Unit 23: Laboratory Practice in the HFEA-licensed Reproductive Science Laboratory

Level:	**4**
Unit type:	**Optional (Reproductive Science)**
Credit value:	**3**
Guided learning hours:	**25**

Unit summary

In this unit, you will be introduced to the multidisciplinary team in the workplace of the HFEA-licensed Fertility Clinic, and to the key roles of a Healthcare Science Associate in reproductive science. You will build professional practice in accordance with Good Scientific Practice.

The Human Fertilisation and Embryology Act 1990, as amended, 2008, provides a highly specialised working environment where all staff are required to understand the legal framework in order to safeguard the requirements of the Human Fertilisation and Embryology Act, the Human Fertilisation and Embryology Authority (HFEA) licence conditions and the requirements of the EU Tissues and Cells Directives.

On completion of this unit, you will be able to operate safely within a defined role, which may include tasks for laboratory administration, cleaning, stock control, assistance with audit and witnessing of clinical procedures. You will also undertake tasks requiring sterile techniques and the use of specialised laboratory equipment, and other duties, including semen assessment. You will have a patient-facing role. You will be aware of the legislative framework of services within the HFEA-licensed reproductive sciences laboratory and the safety implications of working in the laboratory and the cryostorage facility, including infection control. You will use effective communication skills in the context of patient-centred care and will recognise the role of the specialism in patient care. You will be expected to adhere to health and safety procedures, and work safely in the workplace adhering to the HFEA Code of Practice and local procedures and governance, including patient confidentiality and the Data Protection Act 1998.

The knowledge acquired in this unit underpins the delivery of the care pathways for individuals attending the HFEA-licensed Fertility Clinic. This knowledge is required to support the role of the Healthcare Science Associate in the HFEA-licensed reproductive science laboratory.

Unit assessment requirements

There are no specific assessment requirements for this unit. Please refer to the assessment strategy in *Annexe B*.

Additional information

Any external assessor or trainer must be authorised to access the HFEA-licensed Fertility Clinic.

Evidence must be anonymised to remove patient-identifiable data. Section 30 of the Human Fertilisation and Embryology Act 1990 imposes a legal duty of confidentiality and a breach of this provision is a criminal offence.

All learners must complete formal training in the safe use of liquid nitrogen.

AC1.1 includes:

- how Standard Operating Procedures are structured, how to access them and the importance of their use
- the procedures required to safeguard the quality and safety of human gametes and embryos
- how the security of the laboratory is ensured
- the clothing policy for the different areas within the laboratory
- the requirements for air quality for different areas within the laboratory
- how the environment is maintained, including cleaning, movement of stock and waste disposal
- the types of cleaning products and their appropriate use within the laboratory.

AC1.2 includes:

- the requirements for quality management as specified by the HFEA Code of Practice
- the methods used to track the use of laboratory equipment
- the methods used to track the use of laboratory consumables
- the methods used to track the status of the laboratory environment
- the purpose and methods for daily monitoring undertaken within own laboratory
- how audit procedures are used in own laboratory.

AC1.3 includes:

- the completion of formal training in the safe use of liquid nitrogen
- the operational principles and requirements for safe operation within the cryopreservation facility of the HFEA-licensed Fertility Clinic, to include:
    - risks of liquid nitrogen
    - action to take in the event of an emergency
    - personal protective equipment (PPE)
    - low-oxygen alarms

    - cross-contamination risks for samples
    - storage under liquid nitrogen
    - storage in vapour phase
    - alarm systems
    - security of the cryopreservation facility
- the functions and purpose of the equipment located in the cryopreservation facility
- the specific safety considerations for each piece of equipment in the cryopreservation facility.

AC1.4 includes:

- the communication methods used in the context of delivery of services within the HFEA-licensed Fertility Clinic. This includes examples of communication:
    - in the laboratory team
    - in the wider multidisciplinary team
    - with external agencies, including HFEA
- tasks that require the use of effective communication
- use of communication skills:
    - in the laboratory
    - in the wider multidisciplinary team
- effects of poor communication
- the definition of 'an incident' and a 'near miss' as specified by the HFEA Code of Practice
- how to report an incident at both local level and to the Human Fertilisation and Embryology Authority.

AC1.5 includes:

- the role of the Healthcare Science Associate in the HFEA-licensed reproductive science laboratory:
    - the context
    - troubleshooting
    - when to seek advice
- the limits of the learner's own authority and to whom they should report if the encounter problems that they cannot resolve.

General reproductive science laboratory skills: applies to all procedures, including those specified in AC2.2 – 2.5.

AC2.1 includes:

- Working safely at all times, complying with health and safety and other relevant regulations and guidelines.
- Keeping contemporaneous records in accordance with local policies and procedures.

- Checking batch/lot numbers and expiry dates for items that could affect the quality and safety of gametes or embryos.
- Selecting appropriate cleaning products to use within the laboratory.
- Using cleaning products within the laboratory.
- Disposing of used items in accordance with local policies and procedures.
- Taking appropriate remedial action when adverse situations, problems or events occur.
- Acting on any events that require immediate action in accordance with local policies and procedures.
- Ensuring effective and appropriate communication in the laboratory team and in the multidisciplinary team, in accordance with local policies and procedures.

AC2.2 includes the safe use of centrifuges:

- requirements for safe operation and use of a centrifuge
- selecting the correct method for use of a centrifuge
- how to check centrifuges are working within operational limits
- following the Standard Operating Procedures for any procedure requiring the use of a centrifuge
- following the Standard Operating Procedures for cleaning and decontamination of a centrifuge
- ensuring effective communication on all aspects of centrifuge use in accordance with local policies and procedures.

AC2.3 includes safe use of laboratory workstations:

- the different types and appropriate use of the workstations in the laboratory
- the operational principles and requirements for operation of the workstations in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes, embryos and the operator
- safe and appropriate use of each workstation in own laboratory
- selecting the appropriate workstation for tasks, to ensure sterile technique
- how to check workstations are working within operational limits
- following the Standard Operating Procedures for:
    - sterile technique within the workstation
    - cleaning and decontamination of workstations
    - ensuring effective communication on all aspects of use of workstations in accordance with local policies and procedures.

AC2.4 includes the safe use of incubators:

- the different types and appropriate use of the incubators in the laboratory
- the operational principles and requirements for operation of incubators in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos

- safe and appropriate use of each incubator in own laboratory
- selecting the appropriate incubator for tasks, to ensure correct culture of gametes, embryos and the operator
- how to check incubators are working within operational limits
- following the Standard Operating Procedures for:
    - use of an incubator
    - cleaning and decontamination of incubators
    - monitoring of the incubators and alarm systems
    - ensuring effective communication on all aspects of use of incubators in accordance with local policies and procedures.

AC2.5 includes:

- the operational principles and requirements for operation of microscopes in own laboratory, including the features that safeguard the culture system and the quality and safety of gametes and embryos
- safe and appropriate operation and use of microscopes, to include:
    - bright field binocular dissecting microscope
    - bright field and phase contrast compound microscope
    - inverted microscope with Hoffman modulation contrast
    - other microscopes in use in own laboratory
- following the Standard Operating Procedures for:
    - use of a microscope
    - cleaning and decontamination of a microscope
- equipment for temperature control during microscopy and its monitoring
- equipment for acquisition of images during microscopy
- ensuring effective communication on all aspects of the use of microscopes in accordance with local policies and procedures.

Learning outcomes and assessment

To pass this unit, learners need to demonstrate that they can meet all the learning outcomes for the unit. The assessment criteria outline the requirements that the learner is expected to meet **in own area of work in accordance with Standard Operating Procedures (SOPs)** to achieve the learning outcomes and the unit.

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
1	Understand the principles and practice of working within the HFEA-licensed reproductive science laboratory	1.1	Evaluate how adherence to Standard Operating Procedures underpins a safe laboratory environment and safeguards the quality and safety of human gametes and embryos			
		1.2	Explain the key components of quality management in the HFEA-licensed reproductive science laboratory			
		1.3	Explain the requirements for safe working within a cryopreservation facility			
		1.4	Explain the requirements for reporting and communication within the HFEA-licensed Fertility Clinic			
		1.5	Discuss the role of the healthcare science associate in the HFEA-licensed reproductive science laboratory			

Learning outcomes		Assessment criteria		Evidence type	Portfolio reference	Date
2	Be able to use equipment within the HFEA-licensed reproductive science laboratory	2.1	Work safely in the HFEA-licensed reproductive science laboratory			
		2.2	Use a centrifuge in the HFEA-licensed reproductive science laboratory			
		2.3	Operate using sterile technique within a workstation to protect both the culture system and the operator			
		2.4	Use incubators in the HFEA-licensed reproductive science laboratory			
		2.5	Operate microscopes used in the HFEA-licensed reproductive science laboratory			

Learner name: _____ Date: _____

Learner signature: _____ Date: _____

Assessor signature: _____ Date: _____

Internal verifier signature: _____ Date: _____
(*if sampled*)