Executive Licensing Panel - minutes

Centre 0332 (Oxford Cell and Tissue Biobank)

Renewal Inspection Report

Tuesday, 21 May 2019

HFEA, 10 Spring Gardens, London SW1A 2BU

Panel members	Clare Ettinghausen (Chair) Howard Ryan Yvonne Akinmodun	Director of Strategy and Corporate Affairs Report Developer Head of Human Resources
Members of the Executive	Bernice Ash	Secretary
External adviser		
Observers	Catherine Burwood	Licensing Manager

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:

- 9th edition of the HFEA Code of Practice
- Standard licensing and approvals pack for committee members.

1. Consideration of application

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

1.2. The panel noted that the Oxford Cell and Tissue Biobank has held a storage only licence with the HFEA since 2013. The centre provides an ovarian tissue storage service for women and children who are to undergo chemotherapy or radiotherapy and are at risk of premature ovarian failure. Ovarian tissue is procured in the main hospital operating theatres in the John Radcliffe Hospital, Oxford University Hospitals NHS Trust, under the auspices of a third-party agreement (TPA). The tissue is transported to the centre for processing and storage. The centre is starting to expand its service to include other hospitals, which will procure ovarian tissue under TPAs with centre 0332 and transport it to the centre for processing and storage. This expansion is at a very early stage involving training surgical staff at the third-party hospitals.

1.3. The panel noted that immature eggs can be harvested from ovarian tissue during processing. These eggs are transported to Oxford Fertility (centre 0035) for in vitro maturation and storage. This aspect of the service is currently suspended, but the Person Responsible (PR) plans to start it again within the term of the licence applied for and may process and store the immature eggs at the centre

1.4. The panel noted that the centre also procures and stores testicular tissue for young boys who have to undergo rapid medical treatment which may cause them to become infertile. This tissue is likely to be used in a transplantation approach, however, depending on the development of technology in this fast-moving area, an in vitro approach to fertility preservation could feasibly be used in future.

1.5. The panel noted that the Human Tissue Authority (HTA) conducted an on-site inspection of the centre on 13 and 14 February 2019, including the ovarian and testicular tissue storage service. The report of that inspection was made available to the HFEA; it found that the centre had met HTA standards, except for one shortfall concerning air quality monitoring to HTA requirements. This was not relevant to the centre's HFEA licence renewal application because HTA requirements for processing and storage of material for transplant are stricter than HFEA requirements for processing and storage of oocytes for future use in IVF. Several advisory comments were also made in the HTA report and, where relevant, they are referred to in the HFEA inspection report.

1.6. The panel noted that an HFEA licence is not required for ovarian and testicular tissue processing and storage if the tissue will subsequently be used in a transplantation approach to fertility treatment: such activities are performed under the centre's licence from the HTA. However, the Person Responsible (PR) has applied to renew the centre's HFEA licence because of its plans to process and store immature eggs.

1.7. The panel noted that the HTA report has been used as evidence of compliance with HFEA requirements where relevant. The inspection team considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements.

1.8. An inspection was carried out at the centre on the 19 March 2019.

1.9. The panel noted that at the time of the inspection, there was one major area of non-compliance concerning premises and facilities. Since the inspection visit, the Person PR has provided evidence the recommendation, regarding premises and facilities, has been fully implemented.

1.10. The panel noted that the PR is encouraged to use the Quality Management System (QMS) to best effect to monitor and improve the service provided.

1.11. The panel noted that, the inspection team recommended the renewal of the centre's storage only licence for a period of four years, without additional conditions.

2. Decision

2.1. 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.

2.2. The panel noted that the premises to be licensed are suitable for the conduct of the licensed activities.

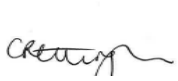
2.3. The panel was satisfied that the qualifications and character of the PR are such as is required for the supervision of licensed activities and the PR will discharge his duty under section 17 of the HFE Act 1990 (as amended).

2.4. The panel endorsed the inspectorate's recommendation to renew the centre's storage only for a period of four years, without additional conditions.

3. Chair's signature

3.1. I confirm this is a true and accurate record of the meeting.

Signature



Name

Clare Ettinghausen

Date

28 May 2019

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: 19 March 2019

Purpose of inspection: Renewal of a licence to carry out Storage only

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: Sara Parlett and Sandrine Oakes

Date of Executive Licensing Panel: 21 May 2019

Centre name	Oxford Cell and Tissue Biobank
Centre number	0332
Licence number	L/0332/2/c
Centre address	Oxford University Hospital NHS Foundation Trust, Children's & Women's Division, Cardiac Unit, Level 0 John Radcliffe Hospital, Headington, Oxford, OX3 9DU
Person Responsible (PR)	Ms Jill Davies
Licence Holder (LH)	Dr Sheila Lane
Date licence issued	5 August 2015
Licence expiry date	4 August 2019
Additional conditions applied to this licence	None

Contents

Section 1: Summary report

Brief description of the centre and its licensing history:

The Oxford Cell and Tissue Biobank has held a storage only licence with the HFEA since 2013. The centre provides an ovarian tissue storage service for women and children who are to undergo chemotherapy or radiotherapy and are at risk of premature ovarian failure. Ovarian tissue is procured in the main hospital operating theatres in the John Radcliffe Hospital, Oxford University Hospitals NHS Trust, under the auspices of a third party agreement (TPA). The tissue is transported to the centre for processing and storage. The centre is starting to expand its service to include other hospitals, which will procure ovarian tissue under TPAs with centre 0332 and transport it to the centre for processing and storage. This expansion is at a very early stage involving training surgical staff at the third party hospitals.

Immature eggs can be harvested from ovarian tissue during processing. These eggs are transported to Oxford Fertility (HFEA licensed centre 0035) for in vitro maturation and storage. This aspect of the service is currently suspended but the PR plans to start it again within the term of the licence applied for and may process and store the immature eggs at the centre.

The centre also procures and stores testicular tissue for young boys who have to undergo rapid medical treatment which may cause them to become infertile. This tissue is likely to be used in a transplantation approach, however, depending on the development of technology in this fast-moving area, an in vitro approach to fertility preservation could feasibly be used in future.

An HFEA licence is not required for ovarian and testicular tissue processing and storage if the tissue will subsequently be used in a transplantation approach to fertility treatment: such activities are performed under the centre's licence from the Human Tissue Authority (HTA). However, the PR has applied to renew the centre's HFEA licence because of its plans to process and store immature eggs.

This current licence has been varied to reflect the following changes:

- Change of centre name – 13 March 2017
- Change of LH – 7 March 2017.

The use of the HTA inspection report, in support of evidence of compliance at this inspection:

The HTA carried out an on site inspection of the centre on 13 and 14 February 2019, including the ovarian and testicular tissue storage service. The report of that inspection has been made available to the HFEA; it found that the centre had met HTA standards, except for one shortfall concerning air quality monitoring to HTA requirements. This was not relevant to the centre's HFEA licence renewal application because HTA requirements for processing and storage of material for transplant are stricter than HFEA requirements for processing and storage of oocytes for future use in IVF. Several advisory comments were also made in the HTA report. Where relevant they are referred to in this inspection report.

The HTA report has been used as evidence of compliance with HFEA requirements where relevant. The inspection team considers that the HTA inspection report provides suitable and appropriate evidence for compliance with HFEA requirements because:

- The HTA inspection directly reviewed the ovarian and testicular tissue storage service.
- The HTA inspection was performed only one month before this HFEA inspection, so findings are current.
- The regulatory requirements of the HTA and HFEA have considerable commonality, as the European Union Tissues and Cells Directives are a major component of the regulatory frameworks of both organisations. Thus many HTA standards, which the centre is compliant with, are equivalent to HFEA standards.

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) and standard licence conditions (SLCs), 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 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;
- the application contains the supporting information required by General Direction 0008, in application for renewal of the centre's 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 was one area of practice that required improvement, comprising one major non compliance, which resulted in the following recommendation:

Major areas of non compliance:

- The PR is reminded to consider HFEA requirements before making changes to premises or processes and should ensure that fire extinguisher servicing and electrical safety testing are performed at the frequency designated by local risk assessment.

The PR has provided evidence to the executive that this recommendation has been implemented.

Recommendation to the Executive Licensing Panel – pre-review by PR

The centre has one major area of non compliance. The PR is encouraged to use the Quality Management System (QMS) to best effect to monitor and improve the service provided and to implement the recommendations to address this non compliance.

The inspection team recommends the renewal of the centre's Storage only licence for a period of four years, subject to the recommendation in this report being implemented within the prescribed timescale.

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) 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 reproductive tissue and oocytes and the patient to whom they relate are compliant with HFEA requirements. This ensures that no mismatches occur between patients and stored tissue and oocytes when used in medical treatment.

What the centre could do better
Nothing identified at this inspection.

Donor selection criteria and laboratory tests
Screening of donors prior to procuring and processing gametes
Payments for donors
Donor assisted conception

What the centre does well

Screening of donors (Guidance note 11), Payments for donors (Guidance note 13; General Direction 0001), Donor assisted conception (Guidance note 20)
The centre does not recruit donors; 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
Transport and distribution of gametes
Receipt of gametes
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 broadly 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 compliant with requirements to ensure that risks are taken into account so that patients and staff are in safe surroundings that prevent harm.

The premises of the centre's third parties providing reproductive tissue procurement and oocyte storage services as well as laboratories conducting tests that impact on the quality and safety of gametes are suitable.

The centre is compliant with HFEA requirements to process 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 patients, patients' partners or donors, or their gametes, are compliant with HFEA requirements to be accredited by UKAS, the national accreditation body for the UK, or another accreditation body recognised as accrediting to an equivalent standard. This is important to assure the quality of the services provided.

Infection control; Medicines management; Pre-operative assessment and the surgical pathway (Guidance Note 25) and Multiple births (Guidance note 7; General Direction 0003)
The centre does not provide fertility or other medical treatment and tissue procurement is undertaken in hospital theatres under third party agreements. Therefore these areas of practice are not directly relevant to this inspection. The PR relies on CQC inspections to ensure the compliance of the hospital theatres with these requirements.

Procurement of gametes (Guidance note 15)
The centre's procedures are compliant with HFEA requirements to document the justification for the use of the patient's reproductive tissue and any oocytes harvested, in licensed activity, based on the patient's medical history and therapeutic indications;

Transport and distribution of gametes (Guidance note 15; General Direction 0009)
The centre's procedures for the transport of reproductive tissue and any immature eggs harvested, are 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 reproductive tissue/gametes;
- shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the reproductive tissue/gametes;
- appropriately labelled with the transport conditions, including temperature and time limit being specified;
- the container/package is secure and ensures that the reproductive tissue/gametes are maintained in the specified conditions. All containers and packages are validated as fit for purpose.

Receipt of gametes (Guidance note15)
The centre does not receive gametes from other centres and so this area of practice is not relevant to this inspection.

Imports and exports (Guidance note 16; General Direction 0006)
The centre does not import or export gametes, therefore this area of practice is not relevant to this inspection.

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

Quality management system (QMS) (Guidance note 23)
The establishment and use of a QMS is important to ensure continuous improvement in the quality of treatments and services. The centre has a QMS that is compliant with HFEA requirements. The HTA report advised that the centre should keep to the audit schedule. The PR reported that this advice is being addressed.

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

Transport and satellite agreements (Guidance note 24; General Direction 0010)
The centre does not have transport or satellite arrangements, 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 compliant with HFEA requirements. All 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 HTA inspection report noted that some disinfectants in use at the centre now have a specified storage temperature range, and the centre was advised to store them in monitored locations. The PR reported that this matter has been addressed.

The PR is reminded that should the centre re-commence immature oocyte harvesting, processing and storage, the materials and devices used should be reviewed before starting work, to ensure they are CE marked at an appropriate level where such goods are available.

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 reproductive tissue/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 has had very little HFEA licensable activity and no incidents in this area of practice have occurred, so the centre has not needed to report or investigate any incidents. 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)
The centre relocated its crystore from a portacabin to a room in the hospital, directly adjacent to the portacabin, without liaising with its HFEA inspector or submitting an application to the HFEA to vary its licence to reflect the premises change. The HTA was informed prior to relocation and considered the new cryostore to be suitable. The inspection team also considered the new cryostore to be compliant with HFEA requirements and notes that all stored material is stored under the centre's HTA licence; no HFEA licensable material is stored, or has been stored, at the new cryostore. Furthermore the new cryostore is at the address on the centre's licence (General Direction 0008; CoP guidance 25.5-25.8).

A fire extinguisher was outside of its servicing interval and an extension lead was in use which had not been tested for electrical safety (SLC T26).

Recommendation 1

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, not withstanding the concern raised in 'Premise and Facilities' concerning the relocation of the cryostore without advising the HFEA or seeking a licence variation.

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.

Staff (Guidance note 2)
The centre is compliant with HFEA requirements to have 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 provide fertility treatment, therefore this area of practice is not relevant to this inspection.

Safeguarding (Guidance Note 25)
The centre does not provide fertility or other medical treatment and tissue procurement is undertaken in hospital theatres under third party agreement. Therefore this area of practice is not relevant to this inspection.

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 centre.

2. The experience of patients

Patient feedback

What the centre does well

The centre does not provide fertility or other medical treatment so patient feedback to the HFEA was not available. The centre is committed to getting feedback on the service and has prepared surveys for patients and parents to be used within third party hospital settings. The centre has also engaged with previous patients to try to ensure their service is as user friendly as possible.

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 does not provide licensed treatment to patients and therefore this area of practice is not applicable to this inspection.

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 patients providing relevant consent.

Egg sharing arrangements (Guidance note 12; General Direction 0001); Surrogacy (Guidance note 14)

The centre does not offer gamete sharing services or surrogacy treatments and therefore these areas of practice are not applicable to this inspection.

Complaints (Guidance note 28)

The centre's procedures are compliant with HFEA requirements to seek patient feedback and to respond to complaints. This is important to ensure that the centre uses patient feedback and 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 patients.

What the centre could do better

Nothing identified at this inspection.

Information

What the centre does well

Information (Guidance note 4; Chair's Letter CH(11)02)
The centre's procedures for providing information to patients are compliant with HFEA requirements. This ensures that the centre gives prospective and current patients 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 patients have provided all relevant consents before carrying out any licensed activity.

Legal parenthood (Guidance note 6)
The centre does not provide licensed treatment to patients and therefore this area of practice is not applicable to this inspection.

Disclosure of information, held on the HFEA Register, for use in research (General Direction 0005)
The centre does not provide licensed treatment to patients and therefore this area of practice is not applicable to this inspection.

If immature oocytes stored by the centre are to be used in treatment at a later date, this treatment will be provided at a licensed IVF centre which will address the matter of consent to disclosure to researchers.

Taking consent to disclosure to researchers in a manner compliant with HFEA requirements is important, as it to ensure that the HFEA holds an accurate record of consent, so that it only releases a patient's 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.

What the centre could do better
Nothing identified at this inspection.

3. The protection of gametes

Respect for the special status of the embryo

What the centre does well
This area of practice is not applicable to this inspection.

Screening of patients and Storage of gametes

What the centre does well

Screening of patients (Guidance note 15)
The centre's procedures for screening patients are compliant with HFEA requirements. It is important that gamete providers are appropriately screened to minimise the risks of cross infection during treatment, processing and storage of gametes.

Storage of gametes (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.

What the centre could do better
Nothing identified at this inspection.

Use of embryos for training staff

What the centre does well
This area of practice is not applicable to this inspection.

4. Information management

Record keeping and 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. Good medical records are essential for the continuity of the patient's care.

Obligations and reporting requirements (Guidance note 32; General Direction 0005)
The centre's procedures for submitting information, about licensed activities to the Authority are compliant with HFEA requirements.

The centre has not needed to report any data to the HFEA regarding eggs stored at the centre, as yet, and has not been equipped by the HFEA with an electronic data interface (EDI) system. The PR is advised that in future, the HFEA will need to be informed about eggs placed into storage at the centre or transported from the centre to another licensed clinic. The PR should liaise with HFEA register staff regarding the processes for doing this once the PRISM system is functional.

What the centre could do better
Nothing identified at this inspection.

Section 3: Monitoring of the centre's performance

Following the interim inspection in 2017, recommendations for improvement were made in relation to two 'other' areas of non compliance.

The PR provided information and evidence that both recommendations were fully implemented.

On-going monitoring of centre success rates

The centre does not provide treatment to patients so has no success rates to monitor through the risk tool.

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, General 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 area 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.

A critical area of non compliance is identified in the report by a statement that an area of practice is not compliant with requirements.

Area of practice and reference	Action required and timescale for action	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, 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.

A major area of non compliance is identified in the report by a statement that an area of practice is partly compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
1. **Premises and facilities** The centre relocated its crystore from a portacabin to a room in the adjacent hospital without submitting an application to the HFEA to vary its licence (General Direction 0008; CoP guidance 25.5-25.8). It is noted that the HTA had approved the relocation and considered the new premises suitable and that no HFEA licensed material has been stored at the new location A fire extinguisher was outside	The PR is reminded to consider HFEA requirements before making changes to premises or processes. The PR should discuss with the centre's inspector any plans to vary the centre's premises. A formal application to vary its licence may be required. The inspection team do not consider a retrospective application is required in this case, given the new cryostore is at the same address as on the licensed premises, is compliant with HTA requirements and was	Before making any future changes to premises or processes, OCTB PR will discuss with the centre's inspector any plans to vary the centre's premises. A formal application to vary its licence will be submitted as required. No future changes are planned. All fire extinguisher servicing and electrical safety testing has been reviewed with OUHFT Estates manager and will in future be performed at the frequency following local OCTB risk assessment.	The PR's response is noted and includes actions to implement the recommendation. No further actions are required.

of its servicing interval and an extension lead was in use which had not been tested for electrical safety (SLC T26).	considered compliant at this inspection. The PR should ensure that fire extinguisher servicing and electrical safety testing are performed at the frequency designated by local risk assessment. The actions taken to implement this recommendation should be advised to the executive when the PR responds to this report.		

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 statutory requirements or good practice.

An ‘other’ area of non compliance is identified in the report by a statement that an area of practice is ‘broadly’ compliant with requirements.

Area of practice and reference	Action required and timescale for action	PR Response	Executive Review
None			

Reponses from the Person Responsible to this inspection report