Licence Committee - minutes

Centre 0005 (Fertility Exeter) – Treatment and Storage Licence renewal application

Thursday, 12 January 2017

Church House Westminster, Dean's Yard, Westminster SW1P 3NZ

Committee members	Andy Greenfield (Chair) Kate Brian Anita Bharucha Lee Rayfield (teleconference) Ruth Wilde (teleconference)	
Members of the Executive	Siobhain Kelly Dee Knoyle	Interim Head of Governance Secretary
Legal Adviser	Eve Piffaretti	Blake Morgan LLP
Observers	Bernice Ash	Committee Secretary

Declarations of interest:

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

The committee had before it:

- 8th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members

The following papers were considered by the committee:

- executive update
- renewal inspection report
- application form
- licensing minutes from the last three years

1. Consideration of application

1.1. The committee noted that Fertility Exeter, centre 0005 has held a treatment and storage licence with the HFEA since 1992 and provides a full range of fertility services. The Executive is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

1.2. The committee noted that the centre provided 441 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 July 2016. In relation to activity levels this is a small centre. Other licensed activities of the centre include storage of gametes and embryos.

1.3. The committee noted that for IVF and ICSI, HFEA-held register data for the period July 2015 to June 2016 showed the centre's success rates were in line with national averages with one exception: success rates following IVF treatments involving fresh embryos in women under 38 years old were lower than average at a statistically significant level. The committee noted that data reviewed after inspection showed that these rates have been lower than the national average at a statistically significant level, consistently since 2011 with the exception of the period July 2012 to June 2013, which was at a 'below average alert' level. The centre was asked to review the pregnancy success rates for this group of patients at the last renewal inspection in 2013 and the interim inspection in 2014. To date there has been no statistically significant improvement in these success rates.

1.4. The committee noted that in 2015 the centre reported 226 cycles of partner insemination with 41 pregnancies. This represents a clinical pregnancy rate of 18%, which was in line with the national average.

1.5. The committee noted that between July 2015 and June 2016 the centre's multiple pregnancy rate for all IVF, ICSI and FET (frozen embryo transfer) cycles for all age groups was 14%. This represents performance that is not likely to be statistically different from the 10% maximum multiple live birth rate target for this period.

1.6. The committee noted that the centre's current licence is due to expire on 28 February 2017.

1.7. The committee noted that following the licence renewal inspection in 2013, recommendations for improvement were made in relation to nine major and ten other areas of non-compliance. As a result, the Executive Licensing Panel that considered the renewal application, granted a three-year licence and requested that a further targeted interim inspection, focussing on the quality management system and the validation of critical equipment, be performed within twelve months of the renewal of the licence.

1.8. The interim inspection took place in September 2014, immediately after the current Person Responsible (PR) came into post. Three major and one other area of non-compliance were identified at this inspection. The Executive Licensing Panel that considered this interim inspection report noted the PR's commitment to implementing the recommendations and agreed to the continuation of the centre's licence.

1.9. The committee noted that at the time of the centre's renewal inspection on 27 and 29 September 2016, the inspectorate found one critical, nine major and three other areas of non-compliance, five of which were identified at previous inspections at the centre. The committee noted that after the inspection there were concerns that the PR had only partially discharged her duty under section 17 of the HF&E Act 1990 (as amended). Following discussions and a meeting with the PR post inspection, the inspectorate is assured that the PR will fully discharge her duty and fully implement the recommendations within the agreed timescales. Since the inspection visit, the PR has fully implemented some of the recommendations, including the recommendation to address the critical area of non-compliance. The PR has committed to implementing the outstanding recommendations within the prescribed timescales.

1.10. The committee noted that significant improvement is required in order for the centre to reflect suitable practices.

1.11. The committee noted the PR's engagement with the Executive and the outcome of the management reviews.

1.12. The committee noted, with concern, the PR's reluctance to commission an expert review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years. The PR had requested more time to assess whether recently implemented measures to address the pregnancy success rates have had a positive impact on pregnancy outcomes. The Executive considered that further delay in implementing this recommendation could have a detrimental impact on patient outcomes.

1.13. The committee noted that the Executive gave consideration to the length of licence to be granted. Given the assurances received from the PR at the meeting post inspection and the actions taken to date to implement a number of the recommendations in this report, the Executive recommends the renewal of the centre's treatment and storage licence for a period of three years (rather than the standard four) without additional conditions.

1.14. The committee also noted that the Executive recommends that an interim inspection is conducted within 12 months of the renewal inspection, focussing on the quality management system, surgical pathway and pregnancy success rates.

2. Decision

2.1. The committee had regard to its decision tree. The committee was satisfied that the application made by the PR was submitted on the form required and contained the supporting information required by General Direction 0008. Furthermore, the committee was satisfied that the appropriate fees had been paid.

2.2. The committee was satisfied that the PR possesses the required qualifications and experience and that the inspectorate was satisfied that the PR had satisfactorily completed the PR entry programme. The committee also noted, with some concern, that the inspectorate had previously indicated that the PR had only partially discharged her duty under section 17 of the HF&E Act 1990 (as amended). However, the committee was satisfied that the PR has engaged with the HFEA and noted that the inspectorate is now assured that the PR will fully discharge her duty and fully implement the recommended improvement actions in areas of non-compliance within the specified timescales.

2.3. The committee noted the non-compliances, in particular, the non-compliance relating to legal parenthood, consisting of two cases identified by the 2014 legal parenthood consent audit where consenting anomalies were found. The committee noted that the inspectorate had discussed these cases with the PR during the inspection, with reference to recent judgements made by the President of the Family Division of the High Court, Sir James Munby. The inspectorate had discussed with the PR the HFEA's expectations with regards to the centre's duty to inform and support couples where legal parenthood anomalies exist. The committee acknowledged that the PR had taken legal advice on the matter, however, it was disappointed to learn that the PR does not intend to contact either couple. The HFEA expect the PR to very carefully consider her duty of candour obligations and reconsider her stance. It has been made clear that only the court can make declaration of legal parenthood, where there is any doubt. The committee has asked that the PR considers informing and supporting the couples concerned in any decisions taken to seek a declaration, or otherwise.

2.4. The committee had regard to the HFEA Guidance on Licensing. The committee noted that where there is a history that indicates a previous failure to implement recommendations for improvement in the time since the last licence renewal and, where there are concerns relating to the quality of service, a licence of up to three years is indicated; however, a shorter licence of one year may be considered. The committee considered the length of licence to be granted and also considered adding additional conditions to the licence. After much discussion, the committee agreed that it was proportionate to renew the centre's treatment and storage licence for a period of three years with no additional conditions on this occasion, due to the PR's

engagement and commitment to fully implementing the inspectorate's recommendations within the prescribed timescales.

2.5. The committee noted that the inspectorate will continue to monitor the centre's performance closely and failure to implement the recommended improvement actions relating to these major areas of non-compliance within the specified timescales may result in the submission of a further report to the Licence Committee with the recommendation that regulatory action be taken in accordance with the HFEA's compliance and enforcement policy. The committee requested regular updates on the centre's progress and would like to see evidence that the recommended improvement actions have been completed within the specified timescales. The committee would like to see the outcome of an external review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years and would also like to see an action plan.

2.6. The committee endorsed the inspectorate's recommendation to carry out an interim inspection within 12 months of the renewal inspection, focussing on the quality management system, surgical pathway and pregnancy success rates. The committee requested a report on the outcome of this inspection.

2.7. The committee had serious concerns about the culture of this centre and expects it to become more proactive in its compliance with the requirements of the HF&E Act 1990 (as amended), the HFEA Act 2008 and the HFEA Code of Practice, acting at all times in the best interest of its patients.

3. Chair's signature

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

Signature

Name

Andy Greenfield

Date

31 January 2017

Executive Update for Licence Committee
12 January 2017

Centre number	0005
Centre name	Fertility Exeter
Person Responsible	Lisa Joels

Update to renewal inspection report

Background

1. Centre 0005's renewal application is being considered by this Licence Committee on 12 January 2017.

2. The inspection took place on 27 and 28 September 2016 and the PR responded to the inspection report on 5 December 2016.The report of the renewal inspection of centre 0005 made a number of recommendations for improvement, three of which had elements that were due to be completed by 28 December 2016. This is a revised recommendation list based on the updates provided by the PR within that timeframe.

3. Annex 1 provides an update on the implementation of these recommendations.

Annex 1: Recommendations that required further action

Note: Only recommendations that were due to be implemented or required a further update by 28 December 2016 have been included in the list below. The original numbering for non-compliances from the inspection report has been retained.

Major area of non-compliance

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. Medicines management On inspection, the following issues were noted: • medication for the nebuliser on the emergency resuscitation trolley was partially opened and not labelled or stored in line with regulatory and practice guidance; • there are no stock control checks undertaken of non-controlled drugs; • disposal of controlled drugs is not done in line with regulatory and guidance or the centre's own SOP;	The PR should ensure compliance with medicines management regulations and best practice guidance. The PR should commission a review of the centre's medicines management practices by a qualified pharmacist. The review should include the management of and documentation for controlled drugs and procedures for the dispensing of medicines to patients for self-administration. This review should also encompass any training	The medication for the nebuliser on the emergency resuscitation trolley was reviewed immediately that this was raised at the inspection. The plastic ampoules each containing a single dose of nebuliser solution were not opened. The foil tray of the pack of five had been opened and resealed and it is recognised that the expiry date couldn't be seen from the outside of the packet but the expiry date was clearly labelled on each ampoule and were in date. The packet was replaced with immediate effect so that now the expiry date is	The Executive acknowledges the PRs response and actions taken to comply with this recommendation. The PR should provide a copy of the pharmacy review by 28 December 2016 and of the subsequent audit by 28 April 2017. Further action required. **Update 4 January 2017:** Pharmacy review received from PR to the satisfaction of the Executive. No further action beyond submission of audit due 28 April 2017.

• medicines are not dispensed in line with practice guidance and pharmaceutical standards. The drugs are not checked by two people; the dispensing labels do not contain information regarding the dispenser or checker. Misuse of Drugs Regulations (2001) regulation 27. NMC (2010) Standards for medicines management, standard 4. DH (2007) 'Safer Management of Controlled Drugs; A guide to good practice in secondary care (England)'.	and competency requirements identified. The PR should provide a copy of the review and a plan of action in response to the review findings by 28 December 2016. Three months after the implementation of corrective actions, the PR should perform an audit to ensure that these corrective actions have been effective. A summary report of this audit should be provided to the centre's inspector by 28 April 2017.	now clearly visible on the outside of the packet as well. The Chief Pharmacist has undertaken a review of the Medicines Management processes within the unit and a number of actions have been agreed as detailed below. There is an agreed stock list of drugs which is annually updated by the pharmacy department and the Matron. There are weekly stock orders placed with pharmacy against the agreed stock list with the nursing staff checking stock levels and ordering more drugs if necessary. Training will be provided by the pharmacy department regarding expiry date checking, stock rotation and avoiding over-stocking. Going forward there will be three monthly stock checks by a member of the	

		pharmacy team to support the nursing staff in this. The PR was very concerned to hear from the inspectors that CDs were not being disposed of in accordance with the RD&E Trust's medicines management policy and addressed the matter immediately. The necessity to comply with Trust policy has been made clear to all staff concerned. The Chief Pharmacist has advised the PR that where drugs are packaged and labelled within an MRHA licensed unit and issued to a clinical area, at the point of issuing the drug to the patient this is administration of the drug, not dispensing, and in accordance with regulation and Trust policy does not require the signature of two practitioners. The Trust Medicines Management	

		Policy states that this only requires a single person to check. For items that are currently unlabelled, essentially the cold chain items, it has been agreed that pharmacy will now provide labelled packs through its licensed unit or dispensary. A copy of the Chief Pharmacists report and associated actions will be shared with the inspection team. The PR will undertake an audit of compliance against these changes in three months and this will be provided to the centre's inspector.	
5. Quality management system: The centre's quality management system is not suitably effective because: • the robustness of the audit programme was considered inadequate to satisfy regulatory requirements, since a	The PR should review the quality management system to ensure it is effective and provides assurance of compliance of the range of activities carried out in the course of providing treatment services, against regulatory requirements, the centre's	The PR does not agree with the assertion that the audit programme is not fit for purpose as it did not identify issues subsequently identified by the inspection team. It is the understanding of the PR that the reason that both audits and inspections are	Since the inspection the PR has updated the welfare of the child SOP to indicate the actions to be taken in the event of a concern. The Executive acknowledges the PRs response and general commitment to implement

number of audits performed by the centre did not identify issues subsequently identified by the inspection team; • donor recruitment has not been audited within the last two years; the scope of some audits was limited because: • the counselling audit does not audit the quality of service provision; • the confidentiality audit did not identify the issues noted at this inspection; • the corrective and preventative actions noted in the audit of the satellite centre were not measured, timely or specific to assure ongoing compliance. the QMS does not contain the following SOPs; • withdrawal of consent; • legal parenthood; • confidentiality and privacy; • recall of gametes and embryos;	SOPs and quality indicators. The PR should provide a summary report of the review and an action plan for the timescales for implementation of corrective actions, to the centre's inspector by 28 December 2016. The PR should address the non-compliances within the QMS identified in this report. It is anticipated that this will be completed by 28 March 2017. The centre's inspector will then request a sample of documents to review including, audits, SOPs, quality indicators to ensure they are compliant with regulatory requirements. A number of non-compliances described in this inspection report have also been noted at	repeated regularly is that each is a snapshot in time and being 100% compliant on one occasion does not obviate the need to repeat an audit which might ten find less than 100% compliance. Donor recruitment and the quality of counselling will be audited within the next three months and these will be shared with the inspection team. It is important to note that the confidentiality audit reviewed during the inspection was a re-audit against a specific issue raised at the previous inspection. Corrective measures were put in place and the purpose of the re-audit was to demonstrate that the reception area was now secure. The re-audit was therefore focussed on this specific issue. It is recognised that the scope	this recommendation. However, the Executive is concerned that the PR has not given firm assurance that a full review of the QMS will take place and only refers to specific issues identified in this report. There is concern that in doing so, the QMS may not be robust enough to meet regulatory requirements and as such, non-compliances may continue to occur. The PR will be reminded of this part of the recommendation and an extension will be given for the review to be completed by 28 January 2017. Further action required. **Update 4 January 2017:** A summary report of the QMS has been provided. Further action remains as regards the original recommendation and this is due by 28 March 2017.

• the welfare of the child SOP was insufficient in detail as it did not indicate the actions to be taken in the event of a concern; • the SOP for data submission was out of date; • quality indicators have not been established for all licenced activities for example, counselling and withdrawal of consent; • the quality indicators for some audits are limited in scope; o counselling o confidentiality and privacy Non-compliances in the QMS have been cited in both the renewal inspection in 2013 and the additional targeted inspection in 2014. CoP mandatory requirements 15c; SLC T32, T33b, T34, T35, T36.	previous inspections at this centre. This raises concerns that the centre's QMS is not being used to best effect to ensure that services are provided in accordance with the conditions of this licence. The PR should investigate why this non-compliance has not been appropriately addressed previously, despite assurances to the Executive, for the past three years. The PR should ensure that changes made to centre practices to resolve non-compliances are maintained by using the centre's QMS effectively.	of future audits should ensure that all aspects of privacy and dignity associated with the reception area should be covered. The results of the satellite audit have been sent to the satellite unit were discussed the annual meeting on 23rd November 2016. The satellite team have agreed to address the issues raised and a re-audit will be carried out in three months. The PR has updated welfare of the child guideline to include instructions on the action to take if concerns about the welfare of the child were raised. The changes to the guideline were ratified in the fertility governance meeting on 11th October 2016. The PR recognises that there wasn't an SOP addressing legal	

		parenthood. The SOP has now been written and will be ratified at fertility governance on 13th December 2016 to correct this omission The PR has drafted a confidentiality and privacy SOP which will be ratified at the fertility governance meeting on 13th December 2016. The PR would however draw to the attention of the inspectors that the existing RD&E trust SOPs do cover all aspects of confidentiality and privacy: • Privacy, dignity and compassion policy • Information governance policy • Patient identification policy It is expected that these policies are followed by all staff within the Trust. The PR notes the statement in the inspection report that	

		processes for recall of gametes were compliant. A review of the SOP for transportation shows that the steps for recall of gametes are contained in this SOP. The PR accepts this could be clearer and the SOP has been revised to highlight this aspect of the SOP. The PR accepts that the SOP for consenting lacks detailed guidance about withdrawal of consent and the SOP will be revised. The PR will ensure that quality indicators are in place for counselling and withdrawal of consent.	
7. Equipment & materials (validation and monitoring): On inspection the following issues were noted: • the suction pump and Gilson pipettes had not been validated;	The PR should review procedures for monitoring and validating critical equipment. The PR should provide evidence of validation of the equipment identified in	The PR confirmed that the suction pump had been validated by a third party and those reports had been shown to the inspector during the inspection however it is accepted that an operational quality report	The Executive acknowledges the PR's response and commitment to implement this recommendation. Full evidence of validation of the suction pump was not available at the inspection

• alerts have not been established for 'out of range' parameters on the incubators. Validation of critical equipment was cited as a non-compliance at the last renewal inspection in 2013. SLC T24.	this report to the centre's inspector by 28 December 2016. The PR should ensure that alerts are established for all critical equipment and confirm that has been done by 28 December 2016.	was not in place for the suction pump at the time of the inspection. This omission has been corrected. The PR accepts that the method to validate the Gilson pipettes internally was incorrect. As a result, a decision has been made to source a third party to provide calibration and service for the pipettes and this is currently underway with the procurement team. The PR will confirm this has taken place by 28th December 2016. The PR confirms that "out of range" parameters for the incubators are identified and detailed in the validation documents. The PR has modified checklists to include the alerts and instructions about the action to take if readings are out of range. The PR took Chairman's action on 30th	and the PR is reminded to submit this by 28 December 2016. Further action required. **Update 4 January 2017:** Evidence of validation of suction pumps and Gilson pipettes has been provided. Alerts have been established for all critical equipment. No further action is required.

		November 2016 and the revised checklists were implemented on that date and will be ratified at fertility governance on 13th December 2016.	
9. Legal parenthood: The centre's 2014 audit of legal parenthood consent identified two instances where there were anomalies on the consent forms. No action was considered necessary at the time with regard to informing the couples of these anomalies or to seek legal advice regarding them.	The PR should seek legal advice regarding the two cases identified by the 2014 legal parenthood consent audit where consenting anomalies were found, and consider what actions should be taken in light of this advice. Whilst it is recognised that the current PR was not in post at the time and the centre was under different ownership, the PR is reminded that, especially in the light of learning from recent legal judgements, the centre has an obligation to observe a duty of candour by informing the	The PR has contacted the Trust Solicitor and a meeting is scheduled for 13th December. The advice will be considered and appropriate action taken. With regards to the requirement to contact the couples, this will be carried out and advice and support provided if appropriate following the legal advice received.	The Executive acknowledges the PR's commitment and actions taken. Further action required. **Update 4 January 2017:** The PR has taken legal advice that states (in summary): Case 1: '…the couple's intention in respect of legal parenthood can be clearly construed and there is no reason to require any additional signed undertaking and therefore no cause to contact the couple' and.

	couples of these anomalies and to facilitate guidance and support during this process. The PR should provide the centre's inspector with a summary of the advice received and a plan of action to support the couples affected, in the light of that advice. This should be provided no later than 28 December 2016.		Case 2: 'is a clear case where the intention of both man and woman can be clearly 'constructed' from the available documentation, without the need for 'rectification'. As in Case 1 there is no need to inform the couple of the error on the PP form.' The PR has confirmed that in light of this legal advice, she does not intend to contact either couple. The executive is currently corresponding with the PR to reconsider this stance. The Court has made it clear that only *it* can make a declaration of parenthood, where there is any doubt, on application. We expect the PR to very carefully consider her duty of candour obligations and to involve the affected patients in any decisions taken to seek a declaration, or otherwise.

			This matter is ongoing, further action required.
10. Pregnancy success rates: The centre's success rates for IVF treatments involving fresh embryos in women under 38 years old are lower than the national average at a statistically significant level. In 2013 and 2014 the centre was asked to review procedures for the provision of these treatments. Despite assurances of measures taken to rectify the issues the centre has continued to receive risk tool alerts since 2013 and has received four risk tool alerts since February 2015. Data reviewed post inspection shows these success rates have been lower than the national average at a statistically significant level, consecutively, since 2011	The PR should seek to improve the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years old. The PR should commission an independent expert review of all clinical and laboratory practices and procedures that can have an impact on the pregnancy success rates for IVF treatments involving fresh embryos in women under 38 years. The review should include an action plan for addressing the success rates, a schedule for implementation and review of any corrective actions identified. A summary of the review and action plan for the implementation of any	The PR shares the concerns of the inspectors about persistently low pregnancy rates in fresh IVF treatment for women <38 years. The PR has conducted a series of reviews of practice and audits. Factors that were noted to be contributing to the low pregnancy rate included a high cancelled cycle rate and this has been addressed reducing the rate by approximately 10%. There remains a high failed fertilisation rate which is largely related to women with <5 eggs collected. The centre has never previously denied treatment to women on the basis of low egg reserve. Improved decision making tools have also reduced the number of cycles abandoned due to concerns about the risk of OHSS leading to a very low rate of OHSS. No cases of	The Executive acknowledges the PR's response to this recommendation and understands the request to allow another six months before an external review is commissioned. However, this issue has been ongoing for a number of years and the Executive remains very concerned that the pregnancy rates for this group of patients remains below the national average. After careful consideration of the PR's request, the Executive remains of the view that it is proportionate to require assurance that an independent expert review will be commissioned without delay. Further action required.

with the exception of the period July 2012 to June 2013. The inspection team remains concerned that the centre has continued to receive risk alerts for this group of patients with no improvement in success rates.	recommendations to address the success rates should be provided to the centre's inspector by 28 January 2017.	severe or critical OHSS have occurred in 2016. The majority of treatments are NHS funded and therefore subject to strict rules about elective single embryo transfer. The rules changed in April 2015 and have had an impact on pregnancy rates as the majority of treatment result in cleavage stage embryo transfer. During the first half of 2016 there was also an unexpectedly high miscarriage rate, well above 33% which was unexplained. Since Sept 2016, the centre has been using a tri-gas Geri incubator and has noticed a significant increase in clinical pregnancy rates to 34.5% per embryo transfer, implantation rate 22.9% compared with the month of August where the pregnancy rate was 16.7%,	**Update 4 January 2017:** The PR has noted the need to commission an external review of pregnancy rates. Further action required.

		implantation rate 11.6%. Of the 10 blastocyst transfers (eSET) there are 5 pregnancies. Accepting that this is still very early, to date there have been 2/12 miscarriages (16.7%) observed in the small group of patients who have been able to benefit from the Geri incubator during the trial period, a havling of the miscarriage rate. There has also been a rise in patients having single blastocyst transfer rather than cleavage stage transfer. The PR believes that while improving decision making and patient preparation has been important, ultimately the lower pregnancy rates resulted from increased number of eSET cycles where embryos were cultured in conventional incubators and that the best way to improve pregnancy rates is to invest in new technology and increase	

		blastocyst eSET. This proposal has the support of the senior management team of the RD&E and equipment will be updated as soon as is practicle. The PR understands the recommendation to commission an external review but would suggest that this be deferred for a six month period to establish whether the introduction of tri-gas incubators resolves the concerns about pregnancy rates. The PR proposes that she report the pregnancy rates to the centre's inspector in April 2017 after 6 months of use of tri-gas incubation in order to reconsider this recommendation.	

Other areas of practice that requires improvement

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
11. Obligations and reporting requirements: 7% (8/108) of the IVF and 57% (21/37) of the DI treatments reviewed had been reported to the HFEA outside the period required by General Direction 0005. Data submission was cited as a non-compliance at the 2013 renewal inspection and the previous 2012 inspection.	The PR should ensure that data provided to the Authority about activities and data which the Authority are required to hold on its Register of Information, is provided by the dates specified in Directions. The PR should review the processes for data submission and reporting to the HFEA and ensure they are compliant with statutory and regulatory requirements. The PR should provide a summary report of this review including corrective and preventative actions to the centre's inspector by 28 March 2017.		There has been a number of discussions with the PR regarding data submission requirements which have only recently been resolved. The centre is compliant with all reporting requirements with this one exception. The PR has not had the opportunity to respond to this non-compliance, which for various reasons has had to be included in the report at a much later date. It is not considered a significant risk and will be followed up with the PR. Further action required. **Update 4 January 2017:** The PR has confirmed that she has initiated a review of the centre's processes for data submission and reporting.

			A copy of the report to be provided by 28 March 2017.