# Radiopharmaceuticals

## Purpose of this procedure:

Radiopharmaceuticals are medicines containing a radioisotope attached to a pharmaceutical agent, used for the diagnosis or treatment of various conditions or diseases, including cancer.

Most radiopharmaceuticals used in NHS Lothian are manufactured in the Radiopharmacy at the Royal Infirmary (RIE) or procured by the Radiopharmacy from external pharmaceutical manufacturers. All radiopharmaceuticals prepared by the Radiopharmacy are unlicensed medicines, manufactured under the Radiopharmacy's Manufacturer's "Specials" Licence.

## The Procedure:

### 1.0 Administration

1.1 Diagnostic radiopharmaceuticals used for imaging are administered in Nuclear Medicine departments within Radiology, as well as in Medical Physics departments, theatres and occasionally in other areas which must be designated as Controlled or Supervised Radiation Areas.

1.2 Administration of radiopharmaceuticals and the use of radioactive sources in diagnosis, treatment and research is governed by the Ionising Radiation (Medical Exposure) Regulations (IRMER). The main requirements of IRMER are contained in the Local Radiation Rules for any department handling radiopharmaceuticals.

1.3 IRMER has an impact on the Human Medicines Regulations (HMR), such that a prescription is not required for the administration of a radiopharmaceutical, or any other medicine associated with the administration of a radiopharmaceutical (HMR 2012, Regulation 240). However, it is NHS Lothian s policy for Nuclear Medicine Departments to record the administration of certain prescription-only medicines (such as potassium iodide, adenosine, furosemide and regadenoson) that are given as an adjunct to radiopharmaceuticals when performing certain imaging studies.

1.4 The responsibility for the administration of radiopharmaceuticals can only be undertaken by medically qualified individuals who possess an Administration of Radioactive Substances Advisory Committee (ARSAC) licence. All other individuals involved in the administration of radiopharmaceuticals must be designated as such in IRMER procedures, by the ARSAC licence holder. ARSAC licenses are specific to the individual, the procedures listed, the site where the procedure is performed and are time-limited, subject to renewal.

## 2.0 Safe Handling

2.1 All staff associated with the manufacture and administration of radiopharmaceuticals must be trained in the safe handling of unsealed sources of radiation, including the appropriate personal protective equipment to wear, techniques to minimise radiation exposure, how to properly dispose of radioactive waste and how to deal with spillage.

2.2 All staff handling radiopharmaceuticals must wear radiation dosimeter badges and their radiation exposure must be reviewed regularly by their department's Radiation Protection Supervisor (RPS). Pregnant staff members can work with radiopharmaceuticals, but each pregnant staff member's roles and responsibilities must be individually risk assessed by the RPS.

## 3.0 Molecular radiotherapy

3.1 (MRT) is the systemic treatment of cancer, using radiopharmaceuticals. While not a legal requirement under IRMER, the NHS Lothian Guidelines on the Use of MRT state that MRT should be prescribed by an ARSAC licence holder, or another individual delegated to prescribe in an approved IRMER procedure.

3.2 The radiation dose prescribed on the MRT prescription must be clinically verified by a Medical Physics Expert (MPE) and their bloods and toxicity results must be clinically verified by a suitably trained cancer pharmacist, prior to administration at each cycle.

3.3 Administration of MRT is undertaken by a nurse trained in the administration of systemic anti-cancer therapy, or a suitably trained Medical Physics technician. An MPE must be involved in the administration of every dose of MRT to verify the radiation dose and ensure administration is conducted in compliance with the Local Rules for radiation safety.

## 4.0 Transport

4.1 Vehicles used to transport radiopharmaceuticals must comply with the Carriage of Dangerous Goods by Road Regulations, by drivers that have undertaken suitable training in the transport of radioactive material.

4.2 Radiopharmacy staff will regularly audit drivers and their vehicles for compliance with the transport regulations.

## 5.0 Return and disposal

5.1 Disposal of unused radiopharmaceuticals and residues of used radiopharmaceuticals must be in accordance with the methods specified in the Local Radiation Rules for Radioisotope Departments.

5.2 Empty radiation shields must be returned to the Radiopharmacy after labels have been removed.

## Associated materials/references:

The Safe Use of Medicines Policy

1. The Ionising Radiation (Medical Exposure) Regulations 2017 (SI 2017/1322). Available at: The Ionising Radiation (Medical Exposure) Regulations 2017 (legislation.gov.uk) (accessed 08 April 2024).

2. The Human Medicines Regulations 2012 (SI 2012/1916). Available at: The Human Medicines Regulations 2012 (legislation.gov.uk) (accessed 08 April 2024).

3. The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (SI 2009/1348). Available at: The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (legislation.gov.uk) (accessed 08 April 2024).