Interim Inspection Report

Date of Inspection: 6 May 2010
Length of inspection: Six hours
Inspectors Mim Glenn (Lead Inspector); Andrew Leonard

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between 11 February 2009 and 28 July 2010.

Date of Executive Licensing Panel: 28 July 2010

Purpose of the Inspection report

The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the 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 interim 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 Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Gloucestershire Hospitals NHS Foundation 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	Sean Elyan
Date Licence issued	01/10/2009
Licence expiry date	31/10/2011
Additional conditions applied to this licence	None

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Report to Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

The inspector considers that, overall there is sufficient information available to recommend the continuation of the centre's licence without additional conditions.

A number of non compliances were identified in the course of the inspection and recommendations were made in relation to the following:

- The PR should ensure that a member of staff is present during the weekly filling of the liquid nitrogen reservoir tanks located within the cryostore and that the cryostore is locked afterwards.
- 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
- 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.
- 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.
- 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 PR provided evidence and or reassurance that these recommendations have been implemented subsequent to the inspection and no further action is required in relation to these recommendations.

The following recommendations were also made:

- 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
- The PR should undertake a risk assessment for the process of filling the liquid nitrogen reservoirs in a publicly accessible area
- 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
- 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

- 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
- Centre staff described plans to implement quality indicators (QIs) for witnessing and it is recommended that these plans are devised and implemented to achieve compliance with T35.

In his response to the report the PR commented that the centre is working towards resolution of these outstanding actions.

The inspector recommends that the Executive Licensing Panel requires that the Person Responsible (PR) complies with these recommendations within the prescribed timeframes set out in the inspection report.

Details of Inspection findings

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 on the 25 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, at the Cheltenham General Hospital or within a dedicated private facility, located on the ground floor of the Edward Jenner laboratories.

Activities of the Centre:

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

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well The centre provides storage facilities for oncology patients and so this theme is not relevant.
What they could do better.

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well Evidence from an audit of five sets of patients' notes confirmed that patients are completing the appropriate HFEA consent forms, including consent to disclosure to researchers and consent to storage. Staff did state that they do find it difficult to discuss 'consent to disclosure to researches', with patients, when they have just received the devastating news that they have cancer.
What they could do better.

Multiple births
What the centre does well The centre provides storage facilities for oncology patients and so this theme is not relevant.
What they could do better.

Validation of critical equipment and processes
What the centre does well Evidence seen on inspection in the form of academic papers and recommendations from other professionals, indicated that processes are being validated.
What they could do better. Evidence presented on inspection indicated that validation of equipment is being undertaken. However, the evidence did not demonstrate how the centre had been assured that the equipment was 'fit for purpose' or that it had been re-validated following service or repair. 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 (T25).

Witnessing
What the centre does well.

There is an SOP in place which details witnessing steps during sperm processing and cryostorage including witnessing sperm movements into and out of the cryopreservation tanks.

The PR stated in the pre-inspection self assessment questionnaire (SAQ) that the centre was 'almost compliant' in relation to staff being assessed for their competence to perform witnessing. On the day of the inspection evidence was presented for one staff member who has been assessed for competence in this area. The assessment programme is being rolled out to all staff involved with witnessing.

What they could do better.

Through discussion with the centre's staff and review of the witnessing SOP, it appears that witnessing of all pots and ampoules against the patient's records at the end of laboratory processing is performed. However, a witnessing check is not performed on sample receipt in the laboratory or at the start of processing, as 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). 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 as well as the person who witnesses the procedure (T71 Guidance 18.4 and 18.30).

The SAQ stated that the centre has not established quality indicators (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 completed and implemented to achieve compliance with T35

The SAQ stated that an audit of witnessing procedures had been carried out in the last two years, the findings documented and corrective actions implemented. Observations detailed above suggest that a further audit of witnessing protocols and practices against regulatory requirements and QIs is needed. The findings of this audit and corrective actions taken should be documented.

Gamete and embryo donation – reimbursement, information provision and screening

What the centre does well.

The centre provides storage facilities for oncology patients and so this theme is not relevant.

What they could do better.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. The centre provides storage facilities for oncology patients and so this theme is not relevant.
What they could do better.

Embryo testing (if applicable)
What the centre does well. The centre provides storage facilities for oncology patients and so this theme is not relevant.
What they could do better.

2. Changes / improvements since the last inspection on 18 December 2008

Area of practice	Reference	Action required	Timescale for action	Executive Review
Third party agreements have not been completed with all suppliers whose goods/services may have an impact on the quality of the gametes	7 Code of Practice *Annex .5.1 and* Standard*.4.2.10*	The centre should establish written agreements with all third parties for external activities which influence the quality and safety of gametes procured or processed.	To be reviewed at the next inspection	Evidence seen on the day of the inspection demonstrated that there is only one third party agreement outstanding. The PR needs to ensure that a written agreement is established between the Microbiology (licensed premises) and Oncology departments of the Gloucestershire Hospitals NHS Foundation Trust
A member of staff interviewed during the inspection was unaware of the HFEA Alert system.	7 Code of Practice Standard 6.2.13	The PR should ensure that the centre has an effective means for communicating information to staff in particular alerts issued by the HFEA	With immediate effect	Evidence seen on the day of the inspection in the form of an e-mail, demonstrated that alerts are disseminated to all laboratory staff. The PR stated that the system is able to register when staff have received and opened the e-mail. However, 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. The PR needs to add the oncology nurse and radiology

				oncology counsellor to the centre's mailing list, to ensure that they are informed of changes to policies and SOPs, and are informed of HFEA alerts. 8 CoP Guidance 2.1 (f)
Records of the cleaning of critical pieces of equipment are not maintained.	7 Code of Practice Standard 6.4.2.	The PR should ensure that maintenance, servicing, cleaning, disinfection and sanitation of all critical equipment is performed regularly and recorded accordingly as per Code of Practice	With immediate effect	Evidence seen on the day of the inspection in the form of written records and a SOP, confirms that daily cleaning is being undertaken in the patient preparation room, cryopreservation store and laboratory and is checked daily to ensure it is to the standard required. No further action required
Traceability records for key equipment used during the processing of gametes/embryos have not been retained. The centre must ensure that logs of equipment, environmental monitoring and of products coming into contact with embryos or gametes are maintained and stored for the relevant time periods, as outlined in standard licence conditions and Code of Practice	Licence conditions A. 3.2, A.10.30 and Code of Practice Standard 7.3.1.	Appropriate records must be maintained as per standard licence conditions and Code of Practice	With immediate effect.	With the exception of the name of the manufacturer who provides equipment and or services, the centre records all the required information in order to be compliant with licence conditions T99 & T100. To ensure full compliance with licence condition T100, The PR needs to review the current traceability form and SOP to ensure that the manufacturer's name is recorded.

				Licence condition T100
There is no system in place for confirming the identity of sperm providers either producing samples at the Cheltenham General Hospital site or for those delivering them to the pathology unit at Gloucester hospital. This is non compliance with Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6.	7 Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6.	In accordance with Code of Practice Guidance 13.7.1, 13.7.3 and 13.8.6 it is recommended that the centre establishes a procedure to ensure the accurate identification of patients and their gametes. At sperm collection patients should be asked to actively supply the identifying information (full name and date of birth) requested by verbally stating it, rather than confirming or rejecting information read out by a member of staff. When sperm samples are produced at home centres should ensure that protocols are in place to make sure the sperm receptacle is clearly labelled with the sperm providers full name and unique identifier, that the identity of the sperm provider is confirmed and the sperm provider confirms that the sample is his.	With immediate effect	A system is now in place which requires the patient's identification to be checked and recorded when providing samples for storage regardless of whether the sample has been produced at home or on site. The patient is asked to bring photo identification on all visits to the centre. The information is then recorded on the production form and retained in the patient's medical records. Very occasionally the patient may forget to bring photo identification, but the PR stated that this is noted and photo identification is expected at subsequent visits. No further action is required.
The inspectorate considered that the patient information leaflet entitled "sperm storage for those undergoing radiotherapy or	7 Code of Practice Guidance 5.10.1	The PR should ensure that they provide accurate information about regulations relating to statutory storage periods for	With immediate effect.	The patient information leaflet entitled "sperm storage for those undergoing radiotherapy or chemotherapy" has been updated

chemotherapy" could potentially be misleading to patients in respect of storage periods.		gametes		in respect of storage periods. No further action is required
Audited patient records lacked a witness step of cross checking of identifying information provided by the sperm provider against records, laboratory data sheet and sperm receptacle or cross checking of information entered into system and allocation of barcode/RFID tag (Code of Practice Guidance 13.1.1b) and one discrepancy was noted in the witnessing records held in one patient file; the placement of gametes into the storage dewar had not been witnessed as per Code of Practice Guidance 13.1.1.	7 Code of Practice Guidance 13.1.1b	The PR should review the witnessing procedure and ensure compliance with Code of Practice Guidance 13.1.1b. Furthermore it is recommended that the PR monitors compliance with witnessing protocols, including at the time of the centre's quality management system audit (Code of Practice Guidance 13.3.4).	With immediate effect	The evidence presented on inspection demonstrated that the centre has added an extra witnessing check to ensure compliance with licence condition T71. No further action is required at this time.
An external company is responsible for topping up liquid nitrogen reservoir tanks in the cryostore. To fulfil this role they have access to the cryostore and staff explained that they are not always accompanied by licensed personnel.	7 Code of Practice Guidance 6.3.8	PR considers the risks, including security risks, associated with this practice and ensures compliance with Code of Practice Standard 6.3.8.	With immediate effect.	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. 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. 8 CoP Guidance 17.5
On rare occasions sperm samples may be produced at the oncology unit at Cheltenham General Hospital and then be delivered to the pathology department via hospital bus. The inspectorate have concerns about the safety of samples transported in this manner, the risks that they could be tampered with or delivered outside of the optimal time parameters	Code of Practice Standard 7.7.14.	It is recommended that the PR evaluates the risks involved with movement of samples between sites and ensures compliance with Code of Practice Standard 7.7.14	With immediate effect.	An SOP was seen for the urgent transportation of semen samples from Cheltenham General Hospital to the centre. A trained hospital driver supports this service No further action is required
Staff reported that they have concerns that the dry shipper used to transport frozen samples to fertility centres is no longer fit for purpose. A request for funding has been made to one of the charities supporting the oncology department.	7th CoP Practice Standard S.7.7.12.	The PR must ensure that suitable equipment is available for the transportation of samples as required in Code of		A new dry shipper is in place and validation documents and quarterly performance testing data for it were observed on inspection. A transportation SOP governs the use of the shipper and it was noted that it does not list the information required to be included with the dry shipper and on its label, or detail appropriate recall procedures as required by HF&E Act 1990 (as amended), Schedule 3A

3. Areas of concern

The analysis of the centre's self assessment questionnaire and the information the centre has submitted to the HFEA e.g. staff changes and the treatment cycles carried out at the centre, have identified that the following areas needed to be looked during the inspection visit to this centre.

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
The SAQ stated that the counsellor was not accredited under the British Infertility Counselling Association (BICA) accreditation scheme, but was working towards accreditation.	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. She stated that she is trying to work towards accreditation but that she is finding it difficult to achieve this as the Trust have yet to recognise her as a trainee and provide appropriate support. For this reason she has yet to register with the BICA accreditation scheme.	The PR needs to assure himself that 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. Licence condition T12

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 require are given as well as the timescales in which these improvements should be carried out.

Critical area of non compliance

A critical are of non compliance is an area of practice which poses a significant direct risk of causing harm to a patient, donor or to an embryo. A critical area of non compliance requires immediate action to be taken by the Person Responsible.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
None identified during this inspection					

Major area of non compliance

A major are of non compliance is a non critical are of non compliance:

- which poses an indirect risk to the safety of a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- 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 represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
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.	8 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.	To be implemented by 18 June 2010	Action completed. Driver no longer has a key and is now accompanied by licensed personnel whilst at the cryostore.	The lead inspector considers this response to be sufficient and will review the new practice at the next inspection. 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	Licence Condition T71 8 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	18 June 2010	Action completed. Sample processing and witness checks documentation (MI MISC AC 023) updated to include these requirements and copy of this document sent to Clinical Inspector.	The PR has submitted a revised witnessing form, which now documents the points the PR was asked to address.

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.		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.			The lead inspector considers this response to be sufficient. No further action required

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 good practice.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
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	12 September 2010		Written evidence received 9 July 2010 in the form of a draft third party agreement with the Microbiology Department, Gloucestershire Royal Hospital and Oncology Cheltenham General Hospital. Further clarity was sought from the PR as to when this would be completed. The PR stated in an email on 12 July 2010 that this should be 'finalised within the next 2 months (taking into account staff annual leave during this period.)'. The lead inspector expects this to be complete in the specified timeframe.
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.	1 July 2010	Action completed. Oncology nurse and radiology oncology counsellor are included on email distribution list for the centre	The lead inspector is satisfied with this response from the PR. The lead inspector considers this response to be sufficient and will review the new practice at the next inspection.

				and will be informed of alerts and changes to policies and procedures	
Names of the manufacturers who provide consumables are not recorded. This information is required in order to be compliant with licence conditions T99 & T100.	Licence Condition 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.	1 August 2010	Action completed. Sample processing and witness checks documentation (MI MISC AC 023) updated to include these requirements and copy of this document sent to Clinical Inspector.	The PR has submitted a revised witnessing form, which now documents the points the PR was asked to address. The lead inspector considers this response to be sufficient. 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.	1 August 2010		The lead inspector expects this to be complete in the specified timeframe.
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	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	1 August 2010		9 July 2010 SOP Transport of Cryo samples was received, 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

when in use, or detail appropriate recall procedures, as required by HF&E Act 1990 (as amended), Schedule 3A		when in use, and details appropriate recall procedures, to comply with HF&E Act 1990 (as amended), Schedule 3A,.			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 had been assured that the equipments was 'fit for purpose' or that it had been re-validated following service or repair.	Licence Condition T25	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.	1 August 2010		The lead inspector expects this to be complete in the specified timeframe.
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	1 August 2010		The lead inspector expects this to be complete in the specified timeframe.
Although the radiology	Licence	The PR needs to assure	Written		The lead inspector expects this to be

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.	Condition T12	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.	confirmation that the counsellor has been registered and is working towards accreditation with BICA to be submitted to the inspectorate by 1 September 2010		complete in the specified timeframe.
The SAQ stated that the centre has not established QIs or objectives relevant to witnessing, non-compliant with Licence Condition T35.	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	1 September 2010		The lead inspector expects this to be complete in the specified timeframe.

Additional Information from the Person Responsible
We are happy with this report and are working towards resolution of outstanding actions.

HFEA Executive Licensing Panel Meeting

28 July 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – item 1

Gloucestershire Hospitals NHS Trust (0151) Interim Report

Members of the Panel:	
Peter Thompson, Director of Strategy & Information (Chair) Mark Bennett, Director of Finance & Facilities Ian Peacock, Analyst Programmer	Committee Administrator: Joanne McAlpine

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

The following papers were considered by the Panel:

- Papers for Executive Licensing Panel (30 pages)

The Panel also had before it:

- HFEA Protocol for the Conduct of Licence Committee Meetings of the Authority's Executive Licensing Panel
- 8th edition of the HFEA Code of Practice
- Human Fertilisation and Embryology Act 1990 (as amended)
- Direction 0008 (where relevant), and any other relevant Directions issued by the Authority;
- Decision Trees for Granting and Renewing Licences and Considering Requests to Vary a Licence
- Guidance for members of Authority and Committees on the handling of conflicts of interest approved by the Authority on 21 January 2009
- Indicative applications guidance on the time period for which licences should be granted approved by the Authority on 21 October 2009
- Indicative sanctions guidance approved by the Authority on 18 March 2009
- Licence application and any relevant documentation

1. The Panel considered the papers which included an interim inspection report and previous licence committee minutes.
2. The Panel noted the additional tabled information which included a draft service level agreement – Microbiology and Oncology and an SOP on transport of Cryostore samples, which the Panel agreed to accept.
3. The Panel noted that the inspection took place on 6 May 2010 for six hours.
4. The Panel noted that this is a sperm storage centre and is part of the Gloucestershire Hospitals NHS Foundation Trust.
5. The Panel noted that the centre was granted a storage licence on 25 June 2008 following a move from the pathology department, Cheltenham General Hospital where it had held an uninterrupted HFEA licence since 1995.
6. The Panel noted that the Inspectorate recommends the continuation of the centre's licence without additional conditions.
7. The Panel noted that the Inspectorate identified a number of areas of non-compliance on which recommendations were made and the Inspectorate confirmed that evidence has been provided that these have now been addressed.
8. The Panel noted that there were other outstanding recommendations made on pages five and six and that the Person Responsible (PR) has responded that the centre is working towards implementing.
9. The Panel noted that, of the recommendations made in the report, none were critical.
10. The Panel noted the positive response from the PR and encourages him to continue to address the outstanding recommendations identified in the report.

<u>The Panel's Decision</u>

11. The Panel endorsed the Inspectorate's recommendations and agreed to the continuation of the centre's licence with no additional conditions.

Signed.....Peter Thompson.....Date...30/7/10.
Peter Thompson (Chair)