



AUSTRALIAN AND NEW ZEALAND SOCIETY OF NUCLEAR MEDICINE INC.

(Incorporated in NSW)

3rd October 2008

Ms Megan Cahill
Chair, Practitioner Regulation Subcommittee
Level 12 / 120 Spencer Street
MELBOURNE VIC 3000

Dear Ms Cahill,

Submission to the Practitioner Regulation Sub-Committee of the Health Workforce Principal Committee

Re: Inclusion of Medical Radiation Practitioners into the National Registration and Accreditation Scheme

Medical Radiation practitioners (Nuclear Medicine Technologists, Diagnostic Radiographers and Radiation Therapists) are part of what is, across Australia, only a partially regulated profession, as registration does not exist in New South Wales or South Australia. The Australian and New Zealand Society of Nuclear Medicine (ANZSNM), is responsible for the Accreditation of Nuclear Medicine Technologists throughout Australia and New Zealand and fully supports the registration of its members and, indeed, all practitioners in all states and territories and therefore would strongly support the inclusion of Medical Radiation practitioners in the Intergovernmental Agreement for a National Registration and Accreditation Scheme.

The ANZSNM believes the registration of practitioners by a national registration board would be beneficial to the profession and to the public interest; as such we have supported a joint submission by the existing state registration boards and the Australian Institute of Radiography (AIR).

However we have chosen to present a separate submission to emphasise the unique and complementary roles played by professional associations in areas such as National Competency Base Standards (CBS), Continuing Professional Development (CPD), university program approval and in negotiating reciprocity of qualifications with international professional associations such as the USA Nuclear Medicine Technology Certification Board (NMTCB) under the USA/Australian Free Trade Agreement (FTA). While the proposed national registration boards will have some startup funding from the federal government, there are significant ongoing costs in all of the above functions which rely heavily on a large body of pro bono work provided by individual practitioners.

It should be noted that the terms "Nuclear Medicine Technologist" and "Nuclear Medicine Scientist" are interchangeable and refer to the same group of practitioners.

You have outlined six criteria which must be met for a profession to be considered for inclusion, with two key principles. The ANZSNM would comprehensively identify with the sole purpose of occupational regulation being to protect public interest as will be demonstrated below.

Criterion One

Is it appropriate that Health Ministers exercise responsibility for regulating the occupation in question?

Medical Radiation is clearly the regulatory responsibility of the Health Ministers rather than any other Ministry. The balance of activities undertaken by Medical Radiation practitioners is with those people referred from other health practitioners and the Medical Radiation practitioners records are most properly described as 'health records'. It would be the common view of the public that when they went to have a nuclear medicine procedure or radionuclide therapy they were having 'health related' treatment.

This has also already been debated when the Australian Health Ministers Advisory Council (AHMAC) Mutual Recognition Working Party recommended in 1992 that medical radiation practitioners should be regulated throughout Australia. At the consequent conference of Australian Health Ministers (AHMC) in 1993, this recommendation was fully supported. The view of the Working Party and the Health Ministers would appear to accord fully with Criterion One and is entirely consistent with the view of the ANZSNM.

Criterion Two

Do the activities of the occupation pose a significant risk of harm to the health and safety of the public?

Medical Radiation, used improperly, carelessly, or without adequate training and ongoing competency review, can have lethal consequences. These consequences can extend, in extreme circumstances, beyond those involved in the immediate treating relationship. Ionising radiation is, however, one of the basic tools of contemporary medicine, both in diagnosis and therapy. The imaging and treatment protocols are well established and regularly reviewed, and changes to protocol developed through best evidence-based practice. There is widespread public general awareness of the risks involved; most people who have had treatment at a hospital will be familiar with the practice during an X-ray or a Nuclear Medicine procedure of the Medical Radiographer or Nuclear Medicine Technologist, respectively, using shielded screens or shielding devices. There is a further risk when a Nuclear Medicine Technologist may fail to exercise competency in the preparation, quality control, dispensing or administration of the radiopharmaceutical, and therefore require the re-scheduling of the procedure, resulting in an additional dose of the correct radiopharmaceutical. This is less than optimal practice and poses risks not only of patient dosage but also in the timelines of treatment.

To illustrate that activities of Nuclear Medicine Technologists pose a significant risk to the public we will:

- outline a group of activities related to the radiopharmacy performed by Nuclear Medicine Technologists as an integral part of every nuclear medicine procedure, that present a constant risk to the public,
- present the results of a five year review of Nuclear Medicine Incidents in New South Wales, published in 2005.

We present these illustrations in detail since (a) they are on the public record and (b) provide a clear response to Criterion Two.

(A) Nuclear Medicine Technologist Radiopharmacy Activities

A Nuclear Medicine Technologist/Scientist is a Health Professional trained in the delivery and development of patient services utilising radiopharmaceuticals or other medical radiations. This involves the imaging and measurement of physiological processes both in the patient and in the laboratory.

A Nuclear Medicine Technologist/Scientist acquires and analyses qualitative and quantitative data to facilitate medical diagnosis and treatment and administers treatment by prescription

http://www.anzsnm.org.au/nmofs/677348695/CBS_2006.pdf

All nuclear medicine procedures utilise radiopharmaceuticals that must be prepared, quality controlled, dispensed and administered, mostly via intravenous injection, by the Nuclear Medicine Technologist. In addition some nuclear medicine procedures, such as imaging for sites of infection in the body, involve withdrawing, radioactively labelling and re-injecting blood products.

The radiopharmaceuticals emit a range ionising radiation such as gamma rays, beta rays and positrons which are emitted from the patient's body. These radiation emissions from the body are then detected by sophisticated imaging devices such as Single Photon Computerised Emission Tomography (SPECT) or Positron Emission Tomography (PET) scanners to produce images and functional information about disease.

The radiopharmaceuticals used for imaging, treatment and palliation by Nuclear Medicine Technologists are in four broad categories:

- 1 Radiopharmaceuticals for SPECT imaging such as:
Technetium 99m labelled to [DTPA, DMSA, Sestamibi or MDP], Indium 111- DTPA, Gallium 67- citrate, Iodine 131-MIBG, Iodine 123-MIBG and Thallium 201-thallous chloride.
- 2 Radiopharmaceuticals for PET imaging such as:
Fluorine 18-FDG, Oxygen 15-water, Carbon 11-PIB and Nitrogen13-ammonia.
- 3 Radiopharmaceuticals for the palliation of bone metastases such as:
Phosphorus 32, Strontium 89-strontium chloride, Samarium 153-EDTMP and Strontium 89-Metastron.
- 4 Radiopharmaceuticals used for Cancer treatment such as:
 - 4.1 Yttrium 90 -SIR-spheres for radiation intra-arterial therapy of liver metastases.
 - 4.2 Radiopharmaceuticals for radiation neuroendocrine therapy such as:
Iodine 131 - MIBG, Indium 111- Pentreotide, Lutetium 177- Octreotate and Yttrium 90- Octreotate.
 - 4.3 Radiopharmaceuticals for radiation peptide receptor therapy such as:
Indium 111- Pentreotide, Yttrium 90- DOTA and Lutetium 177- Octreotide.
 - 4.4 Radiopharmaceuticals for radiation radioimmunotherapy such as:
Indium 111- Ibritumomab, Yttrium 90-Zevalin and Iodine 131I-Mabthera.
 - 4.5 Iodine 131 for the radiation treatment of thyroid disease and thyroid ablation.

While this is an extensive list of radiopharmaceuticals, it does not include all radioactive products administered by Nuclear Medicine Technologists. Rather, it is intended to illustrate the broad range of products being used and thus the extent of the potential risk to the public.

(B) Review of Nuclear Medicine Incidents in New South Wales

In November 2005, Yenson and colleagues published a review of reports received by the New South Wales Environment Protection Authority (EPA) over the 5-year period, 2000-2005 (Yenson et al (2005) Nuclear Medicine Communications. 26(11):1037-1041).

According to the Yenson review, "Fifty-seven maladministrations were reported to the New South Wales Environment Protection Authority. There were 666,179 nuclear medicine procedures recorded in New South Wales for the same period. Of the 57 reported maladministrations, the majority (n=34; 61%) were a result of incorrect radiopharmaceutical dispensing. Incorrect reading of labels attached to the syringe (n=8; 14%) and incorrect patient identification (n=7; 12%) accounted for most of the rest of the accidents. Most (n=48; 84%) involved 99mTc-based radiopharmaceuticals for diagnostic use, with three cases involving 131I for therapeutic use. In 96% of cases – those which involved diagnostic radiopharmaceuticals – there were no immediate adverse clinical outcomes. However, one subject developed unintended hypothyroidism as a result of the maladministration of 131I for therapy.

Conclusion: Nuclear medicine maladministration's in New South Wales are uncommon, with approximately 8-9 incidents per 100 000 procedures. Most maladministrations are the consequence of incorrect radiopharmaceutical dispensing. All those which involved diagnostic radiopharmaceuticals resulted in no immediate adverse effects from the radiation exposure."

While the maladministration of Iodine 131, in the above report, was not fatal, it did result in the patient becoming hypothyroid necessitating life-long thyroid hormone therapy, again emphasizing the potential risk to the public.

Criterion Three

Do existing regulatory or other mechanisms fail to address health and safety issues?

The Australian & New Zealand Society of Nuclear Medicine (ANZSNM) Incorporated is the only Accrediting body for Nuclear Medicine Technologists in Australia and New Zealand. The ANZSNM is required to issue Statements of Accreditation for a fee of \$330 to:

- all Nuclear Medicine Technologists who successfully complete (a) a University program in Nuclear Medicine, approved by the ANZSNM and (b) a professional development year (PDY) in accordance with the ANZSNM's guidelines.
- overseas trained Nuclear Medicine Technologists who are successfully assessed by the ANZSNM.

The ANZSNM also:

- nationally approves undergraduate and graduate entry University programs in Nuclear Medicine. The ANZSNM Accreditation Board comprises Accredited Nuclear Medicine Technologists, a member of the Australian and New Zealand Association of Physicians in Nuclear Medicine and a member of any other special interest group within the ANZSNM
- manages:
 - the Professional Development Year (PDY)
 - The PDY must be completed at a Nuclear Medicine Centre approved by the ANZSNM to supervise PDY/Interns
 - The Nuclear Medicine Centre must be approved by the ANZSNM to supervise PDYs
 - The PDYs must be supervised by a Mentor approved by the ANZSNM
 - Workplace Approvals for Nuclear Medicine Centres to supervise PDYs. This includes centres in Australia and New Zealand as well as two centres in the UK
 - the Mentor program for PDYs
 - revalidation of Accreditation.
- assesses overseas qualifications
 - The Accreditation Board is the Gazetted Authority for the assessment of overseas qualifications in Nuclear Medicine the purpose of skilled migration into Australia.
- keeps a database of all Accredited Nuclear Medicine Technologists and provides information when requested to state Radiological Advisory Councils (RACs) and Registration Boards.
- has a publication which provides professional updates and expertise in areas related to the profession.
- Provides regular Seminars, Conferences and ongoing educational programs which play a significant role in imparting knowledge to members.
- developed the initial Competency Based Standards in 1992 and the Competency Based Assessment in 1993 with funding from the National Office of Overseas Skills Recognition. The ANZSNM subsequently updated the Competency Based Standards in 1996, 2000 and 2006.
- manages the Continuing Professional Development (CPD) for Nuclear Medicine Technologists throughout Australia and New Zealand.
- is currently negotiating reciprocity of qualifications with the USA Nuclear Medicine Technology Certification Board (NMTCB) under the USA/Australian Free Trade Agreement (FTA). This project is supported by the Professional Services Development Program (PSDP) within the Australian Education International Section of the Department of Education, Science and Training (DEST). This project was supported by DEST because the ANZSNM is a national body, as opposed to a state-based organization, that is well placed to negotiate with the USA NMTCB, also a national body, under USA/Australian FTA.

The ANZSNM has been specified by the Minister for Immigration and Citizenship in accordance with the Migration Regulations (1994) as the assessing authority for the occupation Nuclear Medicine Technologists (ASCO Code 2391-15).

It would be the view of this professional association, the ANZSNM, that education and professional standards ought to be established by the profession through the various professional bodies of which the ANZSNM is one. The ANZSNM has its Competency Based Standards (CBS) which are currently recognised as benchmarks for practice in Australia and New Zealand and which are continuously undergoing review and revision in line with technological changes, professional development and evidence based practice. It is desirable that such standards be exposed to external review and scrutiny by a public entity such as a regulatory Board, which has the statutory responsibility for ensuring that practitioners meet the standards. The risks associated with the delivery of medical radiation services are well understood and the Yenson et al (2005) Review of Nuclear Medicine Incidents in New South Wales, outlined above, clearly highlights some of these.

Given the potential for risk of harm to the public, there are a range of regulations which apply to premises, equipment and radiopharmaceuticals. These are clearly outlined in the following interchange during the debate on the introduction of registration in New South Wales. In November 2006, in response to a question from Ms Sylvie Hale during this debate about a proposal to register practitioners in New South Wales, the Honourable John Hatzistergos replied that existing regulation of the medical radiation science practitioners profession in New State Wales consists of registration of apparatus, including fixed radiation gauges, diagnostic imaging apparatus and cyclotrons, licensing of persons using, selling, or possessing radioactive substances and ionising radiation apparatus, and the accreditation of persons as radiation experts. It was on this basis that New South Wales has not proceeded further with the registration of practitioners.

Such are the inherent risks in service delivery, the National Health and Medical Research Council (NHMRC) based its recommendations for the management of radiation doses on the levels recommended by the International Commission on Radiological Protection (ICRP) in 1991 (ICRP Report No. 60—1991). They assumed that all exposures to ionising radiation carry some risk of harm to health, and the risk increases each time a person is exposed to this form of radiation. There are bodies such as the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) which provide direct support of nuclear medicine, radiotherapy and radiology through the maintenance of the Australian primary and secondary measurement standards for exposure and absorbed dose, and the calibration of hospital reference instruments to measure radiation dose. A radiotherapy audit program is conducted to assess the transfer of ARPANSA calibrations to hospital quality assurance procedures.

ARPANSA also assesses radiation doses to the Australian population from medical radiation practices through national surveys. Advice is provided to medical professionals, patients and the public on medical exposures and risks. Under a Memorandum of Understanding with the Therapeutic Goods Administration (TGA), ARPANSA conducts a quality assurance test program to monitor the quality of radiopharmaceuticals and undertakes for the TGA the evaluation of the chemistry, manufacture, quality control and radiation dosimetry aspects of new drug applications and variations to conditions of TGA registration.

ARPANSA also contributes to the development of codes and standards and provides expert advice on medical exposures and radiation protection.

There are also requirements for practice under close supervision and on working in a cross-checking process in various environments. In public health practice there are extensive internal arrangements for supervision and peer review of practice.

Finally, there is a mandatory requirement for continuing professional development (CPD) as part of accreditation by the ANZSNM. The ANZSNM revokes Accreditation of members for failing to maintain their mandatory CPD obligations – as of September 2008 some 46 members have lost accreditation. This has a consequent impact on their ability to hold a current validated statement of Accreditation, necessary proof in most territories and states (though not Queensland, West Australia and Victoria – all states with Medical Radiation Practitioner Boards) of competency to practice. The ANZSNM acknowledges that, as a voluntary professional membership organization, not all practitioners choose to be members; however 94% of financial Nuclear Medicine Technologist members are Accredited. This high percentage of Accredited practitioners highlights the significance of the standards which the ANZSNM has worked to establish and to which all other bodies refer when assessing competence and professional readiness.

Some employers understand the importance of maintaining a current validated statement of Accreditation (IMED for example) and have written it into employment contracts as mandatory.

Consequently it must be acknowledged that existing mechanisms do not fail to address health and safety issues. This does not preclude the desirability of national registration however so as to ensure that all practitioners are of sufficient competence to practice.

Criterion Four

Is regulation possible to implement for the occupation in question?

The occupation is very well defined, professional practice requires recognition by the ANZSNM, and the knowledge needed in order to practice is well defined and must be accredited. The knowledge is internationally recognized with defined core competencies; teachable and testable.

Criterion Five

Is regulation practical to implement for the occupation in question?

In many respects the profession is currently regulated either overtly, as in those states with Medical Radiation Practitioner Boards, or indirectly in New South Wales, South Australia and Northern Territory where the practitioner is issued with a license by the EPA or its equivalent, which allows them to use ionising radiation or radiation apparatus. The only competency testing of practitioners in these three states is that provided by the ANZSNM when they are issued upon completion of the appropriate education and clinical training, with their validated statement of Accreditation.

Therefore extension into national registration is more a legislative issue than a professional hurdle. This is not to underestimate the challenges of introducing such national regulation.

Criterion Six

Do the benefits to the public clearly outweigh the potential negative impact of such regulation?

The benefits to the public of the national registration are many. Ease of workforce movement in a profession with shortage of practitioners is clearly a major plus for the profession. Consistent registration title across Australia is of benefit to the consumers. We already have a consistency in standards of practice through the CBS as laid down by ANZSNM, which is, in general recognised and adhered to. With the ANZSNM's national rigorous approach to CPD and its willingness to withdraw Accreditation from members who fail to maintain the CPD currency, the public can be confident that consistent standards/quality of practice applies across all states.

The single greatest negative impact is that of cost. Nuclear Medicine Technologists are not so readily able to pass on the costs of regulation as some health professionals. When professional membership fees, which provide many benefits other than just membership, such as reduced conference fees, significantly reduced professional indemnity insurance and other services are taken into account then the additional costs associated with registration are not insignificant. Many practitioners are faced with the difficult choice of where to direct their money to best advantage and the mandatory registration has precedence.

Conclusion

The ANZSNM believes the registration of practitioners by a national registration board would be beneficial to the public interest and the profession and strongly supports the inclusion of Medical Radiation practitioners in the Intergovernmental Agreement for a National Registration and Accreditation Scheme.

The ANZSNM recognises that registration boards and professional association have common, complementary and unique roles. On certain issues, therefore, they will naturally have divergent view.

The ANZSNM would not be favour of national registration if there was a duplication of activities which are currently done nationally by professional associations such as the ANZSNM in association with regulators. This would see a major increase in costs and have a significant impact on the pro bono work which the regulators rely upon from the profession. Specifically, this is a potential issue in the areas of national Competency Based Standards (CBS), Continuing Professional Development (CPD) and university program approval for Nuclear Medicine Technologists that are currently developed and updated by the national professional association, the ANZSNM.

Yours faithfully

A handwritten signature in black ink, appearing to read "Judi Anderson". The signature is written in a cursive, flowing style.

for
Geoffrey Roff
President