New Premises Site Visit Report

Name of Applicant	Dr Alan Lees
Address of Proposed Premises	Gloucestershire Hospitals NHS Foundation Trust Microbiology Department Gloucestershire Royal Hospital Great Western Road Gloucester GL1 3NN
Has the applicant been licensed before	Yes
If yes: Centre Number and Address of previous premises	0151 Department of Microbiology, Cheltenham General Hospital, Sandford Road Cheltenham Gloucestershire, GL53 7AN
Inspector(s)	Miss Sarah Hopper Mr Wil Lenton
Date of visit	6th June 2008
Date of any previous visits to these premises	N/A

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

Centre 0151 has been licensed since 1992 and offers a storage service for oncology patients in the Gloucestershire, Herefordshire and Worcester area.

The HFEA last inspected the centre on the 25th May 2006. Due to a low risk score the centre was granted an inspection holiday in the period March 2007-April 2008. An interim inspection is due to be conducted at the centre in the Autumn of 2008.

Purpose of inspection

The centre is currently situated within the pathology department of Cheltenham General Hospital. The move to new premises at Gloucester Royal Hospital has been prompted by a Trust decision to reorganise pathology provision in Gloucestershire. The current premises are due to be demolished in July 2008.

The new premises were inspected on the 6th June 2008. Other areas of practice, e.g. information, access to counselling and scientific practice, within the centre were not inspected as these will be addressed at the interim inspection which is due to take place in the Autumn of 2008.

Consequently, this report comprises an assessment of the proposed new premises only.

1. 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
It is proposed that the sperm processing laboratory and storage tanks will be moved to a new pathology unit at Gloucestershire Royal Hospital. The PR explained that the sperm production room will remain at the Cheltenham hospital but that a sperm production room will be built within the new premises later in the year. For those patients who are receiving treatment at the oncology unit at Cheltenham hospital and are unable to travel to Gloucester, arrangements will be made to courier the samples across to Gloucestershire Royal Hospital for freezing. The PR reminded the inspectorate that some patients produce samples at home and that all patients are required to complete a verification form to declare that the sample is theirs. This practice is set to continue following the move to new premises. The counselling service will remain within the Oncology unit at Cheltenham hospital. The PR stated that patients will be informed that the service will be provided between two sites. **Sperm processing laboratory** The sperm processing laboratory is a purpose built room which will be used for semen analysis and cryopreservation only. The room was seen to be fitted with benching and a basin. A laminar workstation and incubator will be moved to these premises from the old laboratory when approval is obtained. The PR advised the inspectorate that freeze records will be stored in this room within a locked filing cabinet. At the time of inspection, a lock had not been fitted to the sperm processing laboratory. The PR advised that a swipe card lock will be fitted and that security will be restricted to licensed staff. Air quality within the room has been monitored and records shown to the inspectorate indicated it was in accordance with HFEA requirements. The PR confirmed that these tests will be repeated when the equipment has been moved into the new laboratory. It is advised that the PR ensure that the results are satisfactory prior to processing samples for cryopreservation. **Cryostore** The five storage dewars are to be stored in a separate stand alone unit external to pathology unit. The inspectorate shared concerns about the vulnerability of the cryostore as it is sited alongside a public pathway and hospital road and is secured by a single lock only. In response to the inspectorate's recommendations a risk assessment has now been conducted on the security of the cryostore. In response to the findings of the risk assessment, door hinge protectors are to be fitted to maximise security. The key will be stored within the sperm

processing laboratory when not in use. The PR is also planning to ask the Trust security department to assess the safety of the cryostore.

The PR informed the inspectorate that the dewars will be fitted with a new low nitrogen alarm system and that this will be tested by the supplier once the dewars are in place. The alarm system will link to an autodialler and the current protocol for responding to alarms is expected to be followed albeit with some minor modifications. The senior andrologist is looking to purchase sensors for all four dewars so that the temperature can be logged electronically.

A forced ventilation unit has been fitted within the store. This is designed to facilitate 30 air room changes per hour and is connected to a central monitoring system within the hospital.

A low oxygen sensor had been installed within the cryostore and an alarm unit has been fixed to the outer wall of the store. In the event of low oxygen this will produce an audible and visible alarm. The inspectorate was informed that a cage is to be fitted around the alarm unit to protect it from vandalism. The Person Responsible stated that warning notices about liquid nitrogen will be placed on the door to ensure that staff and public are aware of the hazards in this area.

Safe equipment, servicing and maintenance

At the time of the inspection, the equipment had not yet been installed into the unit. The inspectorate was informed that original pieces of equipment will be used. The PR assured the inspectorate that the equipment will be re-validated on arrival and prior to use at the new unit.

The air quality within the flow hood has been tested regularly and the andrologist reported that the results indicate compliance with HFEA requirements. It is recommended that the air quality within the hood is checked frequently following the move to ensure that it is working effectively and providing a safe environment for the processing of sperm samples.

The senior andrologist stated that key pieces of equipment will be linked to the hospital's emergency power backup system.

The PR confirmed that there will be no changes to the maintenance and service contracts for equipment that is currently in use.

Plan for moving samples to the new site

An external company has been contracted to move the storage tanks and patient records. The Senior Andologist advised that the company has experience of moving storage tanks but that a risk assessment of the move has not yet been conducted. The PR stated that the dewars will be locked and records stored securely within locked filing cabinet during the move.

The PR has drafted a letter to patients informing them of the move. It is planned that the letter will be sent once the date for the move is confirmed. A copy of the letter was provided to the inspectorate and some minor amendments were recommended, namely that patients should be made aware that the counselling service will remain at Cheltenham General Hospital.

Areas for improvement
The letter which is to be sent to patients with samples in storage includes the following statement “we do not expect your samples to be at risk in any way”. It was suggested to the PR that he conducts a risk assessment of the move of samples to be carried out so that this statement could be supported in the event of any incident resulting from the move. In response to this, the PR has asked the external removal company to conduct a risk assessment. It is further recommended that the PR should establish a third party agreement with the contractors employed to move the samples as required by Code of Practice Standard 4.2.1. The inspectorate was informed that on occasion staff may enter the cryostore unaccompanied. The inspectorate had concerns about this as the cryostore is isolated from the pathology unit. During the inspection it was recommended that the PR considers the personal safety of sole workers and introduces any measures he sees fit to reduce the risks. The PR has stated that he is looking into the provision of personal low oxygen monitors and alarms for staff. There is no protocol in place which explains what should be done in the event of the low oxygen alarm sounding. It is advised that the PR takes action to ensure that all licensed staff who work in the area are aware of how to respond to the low oxygen alarm. The PR must also ensure that emergency procedures are in place to deal with damage to storage vessels, as required by Code of Practice Standard 6.3.8.
The standard of the premises and equipment
The inspectorate agreed that, subject to the validation of all equipment prior to use and the addition of security locks and alarms, the new laboratory and cryostore are fit for purpose.

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

The executive are satisfied with the proposed new facilities and would recommend the variation of the licence to reflect the change of premises, subject to receipt of confirmation from PR that the following actions have been taken:

- Lock fitted to sperm processing laboratory.
- Further security (door hinge protectors) to be added to the doors of the cryostore.
- Validation and re-commissioning of key equipment following move.
- Testing of background and working environment air in the sperm processing laboratory which demonstrates that the air quality meets the requirements of Licence Condition A.10.19, Code of Practice Standard 6.3.6 (b), Standard 7.8.5 and Guidance 9.4.
- Development of a protocol for response to low oxygen alarms.
- Placement of warning signs outside the cryostore.

The Licence Committee are asked to approve this new premises application.

Appendix A: The inspection team and staff interviewed

The inspection team

Sarah Hopper	Chair, Inspector, HFEA
Wil Lenton	Inspector, HFEA

Report compiled by: Sarah Hopper

Signed _____

Designation: Inspector

Date: 06/06/08

Appendix B: Licence History

Licensing History

Centre: Gloucestershire Hospitals NHS Trust

Number: 0151

2007

Licence Committee 14 May 2007
The Committee agreed to vary the centre's licence pursuant to the Human Fertilisation and Embryology Act 1990, as amended by the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007.

2006
Inspection 25th May 2006

Licence Committee 27 July 2006
The Committee noted the centre's low risk status and agreed to renew the centre's licence for a period of 5 years, with no conditions.

2005
Inspection 19th July 2005

Licence Committee 28 April 2005
The licence committee agreed to recognise Dr Alan Lees as the person responsible

Licence Committee 5th September 2005
The Committee noted the progress being made by the centre to address the issues raised in the inspection report. However, the Committee agreed that the centre should be strongly advised to ensure that the splitting of its oncology samples is completed by the end of December 2005 at the latest.

2004
Inspection 14th July 2004

Licence Committee 13 October 2004
The committee added no additional conditions and one recommendation

2003
Inspection 9th May 2003

Licence Committee 11th July 2003
The committee added no additional conditions and two recommendations.

Appendix C

RESPONSE OF PERSON RESPONSIBLE TO THE SITE VISIT

Centre Number 0151……..….

Name of PR Dr Alan Lees…....

Date of Inspection…6th June 2008…….…....

Date of Response…17th June 2008……..….....

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

Sperm store actions, all by end June 2008

1. Put in door hinge protectors
2. Trust security to assess door safety
3. Safety policy to include lone worker guidance
4. Training/competency log for staff/on call staff (including protocol for response to low oxygen alarm)
5. Purchase of personal O2 monitor
6. Hazard signage on door

Sperm processing laboratory, action by end June 2008

1. A swipe card lock will be fitted and access restricted to licensed staff.

Proposed move of sperm store, action prior to move

1. external removal company to conduct a risk assessment of the move of stored samples
2. establish a third party agreement with the contractors employed to move the samples

Information for patients with stored samples, action on approval of move

1. Draft letter to patients to be modified to clarify that the counselling service will remain at Cheltenham General Hospital.

Actions following move

1. Validation and re-commissioning of key equipment
2. Testing of background and working environment air in the sperm processing laboratory

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

Signed….  ……..…

Name…Dr Alan Lees

Date…17/6/2008

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).

Page 2 “purpose of inspection” section line 4. The current premises at Cheltenham aren’t actually going to be demolished, they will be vacated by microbiology and renovated to create a histopathology laboratory.

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:
Dr Debra Bloor
Head of Inspection, HFEA
21 Bloomsbury Street
London
WC1B 3HF

Licence Committee Meeting

27 July 2006
21 Bloomsbury Street London WC1B 3HF

MINUTES Item 1

Cheltenham General Hospital (0151)
Licence Renewal

Members:
Clare Brown, Lay Member – Chair
Ivor Brecker, Lay Member
David Barlow, Executive Dean of Medicine, University of Glasgow

Observing:
Ruth Fasht, HFEA Member

In Attendance:
Marion Whitton, Head of Inspection
Claudia Lally, Secretary to the Committee

Providing Legal Advice:
Sinead Glasgow, Legal Adviser to the HTA

Conflicts of Interest: members of the Committee declared no conflicts of interest in relation to this item.

The following papers were considered by the Committee:

- papers for Licence Committee (34 pages)
- no tabled papers.

1. The papers for this item were presented by Neelam Sood, HFEA Inspector. Dr Sood informed the Committee that this small centre has been licensed since 1995, and stores sperm for NHS patients prior to oncology treatment. Dr Sood updated the Committee about the two main issues identified at the centre's previous inspection: the requirement to split oncology samples and to install an auto-dialout to the low nitrogen level alarms. Both of these issues now been addressed.

2. Dr Sood further informed the Committee that the centre has fulfilled the recommendations made by the inspection team. However, the centre had appointed a new Nominal Licensee without having previously informed the Authority. They have since apologised for this lapse and have since submitted a CV for the person concerned.

3. The Committee agreed to remind the centre that only a Licence Committee can make the decision to vary a licence to change the Nominal Licensee. On the

basis of the supporting information included in the committee papers the Committee decided that Mr Sean Elyan was a suitable person to be the Nominal Licensee at the centre, and agreed to record this change on the centre's new licence.

4. The Committee noted the centre's low risk status and agreed to renew the centre's licence for a period of 5 years, with no conditions.

Signed…….. … Date……..
Clare Brown (Chair)