Initial Licence Inspection Report

Date of Inspection: 5 May 2010.
Length of inspection: 6 hours.
Inspectors: Bhavna Mehta, Ellie Suthers and Wil Lenton.

Inspection details:
The report covers the pre-inspection analysis, the visit and information received with the new licence application.

Date of Licence Committee: 24 June 2010.

Purpose of the Inspection report
The purpose of the inspection is to assess that centres will comply with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice to ensure that centres will provide a quality service for patients. The report summarises the findings of the inspection to meet regulatory requirements. It is primarily written for the Authority's Licence Committee which makes the decision about the centre's licence application.

Centre details

Centre Name	Centre for Reproductive Medicine Wales (CRMW)
Centre Number	Centre 0316
Centre Address	ELY MEADOWS, Rhodfa Marics , Llantrisant, CF72 8XL
Telephone Number	01443 443999
Person Responsible	Dr Umesh Acharya
Licence Holder	Dr Amanda O'Leary
Date of proposed Licence issue	24 June 2010

Contents

Report to Licence Committee

Brief description of the centre:

An initial enquiry was received by the HFEA from Dr Umesh Acharya (proposed Person Resposible), in December 2009, regarding licensing requirements for an IVF centre, which he and his partners planned to have operational by June 2010. Although the application form includes PGD/PGS, the proposed PR has confirmed (in an email) that he no longer wishes to apply for PGD/PGS at this stage. Dr Acharya and his four business partners, have incorporated this business as a private limited company in the United Kingdom. The business name is CRMW Limited. The centre name is to be Centre for Reproductive Medicine Wales (CRMW).

The proposed Person Responsible (PR) has stated that the partners are an experienced team and have been working in the assisted reproduction sector for many years (with one partner having 21 years' experience in fertility treatment). The centre is a state of the art, purpose built centre. The building project has been managed by a company with considerable experience in this field, having been involved with similar builds around the UK. The PR has stated that they hope to provide the best care using a patient centred approach and evidence based medicine.

CRMW is a new fertility treatment centre. It is situated in a recently developed science park, to the north west of Cardiff city centre off junction 34 to the M4. CRMW is approximately 100 metres from an acute hospital and has access to emergency and inpatient services. CRMW is located on two floors.

At inspection, the proposed PR stated that he is in discussion with the Healthcare Inspectorate of Wales' (HIW) regarding the HIW visit/inspection. The proposed PR has agreed to forward a copy of the HIW report as soon as it is made available to him.

The centre comprises:
Ground floor:

- andrology/embryology laboratory
- two theatres, one for egg collection, the other for embryo transfer
- four patient recovery rooms
- a sperm production room
- a nurses station
- a cryostore, housing three dewars
- medical gases store
- plant room.

First floor:

- main reception
- patient waiting area
- three consulting rooms
- a counselling room
- a scanning room

- staff/administration office
- Staff room
- Nurses office
- Staff changing room
- Meeting room.

The centre plans to provide treatment to privately funded patients. The proposed PR has stated that the centre hopes, in the first year, to provide treatment to 100 patients and that the centre has the capacity to provide:

Projected activities of the Centre:

Type of treatment	Proposed/estimated Number of treatment cycles in the first year of licence
IUI/DI IVF/ICSI/FET	111
PGD	N/A

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

Quality management system (QMS), witnessing and traceability

The centre has a quality policy and is in the process of developing a quality manual. The centre is considering ISO 9001:2000 accreditation. The Senior Embryologist is the centre's Quality Manager and has experience of ISO accreditation registration.

The centre has established quality indicators for clinical and laboratory procedures, including staff performance measurements. These will be measured and assessed at regular intervals. For example, the centre will assess patient satisfaction every six months via an external survey. The centre is aiming to achieve 90% patient satisfaction. An internal audit of all its processes is planned in the months after the centre commences licensable activity.

The centre has standard operating procedures (SOP) for clinical and laboratory procedures. The inspection team reviewed the SOP for witnessing clinical and laboratory procedures and was satisfied that this met the requirements set out in the HFEA Code of Practice, 8th edition (CoP). The centre also has written procedures in place to ensure the traceability of all gametes and embryos and any equipment or material that will come into contact with the gametes and embryos from their procurement to their use in treatment or disposal. The SOP for traceability was reviewed at inspection and appeared compliant with CoP requirements.

Third party agreements (TPA)

The centre has a SOP for TPA. A list of suppliers who will provide goods or services that influence the quality and safety of gametes and embryos, in accordance with Licence

condition T111 has been identified. These agreements will be finalised if/when a licence is granted.

Multiple births strategy

The centre has a multiple births minimisation strategy (MBMS), submitted with the initial licence application form, which appears compliant with the General Directions 0003, version 1. The centre will maintain a summary log of cases in which multiple embryos have been transferred to any patient who meets the criteria for single embryo transfer as set out in its MBMS and in accordance with General Directions 0003. During discussions concerning this issue, the inspection team highlighted that the proposed PR should revise the strategy in line with the General Directions 0003, version 2 and the Chair's letter CH (10) 01 to set the year two (2010-2011) target to 20%.

Donor recruitment programme

The centre has a donor recruitment SOP in place but does not propose to initiate a recruitment programme until the centre is more established. Donor patient information leaflets were reviewed at inspection and appeared to be compliant with Direction 0001-Gamete and embryo donation.Until the sperm donor programme is established, the centre will be importing donor sperm from appropriately accredited centres as per General Directions 0006.

Contingency cover

The centre discussed with the inspection team their provisional plans for establishing a contingency arrangement with other licensed centres in the vicinity. These plans will be finalised contingent on the Licence Committee agreeing this licence.

Records storage

The proposed PR explained that the long term plan is to have a 'paper less' clinic with all records being stored electronically. In the meantime, the patient records are to be stored securely in the administration office. Access is by keypad entry.

Patient information

A sample of patient information leaflets was received by the inspection team before the inspection. This was reviewed and appeared broadly compliant with the requirements of the CoP but required some minor amendments. At the inspection visit, the centre staff provided some more updated patient information leaflets which appeared to comply with the CoP requirements. The staff explained that further patient information is being developed.

Summary for licensing decision:

The proposed PR has liaised closely with the lead inspector in preparing this application. All the business partners have stated that they hope to start licensable activity from approximately the end of August 2010. If a licence is granted by the Licence Committee, the staff at the centre aim to use the time between the granting of the licence and the commencement of licensable activities at the end of August, to address and finalise any outstanding issues.

The proposed PR has referred to the requirements of Directions 0008-Information to be submitted to the Human Fertilisation and Embryology Authority as part of the licensing process (version 1) and in accordance with this Direction, has provided the following documents:

(a) completed Initial treatment and storage licence application form and application fee;

(b) an up to date CV of the proposed Person Responsible listing academic and professional qualifications, work experience and registration details with the relevant professional body;

(c) up to date CVs and information about the qualifications and experience of the following proposed centre staff:

(i) Licence Holder
(ii) Accredited Consultant,
(iii) Senior Embryologist,
(iv) Nurse Co-ordinator,
(v) Quality Manager;
(vi) Senior Counsellor;

(d) a floor plan of the premises to be specified on the licence;

(e) a room schedule of the premises (including room numbers) to be specified on the licence; identifying which activities are to be carried out in each room;

(f) evidence that a quality management system is in place including an index of all documents in the quality manual to be used by the centre once licensed;

(g) a suite of information documents to be provided to patients undergoing treatment at the centre once licensed;

(h) the PR Entry Programme ("PREP") certificate number, T/1151/8 confirming satisfactory completion of PREP (for Person Responsible appointed after 1 October 2009);

(i) a completed self-assessment questionnaire;

(j) a copy of the centre's organisational chart clearly defining accountability and reporting relationships for named individuals;

(k) copies of protocols for the following:

(i) management of ovarian hyper-stimulation syndrome
(ii) witnessing
(iii) traceability
(iv) transportation of gametes and/or embryos to/from other centres
(v) donor screening;

(l) a contact name for patient record returns to the Authority;

(m) a copy of the centre's MBMS.

The above documents have all been reviewed by the inspection team and appear to be compliant with the CoP requirements.

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

- The proposed PR is suitable and will discharge his duty under section 17 of the HF&E Act 1990 (as amended):

  The proposed PR is the applicant for the initial treatment and storage licence.

  The proposed PR's C.V (attached to Committee papers) states that he holds the qualification of Bachelor of Medicine and is a member of the Royal College of Obstetrics and Gynaecology (RCOG); GMC registration number : 2823632. The proposed PR has appropriately and satisfactorily completed the PR entry programme (PREP) based, both on the, HFEA CoP, 7th edition and subsequently the PREP relating to HFEA CoP, 8th edition. The PREP certificate number issued is: T/1166/8.

  The proposed PR is currently PR at another HFEA licensed centre and has been in that post since 1997. In accordance with the HF&E Act, he has at least two years practical experience which is directly relevant to the activity to be authorised by the licence. This satisfies the statutory requirements of the Act.

  Two referees, provided by the proposed PR, have attested to his suitability of character for the post of PR, as required by the new application process.

- The initial treatment and storage licence details appointment of a Licence Holder. The proposed Licence Holder's C.V has been submitted (attached to Committee papers).

- The premises are suitable:

  At inspection, the premises appeared appropriate for the proposed licensable activities and should provide a safe, clean and private environment for patients and centre staff. The CRMW premises have been handed over by the contractors and the building regulation certification was made available on the day of inspection. This handover certificate details the Health & Safety, Fire safety and other such safety checks.

  At the time of the inspection, the clinical and laboratory equipment had been purchased but installation of some was awaited. At inspection, the proposed PR stated that the equipment already installed has been commissioned and validated. The proposed PR is reminded of the CoP requirements to show evidence of working towards validation of all equipment and processes.

  A. The proposed PR is requested to send the commissioning and validation documentation of any outstanding critical equipment to the lead inspector as soon as possible (to include the installation, commissioning & signing-off of the Facilities Monitoring System-FMS and the electronic witnessing system)

  The air quality in the IVF Clean room was tested on 22 April 2010 and the certificate shows that the background air quality in the Clean room is of Grade B. These meet the requirements of licence condition T20. Further testing will take place when all the rooms have been furnished and before commencing treatments.

  B. The centre must show evidence to the inspection team, that the air quality in the laboratory gamete/embryo processing area and procedures rooms has been re-tested and meets, at least, Grade C with Grade D background, before commencing licensed activity.

- The practices are anticipated to be suitable:
  The centre has SOPs for the proposed licensed activities. All staff provided evidence that they are suitably experienced to carry out their designated jobs.

- The centre has submitted appropriately completed documentation in application for the grant of their licence.

- The centre has submitted an application fee to the HFEA in accordance with requirements (as confirmed by the HFEA Finance team).

Recommendation to the Licence Committee:

The inspection team considers that, overall, there is sufficient information available to recommend:

1. Granting a treatment and storage licence for a period of two years without additional conditions, subject to the proposed Person Responsible providing evidence of compliance with A and B above, before treatments start (paragraph 4.2 Guidance on periods for which new or renewed licences should be granted).

2. Appointment of the proposed Person Responsible.

3. Appointment of the proposed Licence Holder.

Details of Inspection findings

1. The premises to be used to provide treatment activities under the proposed new licence

The centre will be conducting licensable activity in the following areas/rooms:

- Sperm production room
- Recovery area: four beds
- Procedure rooms/theatres: two
- Laboratory: one
- Cryostore housing three dewars

Sperm production room
The sperm production room is located on the ground floor. The inspection team is satisfied that the dedicated, ensuite, male production room, meets the requirements of licence condition T17 (A centre must have suitable facilities to carry out licensed activities, or other activities carried out for the purposes of providing treatment services that do not require a licence).

Recovery area
The inspection team was shown the dedicated recovery area where the centre's staff will monitor the patients. The recovery area is equipped with recovery and emergency facilities. The recovery area was not fully equipped, although the beds were seen to be in place at the time of the inspection visit. The treatment and recovery areas are equipped with emergency resuscitation equipment, pulse-oxymetry monitoring, suitable facilities for drug/medication storage as well as integral oxygen equipment. The staff reported that this was to be completed in the weeks following the inspection and confirmed that all outstanding equipment had been delivered and was awaiting installation. The proposed PR confirmed that the installation of all equipment would be completed before commencing licensed treatments.

IVF laboratory and procedure rooms (suite)
There is a small reception area situated beside the male production room. Samples for analysis are received and booked in by a laboratory witness who will also show patients into the rooms. The centre staff will carry out both manual and electronic witnessing checks until the electronic witnessing system has been fully validated.

The proposed PR explained that the diagnostic semen analysis will be carried out by a laboratory which is accredited by the Clinical Pathology Accreditation (CPA) Ltd. The staff have stated that all TPAs will be finalised if/when a licence is granted.

The staff changing area is situated on the first floor. The laboratory area is entered via a 'step-over' area where staff will change into dedicated clean area footwear.

The main laboratory has been built to a high specification and is well equipped with power sockets and IT connections. The IVF laboratory appears suitably equipped for licensable activities. The equipment includes: a Class II cabinet (housing ICSI microscope, dissection microscope and IVF Witness), 2x CO_2 140L incubators, 3x mini CO_2 low oxygen incubators,

1 non CO_2 incubator, sperm assessment microscope, stand alone dissection microscope and a 2x media fridge.

In order to facilitate efficient handling of gametes, hatches connect the laboratory to the sperm production and egg collection rooms. There are also doors through to both the egg collection and embryo transfer rooms.

The cryo-storage room is adjacent to the main laboratory and has a viewing panel within the door. The room is fitted with a low oxygen monitor linked to external audio visual alarms. A dual stage extractor fan system has been incorporated to ensure that the room's air is continually changed.Within the room were 3x 47L dewars, a 240L pressurised filling tank, a media fridge and a dry shipper.

Dewars will be fitted with temperature and low level alarms. The system can be interrogated remotely via a secure internet link which will also monitor incubator CO_2 and temperature levels. A SOP for responding to alarms, both within working and outside of normal working hours has been developed. An autodialler system has been installed in order to contact centre personnel in the event of an out-of-hours emergency.

All laboratory equipment is linked to a back-up power system. This comprises a stand alone uninterruptible power supply (UPS). The UPS system is capable of supplying power for three hours in the event of the failure of both supplies. The inspection team were told that the partners will investigate purchasing a back up generator.

A stand alone air handling system has been designed to provide HEPA filtered air to the theatre and laboratory areas.

2. The qualifications and experiences of the key staff

1) The Senior Embryologist
The Senior Embryologist is a scientist with over 14 years' experience as an embryologist and is registered with the Health Professions Council (registration number: CS11090).

2) The Accredited Consultant and Licence Holder
The proposed Accredited Consultant is the proposed Licence Holder. Her C.V states that she is a member of the General Medical Council and holds several RCOG Special Skills Modules, including in Management of the Infertile Couple. There are no specific requirements regarding the character, qualifications and experience of the Licence Holder in the CoP or the HFE Act (1990) as amended. The proposed Licence Holder's CV has also been provided and is included in the committee papers.

3) The Lead Counsellor
Since submitting the application form, the centre has appointed an experienced and qualified counsellor who will provide counselling sessions to patients and their partners as required. The proposed Lead Counsellor's CV has been provided to the inspection team which states that she holds a qualification in general and infertility counselling and is in the process of becoming accredited with the British Infertility Counselling Association (BICA). The CV also

demonstrated lengthy experience in adoption and childrens services in which she has a role with the local authority.
The counsellor was not available for interview at the time of inspection but the training and experience desirbed in the C.V appeared to demonstrate her suitablitiy for the role of counsellor at the centre.

5) The Lead Nurse
There are no specific requirements regarding the character, qualifications and experience of the Lead Nurse in CoP8 or the HF&E Act (1990) as amended.

The proposed Lead Nurse has been intergral to the development of services to be provided at the centre. Her CV states that she is a qualifed nurse registerd with the Nursing and Midwifery Council and has undertaken continued professional development in the speciality of assited reproduction.

3. Risk to patients and children born as a result of the proposed treatment services

Focus

- **The risks of fertility treatment to the health of patients and children born as a result of the activities proposed at the new centre**
- **Welfare of the Child** – all assisted conception processes should only be conducted in a manner that takes into account the welfare of any child that may be born as a result of treatment services
- **Ensuring patients will receive treatment using the correct gametes or embryos** – patients should have confidence that the gametes or embryos used in their treatment are either their genetic gametes or embryos created with their gametes (or in the case of donor gametes that the gametes used are from the correct donor)
- **Ensuring donor gametes will only be used where appropriate screening has taken place** – the health of patients and children, born as a result of treatment services, could be at risk if gametes from unscreened donors are used in the provision of treatment services
- **Inspection themes 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Witnessing

▶ Take account of the welfare of any child who may be born as a result of the proposed licensed treatment provided by the centre, and of any other child who may be affected by that birth (Principle 4). (GN 8; 11; 20)
Evidence of how the centre demonstrates potential future compliance with this principle. The centre has a SOP for assessing welfare of the child. The proposed PR and the other staff described a process for evaluating the welfare of the child including: discussion about the issue at the initial consultation; contacting, as required, the patients GP or any relevant agencies, if any issues are raised. They stated that this would only be done if the patient and/or partner had completed the consent to disclosure form. Any issues would be raised and discussed at the proposed monthly team meetings before any final decision was made. It was suggested on discussion that if any particularly difficult issues or concerns were raised about the welfare of any child born as a result of treatment that staff would access advice and support from a local ethics committee.
What they could do better. No areas were identified as part of this inspection process.

▶ Conduct all proposed licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring (Principle 7). (GN2;3; 7;8;9;10;11; 16;17;18;19; 21; 23; 24; 25; 26.
Evidence of how the centre demonstrates potential future compliance with this principle The centre has SOPs for licensed activities. All staff appear trained and competent to carry

out licensed activities.

What they could do better.

No areas were identified as part of this inspection process.

▶ Ensure that all premises, equipment, processes and procedures to be used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8).

Evidence of how the centre demonstrates potential future compliance with this principle

The premises appeared appropriate for the centre's activities and should provide a safe, clean and private environment for patients and centre staff.

What they could do better.

The low liquid nitrogen probes had not been connected up to the Facilities Monitoring System (FMS).

▶ Ensure that all staff engaged in the proposed licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice (Principle 9). GN11; 15; 17;18; 19; 23; 24; 25; 26

Evidence of how the centre demonstrates potential future compliance with this principle

At inspection the proposed PR reported that, in due course, as activity increases, staff levels will be increased.

What they could do better.

At inspection, the inspection team recommended that the proposed PR may wish to consider the nurse staff levels before commencing any expansion of the treatment or donor programme.

Since the inspection visit, the proposed PR has confirmed that the centre is recruiting two nurses: one full time and the other part time and that job offers have been made.

▶ Will the new centre be able to report all adverse incidents (including serious adverse events and reactions) to the HFEA, investigate all complaints properly, and share lessons learned appropriately (Principle 11). GN15; 27; 28

Evidence of how the centre demonstrates potential future compliance with this principle

The centre's SOP appears compliant with CoP requirements and should enable the centre staff to comply with the requirements of CoP for the reporting of incidents.

There are plans for regular team meetings where incidents will be discussed and HFEA alerts will be disseminated to all staff.
What they could do better. No areas were identified as part of this inspection process.

4. Patient Experience

Focus

- **Ensuring patients and donors will be treated fairly and that any treatment will be conducted in suitable premises by trained competent staff** – treatment should only be carried out in licensed premises and staff must been trained and competent to perform their jobs. All patients and donors should be treated fairly and without discrimination

- **Guaranteeing patients, patients, donors and partners' independent decision making** – this should be done through the careful giving of appropriate and accurate information and the offering of counselling, and the subsequent taking and recording of effective consents

- **Inspection themes 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas:
    - Information about the cost of treatment (costed treatment plans)
    - Legal parenthood

▶ Treat prospective and current patients and donors fairly, and ensure that all licensed activities are conducted in a non-discriminatory way (Principle 1). GN8;11;13; 28; 29
Evidence of how the centre demonstrates potential future compliance with this principle The centre does have a complaints policy and an audit of patient satisfaction is planned every six months with follow up corrective actions taken as appropriate.
What they could do better. No areas were identified as part of this inspection process.

▶ Have respect for the privacy, confidentiality, dignity, comfort and well being of prospective and current patients and donors (Principle 2). (GN2;3;11;12;13; 20; 25; 28; 29; 30
Evidence of how the centre demonstrates potential future compliance with this principle The patients will have access to the centre's site via a secure barrier to the car park. The patient information will give details of how to report to the centre's reception and waiting area. The patients will then be escorted to the procedure rooms. After treatment, the patient will be taken to the recovery area. Counselling is to be provided in a dedicated private, confidential counselling room on the first floor. There are sufficient consulting rooms and office space for patients to speak with staff in private. On inspection it appeared that the premises provided for the privacy, confidentiality, dignity, comfort and well being of the patients, donors and staff.
What they could do better.

In consideration of the requirement for respect for the privacy, confidentiality, dignity, comfort and well-being of prospective and current patients and donors, staff have confirmed plans to replace the glass window on the ground floor over looking the corridor to the first floor, with opaque glass.

Give future patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions (Principle 5). GN4;5;6;7;9;10;11;12;14;17; 20; 21; 28; 29; 30

Evidence of how the centre demonstrates potential future compliance with this principle

The centre has produced (and continue to develop) comprehensive patient information. A review of the patient information demonstrates compliance with the requirements set out in the CoP.

What they could do better.

No areas were identified as part of this inspection process.

Ensure that patients and donors will have provided all relevant consents before carrying out any licensed activity (Principle 6). ((GN5; 6;7;8;11;12;15;17; 20; 30)

Evidence of how the centre demonstrates potential future compliance with this principle

The centre has SOPs for obtaining consent. The PR confirmed that HFEA consent forms are to be used.

What they could do better.

No areas were identified as part of this inspection process.

5. Protection of embryos

Focus

- **Safe procurement, processing, storage, application and disposal of gametes and embryos** – gametes and embryos will only be procured, processed, used, stored and disposed off in accordance with the law

▶ Provide respect for the special status of the embryo when conducting licensed activities (Principle 3). GN15;
Evidence of how the centre demonstrates potential future compliance with this principle The Centre's witnessing protocols have been audited against the tool provided by the HFEA and appear to be compliant.
What they could do better. The electronic witnessing system has not yet been fully integrated into the facilities (e.g. at the nurse station for identification of sperm production) and the Senior Embryologist is to forward appropriate documentation when it has been fully installed and commissioned.

▶ Ensure that all premises, equipment, processes and procedures to be used in the conduct of licensed activities are safe, secure and suitable for the purpose (Principle 8). GN11; 15;17;18; 19; 23; 24; 25; 26
Evidence of how the centre demonstrates potential future compliance with this principle At the time of inspection, staff explained that some equipment, mainly television screens, were awaiting installation - these will be in place before patients are treated. Some of the equipment in the laboratory has been installed and commissioned. Validation certificates were reviewed at inspection. All of the newly purchased equipment is still under manufacturers warranty and will be serviced under the warranty agreement. The operating theatre and recovery rooms contain suitable equipment for safe and secure licensable activity including resuscitation and monitoring equipment.
What they could do better. The centre must show evidence of working towards validation of all equipment and processes. The Facilities Monitoring System (FMS) which is to be used by the centre to monitor all laboratory-based critical equipment such as incubator temperatures and % CO_2 levels; cryodewar temperature & liquid nitrogen levels; low oxygen monitoring in the cryostore etc had not been fully integrated with all of the critical laboratory equipment on the day of inspection. The Executive will need to see a final installation, commissioning and sign-off document from the company stating that this process has been successfully completed.

6. Good governance and record keeping

Focus

- **Where gametes or embryos are used, complete and accurate information will be recorded and reported to the HFEA in a timely manner** – incomplete and / or inaccurate information may lead to the wrong information being provided to offspring and / or researchers

- **Ensuring gametes and embryos will be only stored in accordance with effective consent and within the statutory timeframe**

- **Ensuring identifying information will only disclosed in accordance with consent**

- **Inspection theme 2010 - 2012** – the focus of inspection for 2010 – 2012 should include the following areas
    - Patient consent to the disclosure of information, held on the HFEA register, for use in research
    - Consent issues in relation to the storage of embryos (including cooling off period)

▶ Maintain accurate records and information about all licensed activities (Principle 10). GN 5;6;7;8;12;13;15; 16;17;18;19; 23; 24; 30; 31)
Evidence of how the centre demonstrates potential future compliance with this principle The centre's embryologist has the role of Quality Manager in partnership with the Accredited Consultant. They are intending to further develop the quality management system prior to the commencement of licensed activities. The centre is considering ISO accreditation and the Senior Embryologist has previous experience of having obtained this accreditation. The proposed PR demonstrated a good understanding of the requirements of maintaining accurate records and information in accordance with the CoP, including those specified by the Authority in Directions.
What they could do better. No areas were identified as part of this inspection process.

▶ Conduct all licensed activities with regard for the regulatory framework governing treatment and research involving gametes or embryos within the UK, including: • maintaining up-to-date awareness and understanding of legal obligations responding promptly to requests for information and documents from the HFEA, co-operating fully with inspections and investigations by the HFEA or other agencies responsible for law enforcement or regulation of healthcare (Principle 13). GN7;13; 16

Evidence of how the centre demonstrates potential future compliance with this principle The centre submitted all necessary information to support its application for a treatment and storage licence as described in this report.
What they could do better. No areas were identified as part of this inspection process.

Areas of proposed practice that require the attention of the Person Responsible

The section sets out matters which the Inspection Team considers may constitute areas of potential non compliance. Each area is referenced to the relevant sections of the Acts, Regulations, Standard Licence Conditions, Directions or the Code of Practice, and the recommended improvement actions required are given, as well as the timescales in which these improvements should be carried out.

Areas of potential non compliance in the proposed activities and practices at the new centre

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Premises.	T20 In premises where the processing of gametes and embryos exposes them to the environment, the processing must take place in an environment of at least Grade C air quality, with a background environment of at least Grade D air quality as defined in the current European Guide to Good Manufacturing Practice (GMP_ Annex 1 and Directive 2003/94/EC). It must be demonstrated and documented that the chosen environment achieves the quality and safety required.	The centre must show evidence to the inspection team, that the air quality in the laboratory, cryostore and procedures rooms has been re-tested and meets, at least, Grade C in gamete/embryo 'processing' area with Grade D background, before commencing licensed treatments.	Before commencing treatments.	Air quality: As you know when Atlas tested this we meet all the standards that were required. We will re-test all the rooms before we commence treatment. If needed we could retest again before the licensing committee meeting but also again I August (for our practice) as this would nearer when we want to treat patients.	Action outstanding.

Equipment and materials	T24 All critical equipment and technical devices must be identified and validated, regularly inspected and maintained in accordance with the manufacturer's instructions. Where equipment or materials affect critical processing or storage parameters (eg, temperature, pressure, particle counts, microbial contamination levels) they must be identified and be the subject of appropriate monitoring, alerts, alarms and corrective action, as required, to detect malfunctions and defects, and to ensure that the critical parameters are maintained within acceptable limits at all times. All equipment with critical measuring function must be calibrated against a traceable standard if available.	The Facilities Monitoring System (FMS) which is to be used by the centre to monitor all laboratory-based critical equipment such as incubator temperatures & % CO_2 levels; cryodewar temperature & liquid nitrogen levels; low oxygen monitoring in the cryostore etc had not been fully integrated with all of the critical laboratory equipment on the day of inspection. The lead inspector will need to see a final installation, commissioning and sign-off document from the company stating that this process has been successfully completed.	Before commencing treatments.	This has now been installed and dummy tested this week. I am pleased to say that they were successful. The company now needs to send us the validation and certification which they will once they are also happy with the system. They inform us that this they hope to do by the end of next week and failing that definitely by 14th June. I was hoping they would have done this but today but sadly they have not. I will send you all the paperwork as soon as they deliver but rest assured that the testing this week by our team was successful. I am sorry FMS have nor delivered by today but they tell us they will by end of next week!	Action outstanding.

Additional information from the Person Responsible
I hope this covers all that is required for the committee but if they want anything else or you feel we have made a omission I would gladly re-submit.

HFEA Licence Committee Meeting

24 June 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 2

Centre 0316 – Initial Licence Application by Centre for Reproductive Medicine Wales (CRMW)

Members of the Committee: David Archard (lay) – Chair Debbie Barber (lay) Sally Cheshire (lay) Jane Dibblin (lay) Sue Price (Professional)	Committee Secretary: Terence Dourado Legal Adviser: Rosalind Bedward

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

The following papers were considered by the Committee:

- Initial Licence Inspection Report
- New Treatment and Storage Licence Application
- CV for the proposed Person Responsible – Dr Umesh Acharya
- CV for the proposed Licence Holder – Dr Amanda O'Leary

The Committee also had before it:

- HFEA Protocol for Conduct of Licence Committee Meetings and Hearings
- 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

Tabled Documents

- Correspondence between the Executive a Centre
- Functional Design Specification table of contents

The Chair of the Committee acknowledged the additional information which had been received from the Centre and noted the Executive's view that that this information did not fully meet the recommendations of the report.

Consideration of Application

1. The Committee had regard to its Decision Tree. The Committee was satisfied that the application was submitted in the form required, and contained the supporting information required by General Direction 0008. The Committee was also satisfied that the appropriate fee had been paid.

2. The Committee was satisfied that the application designated an individual to act as the Person Responsible (PR) and that the PR had consented to act as such.

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

4. The Committee was satisfied that the proposed PR possesses the formal qualifications required because he holds a Bachelors degree in Medicine. Furthermore, it was satisfied that the proposed PR had at least two years practical experience directly relevant to the licensed activity to be carried out by the Centre because he is currently PR at another HFEA licensed centre and has been in post since 1997. The proposed PR is also a member of the Royal College of Obstetricians and Gynaecologists (RCOG) and has obtained extensive experience in all aspects of infertility and assisted reproduction techniques. The Committee was also satisfied that the proposed Licence Holder was a suitable person to hold the licence based upon the information contained within her CV.

5. The Committee was satisfied that the licence application did not concern storage of gametes and embryos not intended for human application, the use of embryos for training purposes, nor the testing of embryos. Additionally, it was satisfied that the licence application did not concern research other than the derivation of stem cells not intended for human application.

6. The Committee was satisfied that the character of the PR is such as is required for supervision of the licensed activities and that the PR will discharge the duties under section 17 of the Act: The proposed PR had appropriately completed the PR entry programme (PREP) based both on the HFEA Code of Practice (CoP), 7th edition and subsequently the PREP relating to HFEA CoP, 8th edition. Furthermore, two referees provided by the proposed PR attested to his suitability of character for the post.

7. The Committee was satisfied that the premises to be licensed are suitable for the conduct of licensed activities and noted that the premises appeared appropriate for the proposed licensable activities to the Executive at inspection. The Executive had been of the view that the premises should provide a safe, clean and private environment for patients and Centre staff. It was noted that the building regulations certificate was available on the day of inspection which detailed safety checks.

8. The Committee noted that at inspection the proposed PR stated that the installed equipment had been commissioned and validated. However, the clinical and laboratory equipment which the Centre had purchased was awaiting installation. The Committee noted that the Executive had reminded the proposed PR of the requirements of the Code of Practice and the need to show evidence that the Centre is working towards validation of all equipment and processes.

9. The Committee agreed that the proposed number of annual treatments that the Centre could potentially undertake at capacity was unrealistic. It noted that the Proposed PR had since acknowledged this.

Decision

10. The Committee had regard to the 'Guidance on Periods for which New or Renewed Licences Should be Granted'. The Committee noted paragraph 4.2 of the guidance which states the '[Licence Committee] will normally grant an initial treatment/ storage/ non-medical fertility services licence for up to two years. This is because in granting an initial licence, there will be no history of compliance to support a longer licence'.

11. The Committee granted the Centre a treatment and storage licence of two years with no additional conditions placed upon the licence.

12. The Committee endorsed the Executive recommendation that licensed treatment does not commence at the Centre until the following requirements were satisfied:

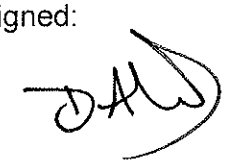
    - The proposed PR sends the commissioning and validation documentation of any outstanding critical equipment (including

installation, commissioning and signed-off Facilities Monitoring System-FMS and the electronic witnessing system);

- The Centre shows evidence to the inspection team that the air quality in the laboratory gamete/embryo processing area and procedures rooms has been re-tested and meets, at least, Grade C with Grade D background.

13. The Committee agreed to the appointment of the proposed Person Responsible and the proposed Licence Holder.

Signed: Date: 9/7/2010



David Archard (Chair)