



## Additional Inspection Report

Centre Name	The Rosie Hospital
Centre Number	0051
Name of PR	Mr Raj Mathur
Name of Inspectors	Ms Allison Cummings
	Ms Sarah Hopper
Date of Visit	1 <sup>st</sup> November 2007
Focus	Suspension of treatment service; change of storage premises and change of nominal licensee.

With notice	X
Short Notice	
Unannounced	

## Purpose of Visit

- Initial visit following first licence (within 3-6 months of starting operating)
- Applications to vary a condition of the licence e.g. PDG
- Follow up visit following concerns, actions needed etc.
- X Change in existing premises e.g. following refurbishment
- Advisory Visit
- Any other circumstances resulting in a visit other than new application, investigation and renewal interim inspection

## *Reasons for visit*

The Person Responsible (PR) recently notified the HFEA that they wish to suspend their treatment service and move their dewars to another laboratory within the curtilage of the existing hospital. The inspectorate made the decision to meet with the PR to discuss these proposals and inspect the new laboratory.

## Points Covered

The inspection involved a tour and meetings with the PR, nurse manager and two members of staff from the stem cell laboratory, department of haematology.

The inspectorate initially met with the PR and the nurse manager of the licensed centre to discuss the reasons for their proposals. The PR reported that the Primary Care Trust had stopped funding intra-uterine inseminations (both partner and donor) since April 2007. Funding constraints within the Hospital Trust impacting on the upgrade of the existing laboratory to meet European Union Tissues and Cells Directive (EUTCD) requirements were discussed as a factor. It was noted that the suspension of treatment services is hoped to be short term. In this meeting, the PR also made the inspectorate aware of proposals for a new nominal licensee. The PR reported that due to a change in post, the current nominal licensee, Kathy Haynes, intends to resign from her position. Amanda Cahn, associate director of operations, is proposed to take on the post.

The existing laboratory containing two dewars was shown to the inspectorate. The nurse manager stated that one dewar contained 17 donor sperm samples for sibling use only. It was noted that the other dewar is for emergency use. The PR reported that in the event samples are requested for sibling use, then the existing staff (i.e. nurses) would remain responsible for

the transportation process to nearby HFEA licensed centre, Bourn Hall (centre 0100). Therefore, The Rosie Hospital would remain a licensed storage centre and a satellite centre for Bourn Hall.

The stem cell laboratory proposed for keeping the remaining gametes was also shown to the inspectorate. There, the inspectorate was introduced to Karen Richardson, Chief Biomedical Scientist and Dr Mike Scott, Consultant Clinical Scientist. They reported their facility is licensed by the Human Tissue Authority although it has not yet been inspected. Despite the new storage facility being located in another building, it was seen to lie within the curtilage of the hospital boundaries.

Access to the new premises was seen to be restricted by a card system although will be shared with other laboratory teams. The Chief Biomedical Scientist stated that an inventory is kept of the access cards and before staff are granted with one of these, training on handling and storage of liquid nitrogen and safety issues relevant to the cryostore is provided.

The inspectorate was informed by the PR that a new tank has been ordered to put the samples into and like all other tanks; it will also be connected to a nitrogen auto-fill and monitoring system. This means that levels will be monitored on a 24 hourly basis. An on-call rota was reported to be in place and the PR was advised to add those four members of staff responsible for being on-call to the centre's licence, ensuring that their suitability is assessed including their awareness of the requirements of the Act and Code of Practice. The PR will ensure that the tank is locked so as to restrict access to only those members of staff on the licence.

A spare dewar was seen to be available in case of an emergency.

The PR proposed that the samples will be moved by two nurses and a porter using the underground tunnels as much as possible so as to make the journey quicker and with fewer obstacles. The PR has risk assessed the movement of the samples and developed a procedure for the move. Both documents were provided to the inspectorate. For this purpose, the PR stated that the shipper belonging to the new laboratory will be used and that it is fitted with a data logger so that the conditions within the shipper during the movement will be recorded. The staff at the new premises stated that the shippers are used regularly and will therefore be prepared prior to the move.

The staff were thanked for their time and their hospitality.

Complete the box below only if outcomes / actions have been agreed

Agreed outcomes / actions to be taken	To be completed by (where applicable)
1. Complete and submit 'change of nominal licensee' form.	3 <sup>rd</sup> December 2007

2. Change of treatments - to remove the treatments you need from your current licence. I have confirmed that from our point of view there is no need to do this, only unless you wish to.	3 <sup>rd</sup> December 2007
3. Notification of changes to the current licensed premises (within curtilage) or change of equipment.	3 <sup>rd</sup> December 2007

Complete the box below only if conditions will need to be imposed, varied or removed

As a result of this visit the following recommendations are made:
Date (where applicable)

**Next action**

The PR should review the content of this report, identifying any factual inaccuracies and providing details of any further progress made. Please submit by 3<sup>rd</sup> December 2007.

The executive have sent the appropriate application forms to the PR. These should be submitted by 3<sup>rd</sup> December 2007 so that the licence committee can consider the centre's case on 17<sup>th</sup> December 2007.

**Report completed by**

**Signed**

**Name** Allison Cummings

**Designation** Inspector

**Date** 16<sup>th</sup> November 2007