HFEA Executive Licensing Panel Meeting

7 October 2014

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

Minutes – Item 1

Centre 0078 – (IVF Hammersmith) – Interim Inspection Report

Members of the Panel:	**Panel Secretary:**
Juliet Tizzard – Director of Strategy & Corporate Affairs (Chair)	Dee Knoyle
Hannah Verdin – Head of Regulatory Policy	**Observing:**
Matthew Watts – Regulatory Policy Manager	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 IVF Hammersmith has held an HFEA licence since 1992. 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 31 December 2016.

3. The Panel noted that the inspection took place on 9 July 2014.

4. The Panel noted that in the 12 months to 31 May 2014, the centre provided 1528 cycles of treatment (excluding partner intrauterine insemination). In relation to activity levels this is a large centre.

5. The Panel noted that for the year 2013, the centre reported 115 cycles of partner insemination with eight pregnancies. This equates to a 7% pregnancy rate, which is consistent with the national average.

6. The Panel noted that HFEA-held register data as at June 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the following exception:

    - Clinical pregnancy rates following IVF or ICSI with FET in patients aged 16 to 39 years are above the national averages at a statistically significant level.

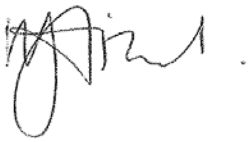
7. Between 1 April 2013 and 31 March 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%. This represented performance that is likely to be greater than the 10% maximum multiple live birth rate target for this period. The Panel noted, however, that the centre has taken successful steps to address this and that the Inspectorate will continue to closely monitor the centre's performance in this area.

8. The Panel noted that at the time of the interim inspection on 9 July 2014, one critical, five major and one other area of non-compliance were identified. The Panel noted that since the inspection, the Person Responsible (PR) had provided evidence that most of the recommendations had been implemented in part and has committed to complete their implementation within the required timescales.

9. The Panel noted that the Inspectorate recommended the continuation of the centre's licence.

Decision

10. The Panel had regard to its decision tree and was satisfied that the centre was fit to have its treatment (including embryo testing) and storage licence continued.



Signed: Date: 15 October 2014

Juliet Tizzard (Chair)

Interim Licensing Report

Centre name: IVF Hammersmith
Centre number: 0078
Date licence issued: 1 January 2013
Licence expiry date: 31 December 2016
Additional conditions applied to this licence: None
Date of inspection: 9 July 2014
Inspectors: Lisa Beaumont (Lead) and Sara Parlett
Date of Executive Licensing Panel: 7 October 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

This report has enabled the inspection team to form a conclusion on the continuation of the centre's licence.

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

The Executive Licensing Panel is asked to note that there are some recommendations for improvement in relation to one 'critical' area of non-compliance, five 'major' areas of non-compliance and one 'other' areas of non-compliance:

Since the inspection visit, the PR has provided evidence that the following recommendations have been implemented in part and has committed to complete their implementation within the required timescales:

'Critical' areas of practice that require improvement:

- **the Person Responsible (PR) should ensure that embryos and gametes are not stored beyond their consented storage period. This was an issue at the last inspection and therefore has been assessed as a critical area of non-compliance.**

'Major' areas of practice that require improvement:

- the PR should ensure that prior to taking consent for the use of embryos in training; all gamete providers are given appropriate information.
- the PR should ensure that patient/partner consents to disclosure of identifying information to researchers are reported accurately to the HFEA.
- the PR should ensure that audits are undertaken for confidentiality and privacy, and the selection of donors.
- the PR should ensure that, wherever possible, only CE marked consumables, including serological pipettes, are used.

'Other' areas of practice that require improvement:

- the PR should assess the risks of not labelling the tubes and dishes used during egg collection and should take action to mitigate any risks identified.

The PR has provided a response confirming his commitment to implement the following recommendation:

'Major' areas of practice that require improvement:

- the PR should ensure that hand washing basins are installed in the two sperm production rooms.

Information about the centre

IVF Hammersmith is located in London and has held a licence with the HFEA since 31 July 1992.

The centre provides a full range of fertility services.

The centre provided 1528 cycles of treatment (excluding partner intrauterine insemination) in the 12 months to 31 May 2014. In relation to activity levels this is a large 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.

Pregnancy outcomes[1]

HFEA held register data as at June 2014 show the centre's success rates in terms of clinical pregnancy rates are in line with national averages, with the following exception:

- Clinical pregnancy rates following IVF or ICSI with FET in patients aged 16 to 39 years are above the national averages at a statistically significant level.

For the year 2013, the centre reported 115 cycles of partner insemination with eight pregnancies. This equates to a 7% pregnancy rate, which is consistent with the national average.

Multiple births[2]

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

Between 1 April 2013 and 31 March 2014, the centre's multiple clinical pregnancy rate for all IVF, ICSI and FET cycles for all age groups was 18%: this represents performance that is likely to be greater than the 10% multiple live birth rate target for this period. Refer to page 7 of this report for further details.

Witnessing

Good witnessing processes are vital in ensuring there are no mismatches of gametes or embryos and that identification errors do not occur.

Witnessing during the following laboratory activities was observed in the course of the inspection: two egg collections and two sperm preparations. All of the procedures observed were witnessed in accordance with HFEA requirements using a combination of electronic and manual witnessing checks. The inspection team was also able to review witnessing

[1]The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems. Centre success rates are considered statistically different from the national averages, and multiple pregnancy rates are considered statistically different from the 10% multiple live birth rate target, when $p \leq 0.002$

[2]The HFEA use a conversion factor of 1.27 to convert the 10% multiple live birth rate (MLBR) target to a multiple pregnancy rate (MPR) target of 13%.

records that were present in five sets of patient notes and concluded that appropriate records of both manual and electronic witnessing are maintained.

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 ten patients were reviewed in the course of the inspection. Five discrepancies were found between completed patient disclosure consents and the related consent data submitted for inclusion in the HFEA register; see recommendation 3.

Consent: To the storage of cryopreserved material

A review of the centre's database indicated that a number of gametes, embryos and ovarian tissue samples are being stored beyond their consented storage period.

Post inspection, the centre provided a summary report of a recent review of the centre's cryopreserved material, which showed the centre did not have written effective consent for the storage of cryopreserved:

- embryos for 26 patients
- sperm for two patients
- ovarian tissue for one patient.

The centre subsequently provided further confirmation that action had been taken and the number of patients with cryopreserved material stored beyond their consented storage period had reduced to ten.

Storage of cryopreserved material without effective consent was cited as an area for improvement at the last inspection; see recommendation 1.

The circumstances under which material has been stored past the consented period were discussed on inspection. These include situations where patients had verbally confirmed their wish to extend the storage period but had then failed to provide completed consent forms. In these situations the centre makes further attempts to communicate with the patients, as required, before taking necessary action.

The inspection team discussed the bring-forward system with the PR and Head of Embryology. The bring-forward system appears to ensure that appropriate contact has been attempted, and includes a full review by the PR before any material is allowed to perish. However the inspection team noted that whilst patients should be first contacted 12 months prior to consent expiry, this was not always undertaken promptly. For example the consent to storage for one set of embryos expired in July 2014 but the first contact letter was only sent to the patient in March 2014.

The centre is fully committed to ensuring that cryopreserved material is not stored beyond its consented storage period, and is currently taking action to address the issues that may be contributing to the bring-forward system not working as well as it should.

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: patients were seen promptly on arrival; 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.

Staffing levels and competence were discussed in relation to the submission of HFEA register data activity and the management of the bring-forward system. The centre informed the inspection team that they are in the process of reviewing team roles and responsibilities to ensure the issues identified in both these areas of practice are addressed. Previously different staff had each been responsible for one area of HFEA data submission. By reviewing roles, allowing sufficient time and ensuring these activities are covered during staff absences, the centre is improving the accuracy and timeliness of HFEA data submissions, therefore the inspection team do not think it is proportionate to cite HFEA data submission as a non-compliance.

Patient experience

During the inspection visit we spoke to one couple who provided feedback on their experiences and we observed interactions between centre staff and patients. A further 26 patients also provided feedback directly to the HFEA in the time since the last inspection. Feedback was mostly positive, with 15 of the individuals providing written feedback to the HFEA commenting that they have compliments about the care that they received.

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;
- has friendly and supportive clinical staff.

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 the following non-compliances:

- Prior to giving consent, not all patients are given the following information before considering consenting to the use of their embryos to train staff: the nature of the training for which the embryos will be used; the decision to donate embryos for use in training will not affect their treatment; that they can vary or withdraw consent; and whether any information will be fed back to them. Centre staff explained that NHS patients are given this information at a group presentation held prior to starting treatment. However, private patients do not attend this presentation and do not receive this information. Please see recommendation 2.
- There are no hand-washing facilities in the two sperm production rooms. Patients have to use the nearby men's cloakroom facility to wash their hands. The inspection team are concerned that appropriate standards of cleanliness and hygiene cannot be maintained within the sperm production rooms, without the appropriate hand washing facilities being available to patients. Please see recommendation 4.
- The following audits have not been undertaken in the last two years to assess compliance against approved protocols, regulatory requirements and quality indicators: confidentiality and privacy and the selection of donors. Please see recommendation 5.
- The serological pipettes used in licensed activity are not CE marked. Please see recommendation 6.
- The follicle aspirate tubes and dishes used during the procurement of eggs are not labelled with the provider's full name and a further identifier or a uniquely identifying donor code. Please see recommendation 7.

Compliance with recommendations made at the time of the last inspection

Following the renewal inspection in July 2012, recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and eight 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented. It is however noted that there have been three reoccurrences of non-compliance on this inspection:

- material being stored beyond its consented storage period
- non CE marked consumables in use
- HFEA data submission

On-going monitoring of centre success rates

In the last 12 months the centre has been sent one risk tool alert in relation to the clinical multiple pregnancy rate in December 2013, to which the centre responded appropriately. Data analysis through the risk tool demonstrates that the centre's actions to reduce the multiple pregnancy rate have been successful and a recommendation is not required. The centre's multiple pregnancy rate will though continue to be closely monitored by the centre's inspector.

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 centre has historically had a very high number of data submission errors and issues with the timeliness of data submission to the HFEA. This was discussed with staff at the centre; please see the Staffing section on page 5 of this report. No recommendation has been included in this report because of significant recent improvement.

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. On the day of the inspection the centre did not have effective consent for the storage of cryopreserved: o embryos for 26 patients o sperm for 2 patients o ovarian tissue for 1 patient. **This was cited as an area for improvement at the previous inspection**.	By 31 August 2014, where gametes and 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 provide monthly updates to the HFEA on progress in implementing the proposed actions. The PR should review the bring-forward system and procedures for	Following the inspection the clinic instructed the embryology lab administrator to call each patient twice a day and inform them that they had until 25th of August to make a decision and send the correct paper work or their gametes/embryos would be destroyed as per the HFEA licence condition. All of the patients had previously been contacted at least twice in writing to inform them of the expiry of their consent. The	The centre has confirmed that it no longer has any gametes or embryos in storage, without effective consent. The Executive acknowledges the action taken by the centre. The PR has committed to implement the remaining element of this recommendation within the required timescale. This will be reviewed by the Executive

(Schedule 3, 8(1) and (2) HF&E Act)	auditing storage of cryopreserved material. Summary reports of the findings of both reviews including corrective actions and the timescale for their implementation should be submitted to the HFEA by 9 October 2014. Within three months of the implementation of corrective actions, the centre should conduct an audit of consent to storage and a summary report of the findings of the audit should be provided to the HFEA. 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.	administrator kept a log which was reviewed by the Deputy Head of Embryology and the outcomes were discussed with the PR. The frequent phone calls resulted in: 3 couples extended their storage and signed the necessary forms 4 couples signed a consent instructing the clinic to dispose of the gametes/embryos 3 couples were unable to be contacted and the PR has signed off on the disposal of their gametes/embryos as several efforts, through different methods of communication, have been unsuccessful.	through the on-going monitoring system.

‘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. Prior to giving consent, not all patients are provided with the following information about the potential use of their embryos to train staff: the nature of the training for which the embryos will be used, the decision to donate embryos for use in training will not affect their treatment, that they can vary or withdraw consent, and whether any information will be fed back to them. (SLC T97a, b, c & d)	The PR is required to review the centre's procedures for taking consent for the use of embryos in training, to ensure that the correct information is given to patients, by 9 October 2014. Once corrective action has been taken, within three months an audit should be undertaken. A summary report of the audit should be submitted to the HFEA by 31 January 2015.	The Consent to Training has been updated to include the required information (attached). To ensure there is no conflict of interest with regards to the person obtaining consent benefitting from the training it has been decided that the consent will be signed when the patient attends their coordination clinic with their named nurse. This will also allow the patient to ask any questions they may have. An unannounced audit will take place prior to the appointed time. The audit will include: • Attending coordination clinic to ensure the correct	The centre has submitted a revised Consent to Training proforma. The PR has committed to implement the remaining element of this recommendation by 31 January 2015. This will be reviewed by the Executive through the on-going monitoring system. .

		information is given to patients • Reviewing the consents to ensure the answers on the IVFH Consent to Training are consistent with the HFEA consents and the information inputted to the HFEA.	
3. Five discrepancies were found out of ten patient records reviewed, between completed patient disclosure consents and the related consent data submitted for inclusion in the HFEA register. (Chair's letter CH (10)05 and supplementary guidance and General Directions 0007).	The PR is required to ensure that the data submissions identified as being incorrect are corrected immediately. The PR is required to review the systems and processes to ensure that going forward, the patient and partner disclosure consent information supplied to the HFEA accurately reflects that given and recorded on completed disclosure consent forms. A report of this review should be submitted to the HFEA by 9 October 2014. An audit should be conducted three months after implementing any changes, to confirm that any changes made to systems and processes are having the desired effect. A report of this audit should be provided to the HFEA by 9 January 2015.	The Quality Manager is waiting for confirmation that the changes have been made to the exact 10 patients' audited. The nurses have attended a learning session on the importance of consent and what constitutes informed consent. They have also completed a Consent Competency Quiz and passed. The Senior Charge Nurse worked with the Quality Co-ordinator to change the coordination sessions to allow nurses more time with each patient to ensure adequate time is spent on consents. The nurses have also been informed in writing that the transcription errors were identified as a major area that required improvement. They	The Executive acknowledges the action taken by the centre. The PR has committed to implement the remaining element of this recommendation by 9 January 2015. This will be reviewed by the Executive through the on-going monitoring system.

		have also been informed that unannounced mini audits will take place periodically over the next 9 weeks to determine if further changes need to be made to the process. A full audit will take place in December and the report will be submitted to the HFEA	
4. There are no hand washing facilities in the two sperm production rooms. Patients have to use the nearby men's cloakroom facility to wash their hands. The inspection team are concerned that the centre is not able to maintain appropriate standards of cleanliness and hygiene within the sperm production rooms, without the appropriate hand washing facilities being available to patients. SLC T2 and SLC T17.	The PR is required to ensure that hand washing basins with hands free mixer taps, are provided for patients in each of the sperm production rooms, in the interests of infection prevention and control standards. The PR is required to provide evidence that hand washing basins with the appropriate taps, have been installed by 9 January 2015.	We have raised this with the Divisional director of operations of the Women's & Children's Department of the Trust. We will continue to raise the matter at our monthly Senior Managers meeting, which Trust officials also attend.	The Executive acknowledges the action taken by the centre. This will be reviewed by the Executive through the on-going monitoring system.
5. The following audits have not been undertaken in the last two years to assess	The PR is required to ensure that the audits are undertaken and a summary report of each one is	The Privacy and Confidentiality audit has been completed. Please see the attached audit report. The	The centre has provided evidence of the privacy and confidentiality audit having

compliance against approved protocols, regulatory requirements and quality indicators: • confidentiality and privacy; • the selection of donors. Schedule 3A (10) 2006/86/EC, Appendix 1F and SLC T36.	submitted to the HFEA, along with any identified actions to be taken, by 9 January 2015.	corrective actions have already been identified and implemented. An additional audit will take place in December to ensure they are being adhered to. The Quality Manager audited all egg donor records since January 2012. In total 30 notes were reviewed. As a result of the audit an incident (IN03949) and two near misses were reported on August 21st. The PR and Quality Manager are in the midst of reviewing the programme, informing the patient and providing the following information to the HFEA on September 5th: 1) Details of analysis and/or risk assessment that has taken place. 2) Learning objectives. 3) Details of revised practice and/or protocols where appropriate. In addition to that the clinic will also provide updated paper work for the donation programme, including:	been undertaken. The PR has committed to implement the remaining element of this recommendation by 9 January 2015. This will be reviewed by the Executive through the on-going monitoring system.

		1) Information provided to patients about egg donation 2) Donor Health Assessment 3) Relevant SOPs 4) Relevant Checklists In the IN03949 report a date will be set for an additional audit prior to January 9th and the report will be submitted to the HFEA.	
6. The serological pipettes used are not CE marked. (SLC T30) **Non CE marked consumables was an issue at the last inspection.**	We would not recommend the implementation of precipitous changes that might impact on the quality of treatment provided to patients; however it is a requirement that all materials coming into contact with gametes and embryos are CE marked. In consideration of this, the PR should consider the CE marked options available to replace non-CE marked consumables, and should also review the possibility that the supplier will obtain a CE mark for this product. The PR should advise the HFEA of the options available and the centre's plans to become fully compliant with SLC T30 by 9 July 2015.	The serological pipettes were ordered on August 6th and the clinic was told it will be approximately four weeks before they can be delivered.	The centre has confirmed that CE marked pipettes are now in use. Further action is required to ensure procedures and audit of practice are robust to prevent a reoccurrence.

	In consideration that the clinic was found to be using different non CE marked products at the time of the last inspection, the clinic is required to review their procedures to ensure that all existing and any new products are CE marked. As the clinic's own audit of compliance failed to identify this non compliance then consideration should also be given to reviewing the robustness of audit procedures. A review report should be submitted to the HFEA by 9 November 2014.		

‘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
7. The follicle aspirate tubes and dishes used during the procurement of eggs are not labelled with the provider’s full name and a further identifier or a uniquely identifying donor code. (SLC T101)	While it is acknowledged that only one egg collection takes place at a time, the PR should assess the risks of not labelling the tubes and dishes used during egg collection. The HFEA should be provided with evidence of the assessment undertaken, and any actions taken to mitigate the risks of misidentification as a result of this practice, by 9 October 2014.	The Head of Embryology will be conducting the risk assessment in September. The Embryology team have already updated the SOP and Witnessing form, the witness will now check the area after every egg collection and tick that the area is clear. The assessment report will be provided to the HFEA by October 9th.	The Executive acknowledges the action taken by the centre. The PR has committed to implement the remaining element of this recommendation by 9 October 2014. This will be reviewed by the Executive through the on-going monitoring system.

Additional information from the Person Responsible