HFEA Executive Licensing Panel Meeting

12 December 2014

Finsbury Tower, 103-105 Bunhill Row, London, EC1Y 8HF

Minutes – Item 1

Centre 0011 – (London Sperm Bank) – Renewal Inspection Report

Members of the Panel:	**Committee Secretary:**
Paula Robinson (Chair) Head of Business Planning Hannah Verdin – Head of Regulatory Policy Matthew Watts – Regulatory Policy Manager	Dee Knoyle

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

The Panel 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 considered the papers, which included a completed application form, inspection report and licensing minutes for the past three years.

2. The Panel noted that this is a storage only centre which stores gametes. The centre recruits sperm donors and provides donated sperm to the fertility clinics within the JD Healthcare Group. The centre is part of the JD Healthcare Group.

3. The Panel noted that the centre has been licensed by the HFEA since April 2010 and is currently on a short term licence (as a result of a recent variation to the licence, in September 2014) which was due to expire on 31 March 2015.

4. The Panel noted that at the time of the inspection on 14 October 2014, the Inspectorate identified three major and four other areas of non-compliance.

5. The Panel noted that some improvement was required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided. However the Panel also noted that since the inspection the Person Responsible (PR) had fully implemented most of the recommendations and committed to fully implement the outstanding recommendations.

6. The Panel noted that the Inspectorate recommended the renewal of the centre's storage licence for a period of four years without additional conditions.

Decision

7. The Panel had regard to its decision tree. It was satisfied that the appropriate application and fee had been submitted and that the application contained the supporting information required by General Directions 0008.

8. The Panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licenced activities, and the PR has discharged their duty under section 17 of the HF&E Act 1990 (as amended).

9. The Panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

10. The Panel endorsed the Inspectorate's recommendation to continue to monitor the centre's performance and the delivery of the remaining work to address the outstanding non-compliances. The Panel was pleased to note the swift response of the PR to the non-compliances that had already been addressed.

11. The Panel endorsed the Inspectorate's recommendation to renew the centre's storage licence for a period of four years without additional conditions.

Signed: Date: 15 December 2014

Paula Robinson (Chair)

Inspection Report

Purpose of the Inspection Report

This is a report of an inspection, carried out to assess whether this centre complies with essential requirements in providing safe and high quality care to patients and donors. The inspection was scheduled (rather than unannounced) and the report provides information on the centre's application for a renewal of its existing licence. Licences are usually granted for a period of four years. The Authority's Executive Licensing Panel (ELP) uses the application and this report to decide whether to grant a new licence and, if so, whether any additional conditions should be applied to the licence.

Date of inspection: 14 October 2014

Purpose of inspection: Renewal of a licence to carry out storage.

The centre has applied to add the following activities: None

Inspection details: The report covers the performance of the centre since the last inspection, findings from the inspection visit and communications received from the centre.

Inspectors: Lisa Beaumont (lead) and Victoria Lamb

Date of Executive Licensing Panel: 12 December 2014

Centre name	London Sperm Bank
Centre number	0011
Licence number	L/0011/19/d
Centre address	112, Harley Street, London, W1G 7JQ, UK
Person Responsible	Dr Meheranghiz Minbattiwalla
Licence Holder	London Sperm Bank
Date licence issued	05/09/2014
Licence expiry date	31/03/2015
Additional conditions applied to this licence	None

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Section 1: Summary report

Brief description of the centre and its licensing history:

The London Sperm Bank (LSB) has held a storage only licence with the HFEA since April 2010. The centre recruits sperm donors and provides donated sperm to the fertility clinics within the JD Healthcare Group. The centre is part of the JD Healthcare Group, has no NHS patients and is not registered with any other regulator.

On 14 December 2012 the ELP approved a change of premises from 99 to 112 Harley Street.

On 22 August 2014 the ELP approved the appointment of Dr Meheranghiz Minbattiwalla as the new PR, replacing Dr Kamal Ahuja.

Centre's activity levels:

Other licensable activities	✓ or Not applicable (N/A)
Storage of gametes	✓
Storage of embryos	N/A
Embryo testing	N/A

Summary for licensing decision

Taking into account the essential requirements set out in the Human Fertilisation and Embryology (HF&E) Act 1990 (as amended), the HF&E Act 2008 and the HFEA Code of Practice (CoP), the inspection team considers that it has sufficient information to conclude that:

- the application has been submitted in the form required;
- the application has designated an individual to act as the Person Responsible (PR);
- the PR's qualifications and experience comply with section 16 (2) (c) of the HF&E Act 1990 (as amended);
- the PR has discharged her duty under section 17 of the HF&E Act 1990 (as amended);
- the premises (including those of relevant third parties) are suitable;
- the centre's practices are suitable subject to implementation of the recommendations below;
- the application contains the supporting information required by General Direction 0008, in application for renewal of their licence;
- the centre has submitted an application fee to the HFEA in accordance with requirements.

The ELP is asked to note that at the time of the inspection there were a number of areas of practice that required improvement, including three major and four 'other' areas of non-compliance. Since the inspection the following recommendations have been fully implemented:

Major areas that require improvement:

- The PR should ensure that staff are adequately protected whilst placing samples into, and removing them from, storage;
- The PR should ensure that the particle counter is calibrated against a traceable standard.

'Other' areas that require improvement:

- The PR should ensure that the recall procedure is reviewed to ensure it is complete;
- The PR should ensure that the following audits are undertaken:
    - record keeping and document control;
    - confidentiality and privacy;
- The PR should ensure that the third party agreement for The Doctors Laboratory is complete.

The PR has given a commitment to fully implementing the following recommendations:

Major areas that require improvement:

- The PR should ensure that relevant staff undertake safeguarding training.

'Other' areas that require improvement:

- The PR should ensure that the dry shipper is validated as fit for purpose;

Recommendation to the Executive Licensing Panel

Some improvement is required in order for the centre to demonstrate suitability of their practices. The centre has a quality management system (QMS) in place and the PR is encouraged to use the QMS to best effect to monitor and improve the service provided.

The inspector will continue to monitor the centre's performance. Failure to implement the recommendations relating to these major areas of non-compliance within the prescribed timescales will result in the submission of a further report to the ELP with the recommendation that regulatory action be taken in accordance with the Authority's Compliance and Enforcement Policy.

The inspection team recommends the renewal of the centre's storage licence for a period of four years without additional conditions subject to the recommendations made in this report being implemented within the prescribed timescales.

Section 2: Inspection findings

This section details what the centre does well and which areas need to be improved to meet essential requirements. We break this down in to four areas covering all the activities of a licensed centre:

1. The protection of the patient, and children born following treatment at this centre
2. The experience of patients at this centre
3. The protection of gametes (sperm and eggs) and embryos at this centre
4. How this centre looks after important information

1. Protection of the patient and children born following treatment

Witnessing and assuring patient and donor identification

What the centre does well

Witnessing (Guidance note 18)
The centre's procedures for double checking the identification of gametes and embryos and the patient or donor to whom they relate are compliant with HFEA requirements. This ensures that patients receive treatment using the correct gametes or embryos.

What the centre could do better

Nothing identified at this inspection.

Donor selection criteria and laboratory tests

Screening of donors prior to procuring, processing gametes and embryos
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11)
The centre's procedures for screening donors are compliant with HFEA requirements. It is important that donors are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Payments for donors (Guidance note 13; Directions 0001)
The centre's procedures are compliant with HFEA requirements for giving and receiving money or other benefits in respect to any supply of gametes. It is important that the principle of altruistic donation be upheld but at the same time donors receive appropriate compensation for their time and any inconvenience caused.

Donor assisted conception (Guidance note 20)
The centre does not treat people with donated gametes or embryos; therefore this area of practice is not relevant to this inspection.

What the centre could do better

Nothing identified at this inspection.

Suitable premises and suitable practices

Safety and suitability of premises and facilities
Laboratory accreditation
Infection control
Medicines management
Pre-operative assessment and the surgical pathway
Multiple births
Procuring gametes and embryos
Transport and distribution of gametes and embryos
Receipt of gametes and embryos
Imports and exports
Traceability
Quality management system
Third party agreements
Transports and satellite agreements
Equipment and materials
Process validation
Adverse incidents

What the centre does well

Safety and suitability of premises and facilities (Guidance note 25)
The centre's premises are suitable. This is important to ensure that all licensed activities are conducted in a suitable environment that is fit for purpose.

The centre has procedures in place that are partially compliant to ensure that risks are taken into account to ensure patients and staff are in safe surroundings that prevent harm.

The premises of the centre's laboratories conducting tests that impact on the quality and safety of gametes (relevant third parties) are suitable.

The centre is compliant with HFEA requirements to processes gametes in an environment of appropriate air quality.

Laboratory accreditation (Guidance note 25)
The centre's laboratories and/or third party laboratories which undertake the diagnosis and investigation of donors, their gametes, or any material removed from them, are compliant with HFEA requirements for accreditation by CPA (UK) Ltd or another body accrediting to an equivalent standard. This is important to assure the quality of the

services provided.

Infection control
The centre has systems in place to manage and monitor the prevention and control of infection that are compliant with guidance.

Medicines management
The centre does not provide treatment, therefore this area of practice is not relevant to this inspection.

Pre-operative assessment and the surgical pathway
The centre does not provide treatment, therefore this area of practice is not relevant to this inspection.

Multiple births (Guidance note 7; Directions 0003)
The centre does not provide treatment, therefore this area of practice is not relevant to this inspection.

Procurement of gametes and embryos (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to document the justification for the use of the donor's gametes in treatment, based on the donor's medical history and therapeutic indications.
Sperm is never procured at home by this centre.

Transport and distribution of gametes and embryos (Guidance note 15; Directions 0009)
The centre's procedures for the distribution and recall of gametes are partially compliant with HFEA requirements. This is important to ensure that all gametes sent to other licensed centres within or outside the UK are:

- packaged and transported in a manner that minimises the risk of contamination and preserves the characteristics and biological functions of the gametes or embryos;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the gametes or embryos are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes and embryos (Guidance note15)
The centre's procedures for the receipt of gametes are compliant with HFEA requirements. This is important to ensure that the centre only accepts gametes from other centres if the gametes and embryos are appropriately labelled and has enough information to permit the gametes to be stored in a way that does not compromise their quality and safety.

Imports and exports (Guidance note 16; Directions 0006)
The centre's procedures for import of gametes are compliant with HFEA requirements.
The centre does not export gametes.

Traceability (Guidance note 19)
The centre's procedures are compliant with HFEA traceability requirements. These requirements are important to ensure that the centre has the ability -

- to identify and locate gametes during any step from procurement to use for human application or disposal,
- identify the donor and recipient of particular gametes,
- to identify any person who has carried out any activity in relation to particular gametes, and
- to identify and locate all relevant data relating to products and materials coming into contact with particular gametes and which can affect their quality or safety.

Quality management system (QMS) (Guidance note 23)
The centre has a QMS in place that is broadly compliant with HFEA requirements. The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services.

Third party agreements (Guidance note 24)
The centre's third party agreements are broadly compliant with HFEA requirements.

Transport and satellite agreements (Guidance note 24; Directions 0010)
The centre does not have any transport or satellite centres, therefore this area of practice is not relevant to this inspection.

Equipment and materials (Guidance note 26)
The centre uses equipment and materials that are partially compliant with HFEA requirements. Most of the equipment and materials used in licensed activity are designated for the purpose and are appropriately maintained in order to minimise any hazard to patients and/or staff.

The centre is compliant with HFEA requirements to validate critical equipment.

The centre has documented procedures for the operation of critical equipment and procedures to follow if equipment malfunctions.

Process validation (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to validate critical processes. This ensures that these processes are effective and do not render the gametes clinically ineffective or harmful to the recipient.

Adverse incidents (Guidance note 27)
The centre's procedures for reporting adverse incidents are compliant with HFEA requirements. The centre reports all adverse incidents (including serious adverse events) to the HFEA. The centre investigates all adverse incidents that have occurred. Reporting and investigation of adverse incidents is important to ensure that centres share the lessons learned from incidents and continuously improve the services it offers.

What the centre could do better

Safety and suitability of premises and facilities (Guidance note 25)
It was noted that centre staff do not use personal protective equipment (PPE) when placing samples into the dewars (SLC T2). See recommendation 1.

Transport and distribution of gametes and embryos
The centre's own dry shipper has not been validated to ensure the correct temperature is maintained for the duration of the transportation (SLC T108). See recommendation 2.

The centre's recall procedure is incomplete, as it does not define what action the centre staff should take when recalled samples are returned to the centre.
(CoP mandatory requirements 15C). See recommendation 4.

Quality management system (QMS)
The centre has not undertaken the following audits within the last two years:
- record keeping and document control;
- confidentiality and privacy.

(SLC T36). See recommendation 5.

Third party agreements
The content of the third party agreement for The Doctors Laboratory (TDL) reviewed in the course of the inspection did not include how information in terms of tests / diagnostic results is relayed to the commissioning centre including sign off and confirmation that the result applies to the correct sample (SLC T114f). See recommendation 6.

Equipment and materials
The particle counter has not been calibrated against a traceable standard at the manufacturer's recommended interval (SLC T24). See recommendation 3.

Staff engaged in licensed activity
Person Responsible (PR)
Staff

What the centre does well

Person Responsible (Guidance note 1)
The PR has complied with HFEA requirements.

The PR has academic qualifications in the field of biological sciences and has more than two years of practical experience which is directly relevant to the activity to be authorised by the licence. The PR has successfully completed the HFEA PR Entry Programme (PREP number T1258/81).

Staff (Guidance note 2)
The centre is compliant with HFEA requirements.
The centre has suitably qualified and competent staff, in sufficient number**,** to carry out the licensed activities and associated services. The centre has an organisational chart which clearly defines accountability and reporting relationships.

The centre has access to a nominated registered medical practitioner and scientist, within the UK, to advise on and oversee medical and scientific activities respectively.

What the centre could do better

Nothing identified at this inspection.

Welfare of the child and safeguarding

What the centre does well

Welfare of the child (Guidance note 8)
The centre does not treat patients, therefore this area of practice is not relevant to this inspection.

Safeguarding
The centre's procedures are broadly compliant with safeguarding guidance. This ensures that the centre's patients and staff are protected from harm where possible.

What the centre could do better

It was noted that there was no evidence of any member of staff having undertaken level 1, or above, safeguarding training (SLC T15). See recommendation 7.

Embryo testing

Preimplantation genetic screening
Embryo testing and sex selection

What the centre does well

Preimplantation genetic screening (Guidance note 9);
Embryo testing and sex selection (Guidance note 10)
These areas of practice are not applicable to this inspection.

What the centre could do better

2. The experience of patients

Patient feedback

What the centre does well

During the inspection visit no donors were available to speak to the inspection team. No donors provided feedback directly to the HFEA in the time since the last inspection.

The inspection team was therefore not able to assess this aspect.

What the centre could do better

Nothing identified at this inspection.

Treating patients fairly

Counselling
Egg and sperm sharing arrangements
Surrogacy
Complaints
Confidentiality and privacy

What the centre does well

Treating patients fairly (Guidance note 29)
The centre's procedures are compliant with requirements to ensure that prospective and current donors are treated fairly and that all licensed activities are conducted in a non-discriminatory way.

Counselling (Guidance note 3)
The centre's counselling procedures are compliant with HFEA requirements. This is important to ensure that counselling support is offered to donors providing relevant consent.

Egg and sperm sharing arrangements (Guidance note 12; Direction 0001)
The centre does not offer egg or sperm sharing services, therefore this area of practice is not applicable to this inspection.

Surrogacy (Guidance note 14)
The centre does not offer surrogacy services, therefore this area of practice is not applicable to this inspection.

Complaints (Guidance note 28)
The centre's procedures are compliant with HFEA requirements to be responsive to donor complaints. This is important to ensure that the centre uses any complaints as an opportunity to learn and improve their services.

Confidentiality and privacy (Guidance note 30)
The centre's procedures are compliant with HFEA requirements to ensure it has respect

for the privacy, confidentiality, dignity, comfort and wellbeing of prospective and current donors.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; CH(11)02)
The centre's procedures for providing information to donors are compliant with HFEA requirements. This ensures that the centre gives prospective and current donors sufficient, accessible and up-to-date information to enable them to make informed decisions.

What the centre could do better

Nothing identified at this inspection.

Consent and Disclosure of information, held on the HFEA Register, for use in research

What the centre does well

Consent (Guidance note 5;6)
The centre's procedures for obtaining consent are compliant with HFEA requirements. This ensures that donors have provided all relevant consents before carrying out any licensed activity.

Disclosure of information, held on the HFEA Register, for use in research (Directions 0005)
The centre's procedures for taking consent to disclosure to researchers are compliant with HFEA requirements.

This is important to ensure that the HFEA holds an accurate record of patients' consent, so that it only releases the patients identifying information to researchers, with their consent. Information can be used by researchers to improve the knowledge about the health of patients undergoing ART and those born following ART treatment.

The centre offers all gamete donors the opportunity to give consent to the disclosure of information to researchers. The centre completed and submitted an audit to the HFEA in October 2013, following a recommendation at the last inspection, therefore a consent to disclosure audit was not undertaken during this inspection.

What the centre could do better

Nothing identified at this inspection.

3. The protection of gametes and embryos

Respect for the special status of the embryo

What the centre does well

The centre does not create or store embryos on the premises, therefore this area of practice is not applicable to this inspection.

What the centre could do better

Screening of patients
Storage of gametes and embryos

What the centre does well

Screening of patients (Guidance note 17)

The centre does not treat patients, therefore this area of practice is not applicable to this inspection. Screening of donors is addressed elsewhere.

Storage of gametes and embryos (Guidance note 17)

The centre's procedures for storing gametes are compliant with HFEA requirements. These measures ensure that the gametes are stored appropriately to maintain their quality and safety. Furthermore, the centre only stores gametes in accordance with the consent of the gamete providers.

What the centre could do better

Nothing identified at this inspection.

Use of embryos for training staff (Guidance note 22)

What the centre does well

Use of embryos for training staff (Guidance note 22)

No embryos are created or stored at the centre so this area of practice is not applicable to this inspection.

What the centre could do better

4. Information management

Record keeping
Obligations and reporting requirements

What the centre does well

Record keeping and document control (Guidance note 31)
The centre's procedures for keeping records are compliant with HFEA requirements to ensure that accurate medical records are maintained.

Obligations and reporting requirements (Guidance note 32 ; Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements This is important to ensure the HFEA can supply accurate information to a donor-conceived person and their parents or donors.

The HFEA register audit team found no evidence of problems with the timeliness and accuracy of the centre's submission of data to the Register.

What the centre could do better

Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2013, recommendations for improvement were made in relation to one area of critical non-compliance, three areas of major non-compliance and four 'other' areas of non-compliance.

The PR provided information and evidence that all of the recommendations were fully implemented.

On-going monitoring of centre success rates

The centre does not provide treatment therefore this area of practice is not applicable to this inspection.

Areas of practice requiring action

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 required are given, as well as the timescales in which these improvements should be carried out.

Critical areas of non-compliance

A critical area of non-compliance is an area of practice which poses a significant risk of causing harm to a patient, donor, embryo or to a child who may be born as a result of treatment services, or a significant shortcoming from the statutory requirements. 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			

Major areas 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
1. It was noted that centre staff do not use personal protective equipment (PPE) when placing samples into the dewars. (SLC T2)	The PR is required to review the process for placing samples into, and removing them from, storage and take action to ensure staff are adequately protected whilst undertaking this activity. A summary of the review together with actions taken should be forwarded to the centre's inspector by 14 January 2015.	Suitable gloves and goggles have been ordered for and will be used whenever required.	The PR has reviewed the process for placing samples into, and removing them from, storage. A summary of the review and actions to be taken has been received by the inspector. No further action.
2. The centre's own dry shipper has not been validated to ensure the correct temperature is maintained for the duration of the transportation.	The PR should take action to ensure that the dry shipper is validated as fit for purpose. A summary of the results of the validation together with any	After looking for an appropriate data logging system for the dry shippers, we have considered going for the one from CMV CHART ref: http://www.chartbiomed.com/g	The checklist noting the weight of the shipper prior to and after priming and after return to the centre has been provided to the inspector.

(SLC T108).	actions taken should be forwarded to the centre's inspector by 14 January 2015.	etattachment/db6344e5-ed7c-4a36-92f8-5ea9b0809fe7/.aspx. I have approached them for the quotation and are waiting for their reply. In the mean while, a new checklist is introduced to log the temperatures but until we have the digital system in place, we have started noting the static holding time by weighing the shipper before and after 12 hrs of priming and also after receiving it back. (ref. doc. 5,017 dry shipper checklist). This is a crude method of validating the shipper but it will nevertheless keep us informed regarding the working status of the shipper before and after dispatching the samples until a proper temperature logger is fixed on them.	The inspector is satisfied with this interim measure and will follow up with the PR regarding the intended additional measures that will be taken by the PR. Further action required.
3. The particle counter has not been calibrated against a traceable standard at the manufacturer's recommended interval (SLC T24).	The PR should take action to ensure that the particle counter is calibrated against a traceable standard. The PR should provide evidence to the centre's inspector that this has	The Particle counter was sent for recalibration immediately to the supplier (Research Instruments) on the 30th October with a view to re-calibration and certification.	The calibration certificate for the particle counter has been provided to the inspector. A log of dates when all items of equipment with a critical measuring function are due to

	been completed by 14 January 2015. The PR should also provide a summary of actions taken to ensure that all equipment with a critical measuring function is calibrated against a traceable standard, and that this non-compliance does not recur. This should be provided to the centre's inspector by 14 January 2015.	The instrument was returned on 17th November with a PASSED certification as attached. A logger already exists that records all equipment requiring calibration and maintenance annually (ref. Service Instruments chart as attached). This is shared with the group's Purchase Officer to create a PO on time for the purpose. All instruments used will be serviced by the end of this year.	be calibrated has also been provided to the inspector. The inspector accepts that the lack of calibration of the particle counter was due to a misunderstanding with the supplier of when the next calibration was due, rather than a failure of the system for identifying when recalibration of equipment was due. No further action.

Other areas of practice that require 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 statutory requirements or good practice.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
4. The centre's recall procedure is incomplete, as it does not define what action the centre will take when recalled samples are returned to the centre. (CoP mandatory requirements 15C).	It is acknowledged that recall is likely to be infrequent, but should a recall be necessary staff should have clear instruction on how to proceed. The PR should ensure that the recall procedure is reviewed to ensure it is complaint with the CoP mandatory requirements 15C. A revised copy of the recall procedure should be provided to the centre's inspector by 14 January 2015.	The generic Recall Procedure used across the JDH clinics has been reviewed; please ref. Recall management SOP - doc1,673 as attached.	A revised copy of the recall procedure has been provided to the inspector. This now includes what action the centre will take when recalled samples are returned to the centre. No further action.
5. The centre has not undertaken the following audits within the last two years: • record keeping and document control; • confidentiality and privacy. (SLC T36)	The PR is required to ensure that audits for; • record keeping and document control; • confidentiality and privacy are undertaken, the results are documented and any corrective actions identified are implemented.	Required audits have been completed: please refer to attached audits INTLSB1324 & INTLAB1322 for record keeping and confidentiality and privacy respectively. Please also ref Doc Control SOP doc no.1,831 as	The PR has undertaken the required audits and provided a summary of these to the inspector. Corrective actions have been documented and appropriately completed. No further action.

	A summary of these audits should be submitted to the centre's inspector by 14 April 2015.	attached.	
6. The content of the third party agreement for The Doctors Laboratory (TDL) reviewed in the course of the inspection did not include how information in terms of tests / diagnostic results is relayed to the commissioning centre including sign off and confirmation that the result applies to the correct sample. (SLC T114f).	The PR should ensure that this and all other third party agreements are reviewed to ensure compliance with SLC T114. A summary report of the findings of the review including a list of all third party agreements included in the review should be provided to the centre's inspector by 14 January 2015. The report should also document any corrective actions required to ensure compliance and the anticipated timescales for the implementation of the corrective actions.	Received TPA with TDL is attached (TPA 21.10.14 pdf). A summary of all TPAs with LSB is also attached (ref; area of practice 6). The results obtained are checked with respect to the donor's name, DOB and date when sample was supplied to the diagnostic centre to ensure that the result applies to the correct sample/donor. The results are signed off and dated by two staff members again stating the date the tests were done on the donor check list; document #2351 attached.	The PR has provided an updated third party agreement with TDL that includes the required information. The PR has also provided a list of third party agreements held by centre 0011 and confirmation that these agreements are compliant with SLC T114. No further action.
7. It was noted that there was no evidence of any member of staff having undertaken level 1, safeguarding training. (SLC T15).	The PR should implement suitable arrangements to ensure that those attending the centre are safeguarded against the risk of abuse, by ensuring that all staff have undertaken safeguarding	Safeguarding training was undertaken by every member of the team on 5th November 2014. Please refer to the risk assessment [as attached]	The PR has provided an assessment of the risks to staff at LSB. The inspector will liaise further with the PR to confirm the PRs understanding of this recommendation and ensure that suitable action is

	training and know how to identify, report and respond appropriately to suspected or actual abuse. The PR should undertake a risk assessment to identify those staff requiring safeguarding training, and at what level. The PR should provide evidence to the centre's inspector by 14 April 2015, to demonstrate that all staff have completed their safeguarding training to an appropriate level on the basis of the assessment.	prepared for untoward behaviour of the donor, if such a behaviour is ever encountered at LSB's recruitment area, which is the only area accessible to the donors where they are seen by the recruitment staff.	taken. Further action required.

Reponses from the Person Responsible to this inspection report
Thank you for bringing up the vital areas that required attention for the purpose of QM assessment. I have tried to complete all but one i.e point 2 although the process has been turned on. Once the quotation is received and PO forwarded to the manufacturer we would be good to go for the devices for our 3xdry shippers.