# HFEA Executive Licensing Panel Meeting

**16 January 2015**

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

## Minutes – Item 1

**Centre 0159 – (Royal Surrey County Hospital) – Renewal Inspection Report**

| **Members of the Panel:** | **Committee Secretary:** |
|---|---|
| Juliet Tizzard (Chair) Director of Strategy & Corporate Affairs | Dee Knoyle |
| David Moysen – Head of IT | **Observing:** |
| Ian Peacock – Analyst Programmer | Sam Hartley – Head of Governance & 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 of Application

1. The Panel considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that the Royal Surrey County Hospital is a storage only centre. The centre provides a sperm storage facility service, mostly for patients undergoing urological surgery, chemotherapy and radiotherapy.

3. The Panel noted that the centre has been licensed by the HFEA since 1994 and is on a four-year licence due to expire on 31 March 2015.

4. The Panel noted that at the time of the inspection on 16 October 2014, the Inspectorate identified three major and one other area of non-compliance. The Panel noted in particular, the non-compliances relating to standard operating procedure for transporting samples and the formal validation of critical equipment and critical processes. The Panel noted that the Person Responsible (PR) had committed to fully implementing the outstanding recommendations and urged the PR to work within the prescribed timescales.

5. The Panel noted that some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

6. The Panel noted the Inspectorate's recommendation to renew the centre's storage only licence for a period of four years without any additional conditions.

## Decision

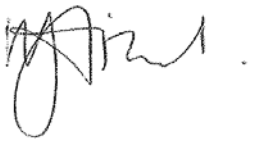
7. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

8. The Panel was satisfied that the qualifications and character of the PR was such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

9. The Panel noted that the premises to be licensed was suitable for the conduct of the licensed activities.

10. The Panel endorsed the Inspectorate's recommendation to renew the centre's storage only licence for a period of four years without any additional conditions.

11. The Panel agreed that all recommendations should be completed within the prescribed timescales. The Panel asked that the Inspectorate provide a progress report to the Executive Licensing Panel by the first week in March 2015.



Signed: Date: 30 January 2015

Juliet Tizzard (Chair)

# Inspection Report

## Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

**Date of inspection:** 16 October 2014.

**Purpose of inspection:** Renewal of a licence to carry out 'storage only'.

**Inspection details:** The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

**Inspectors:** Janet Kirkland MacHattie, Andrew Leonard.

**Date of Executive Licensing Panel:** 16 January 2015.

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|---|---|
| **Centre name** | Royal Surrey County Hospital |
| **Centre number** | 0159 |
| **Licence number** | L/0159/10/c |
| **Centre address** | Department of Cytopathology, Egerton Road, Guildford, Surrey, GU2 7XX, UK |
| **Person Responsible** | Mr Behdad Shambayati |
| **Licence Holder** | Dr Stephen Whitaker |
| **Date licence issued** | 01/04/2011 |
| **Licence expiry date** | 31/03/2015 |
| **Additional conditions applied to this licence** | None |

# Contents

# Section 1: Summary report

### Brief description of the centre and its licensing history:

The Royal Surrey County Hospital has held a 'storage only' licence with the HFEA since 1994. The centre provides a sperm storage facility service for self funding and NHS patients, most commonly for the preservation of fertility prior to urological surgical procedures or chemo/radiotherapy treatment. Sperm samples are maintained in storage and can be sent to a treatment centre to be used by the sperm provider and his partner in fertility treatment, if his fertility has been compromised. The centre does not store embryos nor are sperm samples received by the centre from other fertility units. The inspection team is satisfied that the activities carried out at the centre are necessary or desirable in order to provide licensed treatment services.

The current licence has been varied to reflect the following change: Following the retirement of the previous Person Responsible (PR), the ELP on 7 June 2013 approved an application by the centre to appoint Mr. Behdad Shambayati as the PR for the centre.

### Summary for licensing decision:

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the PR;
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged his duty under section 17 of the HF&E Act 1990 (as amended);
- the premises are suitable;
- the centre's practices are suitable;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were three major areas of non-compliance and one 'other' area of non-compliance.

Since the inspection visit, the following recommendation has been fully implemented:

'Other' area of non-compliance

- the PR should ensure that there is relevant health and safety signage in the laboratory.

The PR has given a commitment to fully implementing the following recommendations:

Major areas of non compliance:

- the PR should ensure that standard operating procedures (SOPs) are established to direct the processes for the safe transport of samples to other licensed centres;
- the PR should ensure that critical equipment in use at the centre is formally validated;
- the PR should ensure that critical processes performed at the centre are formally validated.

**Recommendation to the Executive Licensing Panel:**

The centre has no critical areas of concern but does have three major areas of concern and one 'other' area of concern. Some improvement is required in order for the centre to demonstrate the suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use it to best effect to monitor and improve the service provided.

The inspection team recommends the renewal of the centre's 'storage only' licence for a period of four years without additional conditions.

## Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

### 1. Protection of the patient and children born following treatment

| ▶ **Witnessing and assuring patient and donor identification** |
|---|
| **What the centre does well**<br><br>**Witnessing (Guidance note 18)**<br>The centre's procedures for checking the identity of patients prior to producing a sperm sample for storage and of those sperm samples during processing and storage, were considered to be compliant with HFEA requirements. |
| **What the centre could do better**<br><br>Nothing identified at this inspection. |

| ▶ **Donor selection criteria and laboratory tests**<br>Screening of donors prior to procuring, processing gametes and embryos<br>Payments for donors<br>Donor assisted conception |
|---|
| **What the centre does well**<br><br>**Screening of donors (Guidance notes 11)**<br>The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.<br><br>**Payments for donors (Guidance note 13; General Direction 0001)**<br>The centre does not recruit donors; therefore this area of practice is not relevant to this inspection.<br><br>**Donor assisted conception (Guidance note 20)**<br>The centre does not treat patients with donated gametes or embryos; therefore this area of practice is not relevant to this inspection. |

**What the centre could do better**

Not applicable

## Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

**What the centre does well**

**Safety and suitability of premises and facilities (Guidance note 25)**
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are broadly compliant with the requirement that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The centre does not have any satellite/transport facilities however the room where patients may produce samples is within a clinical area of the hospital. This was seen on inspection and considered to be satisfactory.

The centre is compliant with HFEA requirements to process gametes in an environment of appropriate air quality.

**Laboratory accreditation (Guidance note 25)**
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of patients, or their gametes, are compliant with HFEA requirements that they are accredited by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the services provided.

**Infection control**
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

**Medicines management; Pre-operative assessment and the surgical pathway; Multiple births (Guidance note 7; General Direction 0003)**
These areas of practice are not relevant to this inspection.

**Procurement of gametes and embryos (Guidance note 15)**
The centre's procedures are compliant with HFEA requirements to:

- document the justification for the use of the patient's gametes in licensed activity, based on the patient's medical history and therapeutic indications;
- where the sperm is procured at home, the centre keeps a record of this in the gamete provider's records.

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**
The centre does not store embryos. The centre's procedures for the transport, distribution and recall of gametes are partially compliant with HFEA requirements. It is important that these procedures are fully compliant to ensure that all gametes sent to other licensed centres within the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves their characteristics and biological functions;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- held within secure containers and packaging which ensure that the gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

**Receipt of gametes and embryos (Guidance note15)**
The centre does not receive gametes or embryos from other centres therefore this area of practice is not relevant to this inspection.

**Imports and exports (Guidance note 16; General Direction 0006)**
The centre does not import or export gametes or embryos therefore this area of practice is not relevant to this inspection.

**Traceability (Guidance note 19)**
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability:

- to identify and locate sperm samples during any step from procurement to use for human application or disposal;
- identify the provider of particular sperm samples;
- to identify any person who has carried out any activity in relation to particular sperm samples; and
- to identify and locate all relevant data relating to products and materials coming into contact with particular sperm samples which can affect their quality or safety.

**Quality management system (QMS) (Guidance note 23)**
The centre has a QMS in place that is compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

**Third party agreements (Guidance note 24)**
The centre's third party agreements are compliant with HFEA requirements.

**Transport and satellite agreements (Guidance note 24; General Direction 0010)**
The centre does not have transport or satellite agreements therefore this area of practice is not relevant to this inspection.

**Equipment and materials (Guidance note 26)**
The centre uses equipment and materials that are compliant with HFEA requirements. All of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is partially compliant with HFEA requirements to validate all critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

**Process validation (Guidance note 15)**
The centre is partially compliant with the HFEA requirement to validate all critical processes to ensure that they are effective and do not render gametes clinically ineffective or harmful to the recipient.

**Adverse incidents (Guidance note 27)**
Reporting and investigating adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services they offer.

The centre has not reported any incidents to the HFEA since the last inspection. This was discussed on inspection and the centre's own incident log was reviewed by the inspection team. It was possible to affirm that the centre has not had any reportable incidents and that the centre's procedures for reporting adverse incidents are compliant with HFEA requirements.

**What the centre could do better**

**Safety and suitability of premises and facilities (Guidance note 25)**
It was noted by the inspection team that there was no cryohazard and asphyxiation hazard warning signs displayed on the entrance to the cryostore (SLC T17; see recommendation 4).

**Transport and distribution of gametes and embryos (Guidance note 15; General Direction 0009)**
The centre does not have SOPs in place to describe the processes for the safe transport and distribution of gametes to other centres or for gamete recall and safe handling on return (SLC T105 - T108; see recommendation 1).

**Equipment and materials (Guidance note 26)**
The PR could not provide documented evidence of the validation of equipment used in providing treatment services e.g. the storage dewars and environmental monitoring system (SLC T24; see recommendation 2).

**Process validation (Guidance note 15)**
The PR could not provide documented evidence of the validation of critical processes and procedures followed in the provision of treatment services e.g. cryopreservation (SLC T72; see recommendation 3).

## Staff engaged in licensed activity

### Person Responsible (PR)

### Staff

**What the centre does well**

**Person Responsible (Guidance note 1)**
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme, PREP number T/1246/81.

**Staff (Guidance note 2)**
The centre is compliant with HFEA requirements relevant to staffing. The centre has suitably qualified and competent staff, in sufficient number, to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

**What the centre could do better**

Nothing identified at this inspection.

## Welfare of the child and safeguarding

**What the centre does well**

**Welfare of the child (Guidance note 8)**
The centre provides storage services only therefore this area of practice is not relevant to this inspection.

**Safeguarding**
It was considered that the centre's procedures are compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

**What the centre could do better**

Nothing identified at this inspection.

## Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

**What the centre does well**

**Preimplantation genetic screening (Guidance note 9);**
**Embryo testing and sex selection (Guidance note 10)**
These areas of practice are not applicable to this inspection.

**What the centre could do better**

Not applicable

## 2. The experience of patients

### Patient feedback

**What the centre does well**

The inspection team did not talk to any patients since none were attending the centre at the time of the inspection but it was also considered inappropriate for inspectors to seek feedback from patients at such a sensitive time in their lives. The inspection team did however discuss with the PR ways in which he could assess the patient experience. The PR described a process recently introduced, whereby a short questionnaire is sent to each patient following their completion of storage inviting them to comment on their experience at the centre.

On the basis of discussions with the centre team and from observations made in the course of the inspection, it was possible to assess that the staff at the centre take particular care to:

- respect the privacy and confidentiality of patients in the clinic;
- give patients sufficient, accessible and up-to-date information to enable them to make informed decisions;
- provide patients with satisfactory facilities for their care.

**What the centre could do better**

Nothing identified at this inspection.

### Treating patients fairly

**Counselling**
**Egg [and sperm] sharing arrangements**
**Surrogacy**
**Complaints**
**Confidentiality and privacy**

**What the centre does well**

**Treating patients fairly (Guidance note 29)**
The centre's procedures are compliant with the HF&E Act 1990 (as amended) to ensure that staff members understand the requirements for conscientious objection to providing a particular licensed activity governed by the Act.

The centre's procedures are compliant with requirements to ensure that prospective and current patients are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

**Counselling (Guidance note 3)**
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to patients providing relevant consent.

**Egg [and sperm] sharing arrangements (Guidance note 12; General Direction 0001)**
**Surrogacy (Guidance note 14)**
These areas of practice are not applicable to this inspection.

**Complaints (Guidance note 28)**
The centre's procedures are compliant with HFEA requirements to seek patient feedback and to be responsive to patient complaints. This is important to ensure that the centre uses patient feedback and any complaints as an opportunity to learn and improve their services.

**Confidentiality and privacy (Guidance note 30)**
The centre's procedures are compliant with HFEA requirements and ensure the centre has respect for the privacy, confidentiality, dignity, comfort and well-being of prospective and current patients.

**What the centre could do better**

Nothing identified at this inspection.

## Information

**What the centre does well**

**Information (Guidance note 4; CH(11)02)**
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients accessible and up-to-date information to enable them to make informed decisions.

**What the centre could do better**

Nothing identified at this inspection.

## Consent and Disclosure of information, held on the HFEA Register, for use in research

**What the centre does well**

**Consent (Guidance note 5;6)**
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that patients have provided all relevant consents before carrying out any licensed activity.

**Disclosure of information held on the HFEA Register, for use in research (General Direction 0005)**
The centre provides storage services only and does not ask patients to consider consent to disclosure to researchers, therefore this area of practice is not applicable to this inspection.

**What the centre could do better**

Nothing identified at this inspection.

## 3. The protection of gametes and embryos

### Respect for the special status of the embryo

**What the centre does well**

The centre does not store embryos therefore this area of practice is not relevant to this inspection.

**What the centre could do better**

Not applicable

### Screening of patients
### Storage of gametes and embryos

**What the centre does well**

**Screening of patients (Guidance note 17)**
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during processing and storage of gametes and any subsequent use in treatment.

**Storage of gametes and embryos (Guidance note 17)**
The centre's procedures for storing sperm are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores sperm in accordance with the consent of the gamete providers. The storage of sperm is an important service, as it can enable patients to preserve their fertility prior to undergoing other medical treatment such as radiotherapy.

**What the centre could do better**

Nothing identified at this inspection.

### Use of embryos for training staff (Guidance note 22)

**What the centre does well**

**Use of embryos for training staff (Guidance note 22)**
Embryos are not stored at the centre and therefore this area of practice is not applicable to this inspection.

**What the centre could do better**

Not applicable.

## 4. Information management

**Record keeping**
**Obligations and reporting requirements**

**What the centre does well**

**Record keeping and document control (Guidance note 31)**
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained. Good medical records are essential for the continuity of the patient's care.

**Obligations and reporting requirements (Guidance note 32 ; Direction 0005)**
The centre does not undertake patient treatment therefore this area of practice is not applicable to this inspection.

**What the centre could do better**

Nothing identified at this inspection.

## Section 3: Monitoring of the centre's performance

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

The PR provided information and evidence that the recommendations were implemented within reasonable timescales:

### On-going monitoring of centre success rates

The monitoring of success rates is not applicable to this inspection because the centre does not provide treatment services.

# Areas of practice requiring action

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 to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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 | Executive Review |
|---|---|---|---|
| None | | | |

## 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 to a 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 | Executive Review |
|---|---|---|---|
| 1. The centre does not have SOPs in place to describe the processes for the safe transport and distribution of gametes to other centres or for gamete recall and handling (SLC T105 - T108). | The PR should ensure that SOPs are produced to direct the processes for the safe transport of gametes to other licensed centres and for gamete recall and handling. The SOPs should include all of the requirements of SLCs T105 - T108.<br><br>The PR should ensure that all relevant staff are aware of the establishment of these SOPs and the processes described within them.<br><br>The SOPs should be provided to the HFEA by 16 January 2015. | SOP is in place.<br>Please see attached. | The inspector has reviewed the SOP and considers that it does not include all of the requirements of SLCs T105-T108.<br><br>The PR should refer to the appropriate licence conditions and ensure that the SOP accurately reflects the requirements in addition to ensuring that all staff are aware of the requirements and are trained appropriately in the safe transport of gametes.<br><br>The amended SOP and evidence of staff training to be submitted to the inspector by 23 January |

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| | | | 2015.<br><br>Further action required. |
| 2. Critical equipment in use at the centre has not been formally validated.<br>(SLC T24) | The PR should provide a list of all critical equipment including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the time this report is considered by a licensing committee.<br><br>The PR should provide monthly updates to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk and that validation will be complete by 16 April 2015.<br><br>On completion of the validation programme, the HFEA will ask for a sample of validation documents to be submitted for review. | We will be validating the following:<br>1. Manual Sealer and Cryotubes - this is almost complete. This will be completed by end of Dec 2014.<br><br>2. Incubator and fridge. This will be completed by the end of Dec 2014.<br><br>3. DEWARs. This will be completed by end Jan 2015.<br><br>4. Pipettes. This will be completed by the end of Jan 2015. | The PR's response is acknowledged. The centre's inspector will request a sample of validation documents to be submitted for review in February 2015.<br><br>The PR is also asked to review the list provided to ensure all critical equipment has been included, for example the environmental monitoring system and class two cabinets.<br><br>The revised list should be submitted to the centres inspector by 16 January 2015. |
| 3. Critical processes performed at the centre have not been formally validated.<br>(SLC T72). | The PR should provide a list of all procurement and processing procedures that are considered critical, including the date of validation or the planned date by which validation is expected to be complete. The list should be provided to the HFEA by the time this report is considered by a licensing committee.<br><br>The PR should provide monthly updates | We will be validating the following:<br><br>1.Freezing and use of cryoprotectant. This will be completed by end Jan 2015.<br><br>2.Splitting the sample. This will be completed by end of Jan 2015 | The PR's response is acknowledged and the PR is asked to submit the two validation documents to the centre's inspector in February 2015. |

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| | to the HFEA on progress in completing validation. It is expected that validation will be prioritised on the basis of risk associated with the procedure and that validation will be complete by 16 April 2015.<br><br>On completion of the validation programme the HFEA will ask for a sample of validation documents to be submitted for review. | | |

## 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 | Executive Review |
|---|---|---|---|
| 4. The inspection team noted that there was no appropriate hazard warning signage in relation to the cryostore. (SLC T17). | The PR should, in collaboration with Health and Safety officers at the hospital, ensure that relevant health and safety signage is in place to alert personnel to the dangers of tissue damage and asphyxiation from liquid nitrogen spillage or leak in the cryostore.<br><br>The PR must ensure that all relevant personnel are aware of the risks involved in the use of liquid nitrogen.<br><br>Evidence of the implementation of this recommendation should be provided to the HFEA by 16 January 2015. | In place. Please see attached photo. | 7 November 2014:<br>After the inspection, the PR and centre staff agreed to send photographic evidence of safety signage when it is fitted to the cryostore, as well as evidence of staff training regarding the risks associated with liquid nitrogen usage.<br><br>Following the inspection visit the PR and relevant team members visited another licensed centre to observe their signage and to discuss best practice.<br><br>The PR assures the inspector that the health and safety issues of using liquid nitrogen are included in the induction to the centre and competencies which were seen on inspection.<br><br>No further action. |

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| Reponses from the Person Responsible to this inspection report |
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