with guidance because:
In several entries in the controlled drugs (CD) register, the following was not recorded:

- The time of administration of the CD.
- There was no signature of the person supplying or administering the CD.
- The unit of drug given. This was a major non-compliance at the last inspection. Following the last inspection, the PR had planned to implement the use of an electronic CD register. However, the system did not meet the clinic's requirements.

The clinic has subsequently acquired a register suitable for the area in which it is to be used; and therefore, this non-compliance has not been escalated further. Recommendation 1.

At the time of the DBA pre-inspection, the centre's inspector highlighted to the PR that the centre did not appear to have a Controlled Drugs Accountable Officer (CDAO) registered with the Care Quality Commission (CQC) and/or an exemption in place. This was discussed further, and by the time of the virtual inspection, the centre had provided evidence that a CDAO had been registered with the CQC. Therefore, no further recommendation has been made in this report.

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.

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.

During the inspection, we reviewed infection control practices and found them to be 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'.

The CE mark status of medical devices used at the centre was assessed using the centre's own audit and following discussions with centre staff during the course of the inspection. We found the centre to be compliant with HFEA requirements to use CE marked medical devices wherever possible.

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. Thirty-five patients have provided feedback in the last 12 months, giving an average five-star rating to the clinic. This is a relatively low response, but it is noted that the centre was closed for several months due to relocation and the Covid-19 pandemic. The website also gives the ability for patients to comment on the cost of treatment. Most patients confirmed that they had paid what they expected to. Several patients provided individual comments to the HFEA complimenting the general professionalism and empathy at the clinic.

The centre's own most recent monthly patient survey responses were also reviewed. Out of a sample of 10 patients, the feedback was comparable to that provided to the HFEA. However, an analysis of these responses and/or actions taken by the centre to address negative comments was not completed. This was discussed further with the PR and the Quality Manager. They advised the inspectors that a more detailed analysis of patient survey responses would be conducted moving forward. The inspection team reminded the centre of the importance to continue to monitor patient feedback to ensure the actions taken are effective.

During the inspection, the inspectors did not speak to any patients.

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 fully compliant with HFEA requirements.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in November 2019, recommendations for improvement were made in relation to two critical, seven major and four 'other' areas of non-compliance.

The PR subsequently provided information and evidence that most of the recommendations were fully implemented within the required timescales.

The following recommendations have not yet been implemented. It is to be noted that some corrective actions were delayed due to the Covid-19 pandemic and the PR has been engaging in seeking the relevant extension with the centre's inspector:

- The PR should ensure compliance with CD management, supervision and use regulations and practice guidance.

On discussion at this inspection, the PR has agreed to implement the outstanding recommendation.

On-going monitoring of centre success rates

Since the last renewal inspection in November 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: there are currently no data submission issues at this clinic. This conclusion is based on a review of the clinic's register submissions conducted on 2 October 2020.

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. The centre did have some cases where anomalies in consent to legal parenthood were identified.

Following a renewal inspection in 2016, all affected patients were informed of the anomalies in writing and offered an appointment at the centre. Despite several attempts to contact them, two couples did not respond to communications from the centre. The PR assured the executive at that time that he was committed to providing necessary support to the patients concerned, and to act in accordance with HFEA guidance should any of the patients contact the centre team and wish to pursue a declaration of parenthood through the courts.

The centre's inspector and the Chief Inspector visited the centre in 2017 and were satisfied that the team had taken appropriate action with regards to the patients affected by anomalies in their consent to legal parenthood, and that the processes in place for ensuring effective consent were satisfactory.

At this inspection, the centre's own legal parenthood audit was reviewed and was found to have been performed according to the method specified by the HFEA. Actions had been taken in response to the audit findings.

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 audited by the centre staff with the inspector observing via the video link. 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.

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

This 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 partially compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR response	Executive review
1. Medicines Management In several entries in the CD register, the following was not recorded: • The time of administration of the CD. • There was no signature of the person supplying or administering the CD. • The unit of drug given. This was a major non-compliance at the last inspection. SLC T2 Misuse of Drugs Regulations	The PR should ensure that medicines management practices at the centre are compliant with regulatory and best practice requirements. The PR should review medicines management practices in relation to the non-compliances identified in this report, including a root cause analysis into the circumstances which led to the recurrence of one of the non-compliances identified at the last inspection; and provide a summary report	Online medicines management courses have been completed in December 2020 by all nursing and ODP staff. The new CD register has been implemented in November and is fully compliant with regulatory and best practice requirements. All of the signatories listed for traceability (anasthetic staff, nurses and ODPs). An audit will be completed in March 2021 to ensure compliance with the new	The executive acknowledges the PR’s response and commitment to implementing this recommendation. No further action beyond submission of a root cause analysis by 4 February 2021 and a summary report of the follow-up audit by 4 May 2021.

2001; regulation 19(a) and 20(b). DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'; section 4.11. NICE Guideline [NG46] (April 2016) 'Controlled drugs safe use and management'; section 1.7.4. Association of Anaesthetists 'Controlled drugs in peri-operative care' (2019)); recommendation 5.	of the review with corrective actions, including staff training requirements, implemented to the centre's inspector by 4 February 2021. Three months after this review the PR should audit medicines management practice to ensure that corrective actions implemented have been effective in achieving and maintaining compliance. A summary report of this review should be provided to the centre's inspector by 4 May 2021.	changes, although random checks confirm accuracy. The report will be sent to you in May as requested. A root cause analysis will be sent with updated information requested by the 4th of February 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
2. Quality management system The methodology of the audits reviewed was not clear and audits conducted by the centre that identified non-conformances did not detail CAPA and/or have due dates and closure dates for the CAPA. SLC T36.	The PR should ensure that audits have documented clear methodology and CAPA including dates for implementation and closure. The PR should review the findings of all audits that have been performed since the date of the last inspection and ensure that, where relevant, clear methodology, CAPA with dates for implementation and closure are documented. A summary of the review including details of any corrective actions, should be submitted to the centre’s inspector by 4 February 2021.	A new quality manager with lead auditor training was placed in post in September. New audits will follow clear methodology and CAPA. Repeat audits will be performed to ensure compliance. Audit plan will be provided by 4th of February.	The executive acknowledges the PR’s response and commitment to implementing this recommendation. No further action beyond the submission of a summary of the review by 4 February 2021.

Additional information from the Person Responsible