AHPRA

Consultation: Professional Capabilities for Medical Radiation Practitioners

30 July 2025

Subject: ACPSEM Response to 'Proposed Changes to 'Professional Capabilities for Medical Radiation Practitioners' - Significant Safety Concerns

Dear AHPRA Consultation Team

The Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) seeks the opportunity to formally provide feedback on the document 'Proposed Changes to Professional Capabilities for Medical Radiation Practitioners - Significant Safety Concerns' scheduled for implementation in 2026. We suggest that this conversation is highly appropriate at this time due to steady increase in the number of radio-pharmaceutical products available for clinical use in Australia, a trend which is projected to accelerate, with a related patient, worker and public risk increase.

The ACPSEM respectfully submit this response to the document. The ACPSEM does have a particular concern regarding Nuclear Medicine Technologists (NMTs) capabilities outlined in domain 1B (pages 33-34, summary changes page 62), specifically key capabilities 1 and 4, which is outlined below.

Background and ACPSEM's Role

ACPSEM is responsible for the training and registration of Medical Physicists (MP) and Radiopharmaceutical Scientists (RPS) in Australia. Our members work directly alongside Medical Radiation Practitioners and Nuclear Medicine Specialists in nuclear medicine, radiology, and radiation oncology departments across public and private health facilities. Both MP and RPS professionals require undergraduate science degrees, relevant postgraduate qualifications, and completion of a rigorous three-year mentored Training, Education, and Assessment Program (TEAP) to achieve registration.

Key Concerns with Proposed Changes

We have identified several critical issues with the proposed professional capabilities for Nuclear Medicine Technologists (NMTs), particularly regarding radiopharmaceutical preparation and theranostic activities. It is important to note that the AHPRA/MRPBA capabilities define the minimum standards required for the profession. We are not objecting to advanced practice where further knowledge and training has been gained through additional qualifications, but rather to the establishment of these complex activities outlined below as minimum baseline requirements.

1. Inadequate Training Foundation

The proposed capabilities for radiopharmaceutical "production" and "manufacture" are not supported by the current NMT training curriculum. NMTs do not receive adequate education in:

- Underlying chemistry and radiochemistry principles
- Advanced analytical techniques (particularly High-Performance Liquid Chromatography)
- Validation methodologies for manufacturing and quality control
- Regulatory compliance frameworks (Good Manufacturing Practice, Pharmacopoeias)

2. Patient Safety Risks

The expansion of NMT scope to include independent radiopharmaceutical manufacturing poses significant patient safety concerns:

- Complex equipment operation (cyclotrons, automated synthesis modules, HPLC, GC, Mass Spectrometry) requires extensive specialized training
- Quality control assessment and product release decisions demand deep technical expertise
- Manufacturing validation and ongoing monitoring require comprehensive understanding of regulatory frameworks

3. Regulatory and Legal Implications

The proposed changes create concerning regulatory conflicts:

- NMTs are not recognized as "exempt persons" under Therapeutic Goods Regulation 1990, Schedule 8
- Current exemptions require supervision by qualified radiopharmaceutical scientists or medical practitioners
- Potential reclassification under ARPANSA C-5 could impact licensing requirements across jurisdictions

4. International Standards Discrepancy

The proposed Australian capabilities significantly exceed those recognized internationally:

- European (EANM) and US (SNMMI) standards do not include independent radiopharmaceutical manufacture in NMT capabilities
- International Good Radiopharmacy Practices (GRP) emphasize the need for appropriately qualified personnel in radiopharmaceutical manufacturing
- This discrepancy raises questions about the appropriateness of the proposed Australian standards and their alignment with global best practices

5. Advanced Therapeutic Applications

The inclusion of theranostic radiopharmaceutical manufacturing (including alpha emitters like ^{225}Ac and ^{212}Pb) is particularly concerning given:

- Extremely limited usage and cutting-edge nature of these isotopes
- Complex technical challenges with alpha-emitting radioisotopes
- Few experienced radiochemists/RPS in Australia have hands-on experience with these materials

Impact on Current Practice

Currently, radiopharmaceutical manufacturing under TGA exemptions is performed by or under supervision of qualified radiopharmaceutical scientists (who act in the capacity of radiochemists as specified in Schedule 8 of TGR 1990/TGA 1989) or medical practitioners. This established system ensures:

- Appropriate expertise for complex manufacturing processes
- Compliance with regulatory requirements
- Patient safety through qualified oversight
- Protection of the valuable TGA exemption that enables affordable patient services

Consultation Process Concerns

We note that ACPSEM was not included in the initial consultation despite the significant overlap between MRP activities and those of our members. Given our expertise in radiopharmaceutical science and the direct impact on our profession, we respectfully request inclusion in future consultations on related matters.

Recommendations

1. **Remove or significantly modify** the proposed radiopharmaceutical manufacturing capabilities for NMTs as minimum requirements
2. **Ensure any expanded scope** is supported by appropriate education and training programs aligned with Good Radiopharmacy Practices (GRP)
3. **Include ACPSEM** in future consultations affecting radiopharmaceutical science practice
4. **Align Australian standards** with international best practices including GRP guidelines
5. **Clarify professional boundaries** to ensure compliance with existing regulatory frameworks and protected titles

Conclusion

While we acknowledge that NMTs currently prepare certain kit-based radiopharmaceuticals, the proposed expansion to independent manufacturing and quality control of complex

radiopharmaceuticals as minimum baseline requirements is not supported by current training standards and poses unacceptable risks to patient safety.

The recent focus on improving quality standards in Australia, combined with media attention on license-exempt radiopharmaceutical manufacture, makes this proposed expansion particularly concerning. Rather than advancing patient care, these changes could compromise the quality and safety standards that the healthcare system seeks to improve.

We appreciate AHPRA's willingness to consider feedback beyond the initial consultation period and stand ready to provide additional technical expertise or clarification as needed.

Thank you for your consideration of these critical safety concerns.

Yours sincerely,

Michael Bernardo

President & Board Chair

Australasian College of Physical Scientists & Engineers in Medicine (ACPSEM)

This response represents the collective position of ACPSEM members who are directly involved in radiopharmaceutical science and manufacturing across Australia.