ST MARY'S HEFA ACTION PLAN RESPONSE TO THE DRAFT REPORT –MARCH 2010

Below is St Mary's response to the HEFA review in the requested areas. This is a live action plan that will focus the teams work to ensure that compliance is achieved in all areas. Each section of this document has been risk rated to show our confidence in delivery, green denotes that the issue is viewed as low risk has been immediately resolved or will be resolved in the next 3 months and amber denotes that the are some concerns about compliance within a 3 month period due to either the fact the team has to depend on other outside companies or the issues may take longer than 3 months to resolve.

Critical area of non compliance

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

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Failure to maintain emergency crash trolleys in line with professional body guidelines	(HF& E Act S17 (1) (a); (d); T2; T12; T15; T33b;)	Revision of nurse management, training and practices in order to prevent further failures concerning the emergency crash trolleys	Immediately	All staff spoken to with regards to accountability and responsibility in daily checking resuscitation equipment. All nursing staff made aware of importance of escalating and resolving missing equipment or replacing used equipment with as soon as possible. All staff issued with a copy of Trust guidelines re checking availability of resuscitation equipment (Resuscitation Policy 2009) Nurse in charge of shift aware of responsibility for ensuring that all resuscitation equipment within the	

				facility has been checked. All nurses competency assessed to check resuscitation equipment. Matron ward round will review and document this.	
The present practice of storing the low oxygen cryo-alarm mute key within the cryostore is potentially lethal.	(HF& E Act S17 (1) (a); (d); T2; T15; T33b)	Revision of staff policy and practices when storing and accessing the low oxygen cryo-alarm mute key.	Immediately	Resolved immediately Key has been moved to the new location on the Andrology reception area. Protocol in place but was not followed by one member of staff. This person has been retrained.	

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The continued storage of an embryo beyond the statutory storage period,	(HF&E Act S17(1); D0011; T120;	Submission of an incident report concerning the	Immediately	This issue is resolved Incident has been reported	

which involved the loss of patient records	HFE Act S14(1)(c) – schedule 3 S8(1); T79)	continued storage of an embryo beyond statutory storage period, which involved the loss of patient records		Process completed on a monthly basis Policy written outlining process for internal escalation and then incident report internally & to HEFA Medical records store move is now complete the delay in responding related to the PR wanting to see if the records could be located after the move	

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 staff, a patient, donor or to an embryo through the procurement, use, storage or distribution of gametes and embryos, which do not comply with the centre's licence;
- which indicates a major shortcoming from the statutory requirements;
- which indicates a failure of the Person Responsible to carry out his/her legal duties
- a combination of several "other" areas of non-compliance, none of which on their own may be major but which together may represent a major area of non-compliance.

Area of practice	Reference	Action required	Timescale for action	PR Response	Executive Review
Accurate and timely submission of data to the Authority.	(HFE Act S17 (1)(d)(e); D0005; T9(e)(f); T2; T39)	The PR must resolve regulatory issues concerning the accurate and timely submission of data to the Authority as a matter of urgency.	Within 3 months of the LC minutes being published	Issue being actioned Meeting requested with senior members of the Trust from IT to resolve all network issues Process now in place for ensuring accurate recording within the unit especially in relation to IUI and flow chart produced for all staff documenting the process. Meeting with Acubase provider needs to take place in near future to finalise all system issues Nursing Staff made aware of responsibility of entering accurate data on ACU at required stages of patient pathway • Intention to treat and medication used upto day	

				• Update medication used at HCG stage • Treatment outcome • Pregnancy viability • Cancelled cycles All staff will be reassessed to ensure data entry is accurate.	
Observed practice of drugs cabinet keys being left in situ and patient notes left unattended within a patient treatment room.	(HF& E Act S17 (1) (a); (d); S33A;T2; T12; T15; T33b; T43)	Revision of nursing staff training practices which would prevent the recurrence of drug cabinets keys being left in situ during the inspection	Immediately	Resolved immediately Nursing staff meeting held immediately following HFEA inspection all nursing staff made of their responsibility of the storage and security of medicines. All nursing staff have been issued with section 3 (storage and security of medicines) of the Trust Medicines Policy 2007 This is checked through the weekly Matron ward rounds.	
Potential for breach of patient confidentiality due to the practice of the records store door being left open.	(HF& E Act S17 (1) (a); (d); S33A; T2; T15; T33b; T43)	Revision of staff practices when using the new patient records store to prevent the door from being left open with the potential for a breach of confidentiality	Immediately	Resolved immediately On that day records were still being moved into the records room and personnel were also in the room filing records. The medical record storage is compliant with the Trust's policies and Record Management: NHS Code of Practice and HFEA Code of Practice 8	

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Lack of the management, training and competency assessment within the nursing department	(HF& E Act S17 (1) (a); (d); T12; T15)	Review of the management of nursing staff, to include resourcing, training and competency issues	Within 3 months of the LC minutes being published	Lead Nurse for Gynaecology has been based within Unit with immediate effect Permanent Nurse Manager position to be advertised. Competencies to be assessed to be identified and relevant documents developed. Competencies currently carried out are kept in training records and on the Organisational Development & Training spreadsheets. Training schedule implemented to be linked to RCN specialist Fertility Nurse competencies (RCN 2008)	
				Introduction of competencies in nursing as	

There was a lack of both assessment and recording of staff competency throughout the centre	(HF& E Act S17 (1) (a); (d); T12; T15a)	Review and implementation of periodic staff competency assessment and recording	Within 3 months of the LC minutes being published	outlined above Introduction of competencies in laboratory service in the next 3 months –these are required for laboratory accreditation and will be assessed on an annual basis. Embryology lead has developed a list of critical examination audits which will demonstrate embryology and andrology staff competence.	
The quality management system had not been maintained appropriately during the absence of the quality manager. Systems and processes had not been reviewed/ audited. There had been no annual review.	(HF& E Act S17 (1) (a); (d); T32; T35; T36)	Review of the quality management system to assess areas where quality indicators are not currently in place and audits not being performed	Within 6 months of the LC minutes being published	Quality management system to be reviewed over next 3 months. All SOPs to be reviewed, KPIs have been discussed and amended and the manual to be reviewed. Clarity of roles and responsibilities for line managers and staff on ensuring quality system is delivered Audit programme is being drawn up in relation to all the HFEA standards and will be delivered on a rolling programme	

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Electrical safety (PAT) testing of some critical equipment is presently not being undertaken	(HF& E Act S17 (1) (a); (b) (d); T24)	Implementation of electrical safety (PAT) testing of all critical equipment	Immediately	Immediately resolved All outstanding PAT testing has been undertaken. Process for PAT testing has been confirmed with Sodexho company that the Trust employs to undertake this work	

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.

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Implementation of recommendations from recent external reviews.		A report to be submitted to the Executive detailing the proposed implementation of recommendations from recent external reviews. This should address all areas of practice such as: the senior management structure; nursing resources and training; delivery of the service and strategies to improve live birth rates.	Within 3 months of the Licence Committee minutes being published	The department will submit an action plan within the timescales specified by HFEA.	

Additional information from the Person Responsible

1. As the report states, some of the issues raised cannot be addressed by the PR and these have been escalated to the Nominal Licensee for resolution.
2. It is inappropriate to discuss poor pregnancy rates over the preceding three years without reference to any data from that time, although such data is publically available.
3. The inclusion of a section "What the unit does well". This section was left blank throughout suggesting that there is nothing that the unit does well. This gives an unbalanced slant to any inspection report and is not in keeping with recent recommendations for better regulation.