HFEA Executive Licensing Panel Meeting

11 July 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 2

Centre 0157 – (Assisted Reproduction and Gynaecology Centre) – Interim Inspection Report

Members of the Panel: Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair) Hannah Verdin – Interim Head of Policy & Communications Joanne Anton – Policy Manager	Committee Secretary: Dee Knoyle Observing: Sam Hartley – Head of Governance and Licensing

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:

- HFEA Protocol for the Conduct of Meetings of Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Decision trees for granting and renewing licences and considering requests to vary a licence (including the PGD decision tree)
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009.
- Guidance on periods for which new or renewed licences should be granted
- Standing Orders and Instrument of Delegation
- Indicative Sanctions Guidance
- HFEA Direction 0008 (where relevant), and any other relevant Directions issued by the Authority
- Guide to Licensing
- Compliance and Enforcement Policy
- Policy on Publication of Authority and Committee Papers

Consideration

1. The Panel noted that the Assisted Reproduction and Gynaecology Centre (ARGC) is located in London and has held a licence with the HFEA since 1995. The centre provides a full range of fertility services including embryo testing.

2. The Panel noted that the centre's licence is due to expire on 30 June 2016.

3. The Panel noted that the inspection took place on 11 March 2014.

4. The Panel noted that in the 12 months to 28 February 2014, the centre provided 856 cycles of treatment (excluding partner intrauterine insemination) In relation to activity levels this is a medium-sized centre.

5. The Panel noted that HFEA-held register data for the year ending November 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

    - clinical pregnancy rates following IVF in patients aged 16-37 years are above average at a statistically significant level;
    - clinical pregnancy rates following ICSI in patients aged 16-37 years are above average at a statistically significant level;
    - clinical pregnancy rates following ICSI in patients aged more than 38 years are above average at a statistically significant level.

6. The Panel noted that for the year 2012, the centre reported no cycles of partner insemination.

7. Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 30%: this represented performance that was statistically higher than the 20% maximum multiple live birth rate target for this period.

8. Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 30%: this represented performance that was statistically higher than 15% maximum multiple live birth rate target for this period.

9. Between 1 October 2012 and 30 September 2013, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 29%: this represented performance that was likely to be statistically higher than the 10% maximum multiple live birth rate target for this period.

10. The Panel noted that at the time of inspection one critical and four major areas of non-compliance were identified. The Panel noted with concern the recurrent nature of some of the non-compliances and that four of the timescales for action have already passed without the centre taking action.

11. The Panel was particularly concerned about the critical non-compliance relating to multiple births. A multiple pregnancy is the single biggest risk of fertility treatment. The Panel agreed that the non-compliances relating to multiple births require action from the Person Responsible (PR) to mitigate future potential risks. The Panel noted that the Inspectorate plans to engage with the PR to determine how the centre's multiple births minimisation strategy should be reviewed to ensure that the centre does not exceed the current maximum multiple birth rate of 10%. The Panel agreed that if satisfactory progress is not made in reviewing the strategy and reducing the centre's multiple pregnancy rate by 11 September 2014, then the Inspectorate should consider whether it is appropriate to take further regulatory action, in line with the Compliance and Enforcement Policy.

12. The Panel also noted the non-compliance in relation to donor registration which could have a serious impact on the ability of the HFEA to meet its statutory duty to provide children born as a result of treatment with donor gametes with information about their donor.

13. The Panel noted the non-compliance in relation to storage of embryos and the statutory requirement for effective consent. The Panel noted that although this non-compliance has been cited in previous inspection reports, the centre has made some progress in addressing concerns about storage of cryopreserved material beyond the consented storage period.

14. The Panel noted the non-compliance in relation to witnessing and that the Inspectorate was satisfied that appropriate witnessing is being conducted and that this non-compliance represents a failure of documentation rather than practice and is therefore not considered likely to pose an immediate risk to patients, gametes and/or embryos.

15. The Panel noted the non-compliance in relation to consent to disclosure of information to researchers and that this non-compliance is not considered to pose a risk to patient, gamete or embryo safety but indicates a failure to meet requirements set out in General Directions.

16. The Panel was deeply concerned about the lack of response from the PR on the draft inspection report, particularly given the number of times the Inspectorate attempted to make contact by sending three emails and making five telephone calls. The Panel also agreed that the absence of a response demonstrates a lack of engagement with the HFEA and the findings of this inspection.

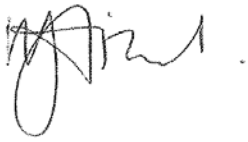
17. The Panel noted that the HFEA's Indicative Sanctions Guidance lists failures identified in this inspection as factors which Licence Committees may consider to be aggravating features of any matters of non-compliance reported to it. The Panel agreed that if satisfactory progress is not made within the prescribed timescales, the Inspectorate should decide whether it is necessary to recommend further regulatory action to a licensing committee.

18. The Panel noted that the Inspectorate considers that it is proportionate to recommend the continuation of the centre's licence, and commits to engage fully with the PR in achieving implementation of these recommendations within the timeframes set. The Panel strongly urges the PR to engage with the Inspectorate and fully implement the recommendations in the report.

Decision

19. The Panel had regard to its decision tree and was satisfied that at present no enforcement action was necessary and, notwithstanding its concerns over the centre's non-compliances and lack of engagement with the Inspectorate in relation to these, it was proportionate for the centre to have its Treatment (including embryo testing) and Storage licence continued.

20. The Panel approved the Inspectorate's recommendation to continue the centre's licence with no additional conditions.



Signed: Date: 21 July 2014
Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: Assisted Reproduction and Gynaecology Centre
Centre number: 0157
Date licence issued: 01/04/2013
Licence expiry date: 30/06/2016
Additional conditions applied to this licence: None
Date of inspection: 11/03/2014
Inspectors: Dr Victoria Lamb (Lead), Mrs Susan Jolliffe
Date of Executive Licensing Panel: 11/07/2014

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 an unannounced 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. For 2012-14 the focus of an interim inspection is:

- **Quality of service**: the quality of service provided by a centre, including its success rates and performance in reducing multiple births – the biggest single risk of IVF.
- **Patient experience**: it is considered crucial that the experiences of service users feed into any evaluation of a centre's performance.

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 with information on which to make a decision about the continuation of the licence.

Summary for the Executive Licensing Panel

The Executive Licensing Panel is asked to note that at the time of the inspection there were recommendations for improvement in relation to one 'critical' area of non-compliance and four 'major' areas of non-compliance as follows:

'Critical' area of non-compliance:

- **The centre's multiple births minimisation strategy should be reviewed to ensure that the centre does not exceed a maximum multiple birth rate of 10%.**

'Major' areas of non-compliance:

- The PR should provide the HFEA with an update on the number of patients for whom embryos remain in store without effective consent. Where embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre's intended actions and the anticipated timescale for their implementation.

- The PR should ensure that witnessing is always fully documented to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process.

- The PR should submit missing consent to disclosure information and take action to correct the submissions that have been identified as being incorrect. The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA.

- The PR must ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005

The PR has not provided a response to these recommendations; the Executive has communicated via email (on three occasions) and telephone (on five occasions) in an attempt to elicit a response. The Executive is not reassured that the recommendations will be implemented, especially considering the recurrent nature of some of the findings. Four of the timescales for action have already passed. The absence of a response also demonstrates a lack of engagement with the HFEA and the findings of this inspection. As a consequence, management review meetings were held on 21 May 2014 and 6 June 2014 in accordance with the HFEA's compliance and enforcement policy and it was concluded that although the non-compliances do not pose an immediate risk to patients, gametes or embryos, the non-compliances relating to multiple births and donor registration do require action from the PR to mitigate future potential risks.

In consideration of this, the Executive considers that it is proportionate to recommend the continuation of the licence, and commits to engage fully with the PR in achieving implementation of these recommendations within the timeframes set. In the event that

these recommendations have not been implemented by the time of the licence renewal inspection it may be concluded that the PR has not discharged his duty as required by Section 17(1) c, d and e. It is also noted that the HFEA's indicative sanctions guidance lists failures identified in this inspection as factors which Licence Committees may consider to be aggravating features of any matters of non-compliance reported to it.

Information about the centre

The Assisted Reproduction and Gynaecology Centre (ARGC) is located in London and has held a licence with the HFEA since August 1995.

The centre provides a full range of fertility services.

The centre provided 856 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 28/02/2014. In relation to activity levels this is a medium centre.

Details of Inspection findings

Quality of Service

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

Outcomes[1]

HFEA held register data for the year ending November 2013 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages with the following exceptions:

- clinical pregnancy rates following IVF in patients aged 16-37 years are above average at a statistically significant level;
- clinical pregnancy rates following ICSI in patients aged 16-37 years are above average at a statistically significant level;
- clinical pregnancy rates following ICSI in patients aged more than 38 years are above average at a statistically significant level.

For the year 2012 the centre reported no cycles of partner insemination.

Multiple births[2]

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

Between 1 April 2010 and 31 March 2011, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 30%: this represented performance that was statistically higher than the 20% multiple live birth rate target for this period.

Between 1 April 2011 and 30 September 2012, the centre's multiple live birth rate for all IVF, ICSI and FET cycles for all age groups was 30%: this represented performance that was statistically higher than 15% multiple live birth rate target for this period.

[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.
[2] The HFEA use a conversion factor of 1.27 to convert the multiple live birth rate (MLBR) target to a multiple clinical pregnancy rate (MCPR) target. The 2012/13 MLBR target of 10% is calculated as equivalent to a 13% MCPR.

Between 1 October 2012 and 30 September 2013, the centre's multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 29%: this represented performance that was likely to be statistically higher than the 10% multiple live birth rate target for this period (Recommendation 1).

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur. The following laboratory activities were observed in the course of the inspection: sperm preparation; embryo transfer; dish disposal. All of the procedures observed were witnessed in accordance with HFEA requirements using a manual system. The inspection team was able to review five records that were present in the laboratory and concluded that records of manual witnessing are maintained, with the exceptions noted below.

For the witnessing of receipt of sperm in the laboratory, while there was evidence that appropriate witnessing had occurred, in two cases this was not fully documented. In both cases the operator had signed appropriately, however the field for the witness to sign only recorded the witness's initials and no signature. For the witnessing of the transfer of samples between containers, in one case the signature of the witness was absent. For confirming the identity of the sperm provider, in one case although the witnessing signature was recorded, the date and time of the witnessing step was not (Recommendation 3).

Consent: Disclosure to researchers

A patient providing informed consent is one of the most important principles in healthcare. Since 1 October 2009, the HFEA has been able to release patient-identifying information held by the HFEA to researchers if patients give their permission. Patients are asked to give their consent to the disclosure of this information and this is recorded in their records and the HFEA is notified of their decision through the electronic data interface (EDI) system. It is important that the reporting through EDI is accurate so that patient information is not disclosed without consent.

The records of consent to disclosure to researchers given by 19 patients were reviewed in the course of the inspection. The consents were completed and reported to the HFEA accurately in only four of the records reviewed.

In four cases the documented consent decision indicated that consent to disclosure had been given by the patient, but the HFEA register indicated that consent had not been given.

In eleven cases the patient had not been registered with the HFEA, by the centre. Therefore there was no record of their consent decision held by the HFEA (Recommendation 4).

Consent: To the storage of cryopreserved material

The centre has a system in place to manage stored material at the end of the consented period. Centre staff reported that embryos currently in store are being stored within their consented storage period for all except 10 patients.

In six of these cases the centre is in contact with the patients and is waiting for the patients to return consent forms. Although patients are contacted in advance of their consent to

storage expiring, in these cases the centre experienced delays in being able to obtain a response from the couples within the planned timescale.

In the remaining four cases centre staff are awaiting final confirmation from the PR that the samples can be removed from storage (Recommendation 2).

Whilst 10 samples are being stored outside the consented storage period, the inspection team recognise that considerable improvements have been made in this area since the last inspection.

Staffing

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

Staffing levels observed in the course of the on-site inspection appeared to be suitable for the activities being carried out: 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.

Patient experience

During the inspection visit we spoke to one patient who provided feedback on her experience and observed interactions between centre staff and patients. A further 27 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was varied with sixteen of these individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received. Seven patients were unhappy with the service received, citing waiting times, busy clinics and expense as the cause of their dissatisfaction.

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

- has respect for the privacy and confidentiality of patients in the clinic;
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

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

From the information submitted by the centre in their self assessment questionnaire and from observations during the visit to the centre, the inspection team identified no additional non-compliances.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in 2012 recommendations for improvement were made in relation to four areas of major non-compliance:

- The centre has embryos in storage beyond the consented storage period;
- The centre has not met the Authority's multiple birth rate target for 2009-10 and 2010-11;
- The PR has not ensured that data provided to the Authority about activities, which the Authority is required to hold on its Register of Information, is accurate and provided by dates specified in Directions or in writing;
- In eight out of 13 cases the consent to disclosure to researchers in the patient records did not match the information held by HFEA.

The Panel which considered the renewal inspection report requested that the Inspectorate revisit in six months from the date of the panel meeting (18 May 2012) if key evidence of progress was not submitted. The Panel also agreed that if progress was not made available to the Inspectorate in relation to any of the recommendations then the Inspectorate should consider further regulatory action.

However, the PR challenged the decision to apply SLC T123 to his licence, (the centre must not exceed the maximum multiple birth rate specified by Directions), and while the judicial review was ongoing the usual regulatory follow up action was not taken. As judgement was received on the judicial review in late 2013, the issues from the renewal inspection were followed up during this inspection. Some evidence of progress with those issues was seen during the inspection but the recommendations from the renewal inspection report were found not to have been fully resolved and further recommendations are made in this report.

On-going monitoring of centre success rates

The centre has received three HFEA risk tool alerts in the last six months regarding multiple birth rates. These alerts indicate that multiple births were likely to be statistically higher than the 10% multiple live birth rate target for this period (Recommendation 1)

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.
The centre has had three risk tool alerts in the last six months for 'treatments with unregistered donors' and/or 'donor treatments with missing outcomes'.

At the time of the inspection the centre was partially compliant with data submission requirements, with issues of concern identified as follows (Recommendation 5):

- There were 15 treatments involving the use of donor gametes where the donor does not appear to be registered with the HFEA;
- There were 60 missing early outcome form submissions;
- There were significant delays in submitting outcome forms. The average time for submission was 280 days, whereas General Directions 0005 state they should be submitted within eight weeks (56 days) of the predicted outcome date.

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 carried out.

‘Critical’ area of non compliance

A ‘critical’ area of non compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or child who may be born as a result of treatment services. A ‘critical’ area of non-compliance requires immediate action to be taken by the Person Responsible.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
1. Between 1 October 2012 and 30 September 2013, the centre’s multiple clinical pregnancy rates for all IVF, ICSI and FET cycles for all age groups was 29%: this represented performance that was likely to be statistically higher than the 10% multiple live birth rate target for this period. General Directions 0003	Although the PR confirmed that he is following professional body guidelines when advising women on how many embryos should be transferred, as both success rates and multiple pregnancy and birth rates at this centre are high, then these guidelines are not proving sufficient to ensure the centre does not exceed the HFEA multiple birth rate target.		The PR has not responded to the inspection report to date. As documented in this report, the single biggest risk of fertility treatment is a multiple pregnancy. Although this non-compliance has been cited in previous inspection reports it is acknowledged that as a result of the PR’s challenge to the

and SLC T2 This was identified as an area for improvement at the time of the last inspection.	The Executive will engage with the PR to determine how the centre's multiple births minimisation strategy should be reviewed to ensure that the centre does not exceed a maximum multiple birth rate of 10%. If satisfactory progress is not made in reviewing the strategy and reducing the centre's multiple pregnancy rate by 11 September 2014 then the inspector will consider whether it is appropriate to take further regulatory action.		imposition of SLC 123 and its subsequent removal from all licences that the centre's implementation of recommendations relating to this non-compliance has not been subject to the usual follow up. In consideration of this it is considered proportionate to provide the PR with a further opportunity to make progress in meeting the 10% multiple birth rate target before further regulatory action is considered.

‘Major’ area of non compliance

A ‘major’ area of non compliance is a non critical area of non compliance:

- which poses an indirect risk to the safety of a patient, donor, embryo or child who may be born as a result of treatment services
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several ‘other’ areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
2. On the day of the inspection the centre did not have written effective consent for the storage of cryopreserved embryos for 10 patients HF&E Act (1990) as amended, Schedule 3, 8(2) This was identified as an area for improvement at the time of the last inspection.	The PR should provide the HFEA with an update on the number of patients for whom embryos remain in store without effective consent. Where embryos remain in store without effective consent, a plan should be submitted to the HFEA documenting the centre’s intended actions and the anticipated timescale for their implementation. By 11 May 2014. The PR should provide monthly updates to the HFEA on progress in implementing the proposed actions.		The PR has not responded to the inspection report to date. Although this non-compliance has been cited in previous inspection reports, the centre has made some progress in addressing concerns about storage of cryopreserved material beyond the consented storage period. This non-compliance is not considered likely to pose an immediate risk to patients, gametes and/or embryos.

	The PR is reminded of guidance issued by the HFEA in CH(03)03 (http://www.hfea.gov.uk/2687.html) in relation to the timely disposal of cryopreserved material where there is consent to do so and actions should there be a possibility of legal challenge to the disposal of cryopreserved material.		
3. The centre does not accurately record the witnessing of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. On inspection, the patient record audit showed that the witnessing of gametes/embryos was not recorded in three cases, and the date and time of one witnessing step was omitted. SLC T71 and CoP 18.8.	The PR should ensure that witnessing is always fully documented to double check the identification of samples and the patients or donors to whom they relate at all critical points of the clinical and laboratory process. The inspector should be advised of the measures taken to ensure that this happens by 11 May 2014. Within three months of the inspection, the centre should conduct an audit of witnessing and a summary report of the findings of the audit should be provided to the inspector by 11 July 2014.		The inspection team were satisfied that appropriate witnessing is being conducted and that this non-compliance represents a failure of documentation. This non-compliance is therefore not considered likely to pose an immediate risk to patients, gametes and/or embryos.

4. The decisions regarding consent to disclosure to researchers held by the HFEA register either do not match or are missing when compared to those recorded on CD consent forms contained in 15 patient files at the centre. General Directions 0005 This was identified as an area for improvement at the time of the last inspection.	The PR should submit the missing forms and take action to correct the submissions that have been identified as being incorrect by 11 June 2014. The PR should audit procedures for submitting patients' consent to disclosure to researchers to the HFEA. A summary of this audit, including corrective actions and the timescale for implementation of the corrective actions, should be submitted to the centre's inspector by 11 June 2014. Six months after the inspection, the centre should audit a minimum of 10 sets of records chosen at random, and submit this audit to the inspector by 11 October 2014.		The discrepancies observed on inspection mean that patients' wishes that their data be made available to researchers will not be acted on. It is not considered likely that the errors could result in disclosure of data where patients have not given consent, however there are clearly inadequacies in the centre's procedures for reporting these consents. It is noted that this non-compliance is not considered to pose a risk to patient, gamete or embryo safety but indicates a failure to meet statutory requirements
5. The PR has not provided the information required by the Authority within the timescales required. The centre has had three risk tool alerts in the last six months for 'treatments with unregistered donors' and/or	The PR must ensure that all licensed treatment activity is reported to the Authority within the timeframe required by General Directions 0005. Activity that has not been reported within that timeframe should be reported by 11 June		As above, this non-compliance is not considered likely to pose a risk to patient, gamete or embryo safety but indicates a failure to meet statutory requirements. The non-compliance could

'donor treatments with missing outcomes'. At the time of the inspection there were: • 15 treatments involving the use of donor gametes where the donor does not appear to be registered with the HFEA; • 60 missing early outcome form submissions; • significant delays in submitting outcome forms. SLC T9e, T41 and General Directions 0005 This was identified as an area for improvement at the time of the last inspection.	2014. The PR should review the process for submitting data to the HFEA. The inspector should be informed of the outcome of the review; any corrective actions identified as necessary and the timescale for their implementation by 11 June 2014.		have a serious impact on the ability of the HFEA to meet its statutory duty to provide children born as a result of treatment with donor gametes with information about their donor.

‘Other’ areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a ‘critical’ or ‘major’ area of non compliance, but which indicates a departure from statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Inspection team’s response to the PR’s statement
None			

Additional information from the Person Responsible