Interim Inspection Report

Date of Inspection: 19 May 2010
Length of inspection: 6 hours
Inspectors: Mr W Lenton
Mr R Sawers

Inspection details:
The report covers the pre-inspection analysis, the visit and information received between August 2008 and May 2010.

Date of Executive Licensing Panel: 12 August 2010

Purpose of the Inspection report
The purpose of the inspection is to assess 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 Authority's Licence Committee/ Executive Licensing Panel which make the decision about the continuation of the centre's licence.

Centre details

Centre Name	Royal Derby Hospital
Centre Number	0149
Licence Number	L0149/9/C
Centre Address	Fertility Unit Women's and Children's Services Royal Derby Hospital Uttoxeter Road Derby DE22 3NE
Telephone Number	01332 785 643
Person Responsible	Mr Joe Darne
Licence Holder	Professor Robert Shaw
Date Licence issued	01/11/2008
Licence expiry date	31/10/2012
Additional conditions applied to this licence	None

Contents

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.

The inspector also recommends that the Executive Licensing Panel requires that the Person Responsible complies with following recommendations within the prescribed timeframes set out in the inspection report:

- The third party agreement with primary centre 0101 needs to be reviewed by both parties at an agreed interval
- The centre should undertake the amendment and re-submission of their SAQ in order to accurately record centre activities as they had genuinely misinterpreted the wording on some of the questions
- A specific SOP for the provision of patient information should be formulated and form part of the QMS
- A specific traceability audit SOP should be formulated and form part of the QMS
- Specific quality indicators should be developed for the areas of practice identified on page 25 of this report
- Audits should be established for the specified areas of practice identified on page 26 of this report and be embedded within the QMS
- Staff competence to perform the specific duties cited on page 26 of this report should be assessed and recorded
- The PR should establish a periodic review of the QMS in order to ensure continuous and systematic improvement
- The centre should complete the validation of all critical equipment and processes
- Accurate MBMS policy information from primary centre 0101 to be available to self-funding patients seeking satellite IVF/ICSI treatment. Similar information to be made available to other patients if they are referred on to other licensed centres for treatment

(All the above issues have been addressed by PR – see pages 23-27)

Details of Inspection findings

Brief description of the centre and its licensing history:

The fertility unit at the Royal Derby Hospital was first licensed by the HFEA in 1995 for donor insemination (DI). Since the implementation of the European Tissues and Cells Directive (EUTD) in July 2007, the centre is now licensed for intrauterine insemination (IUI).

The fertility unit also provides a satellite service to CARE Nottingham (centre 0101) and patients are referred there for in vitro fertilisation (IVF).

In December 2007, the centre moved from their temporary premises of the previous 18 months to spacious new premises within the same hospital grounds. The centre re-commenced HFEA licensed treatment in March 2008 after the License Committee was notified. The Committee noted that the premises were suitable and agreed that they were content for licensed work to recommence.

Treatment is available all days of the week, depending on patient needs. The fertility unit is open 08:30 – 15:30 weekdays; and 08:00 – 12:30 at weekends.

The person responsible is a consultant obstetrician and gynaecologist and has maintained registration with the General Medical Council since 1979. He is also a Fellow of Royal College of Obstetricians and Gynaecologists.

The centre varied its licence in November 2009 to incorporate a change of centre title from, ‘Derby City General Hospital’, to ‘Royal Derby Hospital’.

The centre provided 63 natural cycle and 233 stimulated intra uterine insemination (IUI) cycles in 2009. Although the centre is licensed to carry out DI, no cycles have been performed since January 2007.

Since the previous inspection in March 2008, no major changes have been made to the premises.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period Jan-Dec 2009
IUI (stimulated)	233
IUI (non-stimulated)	63

Other licensable activities	
Storage of eggs	N/A
Storage of sperm	✓
Storage of embryos	N/A
Research	N/A

*These data were extracted from the HFEA register for the period Jan-Dec 2009. The data in the Register may be subject to change as errors are notified to us by clinics, or picked up through our quality management systems.

Updated actions since the centre was inspected on 19 May 2010:

The PR responded to the draft report on 7 July 2010 and gave details of when the various issues highlighted within the report were to be addressed by.

These details can be found on pages 23-27 of the report.

The Executive are reassured by the nature of the PR response and recommend that the highlighted issues are followed up at the next renewal inspection.

1. The Executive and centre staff have been in communication on a number of occasions in order to ensure that accurate information has been available for the report. The centre staff have been very cooperative in attempting to resolve issues raised during the inspection and continue to work with the Executive to achieve compliance.

2. The centre has attempted to amend/re-submit their self assessment questionnaire (SAQ), but due to technical difficulties this has not yet been achieved.

3. The centre is aware of the short-comings identified during the inspection concerning their quality management system (QMS) and are attempting to address them by liaising with the NHS Trust quality manager.

1. Focus of inspections for 2010-12

Witnessing
What the centre does well. From documentation supplied, discussions with staff and as seen on inspection when reviewing three sets of IUI patient notes, the centre has a written witnessing SOP in place (T33b), which ensures that all critical stages within the IUI procedure are witnessed by at least two centre staff (T71). Notes audits are undertaken by both centre staff and by staff from the primary centre, during which the witnessing process is reviewed (T36). The latest notes audit, involving the review of thirty sets of IUI patient's notes, was undertaken in April 2010, during which three minor discrepancies were discovered. The results of the audit were discussed during a subsequent team meeting and any learning points shared with team members.
What they could do better. It was stated both within the submitted SAQ and during the inspection that not all staff have been assessed regarding their competency when performing the witnessing process. Further work is required by the centre to address this issue (T15a).

Providing information to patients in relation to Legal Parenthood
What the centre does well In discussion with the PR and staff it was stated that the centre do not presently provide treatment for same sex couples, mainly due to the poor availability of donor sperm. Any patients requiring such treatment are referred on to the primary centre, where all related issues are addressed (consultation; information; counselling and consents.) There is a procedure in place for staff to follow when taking consents. (T33b) Patient consents are audited as part of the notes audit. (T36) Appropriate records of consent are retained by the centre and were seen on inspection. HFEA literature was available to patients. This included, HFEA changes to fertility law; Use of patient information in research; The new HFEA website; Have your say and One at a time. There was also information concerning counselling, surrogacy, UK donor link, Donor conception network, the Daisy network, More to life and various leaflets giving details of ART available at CARE Nottingham.
What they could do better. No Issues.

Providing information to patients in relation to Costed Treatment Plans
What the centre does well. The centre generally receive referrals from two local Primary Care Trusts (PCT's), but have also received them from areas such as north and south Staffordshire The centre provides IUI treatment for self-funding patients (10%) as well as NHS –funded cycles (90%) and there is a comprehensive patient fee schedule that is given to all couples during their first consultation. This explains the cost of treatment at both Royal Derby (consultations; scanning; drugs; IUI treatment) and at the primary centre, CARE Nottingham (0101), where a full range of ART procedures are available (IVF/ICSI; FET; donor insemination; PGD.) The centre also refer NHS patients requiring IVF/ICSI on to other licensed centres within the area such as, Burton (0184); NURTURE (0076) and CARE Sheffield (0061), according to patient choice. Centre staff stated that they are available to answer any queries that self-funding patients may have regarding any aspect of the cost of treatment. A checklist noting areas such as, information given to patients; fees explained & fee sheet given; counselling offered; WoC assessment; medical history; blood test results; advice re SET and consents is maintained within each patient file.
What they could do better. No issues.

Consent to the disclosure of information, held on the HFEA Register, for use in Research
What the centre does well For all IUI patients, information is given and written consents taken by staff within the unit prior to any licensed treatment being performed (T57). For NHS patients travelling to CARE Nottingham under satellite arrangements established between the two licensed centres, some information is made available at Derby, but further consultations, any counselling and written consents are all undertaken by staff at the primary centre. Mr Darne provides information and undertakes the consent process for any of his private patients who choose to undertake treatment at the primary centre under the satellite arrangement, which includes information regarding disclosure of information to researchers. Counselling is again available via the primary centre. There is a written SOP in place for staff to follow when obtaining patient consents (T33b). A notes audit, involving the review of thirty sets of patients' notes, was undertaken in April 2010. Any errors were reported and discussed at the team meeting and appropriate actions taken (T36). The primary centre (0101) undertakes an annual audit of the centre's activities also. From discussions with the PR and staff it was stated that the competency of staff when taking consent has been assessed and recorded in individual training files (T15a).It was confirmed that consents are never taken directly prior to a procedure being undertaken and that the identity of the patient giving consent is verified prior to the signing of any documentation.
What they could do better. Specific quality indicators need to be formulated and monitored with respect to the consent procedure and embedded within the QMS (T35)

Consent issues in relation to the storage of embryos (including cooling off period)
What the centre does well. There is no embryo storage undertaken at the centre. As reported previously centre staff take consents from IUI patients only. Information concerning other ART treatments available at the primary centre is available from the centre, but further consultations, any counselling and written consents are all undertaken by staff at the primary centre. Mr Darne again stated that he provided information and undertook the consent process for his private patients undertaking treatment at the primary centre. He also stated that information concerning the changes to the HF&E Act is discussed and made available, which included the access to a twelve month cooling off period if either of the gamete providers decided to withdraw their storage consent, but that so far no patient had chosen to invoke this option. A guide to the fertility unit at the Royal Derby hospital together with the units philosophy, feedback process details and the current HFEA licence was seen within the comprehensive set of documentation available to patients within the waiting area.
What they could do better. Specific quality indicators need to be formulated and monitored with respect to the consent procedure and embedded within the QMS (T35)

Multiple births
What the centre does well As the centre is to all intents and purposes an IUI centre, it is not required to have a multiple birth minimisation strategy (MBMS) in place. Information concerning multiple births is provided to patients if they choose to have IVF/ICSI treatment at the primary centre. Once arrangements have been established with the primary centre, further consultations are arranged there, where the specific MBMS policy currently in place is discussed.
What they could do better. As the centre give patients a choice when referring on to other licensed centres (0061; 0076 & 0184) as well as the primary satellite centre (0101) for IVF/ICSI treatment, it may be useful for patients to have specific MBMS information from all these centres when trying to make an informed choice as to which centre would best suit their needs.

2. Changes / improvements since the last inspection on 28 May 2008

Area for improvement	Action required	Action taken as evidenced during this inspection
1. A third party agreement (TPA) with the supplier of catheters used for insemination has not been formalised. [T111] (b)	The centre should establish a written agreement with third parties for external activities which influence the quality and safety of gametes and embryos procured or processed. (Standard License Condition A.5.1)	A TPA with a catheter supplier is now in place.
2. Portable appliance testing (PAT) of the incubator, centrifuge, whirlimixer and socket boards was due in April 2008. [T26]	The centre should ensure that all critical equipment is preventatively maintained in accordance with the manufacturers' instructions Standard 6.4.2 (a).	All critical equipment now maintained as per manufacturers instructions
3. Procedure and equipment validation is not yet been performed. [T24]	Laboratory procedures and equipment should be validated as required by Standard 7.8.3.	Reported to have been completed post previous inspection (May 2008), but there are still outstanding issues as identified during present inspection.
4. The centre's witnessing practices were broadly compliant with HFEA witnessing guidelines. The form capturing witnessing signatures in patient records does not however allow witness signatures, their dates and times (as required by Guidance 13.2.1(b)), to be recorded for all processes which require witnessing, as listed in Guidance 13.1.1 [T71]	The document which captures witness signatures in the patient record should be amended, to allow witness signatures, with times and dates in each case, to be recorded, for all processing steps for which witnessing is required by Guidance.13.1.1.	Amended witnessing document supplied to Executive post previous inspection (May 2008)

3. Areas of concern

The analysis of the centre's self assessment questionnaire (SAQ) 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
1. Satellite arrangements with primary centre CARE Nottingham (0101)	The third party agreement with the primary centre had not been reviewed within the last twelve months as part of the annual management review process. ***CoP8 guidance 23.12(d); 23.13. T114(c)***	The third party agreement with primary centre 0101 needs to be reviewed by both parties at an agreed interval as per licence condition ***T114(c) and CoP8 guidance 23.12(d); 23.13.***
2. From the previous report (May 2008) it was stated that, 'all laboratory procedures and equipment should be validated'	PR and staff stated that, 'some validation of critical equipment is in place but not all completed.'	All critical equipment and technical devices must be identified and validated. ***T24***

Area of concern	Inspection findings	Assessment of whether the action taken meets requirement or whether any further action is required
From the SAQ submitted in December 2009 by the centre: **S4 Provision of information** 1.2 – States that there is no SOP currently in place when providing information to patients before they consent to treatment?	When discussed at the inspection it was found that there was a routine checklist in place which was adhered to when staff provided information to patients. This was to be used as the basis for the formulation of a SOP to cover this process.	SOP to be formalised and added to QMS. ***T33b***
1.3 –States that the centre has not established quality indicators when providing information?	Patients can comment on the process of information giving via centre comment cards or via the patient diary, but specific quality indicators need to be developed.	Specific quality indicators need to be developed, measured and reviewed for the process of information giving to patients. ***T35***
1.4 – States that the centre has not audited how far its procedures for the provision of information comply with the approved protocols, the regulatory requirements and quality indicators in the last two years ?	There is an information checklist within the patient records but this was not audited as part of the recent notes audit procedure.	The provision of information to patients needs to be audited as part of the general notes audit process. ***T36***
S5 Consent: 1.2 – States that there is no SOP currently in place for taking effective consent?	There is a SOP in place for staff to follow when taking consent.	No further action required.
1.3 – States that the centre has not established quality indicators relevant to consent procedures?	The completion/inclusion of consents are checked as part of the notes audit procedure,	Specific quality indicators need to be

1.4 – States that the centre has not audited how far its procedures for taking consent comply with the approved protocols, the regulatory requirements and quality indicators in the last two years ?	but specific quality indicators need to be developed in order to be able to assess whether objectives are being achieved. The centre undertakes periodic internal audit of patients IUI notes which involves the completion/inclusion of consents. The primary centre performs an annual notes audit.	developed, measured and reviewed for the process of taking consents from patients. ***T35*** As part of the planned improvement to the QMS, the centre should develop its present audit system in order to establish a robust system which can be evaluated and which facilitates feed back into an ongoing continual improvement process. ***T36***
S6 Legal Parenthood: The centre state that they do not provide treatment with donor gametes or embryos to patients who are not married or in a civil partnership?	The PR stated that any patients requiring treatment with donor gametes and/or embryos are referred on to other licensed centres where all such issues are discussed.	The centre does have information within the waiting room concerning legal parenthood, but as they only provide basic partner (IUI) services, any patients requiring treatment with donor gametes and/or embryos are referred on to other licensed centres.
S7 Multiple Births: The centre state that they do not provide ART treatments such as IVF/ICSI/GIFT and are therefore not required to establish a MBMS They do however refer IVF/ICSI patients on to other licensed centres for ART treatments?	The centre provide literature on multiple births within the patient waiting area, but there is no specific information on the current MBMS in place at the other licensed centres where patients are referred on to for IVF/ICSI treatment.	The centre should ensure that patients are aware of any MBMS policy in place at different local licensed centres when discussing onward referral or arranging treatment at the primary centre (0101) for self-funding patients. ***T58***
S8 WoC: 1.3 – States that the centre has not established	No specific quality indicators have been	Specific quality indicators need to be

quality indicators or objectives relevant to the assessment of WoC?	established for the WoC assessment process.	developed for WoC assessment process. ***T35***
1.4 - States that the centre has not audited how far its WoC procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years ?	The inclusion/completion of the WoC assessment is audited as part of both the internal (IUI) and external (IVF/ICSI) notes audit.	As part of the planned improvement to the QMS, the centre should develop its present audit system in order to establish a robust system which can be evaluated and which facilitates feed back into an ongoing continual improvement process. ***T36***
1.5 - States that the centre cannot provide documented evidence concerning the assessment of staff competence when carrying out a WoC assessment?	Evidence seen within staff training files of assessments undertaken.	No further action required.
S17 Storage of gametes/embryos:		
1.4 - States that the centre has not audited how far its storage procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?	A storage audit had been undertaken and was made available to the inspection team.	No further action required.
1.5 - States that the centre cannot provide documented evidence concerning the assessment of staff competence when storing cryopreserved material?	Only one staff member outside of the laboratory has been trained to store cryopreserved material. Other staff have been shown how to follow the procedure, but their competence has not been assessed or documented.	Any staff member expected to perform cryopreservation duties must be appropriately trained and their competence assessed and documented by the trainer. ***T15a***
S18 Witnessing:		
1.6 – States that the centre has not audited how far its witnessing procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?	Witnessing audit of thirty IUI records undertaken April 2010.	No further action required.

1.7 - States that the centre cannot provide documented evidence concerning the assessment of staff competence in witnessing procedures?	PR stated not all staff assessed as competent in witnessing procedure.	On-going assessment and documentation of staff competency in witnessing procedure required. ***T15a***
S19 Traceability: 1.5 - States that the centre has not established quality indicators or objectives relevant to traceability? 1.6 - States that the centre has not audited how far its traceability procedures comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?	No specific quality indicators have been established for the Traceability process. Some of the items recorded as part of the traceability process were audited as part of the April 2010 notes audit. (IUI catheter lot number & media batch number), but this needs to be expanded to include all factors which could influence the quality of any gametes used within the centre.	Specific quality indicators need to be developed for Traceability process. ***T35*** A specific traceability audit SOP should be formulated and form part of the QMS. ***T33b***
S23 QMS: 1.7 - States that the centre has not audited how far all licensed activities or activities carried out in the course of providing treatment services that do not require a licence, comply with the approved protocols, the regulatory requirements and quality indicators in the last two years? 1.8 – States that the centre does not have a process in place for reviewing the performance of the QMS to ensure continuous and systematic improvement?	Following discussion with the PR and staff it was established that some audits have been undertaken but that this did not cover all licensed/ unlicensed activities undertaken at the centre. There is currently no periodic review of the QMS in place at the centre.	The PR needs to establish a comprehensive audit schedule which covers all activities currently undertaken at the centre as part of the QMS. ***T36*** The PR should establish a periodic review of the QMS in order to ensure continuous and systematic improvement. ***CoP8 guidance 23.13***
S26 Equipment and Materials: The centre stated that it neither; i. processed gametes/embryos or	This section was not fully addressed in the SAQ due to misinterpretation of the wording	The SAQ needs to be amended and re-submitted in order to give an accurate description of centre activity.

ii. provide storage for treatment purposes Whereas it actually provided both services.	During the course of the inspection it was established that there was; 1. a traceability process in place to track all equipment and materials used in the procurement and processing of gametes for human application. 2. evidence that critical equipment was maintained/serviced in accordance with manufacturers instructions 3. some validation of critical equipment in place but not all completed 4. evidence that equipment/materials that affect critical processing or storage parameters are monitored/alarmed 5. use of CE marked medical devices/equipment where possible It was agreed that due to misinterpretation of the wording within some areas of the SAQ submitted in December 2009, it would need to be amended and re-submitted in order to give an accurate description of centre activity.	***T9(e)(f)*** A specific traceability audit SOP should be formulated and form part of the QMS. ***T33b*** Specific quality indicators need to be developed for the Traceability process. ***T35*** Completion of validation of all critical equipment and processes required. ***T24***
S30 Confidentiality and Privacy: The centre stated that it didn't have access to confidential patient or donor identifying information except for that concerning the provision of basic partner services (IUI) but it provides a satellite service for patients to primary centre 0101, which	This section was not fully addressed in the SAQ due to previously mentioned reason. When discussed with the PR and staff it was agreed that 'confidential patient identifying information, except for that concerning the provision of basic partner services (IUI)' was stored at the centre.	The SAQ needs to be amended and re-submitted in order to give an accurate description of centre activity. ***T9(e)(f)***

includes both NHS and self-funding IVF/ICSI patients.	It was agreed that the SAQ submitted in December 2009 would need to be amended to give an accurate description of centre activity.	
S31 Record Keeping and Document Control:		
1.2 States that the centre has not established quality indicators or objectives relevant to submission of data to the HFEA?	No specific quality indicators have been established for the submission of data to the HFEA.	Specific quality indicators need to be developed for the submission of data to the HFEA . ***T35***
1.3 States that the centre has not audited how far procedures for the submission of data to the HFEA comply with the approved protocols, the regulatory requirements and quality indicators in the last two years?	An audit concerning the submission of data to the HFEA has not been undertaken in the last two years.	An audit concerning the submission of data to the HFEA should be undertaken. ***T36***
1.4 States that the centre cannot provide documented evidence concerning the assessment of staff competence when submitting data to the HFEA?	Staff competence has not been assessed/recorded with regard to submission of data to the HFEA	Staff competence when submitting data to the HFEA needs to be assessed and recorded. ***T15a***

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.					

Major area of non compliance

A major are of non compliance is a non critical area 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 may represent a major area of non compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
1.The third party agreement (TPA) presently in place with primary centre 0101 detailing the specific arrangements concerning satellite services is not being reviewed/updated on a regular basis.	***T114(c) and CoP8 guidance 23.12(d); 23.13.***	Regular review of third party agreement (TPA) with primary centre 0101.	3 months from time of inspection (by 20 August 2010)	In place by September 2010	Inspector to follow up progress and review at renewal inspection

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
2. Amendment and re-submission of self assessment questionnaire (SAQ) in order to give more accurate information about centre activities and processes.	***T9(e)(f)***	Amendment and re-submission of SAQ in order to accurately record centre activities.	3 months from time of inspection (by 20 August 2010)	Awaited	This has been delayed due to IT technical difficulties, but is to be followed by inspector
3. SOP's to be developed for: i. the provision of patient information	***T33(b)***	A specific SOP for the provision of patient information should be formulated and form part of the QMS.	3 months from time of inspection (by 20 August 2010)	In place by August 2010	Inspector to follow up progress
ii. the performance of a traceability audit.		A specific traceability audit SOP should be formulated and form part of the QMS.	3 months from time of inspection (by 20 August 2010)		

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
4. Specific quality indicators need to be developed for the following areas: i. Provision of information ii. Consent iii. Welfare of the Child assessment iv. Traceability v. Submission of data to the HFEA	***T35***	Specific quality indicators should be developed for the areas of practice identified.	By the time of the next inspection (April 2011)	In place by August 2010 (not including v)	Inspector to follow up progress

Area of practice	Reference	Action required	Timescale for	PR Response	Executive

			action		Review
5. Development of the centres present audit system to include audits of; i. Information provision ii. Consent iii. Welfare of the child assessment iv. The quality management system v. Submission of data to the HFEA	**T36**	Audits should be established for the specified areas of practice and be embedded within the QMS.	By the time of the next inspection (April 2011)	Audit programme to be forwarded	Inspector to follow up progress
6. Staff competence assessment for: i. Storage of gametes ii. Witnessing iii. Submission of data to the HFEA	**T15(a)**	Staff competence to perform the specific duties cited should be assessed and recorded.	6 months from the time of the inspection (by December 2010	To be in place by December 2010	Review at next inspection

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
7. Quality management review.	***CoP8 guidance 23.13***	The PR should establish a periodic review of the QMS in order to ensure continuous and systematic improvement.	6 months from the time of the inspection (by December 2010	In place	Review at next inspection
8. Validation of all critical equipment and processes.	***T24***	Completion of validation of all critical equipment and processes required	6 months from the time of the inspection (by December 2010	In place	Review at next inspection
9. Accurate information concerning MBMS policy at primary centre 0101 for self-funding IVF/ICSI patients and/or other licensed centres where patients may be referred on to for treatment.	***T58***	Accurate MBMS policy information from primary centre 0101 to be available to self-funding patients seeking satellite IVF/ICSI treatment. Similar information to be available to other patients if they are referred on to other licensed centres for treatment.	3 months from time of inspection (by 20 August 2010)	In place	Review at next inspection

Additional Information from the Person Responsible

HFEA Executive Licence Panel Meeting

12 August 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 4

Centre 0149 (Royal Derby Hospital) – Interim Inspection Report

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy and Information (Chair) Mark Bennett, Director of Finance & Facilities Danielle Hamm, Policy Manager	Terence Dourado

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:

- Interim inspection report with PR response
- Previous Executive Licensing Panel minutes 11 April 2009
- Previous Licence Committee minutes 01 September 2008
- Previous Licence Committee minutes 06 March 2008
- Previous Licence Committee minutes 14 May 2007

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 Directions 0000 – 0012
- 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 was first granted a licence for donor insemination (DI) in 1995 and a licence for intrauterine insemination (IUI) in July 2007. The Centre provided around 300 IUI cycles in 2009.

2. The Panel noted that the Person Responsible (PR) has been accredited with the General Medical Council (GMC) since 1979. He is also a Fellow of the Royal College of Obstetrician and Gynaecologists (FRCOG)

3. The Panel considered the Interim Inspection Report and endorsed the recommendations and the timeframes within which they are to be completed. It noted that the PR had since either met the recommendations or had put together a plan to meet them.

4. The Panel noted that the validation of some equipment remained outstanding since the previous inspection in May 2008. It recommended that the validation of all critical equipment and processes required is completed by December 2010.

Decision

5. The Panel agreed to the continuation of the Centre's licence without any additional conditions.

Signed: Peter Thompson Date: 3/9/10

Peter Thompson (Chair)