Inspection Report

Date of Inspection: 12 May 2011
Purpose of inspection: Licence Renewal Inspection
Length of inspection: 6 hours
Inspectors Parvez Qureshi
Jason Kasraie

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 6 May 2010 and 26 August 2011

Date of Executive Licensing Panel: 26 August 2011

Purpose of the Inspection Report
The purpose of the inspection is to assess whether centres are complying with the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the Human Fertilisation and Embryology (HF&E) Act 2008 and the Code of Practice, to ensure that centres are providing a quality service for patients. The report summarises the findings of the licence renewal inspection highlighting areas of good practice, as well as areas where further improvement is required to improve patient services and meet regulatory requirements. It is primarily written for the Authority's Executive Licensing Panel which makes the decision about the centre's licence renewal application.

Centre details

Centre name	Gloucestershire Hospitals NHS Trust
Centre number	0151
Licence number	L0151/10/c
Centre address	Microbiology Department Gloucestershire Royal Hospital Great Western Road Gloucester GL1 3NN
Person Responsible	Dr Alan Lees
Licence Holder	Dr Sean Elyan
Date licence issued	01/11/2006
Licence expiry date	31/10/2011
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

This sperm storage centre is located immediately outside the Microbiology Department at the Edward Jenner laboratories, Royal Gloucester Hospital. The hospital is part of the Gloucestershire Hospitals NHS Foundation Trust.

The storage centre was granted an HFEA storage licence by a Licence Committee in June 2008, following its move from the Pathology Department, Cheltenham General Hospital, where it had held an uninterrupted HFEA licence since 1995.

The centre offers a sperm storage service for oncology patients in the Gloucestershire, Herefordshire and Worcestershire area. Patients are able to produce sperm at home or at the dedicated facility at the centre.

The centre is currently licensed for procurement and distribution of gametes, processing of gametes and storage of gametes and the Person Responsible (PR) at the centre has confirmed that they wish to renew their licence for all these activities.

The PR is a Consultant Microbiologist and is registered with the General Medical Council (GMC) and has successfully completed the PR Entry Programme.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period
None (Storage only)	N/A

Other licensable activities	✓ or Not applicable (N/A)
Storage of eggs	(N/A)
Storage of sperm	✓
Storage of embryos	(N/A)
Research	(N/A)

Summary for licensing decision

In considering overall compliance, the inspection team considers that they have sufficient information drawn from documentation submitted by the centre prior to inspection and from observations and interviews conducted during the inspection visit to conclude that:

- the PR is suitable and has, with the exception of the areas of non-compliance identified in this report, discharged his duty under section 17 of the HF&E Act 1990 (as amended)
- the premises are suitable
- the practices are suitable
- the centre has submitted appropriately completed documentation in accordance with 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 Executive Licensing Panel is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including four major areas of non-compliance and two other areas of non-compliance or areas of poor practice.

Since the inspection visit on 12 May 2011 the PR has confirmed and provided evidence that the following recommendations have been fully implemented:

Major areas of non compliance*:*

- PR should ensure that all critical equipment is validated.
- The PR should establish and document quality indicators (QIs) relevant to all activities authorised by the licence.
- The PR should identify all activities authorised by the licence to be audited.

Other areas of practice that require improvement:

- The PR should ensure that the centre's organisational chart clearly defines accountabilities and reporting lines.

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

Major areas of non compliance:

- The PR should ensure that all critical processes are validated.

Other areas of practice that require improvement:

- The PR should ensure that the assessment of staff competence to perform their designated tasks is documented as detailed in the body of this report.

Recommendation to the Executive Licensing Panel

The inspection team considers that, overall there is sufficient information available to recommend the renewal of this centre's licence for a period of 4 years without additional conditions. In making this recommendation it is noted that the PR has responded to most of the recommendations made in this inspection report.

Details of inspection findings

1. Protection of patients and children born following treatment

Focus

The purpose of the inspection was to assess whether the centre:

- conducts all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring
- takes into account the welfare of any child who may be born as a result of the licensed treatment provided by the centre, and of any other child who may be affected by that birth
- ensures that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose
- reports all adverse incidents (including serious adverse events and reactions) to the HFEA, investigates all adverse incidents and shares lessons learned appropriately

▶ Witnessing and assuring patient and donor identification (Guidance Note 18)

What the centre does well.

Witnessing – Guidance Note 18

Review of the centre's witnessing standard operating procedure (SOP) and of laboratory sheets indicated that the identification of samples and patients at all critical points is witnessed by two members of staff. This is documented appropriately at the time of the procedure as required by Standard Licence Condition (SLC) T71. Six sets of patients' notes were audited for witnessing during the inspection, all were found to contain a record of all required witnessing checks, including the names, status and signatures of staff performing the checks (Code of Practice (CoP) Guidance 18.8).

Documented evidence was provided by the PR and the laboratory staff showing that the centre has established quality indicators (QI) relevant to witnessing; these QIs are audited and, where required, corrective actions are documented and implemented (SLCs T35 and T36). Also staff involved in witnessing provided documented evidence of the assessment of their competence to perform witnessing (SLC T15 (a)).

What the centre could do better.

Nothing noted.

Good clinical practice

- Quality management system (Guidance Note 23)
- Traceability (Guidance Note 19)
- Validation (Guidance Note 15)
- Equipment and materials (Guidance Note 26)
- Premises – suitability of the premises and air quality (Guidance Note 25)
- Adverse incidents (Guidance Notes 27)
- Third party agreements (Guidance Note 24)

What the centre does well.

The quality management system – Guidance Note 23
The Department of Pathology of the Gloucestershire Hospitals NHS Trust has a well developed quality management system (QMS), which incorporates the HFEA licensed activities undertaken by the centre located within the Microbiology Department (SLC S32). The QMS consists of a quality manual and training and reference manuals, as required by (SLC T33).The centre has established QIs for licensed activities and has conducted audits of all activities except for traceability. The findings of the audits and, where required, the corrective actions taken were seen on inspection (SLCs T35 and T36).

A process is in place for the annual review of the performance of the QMS to ensure continuous and systematic improvement. Evidence of this was submitted as part of the renewal application.

The PR reported that a document control procedure is in place that records the history of document reviews and ensures that only current versions of documents are in use (SLC T34). Evidence of this was noted from the documents submitted for inspection and those reviewed during the course of the inspection.

Traceability (Guidance Note 19)
All gametes are traceable from procurement to any patient treatment or disposal (SLC T99). A process is in place to ensure that all relevant data relating to anything coming into contact with those gametes is traceable. Containers are, at all stages of procurement, processing and storage, labelled with the patient's name and a unique identifier (SLC T89). There is a documented SOP in place to ensure traceability of all gametes (SLC T87). The centre has a procedure in place to ensure that any data necessary for traceability is stored for at least 30 years (SLC T91). Also, staff reported that it was centre's policy to keep data ten years post sample disposal.

Equipment and materials (Guidance Note 26)
Documented evidence was seen of the regular cleaning and disinfection of equipment, the maintenance and regular inspection of equipment in accordance with manufacturer's instructions. In addition, documented evidence was made available during the inspection showing that key equipment that affects critical processing or storage parameters is subject to monitoring, alerts and alarms (SLCs T24 and T26).

Premises – suitability of the premises and air quality (Guidance Note 25)
The activities authorised by the licence are carried out in the premises specified in the licence (SLC T1). All licensed premises (except for the cyostore facilities which are located in a stand-alone building nearby and has been subject to a previous inspection) are located within the same building. A copy of the centre's licence was seen on display in the

main entrance of the building (SLC T5). Review of documents submitted for the inspection and discussions with the laboratory staff showed that the critical work area where gametes are processed achieves Grade C air quality, with a background within the laboratory of Grade D air quality (SLC T20).

Adverse incidents (Guidance Notes 27)
Since the last inspection in May 2010, no reportable adverse incidents had taken place at the centre. The centre has a documented procedure in place for the reporting of adverse incidents to the HFEA (SLC T118). Members of staff were able to demonstrate their understanding of this during discussions with the inspection team.

Third party agreements (Guidance Note 24)
A list of all third party agreements established with third parties who provide goods and services that influence the quality and safety of gametes was seen by the inspectorate (SLCs T111 and T115). The PR reported that no issues have arisen with regard to the ability of third parties to meet the required standards (SLC T112). A review of three third party agreements showed that their content was compliant with requirements (SLC T114).

What the centre could do better.

Traceability (Guidance Note 19)
The centre has established QIs for traceability but these have not been audited or reviewed yet (SLC T36).

Validation (Guidance Note 15 and 26)
The centre has documentation in place for the validation of all critical equipment and cryopreservation processes which influence the quality and safety of gametes but these have not been validated (SLCs T24 and T71).

Equipment and materials (Guidance Note 26)
Not all equipment with a critical measuring function is subject to calibration, laboratory staff were not able to provide calibration records for thermometers and incubators (SLC T24).

Staff engaged in licensed activity

- Person Responsible (Guidance Note 1)
- Staff (Guidance Note 2)

What the centre does well.

Person Responsible (Guidance Note 1)
With the exception of the areas of non-compliance identified in this report, the PR has carried out his duties in accordance with Section 17 (1) (a) of the HF&E Act 1990 (as amended) as documented throughout the body of this report.

Staff (Guidance Note 2)
The PR is the centre's nominated registered medical practitioner and therefore is able to advise on and oversee the medical activities (SLC T16). The centre has assessed the workforce requirements within the last year (CoP 25.10). The PR reported that currently they are operating with a full staff complement and he considered that the number of staff

is adequate for the current volume of work being undertaken by the centre (SLC T12).

There is a documented induction training programme in place for all staff, evidence of this was seen in the training records for the biomedical scientist who has received training in cryopreservation and witnessing. Also, a review of staff training records showed staff having adequate opportunity for relevant professional development, including attendance at conferences and other continuous professional development (CPD) related events (SLC T15).

Counselling: Guidance Note 3
The PR reported that all oncology patients are offered the opportunity of receiving counselling prior to storage of their sperm. Documented evidence of this was seen in patient records reviewed during the inspection. However the uptake rate of counselling is low. Feedback on the counselling service is monitored via regular patient surveys; evidence of this was noted in an analysis of a patient questionnaire conducted in February 2011.

Since the last inspection in May 2010, a new counsellor has been appointed at the centre and is working towards accreditation through the British Infertility Counselling Association (BICA) accreditation scheme (CoP 2.12(b)).

What the centre could do better.

Staff (Guidance Note 2)
The centre has an organisation chart is in place which defines accountability and reporting relationships. However, it does not reflect all the recent staff changes which have taken place at the centre (SLC T11).

2. Patient Experience

Focus

The purpose of the inspection visit was to assess whether the centre:

- treats prospective and current patients and donors fairly, and ensures that all licensed activities are conducted in a non-discriminatory way
- has respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors
- gives prospective and current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions
- ensures that patients and donors have provided all relevant consents before carrying out any licensed activity

Treating patients fairly

- Treating patients fairly (Guidance Note 29)
- Confidentiality and privacy (Guidance Note 30)
- Complaints (Guidance Note 28)
- Provision of a costed treatment plans (Guidance Note 4)
- Egg sharing arrangements (Guidance Note 12) – *if applicable*
- Surrogacy (Guidance Note 14) – *if applicable*

What the centre does well.

Treating patients fairly (Guidance Note 29)
Members of staff reported that there are Trust policies in place on treating patients fairly, which ensure all licensed activities are conducted in a non-discriminatory manner.

Confidentiality and privacy (Guidance Note 30)
Discussions held with staff, a review of information submitted prior to the inspection and the tour of the premises indicate that the privacy, confidentiality, dignity, comfort and well being of patients is maintained (CoP 29.3).

All patient information at the centre is kept confidential. Patient records are kept in a secure area and only staff on the centre‘s licence have access to confidential information. (SLC T43). There is a Trust policy in place to ensure that information is only disclosed in circumstances permitted by law (SLC T43). A SOP for the control of access to health data and records was also seen and was compliant with requirements (SLC T44). The PR reported that as part of the Trust policy all staff have been trained in the maintenance of confidentiality and documented evidence of this was seen during inspection (SLC T15(a)).

Complaints (Guidance Note 28)
Since the last inspection in May 2010, the centre and the HFEA have not received any complaints regarding this centre. There is a complaints procedure in place and staff were able to demonstrate their understanding of how they would resolve a complaint.

What the centre could do better.

Nothing noted.

Information

- Information to be provided prior to consent (Guidance Note 4)

What the centre does well.

Information to be provided prior to consent (Guidance Note 4)

The centre's patient information submitted for the inspection was found to provide the following:

- Sperm collection and storage conditions
- Analytical tests required prior to storage.
- Information on success rates using frozen sperm.
- Consenting for posthumous use of gametes and the requirement on the centre to dispose of stored samples once consent has expired.
- Availability of counselling.

Staff reported that all relevant patient information is discussed with patients during the consultation stage and a record of this is kept in the notes. Evidence of this was seen during a review of patients' notes showing that a checklist for providing information is in place and being used. Also, the centre conducts regular audits for providing information and evidence of this was seen during the inspection.

What the centre could do better.

Information to be provided prior to consent (Guidance Note 4)
Although audits are conducted, the centre has not established QIs for providing information (SLC T35).

Not all staff were able to provide documented evidence of the assessment of their competence to provide information to those consenting to storage (SLC T15(b)).

Consent

- Consent to treatment, storage, donation, training and disclosure of information (Guidance Note 5)

What the centre does well.

Consent to storage and disclosure of information: Guidance Note 5
Five sets of patient notes examined during the inspection were found to contain effective consent for storage of sperm. There is a SOP in place for the process to be followed when obtaining consent for storage (SLC T33(b)). Staff confirmed that the identity of the person providing consent is verified, including examining photographic evidence, when consent is provided (CoP 5.10). The identity of the person who gave consent is also cross referenced to the records when service is provided (CoP 5.11). The centre has established QIs relevant to obtaining consent and documented evidence of these being audited in August 2010 was made available for the inspection, and corrective actions have been documented and implemented (SLCs T35 and T36).

What the centre could do better.

Nothing noted.

3. Protection of gametes and embryos

Focus

The purpose of the inspection was to assess whether the centre has respect for the special status of the embryo when conducting licensed activities

Storage of gametes and embryos

- Storage of gametes and embryos (Guidance Note 17) – *only applicable for centres licensed to store gametes and / or embryos*

What the centre does well.

Storage of gametes (Guidance Note 17)
The centre has a SOP in place documenting the process to be followed when storing gametes (SLC T33(b)). The centre has established QIs relevant to storage (SLC T35). All stored samples are within their statutory storage period and the centre operates a bring-forward system to ensure that samples are not stored beyond their consented storage period (HF&E Act (1990) as amended, 14(1)(c)).

Storage tank audits were conducted for sperm samples in January 2011, which reviewed the stored samples against the storage logs and the storage consents. Where necessary, nonconformities and corrective actions were documented and implemented (SLC T36). Prior to storage, gamete providers are screened for HIV 1 and 2, and hepatitis B and C. In the event of any positive results the centre has facilities to store samples separately (SLC T50). All screening tests are carried out by a laboratory which is accredited by Clinical Pathology Accreditation (CPA) UK Ltd.

What the centre could do better.

Storage of gametes (Guidance Note 17)
Storage processes have not been validated SLC T72.

Distribution and / or receipt of gametes and embryos

- Distribution of gametes and embryos (Guidance Note 15) – *only applicable for centres that has distributed or exported gametes and / or embryos*

What the centre does well.

The centre has a SOP in place that details circumstances, responsibilities and procedures for the release of stored material prior to distribution to other licensed centres. The SOP also defines the critical transport conditions, such as temperature, to ensure that the integrity of the samples is maintained during distribution (SLCs T33(b), T95 and Act Schedule 3A). Evidence was provided by the laboratory staff indicating that the centre's transport container was fit for purpose (T94). Also there is a procedure in place for an effective recall and the handling of returned material. All required information is provided with the distributing material, evidence of this was seen during the inspection (Act Schedule 3A (11).

What the centre could do better.

Nothing noted.

4. Good governance and record keeping

Focus

The purpose of the inspection was to assess whether the centre:

- maintains accurate records and information about all licensed activities
- conducts all licensed activities with regard for the regulatory framework governing treatment involving gametes and embryos within the UK, including
    - maintaining up-to-date wareness and understanding of leal obligations
    - responding promptly to requests for information and documents from the HFEA
    - co-operates fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare

Record keeping

- Record keeping and document control (Guidance Note 31)

What the centre does well.

Record keeping and document control: Guidance Note 31
Patient records reviewed at the time of inspection were seen to be clear, legible, well organised and complete. Each record reviewed was seen to include the patient's first name, surname, date of birth, age and sex. Details of how the patient had been identified by staff were also evidenced. Patients notes also included details of the service provided to them, a medical history; relevant documented consents, laboratory data and the results of tests carried out (SLC T46). The centre has procedures in place to ensure that records are protected from unauthorised amendment and are retained and readily retrieved in this condition throughout their specified retention period (SLC T47).

What the centre could do better.

Nothing noted.

Legal requirements [Human Fertilisation and Embryology Authority 1990 (as amended)]

- Obligations and reporting requirements of centres (Guidance Note 32)

What the centre does well.

Obligations and reporting requirements of centres – Guidance Note 32
The PR provided all information required by the application process prior to inspection. Centre staff cooperated fully with the inspection team and all further information requested for the inspection was provided in a timely manner. The PR has responded to the recommendations from the previous inspection.

What the centre could do better.

Nothing noted.

Disclosure of information

- Confidentiality and privacy (Guidance Note 30)

What the centre does well.

Confidentiality and privacy (Guidance Note 30)
Discussions held with staff, a review of information submitted for the inspection and the tour of the premises indicated that information about patients is not disclosed unless authorised to do so (SLC T43)

What the centre could do better.

Nothing noted.

5. Changes / improvements since the previous inspection on 6 May 2010

Area for improvement	Action required	Action taken as evidenced during this inspection
The PR confirmed that the liquid nitrogen supplier's driver, responsible for topping up the liquid nitrogen reservoir tanks, has his own key to the cryostore and is not always accompanied by licensed personnel. After the delivery, the security of the cryostore is not immediately checked by licensed staff. CoP Guidance note 17.5	The PR should ensure that a licensed person is present during the filling of the liquid nitrogen reservoirs and when the cryostore is locked afterwards.	The PR reported that the driver no longer has a key and is now accompanied by licensed personnel whilst at the cryostore. No further action required.
The witnessing of all pots and ampoules against the patient's records at the end of laboratory processing of sperm is performed, but a witnessing check is not performed on sample received in the laboratory or at the start of processing, as is required by Licence Condition T71 and CoP Guidance 18.4 and 18.30. In addition, while the witness at the end of processing, documents the check in patient records, the processor does not. Licence Condition T71 CoP Guidance 18.4 and 18.30.	The PR should review the witnessing protocols, practices and documentation to ensure that the identity of samples and the patients to whom they relate are double checked at all critical points of the clinical and laboratory process. These checks must be completed and recorded at the time the relevant clinical or laboratory process/procedure takes place. A record must be kept in each patient's medical records. These records must include the name, status and signature of the person performing the activity and the name, status and signature of the person who witnesses the procedure.	Sample processing and witness checks documentation have been updated to include these requirements. No further action required.
Third party agreements have not been completed with all suppliers whose goods/services may have an impact on the quality of the gametes. Licence Condition T111	The PR needs to ensure that a written third party agreement is put into place between the Microbiology (licensed premises) and Oncology departments the Gloucestershire Hospitals NHS Foundation Trust	Evidence was provided by the PR showing that third party agreements have been established with all services and suppliers that influence the quality of and safety of gametes.

		No further action required.
The oncology nurse and the radiology oncology counsellor are not part of the centre's mailing list and may not be aware of changes to SOPs or alerts pertaining to the service. Licence Condition T15 CoP Guidance 2.1(f)	The PR needs to add the oncology nurse and radiology oncology counsellor to the centres mailing list, to ensure that they are informed of changes to policies, SOPs, procedures and informed of alerts.	The PR confirmed that all personnel on the centre's licence are included on an email distribution list and are informed of all relevant information including that from the HFEA. No further action required.
Names of the manufacturers who provide consumables are not recorded. This information is required in order to be compliant with licence conditions T99 & T100 (f)	To ensure full compliance with licence condition T100, the PR needs to review the traceability SOP and documentation to ensure that manufacturers' names are recorded.	Sample processing and witness checks documentation have been updated to include these requirements. No further action required
The liquid nitrogen reservoirs are removed from the storage area and filled some 15 metres away from the actual storage block in a publicly accessible area. Licence Condition T23	The PR should undertake a risk assessment for the process of filling the liquid nitrogen reservoirs in a publicly accessible area.	The PR provided documented evidence confirming that a risk assessment had been undertaken. No further action required.
The transportation SOP governing the use of the dry shipper does not list the information required to be included with the dry shipper and on its label when in use, or detail appropriate recall procedures, as required by HF&E Act 1990 (as amended), Schedule 3A Licence Condition T107	The PR should review the transportation SOP to ensure that it includes all information required to be included with the dry shipper and on its label when in use, and details appropriate recall procedures, to comply with HF&E Act 1990 (as amended), Schedule 3A,.	The centre has a SOP in place for Transport of Cryo samples which includes all the information required to be included with the dry shipper and on its label when in use, and details appropriate recall procedures. No further action required.
Evidence presented on the day of the inspection indicated that validation of equipment is being undertaken. However, the evidence did not demonstrate how the centre	The PR should ensure that evidence is available to demonstrate how equipment has been assessed as 'fit for purpose' and has been revalidated after repair	Since the last inspection in May 2010, no re-validation of equipment has been performed. However, in the event of this being required then the centre has a documented procedure in

had been assured that the equipments was 'fit for purpose' or that it had been re-validated following service or repair. Licence Condition T25		place to for assessing whether any equipment was 'fit for purpose' or it required re-validating after service or repair. No further action required.
The SAQ stated that audit of witnessing procedures had been carried out in the last two years and the findings documented and corrective actions implemented. Observations regarding non-compliant witnessing practices, detailed above, suggest that a further audit of witnessing protocols and practices against the regulatory requirements is needed. Licence Condition T36	The PR should undertake a witnessing audit against compliance with protocols, regulatory requirements and quality indicators. The findings of this audit and corrective actions taken should be documented. to achieve compliance with T36	Documented evidence was made available showing that, since the last inspection in May 2010, further audits of witnessing had been undertaken. No further action required.
Although the radiology oncology counsellor holds a certificate, an advanced diploma and an MSc in counselling, and is a member of the BICA, she has not been accredited by the BICA. Licence Condition T12	The PR needs to assure himself that the staff working under the auspices of the licence are qualified, trained and experienced, so as to be suitable persons to participate in the activities authorised by the licence.	A new counsellor has been appointed at the centre and is working towards accreditation through the British Infertility Counselling Association (BICA) accreditation scheme. No further action required.
The SAQ stated that the centre has not established QIs or objectives relevant to witnessing, non-compliant with Licence Condition T35.	Centre staff described plans to implement QIs for witnessing and it is recommended that these plans are devised and implemented to achieve compliance with T35	Evidence was seen showing that the centre has established QIs relevant to witnessing. No further action required.

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 to a 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	Executive Review
None identified at the time of this inspection.			

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
The centre has not validated all critical equipment. SLC T24.	The PR should ensure that all critical equipment is validated. This action should be implemented by 12 November 2011. An action plan of how this is to be achieved within the required timeframe, identifying all equipment which needs to be validated, should be submitted to the lead inspector at the same time that the PR responds to this report.	Validation of critical equipment (including validation certificates for temperature mapping of dewars) has been undertaken and documentation was reviewed by the inspection team	The inspectorate considers this to be an acceptable response.
The centre has not validated all critical processes. SLC T72.	The PR should ensure that all critical processes are validated. This action should be implemented by 12 November 2011. An action plan of how this is to be achieved within the required timeframe, identifying all processes which need to be validated, should be submitted to the lead inspector at the same time that the PR responds to this report.	A significant amount of process validation work has been undertaken by the department and shown to the inspection team. Further process validation is being undertaken as part of the ABA course on sperm cryopreservation and should be completed by November 2011.	The inspectorate considers this to be an acceptable response. Progress to be monitored.

The centre has not established QIs relevant to all activities authorised by the licence. SLC T35	The PR should establish and document QIs relevant to all activities authorised by the licence. An action plan of how and when this is to be achieved is to be submitted to the lead inspector with the PR's response to this report.	An expanded list of QIs has now been produced which cover all activities authorised by the licence.	Following review of the submitted information, the inspectorate considers this to be an acceptable response.
The centre has not audited all key activities within the last two years. SLC T36	The PR should identify the key activities to be audited against the centres SOP's, quality indicators and regulatory requirements. A schedule of audits should be formulated by 12 August 2011.	The department already undertakes significant audit activity and an audit schedule has been produced. In addition a vertical audit tool has been produced and audit undertaken on 6th July 2011	Following review of the submitted information, the inspectorate considers this to be an acceptable response.

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
The centre's current organisational chart does not reflect all the recent staff changes which have taken place at the centre. SLC T11	The PR should ensure that the centre's organisational chart clearly defines accountabilities and reporting lines. This action should be completed by the time the PR responds to this report.	This has now been undertaken by the Quality Manager.	Following review of the updated organisational chart, the inspectorate considers this to be an acceptable response.

Staff were not able to provide documented evidence of the assessment of their competence to perform their designated tasks. Standard licence condition T15a	A formal plan for the regular assessment of staff competence to perform their designated tasks should be documented and implemented. This action should be completed by 12 November 2011.	All centre staff have an annual appraisal and a microbiology department competency scheme is in place. A draft consent training protocol has now been produced and will be agreed prior to November 2011.	The inspectorate considers this to be an acceptable response. Progress to be monitored and subject to review at the time of the next inspection.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting

26 August 2011

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

Minutes – Item 1

Centre 0151 (Gloucestershire Hospitals NHS Trust) – Renewal Inspection Report

Members of the Panel:	Committee Secretary:
Mark Bennett, Director of Finance & Facilities (Chair) Nick Jones, Director of Compliance Ian Peacock, Analyst Programmer	Lauren Crawford

Declarations of Interest: members of the Panel declared that they had no conflicts of interest in relation to this item.

The Panel also 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 noted that the centre is located outside of the Microbiology Department at the Edward Jenner laboratories, Royal Gloucester Hospital.

2. The Panel noted that the centre is currently licensed for procurement and distribution of gametes, processing of gametes and storage of gametes.

3. The Panel noted the centre was granted an HFEA storage licence in June 2008, following its move from the Pathology Department, Cheltenham General Hospital, where it had an uninterrupted licence since 1995.

4. The Panel noted that, at the time of the inspection, the Inspectorate identified a number of areas of practice that required improvement, including four major areas of non-compliance and two other areas of non-compliance or poor practice.

5. The Panel noted that, since the inspection, the Person Responsible (PR) has provided evidence to the Inspectorate that three major and one other areas of non-compliance have been fully implemented.

6. The Panel noted that one of the major areas of non-compliance referred to the validation of all critical processes. The Panel also noted that the PR has committed to implementing this recommendation.

7. The Panel noted the Inspectorate's recommendation to renew the centre's licence for a four year period with no additional conditions.

8. The Panel confined its consideration to the evidence before it.

The Panel's Decision

9. The Panel referred to its decision tree. It was satisfied that the appropriate application and fee had been submitted, and contained the supporting information required by General Direction 0008.

10. The Panel was satisfied that the qualifications and character of the PR is such as is required for the supervision of the licensed activities and that the PR will discharge the duties under section 17 of the HF&E Act 1990 (as amended).

11. The Panel was satisfied that the licence renewal application concerns treatment, storage or non-medical fertility services which relate to gametes or embryos intended for human application.

12. The Panel was satisfied that premises to be licensed are suitable for the conduct of licensed activities based on evidence provided within the report.

13. The Panel referred to 'Guidance on periods for which new or renewed licences can be granted'. The Panel took into account matters set out in

paragraph 4.3 and noted paragraph 4.4 of the guidance which states [The Executive Licensing Panel] will normally only grant a renewal licence for treatments/ storage non-medical fertility services licence for a period of up to four years where the evidence before it reveals no concerns in the matters specified in paragraph 4.3.

14. The Panel considered it had no concerns in the matters specified as the centre and PR had either already addressed or committed to resolve the areas identified in the report, none of which were critical and only one major area remained to be fully addressed.

15. The Panel agreed to renew the centre's licence for a period of four years with no additional conditions and endorsed the Inspectorate's recommendations in the report.

16. The Panel urged the PR to complete the outstanding recommendations, within the agreed timeframes.

Signed  Date 6 Sept 2011

Mark Bennett (Chair)