**BOARD NOTICE 753 OF 2025**

## SOUTH AFRICAN PHARMACY COUNCIL

### COMPETENCY STANDARDS FOR A SPECIALIST PHARMACIST WHO PROVIDES RADIOPHARMACEUTICAL SERVICES IN SOUTH AFRICA

The South African Pharmacy Council hereby publishes for **implementation**, the **Competency standards for a specialist pharmacist who provides radiopharmaceutical services in South Africa** in terms of Sections 33(o) of the Pharmacy Act, 53 of 1974.

**SCHEDULE**

**(a) Competency standards for a specialist pharmacist who provides radiopharmaceutical services in South Africa**

**VM TLALA**
**REGISTRAR**

Address: 591 Belvedere Street, Arcadia, Pretoria, 0083,

Private Bag X40040, Arcadia, 0007. Telephone: 0861 7272 00

**COMPETENCY STANDARDS FOR A SPECIALIST PHARMACIST WHO PROVIDES RADIOPHARMACEUTICAL SERVICES IN SOUTH AFRICA**

## Table of Contents

ACRONYMS....3
DEFINITIONS....3
1. INTRODUCTION....4
2. BACKGROUND....4
3. RATIONALE FOR DEVELOPMENT OF COMPETENCY STANDARDS FOR RADIOPHARMACIST....5
4. REGISTRATION OF RADIOPHARMACISTS....5
5. QUALIFICATIONS OF A RADIOPHARMACIST....5
6. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS....5
TABLE 1: SUMMARY OF RADIOPHARMACY COMPETENCY STANDARDS....6
DOMAIN 1: PUBLIC HEALTH....7
INTRODUCTION....7
DOMAIN 1: PUBLIC HEALTH....7
DOMAIN 2: SAFE AND RATIONAL USE OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES....8
DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES....9
DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES....10
DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY....11
DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY....11
DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE....12
DOMAIN 6: EDUCATION, TRAINING AND RESEARCH....13
7. REFERENCES....**Error! Bookmark not defined.**

## ACRONYMS

The following acronyms have been included; however, the list is not exhaustive.

| | |
|---|---|
| **CAPA** | Corrective Action and Preventative Action |
| **cGRPP** | current Good Radiopharmacy Practice |
| **GMCP** | Good Medicine Compounding Practices |
| **GMP** | Good Manufacturing Practice |
| **GxP** | Good Practice Guidelines and Regulations e.g., Good Manufacturing Practice (GMP), Good Laboratory Practice (GLP), Good Wholesaling Practice (GWP), Good Radiopharmacy Practice (GRPP) and other pharmaceutical practices |
| **IAEA** | International Atomic Energy Agency |
| **ISORBE** | International Society of Radiolabelled Blood Elements |
| **SOP** | Standard Operating Procedures |

## DEFINITIONS

The following definitions have been included; however, the list is not exhaustive:

**"Change control report"** is a document that records the process of coordinated activities through which a desired change is implemented in an existing function, process, or product in the pharmaceutical industry.

**"Medical Devices"** means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings and animals for one or more specific medical purposes.

**"Nuclear Medicine"** means a medical specialty that uses radiopharmaceuticals to assess bodily functions and to diagnose and treat disease.

**"Radionuclide"** is an unstable form of a chemical element that releases radiation as it breaks down and becomes more stable.

**"Radiopharmaceutical"** means any medicinal product which, when ready for use, contains one or more radionuclides included for medicinal purposes.

**"Radiopharmacist"** means a pharmacist registered with Council to offer radiopharmaceutical services.

**"Specialist pharmacist student"** means a pharmacist who is registered as such in terms of the Pharmacy Act 53 of 1974 (the Act).

**"Specialist pharmacist resident"** means a pharmacist who is registered as such in terms of the Pharmacy Act 53 of 1974 (the Act).

**"Specialist Pharmacist"** means a pharmacist who is registered as such in terms of the Pharmacy Act 53 of 1974 (the Act).

**"Speciality"** means a specialist qualification in one of the fields of pharmacy approved and published in rules made by Council.

## 1. INTRODUCTION

A radiopharmacist is a pharmacist registered with the South African Pharmacy Council (SAPC) with a designation of practising, who is a specialist in the field of radiopharmacy and is involved in the manufacturing, formulation, dispensing and distribution of radioactive compounds. These are specialised medicinal items which may be harmful if not correctly used or controlled. Radiopharmacists need to accept responsibility for their self-development and assessment of continued competence throughout their professional working lives and ensure that they train all the individuals involved in the distribution and utilisation of radiopharmaceuticals.

Part of the radiopharmacist's duty is to develop, monitor and maintain the quality management system in the manufacturing, compounding, supply and distribution of radiopharmaceuticals in accordance with Guidelines for Good Manufacturing Practice (GMP) and Good Medicine Compounding Practice (GMCP) as published by the South African Health Products Regulatory Authority (SAHPRA)

## 2. BACKGROUND

In 2018, the South African Pharmacy Council published the reviewed competency standards for Pharmacists. Competency standards have been developed and used as the basis for pharmacy education and practice since 2006. The competency standards for a pharmacist providing radiopharmaceutical services are based on the competency standards for pharmacists. The scope of practice of a pharmacist providing radiopharmaceutical services was considered in the development of these competency standards.

### 2.1 THE SCOPE OF PRACTICE OF A RADIOPHARMACIST

In addition to the acts and services which form part of the scope of practice of the pharmacist as prescribed in terms of Regulations 3 and 4 of the Regulations relating to the practice of pharmacy, a pharmacist who has completed a Master's degree in Radiopharmacy must be allowed to provide the following services or acts pertaining to the scope of practice of a radiopharmacist:

(a) Take a leading pharmaceutical role in protocol and guideline development for the use of radiopharmaceuticals in nuclear medicine.

(b) Act as a leading pharmaceutical partner within a multi-professional healthcare team in nuclear medicine;

(c) Develop, implement, evaluate and provide strategic leadership for radiopharmaceutical services;

(d) Appraise information, make informed decisions regarding the supply and use of radiopharmaceuticals with the evidence available and be able to justify/defend the decisions;

(e) Develop policies and procedures specifically for the speciality area;

(f) Provide education and training related to radiopharmacy; and

(g) Perform research, teach and publish articles related to radiopharmacy.

The scope of practice of a specialist pharmacist student is the same as the scope of practice of a specialist pharmacist practiced under the auspices of a provider.

The scope of practice of a specialist pharmacist resident is the same as the scope of practice of a specialist pharmacist practiced under the supervision of a specialist pharmacist.

## 3. RATIONALE FOR DEVELOPMENT OF COMPETENCY STANDARDS FOR RADIOPHARMACIST

Radiopharmacists are experts in radiopharmaceuticals for diagnostic and therapeutic purposes and are thus required to keep abreast with new treatment and diagnostic trends. The competency standards have been developed to encompass the changes and developments including new technologies, work processes, changes in legislation and international trends, primarily to ensure the production of quality, safe and efficacious radiopharmaceuticals and the promotion of proper medicine usage for improved health outcomes.

## 4. REGISTRATION OF RADIOPHARMACISTS

Radiopharmacists are obliged to be registered with Council for the purposes of offering the acts related to their scope of practice as follows:

(a) Specialist pharmacist student.

(b) Specialist pharmacist resident.

(c) Specialist pharmacist.

## 5. QUALIFICATIONS OF A RADIOPHARMACIST

For purposes of registration as a radiopharmacist, a pharmacist must have obtained -

(a) a professional master's degree in radiopharmacy as determined by Council and published from time to time, or

(b) a qualification deemed to be equivalent or higher than the professional master's degree in radiopharmacy as assessed by Council.

## 6. STRUCTURE OF THE COMPETENCY STANDARDS AND DOMAINS

A competency framework consisting of six (6) domains suitable for the South African context was developed, together with several associated competencies. A domain represents an organised cluster of competencies within a framework and the domains with associated competencies are summarised in Table 1. The behavioural statements indicating how individuals working within the competency framework should behave in practice have also been drafted.

## TABLE 1: SUMMARY OF RADIOPHARMACY COMPETENCY STANDARDS

| DOMAIN | COMPETENCY STANDARD |
|---|---|
| 1. Public Health | 1.1 Promotion of radiopharmaceutical services. |
| 2. Safe and rational use of radiopharmaceuticals and medical devices | 2.1 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals.<br>2.2 Knowledge and understanding of radiopharmaceuticals and medical devices safety. |
| 3. Supply of radiopharmaceuticals and medical devices | 3.1 Manufacturing of radiopharmaceuticals.<br>3.2 Compounding of radiopharmaceuticals.<br>3.3 Supply chain management.<br>3.4 Radiopharmaceutical dispensing. |
| 4. Quality management in radiopharmacy | 4.1 Quality assurance.<br>4.2 Pharmaceutical infrastructure management. |
| 5. Professional and personal practice | 5.1 Good record keeping.<br>5.2 Clinical application of radiopharmaceuticals.<br>5.3 Professional practice. |
| 6. Education, training and research | 6.1 Provision of education and training.<br>6.2 Practice embedded education or workplace education.<br>6.3 Research. |

## DOMAIN 1: PUBLIC HEALTH

### INTRODUCTION

This domain covers competencies that are required to promote radiopharmaceutical services. Participation of pharmacists in the promotion of public health utilising radiopharmaceuticals requires the following competency:

1.1 Promotion of radiopharmaceutical services.

| DOMAIN 1: PUBLIC HEALTH | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 1.1 Promotion of radiopharmaceutical services. | 1.1.1 Develop, monitor, and maintain radiopharmaceutical services.<br>1.1.2 Demonstrate qualities to improve performance and manage radiopharmaceutical services.<br>1.1.3 Encourage good radiopharmacy practice.<br>1.1.4 Promote continuous updates of core competencies by other related healthcare professionals. |

## DOMAIN 2: SAFE AND RATIONAL USE OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES

### INTRODUCTION

Radiopharmacists must have knowledge of the procedures and operations relating to the safe and rational use of radiopharmaceuticals. The competencies required in the domain for safe and rational use of radiopharmaceuticals are:

2.1 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals; and

2.2 Knowledge and understanding of radiopharmaceutical and medical devices safety.

| DOMAIN 2: SAFE AND RATIONAL USE OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 2.1 Knowledge and understanding of the pharmacology and biodistribution of radiopharmaceuticals. | 2.1.1 Evaluate the administration of radionuclides and radiopharmaceuticals as part of holistic patient care, where applicable.<br>2.1.2 Evaluate the clinical use of radionuclides and radiopharmaceuticals.<br>2.1.3 Understand the different types of radiopharmaceuticals used for diagnosis and therapy.<br>2.1.4 Understand the pharmacokinetic and pharmacodynamic principles in patient management with radiopharmaceuticals.<br>2.1.5 Understand the biodistribution of radiopharmaceuticals.<br>2.1.6 Advise on the provision of effective and cost-effective radiopharmaceuticals.<br>2.1.7 Understand the various routes of administration of radionuclides and radiopharmaceuticals.<br>2.1.8 Appraise the clinical use of radionuclides and radiopharmaceuticals. |
| 2.2 Knowledge and understanding of radiopharmaceutical and medical devices safety. | 2.2.1 Promote safe handling of radiopharmaceuticals.<br>2.2.2 Identify, classify, and analyse the various types of radiopharmaceuticals, their side effects, and toxicities.<br>2.2.3 Demonstrate and apply principles ensuring the safe use of radionuclides and radiopharmaceuticals.<br>2.2.4 Demonstrate and apply principles ensuring the safe storage, distribution and disposal of radionuclides and radiopharmaceuticals.<br>2.2.5 Demonstrate the practical implementation of radiation safety principles.<br>2.2.6 Manage programmes in the radiopharmacy to minimise risks of radioactive contamination. |

## DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES

### INTRODUCTION

A radiopharmacist plays an important role in the supply of radiopharmaceutical medicines by ensuring that relevant policies, procedures, and legislation are followed in the manufacturing, compounding, and dispensing of radiopharmaceuticals. The competencies required in the domain to supply radiopharmaceuticals and medical devices are as follows:

3.1 Radiopharmaceutical production

3.2 Radiopharmaceutical compounding.

3.3 Supply chain management.

3.4 Radiopharmaceutical dispensing.

| DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 3.1 Radiopharmaceutical production (Large scale manufacturing) | 3.1.1 Demonstrate and understand the manufacturing of radiopharmaceuticals.<br>3.1.2 Manufacture radiopharmaceuticals in accordance with GMP.<br>3.1.3 Implement a manufacturing process to ensure the stability of radiopharmaceuticals throughout their shelf-life.<br>3.1.4 Demonstrate and understand how to manufacture radiopharmaceuticals using synthesis modules. |
| 3.2 Radiopharmaceutical compounding (Small-scale manufacturing in centralised and hospital radiopharmacies) | 3.2.1 Implement aseptic preparation of radiopharmaceuticals.<br>3.2.2 Manage the preparation and labelling of radioactive blood products according to prescribed protocols.<br>3.2.3 Demonstrate and apply the necessary knowledge to perform generator elution.<br>3.2.4 Demonstrate an in-depth knowledge of the safe compounding of radiopharmaceuticals from kits and generators.<br>3.2.5 Demonstrate knowledge of the use of synthesis modules in the compounding of radiopharmaceuticals.<br>3.2.6 Ensure that the radiopharmaceutical product is sterile.<br>3.2.7 Understand the IAEA operational levels for hospital radiopharmacies. |

| DOMAIN 3: SUPPLY OF RADIOPHARMACEUTICALS AND MEDICAL DEVICES | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 3.3 Supply chain management | 3.3.1 Design a compounding area suitable for the preparation of radiopharmaceuticals.<br>3.3.2 Ensure that the sterility and stability of radiopharmaceuticals are maintained throughout the supply chain.<br>3.3.3 Maintain an inventory of radiopharmaceuticals.<br>3.3.4 Maintain an inventory of non-radioactive kits, starting materials and reference standards. |
| 3.4 Radiopharmaceutical dispensing | 3.4.1 Evaluate orders and prescriptions and ensure that correct calculations are used to dispense the required radiopharmaceutical quantity or dose.<br>3.4.2 Manage, organise, and prioritise the dispensing of radiopharmaceuticals according to the relevant legislation.<br>3.4.3 Manage the preparation and distribution of radiopharmaceuticals in bulk form.<br>3.4.4 Dispense and distribute individualised patient doses in accordance with GMCP. |

## DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY

### INTRODUCTION

Radiopharmaceuticals must be handled with care to ensure their safety and efficacy. The competencies required in this domain which relates to the implementation of quality management in radiopharmacy according to the applicable guidelines, are as follows:

4.1 Quality assurance.

4.2 Pharmaceutical infrastructure management.

| DOMAIN 4: QUALITY MANAGEMENT IN RADIOPHARMACY | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 4.1 Quality assurance | 4.1.1 Develop, implement, and maintain a comprehensive Radiopharmaceutical Quality Management System (QMS) to ensure the quality, safety and efficacy of the radiopharmaceuticals including the drafting and review of -<br>(a) SOPs.<br>(b) change control reports,<br>(c) risk assessments, and<br>(d) guidance documents.<br>4.1.2 Identify and investigate deviations and create CAPAs.<br>4.1.3 Demonstrate and understand analytical methods and instruments used in the quality control of radiopharmaceuticals.<br>4.1.4 Develop, implement, and maintain validation processes. |
| 4.2 Pharmaceutical infrastructure management | 4.2.1 Design, implement and manage a radiopharmacy environmental monitoring system.<br>4.2.2 Implement a programme for the maintenance of equipment used in the manufacturing and compounding of radiopharmaceuticals.<br>4.2.3 Implement a programme for the maintenance of equipment used in the quality control of radiopharmaceuticals.<br>4.2.4 Implement a programme for the maintenance of the radiopharmacy facility including the air handling unit. |

## DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE

### INTRODUCTION

The competencies required in the domain to ensure good personal and professional practice are:

5.1 Good record keeping.

5.2 Clinical application of radiopharmaceuticals

5.3 Professional practice.

| DOMAIN 5: PROFESSIONAL AND PERSONAL PRACTICE | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 5.1 Good record-keeping | 5.1.1 Develop a patient and prescriber administration and ordering system.<br>5.1.2 Maintain and review records in accordance with GMCP, GMP, GRPP and relevant legislation.<br>5.1.3 Manage record systems for the preparation of radiopharmaceuticals.<br>5.1.4 Manage radiopharmacy cleaning records.<br>5.1.5 Manage record systems for the manufacturing of radiopharmaceuticals.<br>5.1.6 Manage records for the quality control of radiopharmaceuticals. |
| 5.2 Clinical application of radiopharmaceuticals | 5.2.1 Demonstrate an in-depth knowledge of various radiopharmaceutical drug interactions and contraindications.<br>5.2.2 Advise other healthcare professionals on adverse radiopharmaceutical-drug interactions.<br>5.2.3 Advise other healthcare professionals on adverse radiopharmaceutical-food reactions.<br>5.2.4 Advise other healthcare professionals on radiopharmaceutical contraindications where applicable.<br>5.2.5 Demonstrate an in-depth knowledge of the use of radiopharmaceuticals in nuclear medicine. |
| 5.3 Professional practice | 5.3.1 Develop and monitor protocols to ensure that the radiopharmacy operates in line with the current GMP or GMCP, as applicable.<br>5.3.2 Contribute to the review and development of GMP and GMCP.<br>5.3.3 Demonstrate knowledge of the GMP and GMCP processes for radiopharmaceuticals.<br>5.3.4 Play an active role as a member of the nuclear medicine healthcare team. |

## DOMAIN 6: EDUCATION, TRAINING AND RESEARCH

### INTRODUCTION

Education is essential for the initial development of pharmacists and is required throughout a pharmacist's career to maintain currency on knowledge, skills, attitudes, and values. Pharmacists should participate in the education and training of patients and other healthcare practitioners.

Pharmacists should critically evaluate information sources, literature and research on medicines and practice in terms of evidence for decision-making and implementation in practice. Pharmacists should participate in practice-based research and, where applicable, publish research in the radiopharmaceutical field. The domain includes behavioural statements relating to education, training, and research in a radiopharmaceutical setting. The competencies required in the domain are:

6.1 Provision of education and training.

6.2 Practice embedded education or workplace education.

6.3 Research.

| DOMAIN 6: EDUCATION, TRAINING AND RESEARCH | |
|---|---|
| **COMPETENCIES** | **BEHAVIOURAL STATEMENTS** |
| 6.1 Practice embedded education or workplace education | 6.1.1 Develop training policies on radiopharmacy.<br>6.1.2 Tutor specialist pharmacist residents in radiopharmacy.<br>6.1.3 Provide training on the role of radiopharmacy in nuclear medicine, diagnosis and therapy to the healthcare team. |
| 6.2 Provision of education and training | 6.2.1 Assess the performance and learning needs of the radiopharmacy team members.<br>6.2.2 Plan a series of effective learning experiences for radiopharmacy team members and other healthcare professionals. |
| 6.3 Research | 6.3.1 Contribute scientifically to –<br>(a) clinical and pre-clinical trials;<br>(b) the development of new radiopharmaceuticals;<br>(c) the development of new manufacturing and compounding procedures for radiopharmaceuticals; and<br>(d) the development of new quality control methods for radiopharmaceuticals.<br>6.3.2 Publish articles on research findings and present research findings at relevant fora. |