Change of Premises Inspection Report

Date of Inspection: 3 November 2010
Length of inspection: 6 hours
Inspectors: Gill Walsh
Andrew Leonard

The report:
This report covers the pre-inspection analysis of information held by the HFEA, the inspection visit and all information submitted by the centre in support of the applications to vary the centre's licence to reflect a change of premises and a change to licensed activities.

Date of Licence Committee: 17 December 2010

Purpose of the Inspection report
The purpose of the inspection is to assess whether centres are complying with the HF&E Act 1990 (as amended), the HF&E Act 2008 and the Code of Practice (CoP) to ensure that centres are providing a quality service for patients. The report summarises the findings of the new premises inspection and consideration of the centre's application to change the licensed premises and activities, and all the supporting information. It is primarily written for the Authority's Executive Licensing Panel which considers licence variation applications of this nature.

Centre details

Centre Name	Complete Fertility Centre, Southampton
Centre Number	0307
Licence Number	L0307/1/c
Centre Address	Level G, Princess Anne Hospital Coxford Road, Southampton, S016 5YA
Telephone Number	02380 796980
Person Responsible	Professor Nick Macklon
Licence Holder	Dr Michael Marsh
Date Licence issued	1 November 2008
Licence expiry date	31 October 2011
Additional conditions applied to this licence	None

Contents

Report to the Executive Licensing Panel

Recommendation to the Executive Licensing Panel:

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

- the premises and equipment are suitable for the current and proposed licensed treatments;
- the practices adopted by the centre are suitable for the current and proposed licensed treatments;
- the centre has appropriately qualified and experienced personnel available in sufficient number to conduct the current and proposed licensed activities;
- the centre has complied with General Direction 0008, paragraphs 18 and 19, in submitting to the HFEA appropriately completed application forms, all required documentation and the application fee, for variation of the centre's licensed activities and premises.

The Executive Licensing Panel is asked to note that at the time of the inspection there were two areas of practice that required attention. Post inspection the inspectorate made the following recommendations:

- the gamete and embryo transport dewars should be validated;
- the witnessing record templates should be reviewed to include the time at which patients are positively identified at egg collection;

Since the inspection visit on 3 November 2010 and following review of the draft report, the Person Responsible (PR) has provided assurance and evidence that both of these recommendations have been implemented. The PR has also provided evidence of validation for a key piece of equipment which due to a delivery delay was commissioned after the inspection.

The inspection team considers that, overall there is sufficient information available to recommend the Executive Licensing Panel (ELP) approve the variation of the centre's licence to reflect the changes to the premises and to licensed activities.

The inspections would like to commend the centre team on the thoroughness of their preparation for this inspection and for the quality of the information provided.

The PR has requested that the ELP minutes be expedited to minimise the delay to patient treatment planned subject to the ELP's decision regarding the applications to vary the licence.

Details of Inspection findings

The focus of this report

This report details the findings of the new premises inspection visit and analysis of the submitted licence variation application forms, supporting information and a Self Assessment Questionnaire completed by the centre.

Only CoP Guidance Notes relevant to the proposed changes to premises and licensed activities, or to matters arising from analysis of the SAQ, were inspected against on this occasion. All other areas are scheduled to be reviewed as part of the centre's renewal inspection in 2011.

Brief description of the centre and its licensing history:

Complete Fertility Centre Southampton is a dedicated unit housed within The Princess Anne Hospital, Southampton. The centre was first licensed under number 0307 in October 2008 for a period of three years with no additional conditions. The centre is currently licensed for treatment and storage, specifically sperm storage, insemination, procurement and distribution of gametes, processing of gametes, the use of donor gametes in treatment and non-medical fertility services. The centre offers treatment and storage services to both NHS commissioned and self funding patients.

The centre was last inspected in July 2009 (interim) and in September 2010 the centre's licence was varied to change the centre name to Compete Fertility Centre Southampton and the PR to Professor Nick Macklon.

Following approval of a business case to create a full IVF / ICSI service, the centre has in recent months undergone a major refurbishment and expansion programme to their premises. The centre will remain a self contained unit on the existing site having expanded into additional space adjacent to the centre. Applications have been received from the PR to vary the centre's licence to reflect:

1. the changes to the licensed premises [standard licence condition (SLC) T1and T18]
2. the proposed changes in licensed activities. [SLC T6]

Both application forms are considered by the inspection team to have been completed appropriately and to be supported by all the information required by General Direction 0008, paragraphs 18 and 19.

As the proposed changes to the premises and licensed activities represent a major change to the centre's current licence, all documents submitted in support of the applications were reviewed and the centre was asked to submit a Self Assessment Questionnaire (SAQ) and further information. An inspection visit was also performed.

Activities of the Centre:

Type of treatment	Current / proposed
IUI & DI	Current – approx 100 cycles per year
IVF / ICSI / FET	Proposed – cycles anticipated to rise incrementally year on year to a maximum of 1200 collectively.

Other licensable activities	Current / proposed / N/A
Storage of eggs	Proposed
Storage of sperm	Current
Storage of embryos	Proposed
Treatment with donor sperm	Current
Treatment with donor eggs	Proposed
Treatment with donor embryos	Proposed
Research	N/A

The new premises to be used for licensed activities:

The refurbished and expanded premises now comprise:

- Reception and waiting area
- Administration offices
- Three clinical consultation / scan rooms
- One theatre / procedure room
- One dedicated counselling room
- One semen collection room
- One four bed recovery bay
- Three laboratory areas
- One cryostorage room (16 dewars)
- Staff changing /locker/ washroom facilities
- Staff meeting room / rest room with drinks facilities
- Visitor washrooms (with disabled access) with emergency pull cords

Guidance Note 2: Staff

The organisational chart has been revised to reflect the centre's new management and reporting structure [SLC T11]. The PR provided evidence that the workforce requirements have been comprehensively reviewed to accommodate the proposed change to the range of licensed activities. The PR reports that staff resources will be formally reviewed and evaluated as licensed treatment activity increases in line with the planned 'ramp up' of activity documented in the centre's business plan.

The PR has demonstrated that there are appropriately qualified and experienced personnel available in sufficient number, to conduct current and proposed licensed activities safely and effectively, now and in the near future. The PR has confirmed that all staff working under the auspices of the licence are suitable persons to participate in the activities authorised by the licence and has provided the curricula vitae of all key new staff. [Act S.17 (a)]

Staff are able to demonstrate their competence to perform their current designated tasks. [SLCs T12 and T15]. The centre has a comprehensive competence assessment framework in place which incorporates the additional licensed activities; the inspection team considered the framework to be of a high standard. Documented records of ongoing competency assessments for a number of staff were reviewed, including assessments of competence conducted at other licensed centres for staff refreshing their practice in preparation for the additional licensed activities. Arrangements were also seen to be in place for staff to have their competence assessed within the centre by appropriate assessors when the proposed additional licensed activities commence.

The PR is part of the clinical team and is also the nominated registered medical practitioner who oversees and advises on medical activities at all times. [SLC T16].

The centre is considered by the inspection team to be compliant with all SLCs aligned to CoP Guidance Note 2.

Guidance Note: 3 Counselling

The centre reports that there will be no material change to the counselling service as a result of the proposed changes to the premises and licensed treatments offered.

The inspection team are satisfied that the centre is compliant with all SLCs relating to CoP Guidance Note 3.

Guidance Note: 4 Information to be provided prior to consent

Prior to inspection, the centre submitted all written patient information produced or modified as a result of the proposed changes to the premises and licensed treatments provided. A review of this information satisfied the inspection team that the centre is able to provide appropriate written information to patients, partners and donors prior to consent being sought. This information included a clear guide to the anticipated cost of treatments provided by the centre. Discussions with centre staff indicate that written information is supported by opportunities for patients to discuss their treatment and its cost with those directing and supporting their treatment pathway

The centre has appropriate standard operating procedures (SOP) in place to guide the process by which information is provided to patients prior to consenting to treatment, including those treatments involving the proposed additional licensed activities. [SLC T31] Quality objectives and indicators relating to the provision of information are in place [SLC T35] and the provision of information for current treatments has been audited appropriately within the last two years. The scope of information audited will expand to incorporate the additional information provision required for the proposed additional licensed activities.

The inspection team are satisfied that the centre is able to provide patients, partners and donors with appropriate information regarding their treatment or donation, compliant with Schedule 3 S.3 (1) (b) to the HF&E Act 1990 (as amended) and all SLCs relating to CoP Guidance Note 4.

The laboratory manager reports that procedures to guide the use of embryos in training and to inform patients of training processes are to be established by the centre prior to this activity commencing.

Guidance Note: 5 Consent to treatment, storage, donation, training and disclosure of information

The centre reports that their consent process will not change as a result of the proposed change to licensed activities and will incorporate the additional consent requirements of the new licensed activities. There is an appropriate SOP in place to guide the consenting process. It includes directions on the disclosure of information, informing patients of the right to withdraw or vary consent, and on the 'cooling off period' available in the event of a dispute between gamete providers regarding the continued storage of their embryos.

Quality objectives and indicators are already established and are part of the centres audit cycle. Staff were able to provide documented evidence of their competence to seek consent.

From information received and discussions with centre staff, the inspection team are satisfied that consenting practice at the centre is compliant with SLCs T15 (a), T33(b), T35, T36 and schedule 3A (10) 2006/86/EC, Appendix 1 F.

Guidance Note: 15 Procuring, processing and transporting of gametes and embryos

The centre has appropriate SOPs in place to guide the procurement, processing and transporting of gametes and embryos which also details the circumstances, responsibilities and procedures for the release of stored material prior to distribution. [SLCT33(b)] All current procurement and processing SOPs have been validated in accordance with Schedule 3A (11) 2006/86/EC and SLC T72, evidence of which was seen on inspection.

Critical procurement and processing procedures for the proposed licensed activities have been validated. The centre also plans to incorporate into the validation documents reference literature for the processes, reports from an external assessor who will observe practices and review SOPs before the additional licensed activities commence, and on-going quality indicator monitoring data.

The centre has established quality objectives and indicators for all current procurement and processing procedures, which form part of the existing audit cycle. The range of quality objectives and indicators will be expanded to incorporate the addition licensed activities, compliant with Schedule 3 A (10) 2006/86/EC, Appendix 1 F and SLC T36.

Staff are able to provide documented evidence of their competence to perform existing and proposed procurement and processing procedures, evidence of which was seen on inspection. [SLC T15 (a)]

The centre has SOPs for the transportation of gametes which have been revised to include embryo transportation. [Schedule 3A (11) 2006/86/EC and SLCs T95, T107 and T108]

Guidance Note 17 Storage of gametes and embryos

There has been no material change to storage facilities and practices as a result of the change to premises or the proposed additional licensed activities. Storage SOPs have been updated to incorporate embryo cryopreservation and storage requirements. [SLC T33b] The centre is considered by the inspection team to continue to be compliant with SLCs T33(b) (provision of SOPs), T72 (validation of procedures and equipment for the storage of gametes and embryos), T35 (quality indicators relevant to gamete and embryo storage) and Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36 (audit of procedures).

Centre staff provided documented evidence of their competence to perform existing and proposed cryopreservation procedures. [SLC T15(a)]

The centre operates an effective ‘bring forward’ system which monitors the consent and statutory storage status for all samples held.

It was confirmed on inspection that practices and SOPs ensure that prior to storage and / or release, all samples are currently, and will continue to be, screened in accordance with SLCs T50 and T52

The centre is currently in the process of obtaining Clinical Pathology Accreditation (CPA) for their andrology laboratory. All required documentation has been successfully submitted and an accreditation inspection date is due to be scheduled by the CPA body shortly. The centre anticipates that the process will be complete by June 2011. The PR was advised to inform the HFEA when CPA accreditation is obtained as this was a requirement at a previous inspection.

Guidance Note 18 Witnessing and assuring patient and donor identification

The centre's current and proposed documented witnessing procedures, the latter accommodating witnessing of the proposed additional licensed activities, were reviewed and were considered to be compliant with CoP requirements. At inspection, witnessing practices were reviewed and it was confirmed that witnessing is performed contemporaneously by two members of staff at all critical points in the clinical and laboratory process.

The centre has established quality objectives and indicators for witnessing and staff competence in this activity was seen to be assessed and recorded.

The inspection team considered the centre's witnessing practices in all other areas to be compliant with SLCs T71, T15(a), T35, T36 and Schedule 3A (11), and (10) 2006/86/EC, Appendix 1F

It was noted that current witnessing documentation does not provide space to allow the time of the witnessing check of patient identity at egg collection to be recorded.

Guidance Note 19 Traceability

The centre has documented procedures for ensuring traceability of gametes and embryos, which include any materials and equipment used in the assisted conception process that could affect the quality and safety of gametes and embryos. Traceability procedures have been revised to incorporate changes due to the additional treatment activities.

From information received and in discussion with centre staff, the inspection team are satisfied that the centre is compliant with all elements of SLCs T15 (a), T33(b), T35, T36 and schedule 3A (10) 2006/86/EC, Appendix 1 F and SLCs T99, T100, T101, T102 and T103 relative to traceability.

Guidance Note 21 ICSI

The centre has an appropriate SOP in place to be followed when performing ICSI which was submitted to the HFEA prior to inspection. [SLC T33(b)]

The centre has validated the equipment and procedure to be used for ICSI. Plans were seen to be in place for further validation including the use of external assessors to review the ICSI SOP and practices, both before and after the additional licensed activities commence. [SLC T72] The external assessors will also assess staff competence to perform ICSI. [SLC T15a]

The centre has established quality objectives and indicators relative to ICSI and audit of the ICSI processes has been built into the centres existing audit schedule. [Schedule 3A (10) 2006/86/EC, Appendix 1 F and SLC T36]

Guidance Note 22 Training

The centre proposes to use embryos for training purposes sometime after the additional licensed activities are established. The laboratory manager stated that documented procedures are currently being developed and will be in place prior to any use of embryos in training. The PR was advised to provide the centre's inspector with evidence of compliance with SLC T92 – T98 before beginning to use embryos in training.

Guidance Note 24 Third party agreements

The centre has established and retains a complete list of written agreements with third parties who provide goods or services that influence the quality and safety of gametes and embryos. [T111] The agreements specify the terms of the relationship and responsibilities of each party, as well as the protocols to be followed to meet the required performance specifications. [SLCs T113 and T115] The information contained within a sample third party agreement reviewed on inspection was considered by the inspector to be fully compliant with SLC T114.

Guidance Note 25 Premises and facilities

From information received, direct observation and discussions with centre staff, the inspection team are satisfied that the centre's premises and facilities accurately reflect the floor plan submitted with the application and are suitable for their current and proposed licensed activities.

All areas were considered by the inspection team to be well appointed, appropriately equipped for their intended use and protective of the privacy and dignity of prospective and current patients and donors.

The new premises are housed within the extended footprint of the centre's existing premises. Signage to the centre within the host hospital is clear. Service users enter the centre via a secure entrance which opens onto a waiting area with a reception desk. The centre's current licence is displayed within the waiting area [SLC T5] alongside the quality policy, complaints procedure and general assisted conception and counselling information. Service users report to the reception desk on arrival. Sensitive information which may be displayed on the reception desk computer is protected by a privacy screen. Further access to the centre's clinical facilities is via a second double door which is controlled by staff-specific swipe card access. Patients entering this area are accompanied by a member of staff who collects them from the reception area. An administration office adjacent to the reception area may be used for private discussions with service users.

Accommodations in the clinical area include three consultation / scan rooms and a treatment room. The semen production room is adjacent to the andrology laboratory both of which are accessed via a third double door. Access via this door is not currently restricted but staff assured the inspection team that patients and donors are always accompanied by a member of the team when in this area. The PR agreed to consider the inspection team's recommendation that they restrict access via this door to further improve the security to the laboratory and clinical areas.

The area beyond these doors houses the embryology laboratory areas, procedure theatre, recovery area, staff offices, the counselling room and the cryostore. There is also a secure medical gas store room which is monitored by a low oxygen alarm. All staff handing medical gases, including nominated portering staff receive medical gas handling training and competence in this activity is reassessed annually. Appropriate health and safety signage was seen to be in place where required.

The centre's laboratories and treatment areas comply with current professional guidelines and regulations and have been risk assessed for hazards to staff and services users. Precautions have been put in place to minimise potential hazards.

Documented evidence of the assessment of air quality in all critical work areas and of background air quality to these areas was available on inspection and showed that air quality was compliant with SLC T20. Air quality testing includes assessment of airborne volatile organic compounds. The centre has validated their air quality monitoring SOP which requires biennial particle and volatile organic compound counts and quarterly microbiological settle plate counts.

The procedure recovery area is light and well equipped and has an adjoining bathroom with nurse call / emergency call cord. Each recovery bed is served by a nurse call and emergency call facility. The nurse's station is adjacent to this area.

Guidance Note 26 Equipment and material

The centre was able to demonstrate traceability of all equipment and materials used in the course of procurement and processing of gametes and / or embryos intended for human application by retaining a record that used in the embryology worksheets used for each procedure. [SLC T22].

The centre provided comprehensive documented evidence that all equipment and technical devices (existing and for proposed future use) have been identified, calibrated, validated and are subject to regular preventative maintenance. Equipment and materials which affect critical processing or storage parameters are subject to appropriate monitoring, alarms and corrective actions, ensuring that critical parameters are maintained within acceptable limits at all times. For example, an environmental monitoring system has been installed which logs critical parameters (e.g. dewar and incubator temperatures) and initiates alarms if parameters deviate from defined limits. The centre also has a robust contingency plan in place in the event of significant equipment failure. Equipment seen on inspection and identified in logs was CE marked. [SLCs T22, T23, T24, T25, T26, T30 and T31]

The delivery of one new key piece of equipment was outstanding at the time of inspection. The laboratory manager assured the inspection team that commissioning and validation documents for this equipment will be forwarded to the HFEA by the centre as soon as these activities have been completed.

Documented procedures for the operation of all critical equipment and actions to be taken in the event of malfunction were also seen on inspection. [SLC T27] Sterile, disposable CE marked instruments and devices were seen to be used for the procurement of gametes and embryos. [SLC T28]

The cryostore is equipped with low oxygen monitors connected to an alarm system which is tested weekly and the result documented. The system comprises a loud audible alarm which sounds outside the cryostore, a flashing warning light outside the store, a flashing warning light in the main embryology laboratory, and an auto dial facility which will ‘dial out’ to the on-call member of the laboratory team and two other nominated contacts if the alarm is activated..

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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 and reference	Action required and timescale	PR Response	Executive Review
None			

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 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 and reference	Action required and timescale	PR Response	Executive Review
Gamete and embryo transport dewars have not been validated, contrary to Act, Schedule 3A (11) 2006/86/EC and SLCs T108 and T24	The centre must ensure that all transport dewars and containers are appropriately validated. This action should be completed by 17 December 2010.	Validation has now been performed. Please see attached documentation	No further action required
A laboratory air flow cabinet has not yet been installed and will require validation before it is used in licensed activities, to avoid non-compliance with SLC T24	The PR should ensure the air flow cabinet, and any other items of key equipment installed after the inspection, are appropriately commissioned and validated before use in licensed activity. The PR is to forward copies of the relevant documentation to the centre's inspector when this	Completed - relevant documentation attached.	No further action required

Area of practice and reference	Action required and timescale	PR Response	Executive Review
	is action is completed.		
Witnessing documentation does not allow the time of witnessed identification of the patient at egg collection to be recorded, risking non-compliance with SLC T71.	Witnessing documentation should be revised to allow the time of witnessed identification of the patient at egg collection to be recorded This action should be completed by the start of licensed activities		Appropriately revised witnessing documention has been submitted to the Lead Inspector. No further action is required.

Other areas of practice that requires improvement

Areas of practice that requires improvement is any area of practice, which cannot be classified as either a critical or major area of non compliance, but which indicates a departure from good practice.

Area of practice and reference	Action required and timescale	PR Response	Executive Review

Additional Information from the Person Responsible

The visit by the inspection team was very helpful, and a number of issues were raised during our discussions which will help shape our new service. The areas of non-compliance have been addressed, and the necessary documentation forwarded to the inspectors.

The team found the inspections team curteous and very constructive, and we appreciate their understanding of our concern to be able to start providing IVF services to our patients as soon as is possible.

As a new academic IVF centre serving the south of England, we look forward to a long and fruitful relationship with the HFEA.

HFEA Executive Licence Panel Meeting

17 December 2010

21 Bloomsbury Street London WC1B 3HF

Minutes – Item 3

Centre 0307 (Complete Fertility Centre Southampton) – Variation of Premises and Licensed Activities (Treatment and Storage)

Members of the Panel:	Committee Secretary:
Peter Thompson, Director of Strategy & Information (Chair) Nick Jones, Director of Compliance Helen Richens, Policy Manager	Joanne McAlpine

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 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 Complete Fertility Centre Southampton is a dedicated unit housed within The Princess Anne Hospital, Southampton. The centre was first licensed under number 0307 in October 2008 for a period of three years with no additional conditions.

2. The Panel noted that the centre offers treatment and storage services to both NHS commissioned and self funding patients.

3. The Panel noted that the centre was last inspected in July 2009 (interim) and in September 2010 the centre's licence was varied to change the centre name to Complete Fertility Centre Southampton and the Person Responsible (PR) to Professor Nick Macklon

4. The Panel noted that the PR has submitted two applications to vary its treatment and storage licence, to change the premises and the licensed activities.

5. The Panel noted that the Inspectorate have reviewed the supporting information required by General Direction 0008, and are satisfied it meets the requirements.

6. As regards premises, the Panel noted that in recent months the centre has undergone a major refurbishment and expansion programme. The Panel noted that the centre will remain a self contained unit on the existing site having expanded into additional adjacent space.

7. As regards licensed activities, the Panel noted that the centre currently carries out approximately 100 treatment cycles of IUI and DI, and in the future wishes to offer a full range of IVF/ICSI services. The proposed cycles for IVF/ICSI/FET are anticipated to rise incrementally year on year to a maximum of 1200 in total.

8. The Panel noted that at the time of the inspection there were two areas of practice that required attention regarding the following;

    - The gamete and embryo transport dewars should be validated;
    - The witnessing record templates should be reviewed to include the time at which patients are positively identified at egg collection.

9. The Panel noted that since the inspection the PR has provided assurance and evidence that both of the recommendations have been implemented. The Panel noted that the PR has also provided evidence of validation for a key piece of equipment which due to a delivery delay was commissioned after the inspection.

10. The Panel noted that the PR has responded positively to the recommendations highlighted in the report.

11. The Panel noted that the Inspectorate commended the centre team on the thoroughness of their preparation for his inspection and the quality of the information provided, and the Panel would also like to commend the PR. The Panel also noted the PR's complementary comments regarding the inspection team.

Decision

12. The Panel agreed to the variation of licence for the change of premises and for the change of licence activities as specified in the application in accordance with Section 18A of Act (as amended).

13. The Panel endorsed all of the Inspectorates recommendations made within the report, noting the PR's response and progress already made.

Signed: Peter Thompson Date: 22/12/10.

Peter Thompson (Chair)