# New Premises Site Visit Report

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| Name of Applicant | Dr Hemlata Thackare |
| Address of Proposed Premises | London Women's Clinic, Cardiff<br>Cyncoed Medical Centre<br>Dartington Drive<br>Cardiff CF23 8SQ |
| Has the applicant been licensed before | NO |
| If yes:<br>Centre Number and Address of previous premises | --- |
| Inspector(s) | Parvez Qureshi |
| | Vicki Lamb |
| Date of visit | 19th December 2007 |
| Date of any previous visits to these premises | **----** |

**About the Site Visit**
The purpose of the site visit report is to confirm to the PR the findings of the inspection highlighting areas of firm compliance and good practice, as well as areas where further improvement is required. The report may be shared with other regulators on a need to know basis, such as the HC and HTA.

**Brief Description of the Centre**

Currently the London Women's Clinic Cardiff is operating as a satellite centre for other licensed centres (0059 and 0105) within the London Women's Clinic group. An application has been received from the proposed Person Responsible for a Treatment and Storage licence.

The premises are located within Cyncoed Medical Centre on two different floors. The ground floor has a reception area/waiting room which appeared to be quite compact. There is one-way glass between the outside and the waiting room. An office area where notes are stored in lockable cupboards and this room is also lockable (archived notes are kept in the basement). There is a consulting room and a scan room, women's toilet and male production room with toilet.

Access to facilities on the first floor is through the GP surgery waiting room via stairs or the lift. There are two consultation/treatment rooms, a counselling room and a laboratory. The consultation/treatment rooms have keyfob access.

The opening hours will be Monday to Friday.

The Person Responsible (PR) has completed the PR Entry Programme and is appropriately qualified to discharge her duties.

**Summary of findings for Licence Committee**
**(If final visit before Application considered by LC)**

The following issues were identified by the inspection team which require action by the centre:-

- Further development and implementation of a QMS.
- Development of a risk management structure.
- Formalising of all third party agreements.
- Completion of maintenance contracts for all key pieces of laboratory equipment.
- In the event of an emergency, the availability of back up power.
- Information for patients on what screening needs to be done.

- Review of centre's information to ensure that it is both centre and treatment specific.
- Review of laboratory protocols to include witnessing requirements.

Subject to successful resolution of issues highlighted in this report the HFEA inspection team would support the centre's application for Treatment and Storage licence and request the Licence Committee to agree to grant an initial licence for one year.

1. **Organisation**

Desired Outcome: The centre is well-organised and managed and complies with the requirements of the HFE Act.

Summary of findings from inspection

Evidence of: *(Delete areas not reporting on)*

- Leadership and management
- Organisation of the centre
- Resource management
- Risk management
- Incident Management
- Contingency arrangements
- Clinical governance
- Knowledge of the legal requirements and COP

| Summary of Findings |
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| Documentation including an organisational chart showing main functions and lines of accountability within the centre were submitted with the application. These were reviewed by the inspection team and were considered to be satisfactory.<br><br>For many years the London Women's Clinic Cardiff has been a satellite unit for other centres within the London Women's Clinic (LWC) group. This has resulted in key members of staff having extensive experience of working in the fertility field.<br><br>A Quality Manager has been appointed to ensure that the centre will comply with the new HFEA Standards and the requirements of the EU Tissue and Cells Directive.<br><br>The proposed PR stated that currently regular team meetings are held to discuss practice related issues. All staff attend these and minutes are distributed to them via email and paper copy for those not on email. Minutes of recently held meetings were seen during the visit.<br><br>The centre has an adverse incident handling policy in place. Staff interviewed were aware of the procedure for reporting of any incident to the HFEA.<br><br>In the event of an emergency, contingency arrangements will be in place with other centres within LWC group. Any difficult cases will also be referred to the LWC group ethics committee.<br><br>Assessment of the completed PR Entry Programme submitted with the application by the proposed PR indicated a satisfactory knowledge of the legal requirements and Code of Practice. This was further evidenced from the discussions held with her. |
| Areas for improvement |
| Further development and implementation of a quality management system (QMS).<br><br>A risk management structure needs to be developed.<br><br>A list of third party agreements was seen by the inspectorate. However, some still need to be formalised. |

| Points to consider/action for next inspection |
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| Resolution of areas highlighted for improvement. |

## 2. Quality of service

Desired Outcome: Patients receive a good standard of service, appropriate treatment and are treated with courtesy and respect.

Summary of findings from inspection: *(Delete areas not being reported on)*

- 'Welfare of the Child' arrangements
- Confidentiality (including safe storage of patients' records)
- Choice of treatments
- Privacy and dignity of patients
- Complaint handling
- Patient feedback and satisfaction
- Counselling facilities and services

| Summary of Findings |
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| Discussions held with staff and evidence seen during the visit showed patients' confidentiality is well maintained. Currently notes are stored in a secure area with only members of staff having access to them. Consultations with the patients are held in private rooms.<br><br>Counselling service at the centre will be provided by a designated fertility counsellor and reference to this is made in the patient information leaflets. There will be no charge made for counselling service and the notes will be kept in a secure place.<br><br>A complaints procedure is in place which includes HFEA details.<br><br>The proposed PR stated that a patient satisfaction feedback system will be in place to capture the quality of service that will be provided. Staff stated monthly information evenings for prospective patients will continue to take place as present. |
| Areas for improvement |
| The centre will have Welfare of the Child' arrangements in place. The staff were aware of the procedure but this was not reflected in the patient information. |
| Points to consider/action for next inspection |
| Resolution of areas highlighted for improvement. |

## 3. Premises and Equipment

Desired outcome: The premises and equipment are safe, secure and suitable for their purpose.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Suitable premises
- Storage facilities for embryos and gametes
- Safe equipment, servicing and maintenance
- Prevention of incidents/ accidents

| Summary of Findings |
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| There were two liquid nitrogen tanks present in the laboratory. The centre is waiting for a delivery of class II cabinet which has been ordered. Currently no alarms are in place (low oxygen and nitrogen) but the inspectorates were informed by the staff that these would be delivered in January 2008. The laboratory will also have an autodialler system in place. In addition to this, audible and visual alarms outside the laboratory for the low oxygen monitor will be installed.<br><br>The liquid nitrogen store is situated in the basement. The cage which is lockable was seen but the tank has not arrived yet. The basement has staff only access from outside and key only access via the lift. When nitrogen is brought to the laboratory it will come up in the lift. Warning signs will be placed at the lift doorway to prevent anyone using it.<br><br>Maintenance contracts are in place for some of the key pieces of equipment and evidence of this was seen during the visit.<br><br>Centre has an air quality monitor in place to ensure that process will be carried out in an appropriate air quality. |
| Areas for improvement |
| The inspection team suggested to the centre's staff they should consider carrying out a risk assessment associated with transport of liquid nitrogen to the laboratory and the method of filling the storage tanks, as this will involve lifting and handling.<br><br>Set up of maintenance contracts for all key pieces of laboratory equipment.<br><br>In the event of an emergency, staff need to ascertain whether access to a back up power is available or not. |
| Points to consider/action for next inspection |
| Resolution of areas highlighted for improvement. |
| The standard of the premises and equipment |
| All areas seen during the inspection were found to be clean and well presented. Overall the inspection team considered the facilities to be suitable for the proposed activities. |

## 4. Information

Desired outcome: Information is relevant, clear and up to date for patients and to the HFEA

Summary of findings from inspection: *(Delete areas not being reported on)*

- Information management
- Information to patients and donors
- Information to the HFEA
- Protocols
- Record keeping (including consents)

| Summary of Findings |
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| The information management system, both computerised and paper based, seen during the visit was considered to be well organised. All information is stored in accordance with confidentiality requirements in lockable cabinets.<br><br>A procedure will be in place for tracking live birth events from donor gametes. The proposed PR is aware of the reporting requirements for all treatments carried out. All donor sperm samples will be provided by London Women's Clinic centre 0105.<br><br>Patient information submitted for the inspection included: contact details for out of hours emergencies; risks associated with treatment; the legal situation with all aspects of treatment, contact details for queries and treatment costs.<br><br>Viral positive patients will not be treated at the centre but will be referred elsewhere. |
| Areas for improvement |
| Documents submitted for the inspection showed that there was no clear written information for patients on what screening needs to be done other than for Hep B and C, HIV and Chlamydia.<br><br>The centre is not anticipating that treatment sperm samples will be produced at home. However, a handover form could be developed for this purpose.<br><br>Review of centre's information is required to ensure that it is both centre and treatment specific.<br><br>Review of laboratory protocols to include witnessing requirements. |
| Points to consider/action for next inspection |
| Resolution of areas highlighted for improvement. |
| The standard of information provided |
| Overall the information submitted with the application and that seen during the visit was considered to be of a good standard. |

## 5. Laboratory and Clinical Practice

Desired outcome: Staff are competent and recruited in sufficient numbers to ensure safe clinical and laboratory practice.

Summary of findings from inspection: *(Delete areas not being reported on)*

- Assessment of patients
- Safe handling systems
- Laboratory processes and practice
- Clinical practice
- Recruitment and retention of staff
- Staff competence, qualifications, training and CPD

| Summary of Findings |
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| There are policies and procedures in place for assessment of patients. Subject to installation of remaining equipment and any subsequent training of staff the centre is expected to have safe handling systems, laboratory procedures and clinical practice in place.<br><br>The current staff consists of:-<br>3 Full-time nurses,<br>3 administration<br>1 Full time equivalent consultant<br>1 counsellor,<br>2 Part-time seminologists providing 3-4 days cover. The aim is to have 3 Part-time seminologists to provide 5 days cover.<br><br>The recruitment of staff and their suitability to work at the centre is the responsibility of the London Women's Clinic Group's management team.<br><br>Policies are in place to ensure that staff are competent to perform required procedures, have access to training and are able to maintain their CPD. |
| Areas for improvement |
| None. |
| Points to consider/action for next inspection |
| Monitoring of above findings. |
| The provision and quality of staff |
| The current staffing level at the centre is adequate for the anticipated workload. |

**Topic 1**

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **organisation**

Further development and implementation of a quality management system (QMS).

A risk management structure needs to be developed.

A list of third party agreements was seen by the inspectorate. However, some still need to be formalised.

To be completed as soon as possible.

**Topic 2**

(a) The applicant meets the requirements for **quality of service.**

**Topic 3**

(b) The following actions need to be taken by the date shown before the applicant meets the requirements for **premises and equipment.**

Set up of maintenance contracts for all key pieces of laboratory equipment.

In the event of an emergency, staff need to ascertain whether access to back up power is available.

To be completed as soon as possible.

**Topic 4**

b) The following actions need to be taken by the date shown before the applicant meets the requirements for **information.**

Documents submitted for the inspection showed that there was no clear written information for patients on what screening needs to be done other than for Hep B and C, HIV and Chlamydia.

Review of centre's information is required to ensure that it is both centre and treatment specific.

Review of laboratory protocols to include witnessing requirements.

To be completed before 13th February 2008.

**Topic 5**

(a) The applicant meets the requirements for **laboratory and clinical practices.**

**Next Action**

The centre staff to ensure that resolution of areas highlighted in report are completed as soon as possible and the Executive is kept updated on the progress.

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| Report compiled by | Parvez Qureshi |
| Designation | Inspector |
| Date | 28th January 2008 |

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number……0301……

Name of PR……..Dr Hemlata Thackare……

Date of Inspection……9th December 2007……

Date of Response……1st February 2008……..

Please state any actions you have taken or are planning to take following the inspection with time scales

(Comments taken from PR response received)

**Further development and implementation of a QMS.--** In progress and will be completed in 3 months.

**Risk management structure.--** Protocol in place and risk assessments are being carried out in all existing work areas.

**Formalising of all third party agreements.--** Third party agreements for most existing service providers are in place. Awaiting third party agreement with Drug package supplier.

***Maintenance contracts.--*** Maintenance contracts for all existing key laboratory equipment in place. All new equipment will be covered by their warranty.

**Emergency back up power.--** We will recommend this to our landlord. However power has never failed in this brand new site and we undertake no intrusive procedures, except IUI. We will feedback to HFEA the response from our landlord.

**Information for patients on what screening needs to be done.--** Information for leaflet for the screening tests has been drafted.

**Review of centre's information to ensure that it is both centre and treatment specific.--** The centre's information has been amended to be treatment and centre specific.

**Witnessing protocol.--** Laboratory witnessing protocol has been developed.

I have read the inspection report and agree to meet the requirements of the report.

Signed…..Signed copy received from PR ……

Name…… Dr Hemlata Thackare ……..….

Date……1st February 2008……

2. Correction of factual inaccuracies

Please let us know of any factual corrections that you believe need to be made (NB we will make any alterations to the report where there are factual inaccuracies. Any other comments about the inspection report will be appended to the report).

We also welcome comments about the inspection on the inspection feedback form, a copy of which should have been handed out at the inspection. If you require a copy of the feedback form, please let us know.

Please return this section of the report to:
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF