Inspection Report

Date of Inspection: 21 April 2011
Purpose of inspection: Interim inspection of treatment and storage licence
Length of inspection: 7 hours
Inspectors: Sara Parlett (Lead Inspector), Paula Nolan (Clinical Inspector)

Inspection details:
The report covers the pre-inspection analysis, the visit and information received from the centre between 13 May 2009 and 15 July 2011.

Date of Executive Licensing Panel: 15 July 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 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 Executive Licensing Panel which makes the decision about the continuation of the centre's licence.

Centre details

Centre Name	Ninewells Hospital
Centre Number	0004
Licence Number	L0004/15/a
Centre Address	Assisted Conception Unit Ward 35, Ninewells Hospital Dundee Scotland, DD1 9SY
Person Responsible	Dr Vanessa Kay
Licence Holder	Mr Gerry Marr
Date Licence issued	01/10/2009
Licence expiry date	30/09/2012
Additional conditions applied to this licence	None

Contents

Report to Executive Licensing Panel

Brief description of the centre and its licensing history:

The Assisted Conception Unit at Ninewells Hospital has been licensed to provide NHS and self-funded treatments to patients from a wide geographical area since 1992. The unit is open from 08:00 to 17:00 on Monday to Friday and from 08:00 to 12:00 on Saturday.

The centre submitted an application to vary its premises in December 2010. The extension to the existing licensed premises will house the embryology laboratory, cryostore, procedure rooms, laboratory store, disposal room and staff changing facilities. Once the extension is complete, refurbishment of the existing unit will then take place. There has been a delay with the build and the centre estimates completion of the first phase by the end of June 2011.

A tour of the proposed new premises was arranged for the inspection team. The extension is still at the build stage, with room partitions only recently fitted. Once the extension has been completed and the required documentation has been submitted to the Executive for review, the variation application will be submitted to the Executive Licensing Panel for consideration.

Activities of the Centre:

Type of treatment	Number of treatment cycles for the period 1 December 2009 – 30 November 2010*
In vitro fertilisation (IVF)	258
Intracytoplasmic sperm injection (ICSI)	179
Frozen embryo transfer (FET)	130
Donor insemination (DI)	62
Intrauterine insemination (IUI) (01/01/2010 – 31/12/2010)	69
Gamete intrafallopian transfer (GIFT)	0

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

Outcomes*
For IVF/ICSI, DI and FET, HFEA held register data for the period 1 January 2007 – 31 December 2009 show the centre's success rates are in line with national averages. For the year 2010 the centre reported 69 cycles of partner IUI with four pregnancies. This equates to a six percent pregnancy rate. Please refer to page 15 of the report for further information.

*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.

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 draw a conclusion on the continuation of the centre's licence.

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 two major areas of non-compliance and two other areas of non-compliance.

Since the inspection visit the PR has given a commitment to fully implement the following recommendations:

Major areas of non compliance

- To complete the validation of critical equipment.
- To complete the validation of critical processing procedures.

Other areas of practice that require improvement

- To ensure that an approved standard operating procedure (SOP) documenting the process to follow for the withdrawal of consent to legal parenthood is in place and to revise the "withdrawal of consent to storage" SOP to include the provision of information regarding counselling or mediation services available to the gamete providers.
- To ensure that all staff can provide documented evidence of the assessment of their competence in the performance of their designated tasks.

Recommendation to the Executive Licensing Panel

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

Details of Inspection findings

1. Focus of inspections for 2010-12

Providing information to patients in relation to costed treatment plans and parenthood
What the centre does well. **Costed treatment plans** Patients are provided with personalised costed treatment plans prior to treatment (CoP Guidance 4.3). Patients have an initial consultation with a clinician to determine their treatment pathway. A costed treatment plan (including drugs) is then completed by the business manager and sent to the patient. This plan is then further discussed with the patient at their second appointment. The template costed treatment plan was reviewed at inspection and is clear to follow. **Legal parenthood** Centre staff interviewed demonstrated a clear understanding of the legal parenthood provisions. The senior nurse described the process followed for obtaining consent and managing withdrawal of consent to legal parenthood. Written procedures to obtain relevant consent are in place (Licence Condition T33 (b)). Information given to patients reviewed at inspection demonstrated that clear information regarding legal parenthood provisions, including information on withdrawal of consent, is given. Three sets of records of patients who have undergone treatment using donor sperm were reviewed. Consent to legal parenthood was obtained appropriately in all cases.
What they could do better. **Legal parenthood** The centre does not have a SOP documenting the process to follow for the withdrawal of consent to legal parenthood (Licence Condition T33 (b)).

Consent - particularly consent to disclosure to researchers and consent to storage
What the centre does well. **Consent to disclosure of identifying information to researchers** The centre seeks patient consent to identifying information from the HFEA register being disclosed to researchers. Registry information demonstrates that 48% of all patients who have been registered at the centre since October 2009 have opted in for disclosure. Centre staff confirmed that patients are provided with information and the HFEA CD form is sent

out at a different stage in the consenting process, to give patients sufficient time to consider their decision.

An audit of five patient consents to identifying information from the HFEA register being disclosed to researchers, against that recorded on the HFEA register, was performed on inspection and no discrepancies were noted.

Consent to storage

Consent to storage of patient material is obtained by nursing staff. The laboratory manager explained that prior to storage, laboratory staff confirm that patient screening has been completed and that consent to storage is present and completed appropriately. This check step is recorded on the laboratory worksheet. Five sets of records for patients undergoing various treatments were reviewed. Consent to storage was obtained appropriately in all cases.

Dewar audits are performed biennially (CoP Guidance 17.16 (a)). The most recent reports of three dewars audited were reviewed. The findings and corrective action taken were documented (Licence Condition T36).

The laboratory manager described the centre's bring forward system (CoP Guidance 17.17). Letters are sent out each year the material is in storage. Six months prior to the expiry date, a recorded delivery letter is sent. If no reply is received further action, including verification of the address via the patient's general practitioner, is then taken. The spreadsheet for managing the bring forward system was seen and indicated that all material in storage had effective written consent. There is one exception; for one set of embryos in storage after consent was withdrawn by one of the gamete providers. The quality manger described the procedure that had been followed when consent to the storage of embryos had been withdrawn. The cooling off period had been invoked appropriately and the one year period ends in July 2011 (HFE Act 1990 (as amended), Schedule 3, 4A).

What they could do better.

Consent to storage

The centre's "withdrawal of consent to storage" SOP does not include the provision of information regarding counselling or mediation services, as appropriate, to the gamete providers (Licence Condition T33 (b) and CoP Guidance 5.35).

Multiple births

The centre's multiple pregnancy rate for 2009 was 27.2% with an elective single embryo transfer (eSET) rate of 11.7% for the same time period[1].

What the centre does well.

The multiple pregnancy rate is not different from the 2009 multiple pregnancy rate target of

[1] *This data was extracted from the HFEA's Register data as at 23/06/2010. At this time the HFEA had performed a preliminary validation process in which centres were asked to confirm the accuracy of information on treatment cycles carried out up to and including 30/06/2009 for pregnancy outcomes and 30/06/2008 for live birth outcomes. Some of the information used in this analysis may be subject to change.*

30%[2] at a statistically significant level.

In compliance with Directions 0003, the centre has a documented record of its multiple birth minimisation strategy (MBMS), including how the centre identifies suitable cases for eSET. This includes criteria in relation to patient selection and embryo assessment (Directions 0003, 5(a)).

Centre staff confirmed that audits and evaluations of the progress and effectiveness of the MBMS are carried out six monthly. Changes to the strategy based on these reviews were made in August 2009, February 2010 and again in July 2010. The latest review held in 2011 indicates a multiple pregnancy rate of 12% for July – December 2010.

The centre maintains a summary log of cases in which multiple embryos have been transferred to a patient who meets the criteria for eSET (Directions 0003, 3(c)). In the last year, 29 patients met the criteria and had two embryos transferred. An explanation of the reasons for this and a proforma signed by the patients confirming they have understood the risks associated with multiple pregnancy, were recorded in the patient's records reviewed.

The centre maintains a summary log of cases in which three embryos have been transferred (Directions 0003, 1(b)). The log indicated that three patients had three embryos transferred in 2010. All were over the age of 40, with multiple previous attempts (CoP Guidance 7.4 (b)).

Centre staff explained that a patient information leaflet describing the risks of multiple births is sent to patients prior to treatment. Further discussions are then held at the initial consultation, prior to egg collection and then again before embryo transfer.

What they could do better.

Nothing noted at the time of inspection.

Validation of critical equipment and processes

What the centre does well.

A senior embryologist is leading the validation programme at the centre. The embryologist explained that the equipment validation approach was based on a combination of the Association of Clinical Embryologists (ACE) templates and validation workshops attended.

Equipment validation that has been performed is very comprehensive. Equipment qualification reviews for two incubators were reviewed and included review of maintenance records, routine monitoring, microbiological monitoring, temperature mapping studies, power failure simulations and referenced against the centre's clinical pregnancy rates. Copies of certificates of calibration against traceable standards were also seen (Licence Condition T24).

The embryologist confirmed that equipment is revalidated after repair (Licence Condition T25). The embryologist described the validation of an incubator following malfunction and repair. Temperature mapping studies performed demonstrated that a fault remained and that further action was required. This incubator was clearly marked as out of use in the laboratory.

[2] *A multiple pregnancy rate of 30% has been calculated as likely to be equivalent to a 24% multiple birth rate.*

What they could do better.

Validation has not been completed for all equipment (Licence Conditions T24). The inspection team acknowledges that the comprehensive validation approach used at the centre means the programme will take time to complete.

Process validation has commenced and the embryologist explained that a modified version of the ACE template was being used. The centre's egg collection procedure validation document was reviewed. By observation of staff performing an egg collection, the document demonstrates that the centre's SOP had been followed appropriately. However, this did not include evidence to show that the SOP itself had been validated as appropriate for use. Validation was not based on data from published studies or well established processing procedures, by retrospective evaluation of clinical results (Licence Condition T72).

Centre staff explained that one reason for the delay in the completion of the validation programme is that the centre has been concentrating on gaining Clinical Pathology Accreditation (CPA) (UK) Ltd accreditation for its diagnostic semen analysis service. The centre was inspected by CPA (UK) Ltd in February 2011 and staff are currently working through the non critical non conformances reported, prior to accreditation. Centre staff confirmed that they will be focussing on the validation programme during the move to the new extension.

Witnessing

What the centre does well.

The laboratory manager confirmed that the identification of samples and the patients or donors to whom they relate is witnessed by two members of staff at all critical points of the clinical and laboratory processes. Centre SOPs were reviewed and covered all critical points. Witnessing steps observed during the inspection were in accordance with the centre's SOPs (Licence Condition T71).

Four sets of patient notes audited at inspection were found to include records of all required witnessing steps, including the date and time of the procedure (Licence Condition T71). The initials of the person performing the procedure and the person witnessing the procedure are documented. A separate register of the name, status, initials and signature of all staff who witness is maintained in accordance with CoP Guidance 18.8.

The laboratory manager explained that all laboratory records are audited. Once treatment is complete and the required information has been recorded on the centre's database, the records are reviewed by the laboratory manager. The review includes confirmation of completion of all required witness steps. The laboratory manager confirmed that any issues would be raised as a non-conformance via the centre's quality management system (Licence Condition T36).

Evidence of competence assessments of staff performing witnessing steps was seen. The laboratory manager explained that students are employed at the weekends to witness laboratory procedures. These staff have separate training and competence assessments and the records for 2010 were reviewed (Licence Condition T15 (a)).

What they could do better.

Nothing noted at the time of inspection.

Gamete and embryo donation – reimbursement, information provision and screening
What the centre does well.
The centre has a small donor recruitment and egg share programme. The centre's donor assessment and screening procedures are supported by a detailed SOP and checklist. Five sets of sperm and egg donor records were audited during the course of the inspection. This sample of records provided evidence that: • Donors are being selected on the basis of their age, health and medical history, provided in a questionnaire and through a personal history and medical examination performed by a clinician (Licence Condition T52 (a)). • Donors are being selected in accordance with the screening requirements of Licence Condition T52 and relevant professional bodies[3]. The centre's checklist documents when additional screening may be required. • Donor sperm is quarantined for a minimum of 180 days, followed by repeat testing in accordance with Licence Condition T53 (c). • Laboratory tests required by Licence Condition T52 have been carried out by a qualified laboratory which has been accredited by CPA (UK) Ltd (Licence Condition T53 (a)). The PR confirmed that the centre can provide donors with information regarding the number, sex and year of birth of persons born as a result of donation (HFE Act 1990 (as amended), Schedule 31ZD (3)). The availability of this information is included in the information pack given to potential donors and discussed with the counsellor prior to donation. Donor recruitment, assessment and screening audits are performed six monthly. The report of an audit performed in April 2011, of 30 sets of donor records, was reviewed and included corrective action taken (Licence Condition T36). The PR explained that these record audits and the completion of comprehensive checklists are used as evidence that regulatory requirements are complied with and of the competence of centre staff performing donor recruitment, assessment and screening activities (Licence Condition T15 (a)). The PR confirmed that payments made to donors are restricted to expenses incurred in the UK. The donor information sheet reviewed on inspection explains that donors can claim for reasonable expenses incurred during the course of their donation (both travel expenses and loss of earnings), in line with Directions 0001. The centre's written procedures include informing donors at the initial consultation of the expenses that can be claimed and the requirement for receipts to be provided. Donors have an expense form to complete and the centre maintains a spreadsheet recording the expenses claimed. The donor payment spreadsheet reviewed indicated that only travel expenses were being requested by the donors (Directions 0001).
What they could do better.
Nothing noted at the time of inspection.

[3] The 2008 UK guidelines for the medical and laboratory screening of sperm, egg and embryo donors produced by BFS, BAS, ACE and RCOG.

Welfare of the Child (in relation to basic partner treatment services only)
What the centre does well. Not applicable. This centre does not solely provide basic partner treatment services.
What they could do better.

Embryo testing (if applicable)
What the centre does well. Not applicable to this centre.
What they could do better.

2.Changes / improvements since the previous inspection on 13 May 2009

Area for improvement	Action required	Action taken as evidenced during this inspection
The average payment time for treatment fees is 30 days. The HFEA payment terms are 28 days and payment outside these terms is a breach of standard licence condition A.13.3 which states that in consideration of the grant of the licence (or its variation to designate the individual named in this licence as Person Responsible), the Person Responsible agrees that s/he will pay to the Authority any additional fee, as defined in section 16(6) of the Act, within 28 days of the date of the notice of such additional fee.	The PR should take steps to ensure that in future fees are paid within 28 days in compliance with A.13.3. By the next inspection	The HFEA finance department reported that the centre is now paying well within the required 28 days. **No further action is required.**
Some documents seen by the inspection team had not been reviewed in the last 12 months. The quality manager was aware of this and has plans to ensure that all documents are reviewed	The PR should ensure that all documents are reviewed at least every 12 months in compliance with S.5.2.5. By the next inspection	The quality manager described the centre's document review procedure. A spreadsheet detailing all centre documents was reviewed and records the date of the next annual review. The quality manager passes the documents to the relevant members of staff for review prior to this date. All documents referenced on the spreadsheet and those reviewed on inspection were within their annual review date (CoP Guidance

Area for improvement	Action required	Action taken as evidenced during this inspection
every 12 months. This is a breach of S.5.2.5.		31.6). **No further action is required.**
Competence assessments for all staff have not been performed, although staff reported that a system for assessing competencies is being established. This is a breach of S.6.2.2(c) and S.6.2.7(a).	Staff competence assessments should be performed to ensure compliance with S.6.2.2(c) and S.6.2.7(a). By the next inspection	A comprehensive competence framework is now in place for centre staff. Documentation of laboratory staff competence assessments is in progress and the laboratory manager estimated completion for all procurement and processing procedures in approximately six months. A sample of individual staff training folders was reviewed on inspection and included competence assessments for equipment monitoring, diagnostic semen assessment, storage, witnessing, traceability and ICSI. The laboratory manager confirmed that the centre participates in the UK national external quality assessment scheme (NEQAS) for semen analysis and have signed up to the NEQAS embryo grading scheme. Training folders reviewed for two nurses included competence assessments for the provision of information, obtaining consent and confidentiality. The medical staff competence framework was discussed with the PR and includes evaluation for a variety of procedures. This includes new patient review, donor screening, ultrasound scanning and unsuccessful cycle follow up. Egg collection and embryo transfer quality indicators per clinician are reviewed quarterly. The quality manager explained that competence assessments for assessing welfare of the child had not been documented. Licence Condition T15 (a).

Area for improvement	Action required	Action taken as evidenced during this inspection
		Further action is required.
Validation is being performed for new equipment but existing equipment has not been validated. This is a breach of A.10.13.	Validation of all equipment should be performed to ensure compliance with A.10.13. By the next inspection	Refer to page 9 of report. **Further action is required.**
Not all processes have been validated. This is a breach of S.7.8.3.	Validation of all processes should be performed to ensure compliance with S.7.8.3. By the next inspection	Refer to page 9 of report. **Further action is required.**

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 findings meet the requirement or whether any further action is required
Can the centre provide documented evidence of regular cleaning and disinfection of the premises. Licence Condition T26.	The quality manager explained that the centre's cleaners have a training plan and that cleaning supervisors carry out monthly audits of the cleaning service provided. The quality manager confirmed that records of cleaning are kept. Laboratory staff are responsible for the cleaning of the laboratories and cleaning records detailing individual cleaning tasks were reviewed.	No further action is required.
Has the centre established quality indicators or objectives relevant to procurement and processing procedures. Have all licensed activities or activities carried out in the course of providing treatment services that do not require a licence, been audited against compliance with the approved protocols, the regulatory requirements and quality indicators in the last two years.	Key performance indicators including fertilisation rates, clinical pregnancy rates, multiple pregnancy rates and FET rates are audited and discussed at the centre's management group meeting on a monthly basis. The centre's clinical pregnancy rate for IUI was six percent in 2010. The quality manager explained that they were aware of this and are currently reviewing the regime to see if improvements can be	No further action is required.

Area of concern	Inspection findings	Assessment of whether the findings meet the requirement or whether any further action is required
Licence Condition T35 and T36.	made. However, they were not too concerned because the procedure is the same as for DI, for which the success rate is in line with the national average. Audits against compliance with approved protocols are also performed. Audits of staff performing semen analysis (December 2010), egg collection (April 2011) and cryostorage (April 2011) were seen. Audits have been performed and were reviewed for counselling, provision of information, welfare of the child, donor selection, storage, witnessing, and ICSI. Findings are documented and corrective action implemented where required. Traceability audits from September 2010 and April 2011 were reviewed and included audit of consumable batches in use in the lab versus those recorded as in use on the centre's database. Discrepancies were documented and corrective action already implemented and further action planned was described by centre staff (Licence Condition T36).	

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, 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 noted at the time of 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 validation of critical equipment has not been completed. Licence Condition T24. **This was an issue at the last inspection.**	The PR should ensure that the validation of critical equipment is completed. The PR should submit an action plan, including a summary of all equipment requiring validation and timeframes for completion, by the time the PR responds to this report.	Validation of all critical equipment is ongoing and will be completed before moving into new ACU accommodation in September 2011. A list of all critical equipment is attached along with a timetable for validation.	The PR has submitted a copy of the centre's comprehensive validation master plan and a list of the critical equipment requiring validation. The submitted action plan documents a target date for completion of equipment validation of mid September 2011 for both new and existing equipment. The Executive is satisfied with the PR's response and will continue to monitor progress.
The validation of critical processing procedures has not been completed. Validation performed to date is	The PR should ensure that the validation of critical processing procedures is completed. The PR should submit an	Validation of all critical processing procedures is ongoing and will be completed by April 2012.	The submitted validation master plan describes the centre's process validation approach, which includes

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
not based on data from published studies or well established processing procedures, by retrospective evaluation of clinical results. Licence Condition T72. **This was an issue at the last inspection.**	action plan, including a summary of the validation approach, a summary of all procedures that require validation and timeframes for completion. For submission by 21 July 2011. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until it is completed. For full completion by April 2012.	A list of all critical processing procedures is attached, along with a validation action plan. A quarterly report of progress will be submitted of progress in the implementation of this plan (at the beginning of June, September, December and March)	review of current and historic performance data and evaluation of published studies and clinical results. A summary of all procedures that require validation has been submitted, along with an action plan documenting the timeframes for completion of process validation. The Executive is satisfied with the PR's response and will continue to monitor progress.

Other areas of practice that require improvement

Other areas of practice that require 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
Withdrawal of consent The centre does not have a SOP documenting the process to follow for the withdrawal of consent to legal parenthood. The centre's "withdrawal of consent to storage" SOP does not include the provision of information regarding counselling or mediation services available to the gamete providers. Licence Condition T33 (b) and CoP Guidance 5.35.	The PR should ensure that an approved SOP is in place for the process to follow for the withdrawal of consent to legal parenthood. The PR should ensure that the centre's "withdrawal of consent to storage" SOP is revised to include this provision of information. 21 July 2011.	A withdrawal of consent SOP has been designed and implemented from 7/6/2011 and the 'withdrawal of consent to storage SOP has been amended (see attached)	The PR has submitted a "withdrawal of consent to legal parenthood" SOP which documents the process to follow for the withdrawal of consent to legal parenthood. **No further action is required.** The PR has submitted a revised "withdrawal of consent to storage" SOP, which includes the requirement to offer counselling to the gamete provider withdrawing consent. It does not include the offer of counselling to the other gamete provider or the provision of information about mediation services. The PR is asked to further review and revise the SOP and submit to the Executive by 21 July 2011.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
			The Executive will continue to monitor progress.
Competence assessments. Licence Condition T15 (a) **This was an issue at the last inspection.**	The PR should ensure that all staff can provide documented evidence of the assessment of their competence in the performance of their designated tasks. The PR should submit a detailed plan, including a summary of all staff and the competence assessments they need to complete, including anticipated timeframes for completion, by 21 July 2011. The PR should submit quarterly reports to the Executive regarding the progress of the implementation of this plan until it is completed.	Competency assessments of embryology staff is on-going (timetable attached). Some of the competency assessments can be carried out during the validation of all critical processing procedures. Other staff will continue competency assessments as previously. A quarterly report of progress will be submitted of progress in the implementation of this plan (at the beginning June, September, December and March)	The PR has submitted an action plan for laboratory staff, but this does not include an anticipated timeframe for completion. The action plan does not include competence assessments for staff performing WoC assessments. The PR is asked to revise and resubmit the action plan to the Executive by 21 July 2011. The Executive will continue to monitor progress.

Additional information from the Person Responsible

HFEA Executive Licence Panel Meeting
15 July 2011

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0004 (Ninewells Hospital) – Interim Inspection Report (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Hannah Darby, Policy Manager	Joanne McAlpine Lauren Crawford (observing ???)

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 this centre is located in the Assisted Conception Unit of Ninewells Hospital, Dundee, Scotland.

2. The Panel noted that this centre has been licensed to provide NHS and self-funded treatments since 1992.

3. The Panel noted that the centre submitted an application to vary its premises in December 2010 and is currently still undergoing refurbishment.

4. The Panel noted that at the time of the inspection there were a number of areas of practice that required improvement, including two major areas of non-compliance and three other areas for improvement.

5. The Panel noted that both of the major areas of non-compliance were an issue at the last inspection. These areas were:

    - To complete the validation of critical equipment
    - To complete the validation of critical processing procedures

6. The Panel noted that the Person Responsible (PR) has submitted a copy of the centre's validation master plan and a list of the critical equipment requiring validation before moving to new accommodation in September 2011.

7. The Panel also noted the PR has committed to sending an action plan by 21 July 2011 and to submitting quarterly reports thereafter setting out the progress made in the implementation of this plan.

8. The Panel noted the Inspectorates recommendation that the centre's licence should continue with no additional conditions.

The Panel's Decision

9. The Panel endorsed the Inspectorate's recommendations and relevant timescales within the report, and agreed to the continuation of the centre's licence with no additional conditions.

Signed ..... Date 27/7/11.

Peter Thompson (Chair)