



Australian Government

Australian Radiation Protection and Nuclear Safety Agency

**RESPONSE BY THE CEO OF ARPANSA TO THE ADVICE ON MEDICAL
RADIATION ISSUES
from the
RADIATION HEALTH AND SAFETY ADVISORY COUNCIL**

INTRODUCTION

The practice of radiology, nuclear medicine and radiotherapy involve the exposure of patients to ionizing radiation. The balance between the medical benefit of the procedure to the patient and the risk to both patients and staff has to be considered, and radiation procedures and practices have to be justified and optimised. Rapid changes in technology, the introduction of new modalities and changes in medical practice have greatly improved the benefit to patients from medical radiation, but have also resulted in greater radiation exposure of the Australian population. In view of these changes, and the expectation that the trend will continue, I sought the advice of the Radiation Health and Safety Advisory Council (RHSAC) on these issues. The Council undertook a careful process of consideration and discussion of the issues with a number of experts and has provided me with a report. The report discusses new technology and emerging issues and the need for training of the different professions in the light of the changing circumstances. The report also touches upon radiation dose to workers. It includes recommendations to me about activities that ARPANSA should undertake in order to improve the future justification and optimisation of the use of ionizing radiation in medicine.

To add to the information contained in the Council report, some further information about the medical uses of radiation is included as an attachment to this response.

ARPANSA'S TRADITIONAL ROLES

ARPANSA provides direct support of 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.

DIAGNOSTIC REFERENCE LEVELS (DRLS)

ARPANSA believes that the monitoring of patient doses as part of a QA program and the comparison with guidance or diagnostic reference levels (DRLs) are keystone in the dose optimization process. These DRLs should be established nationally, or in exceptional cases locally, by the professional bodies in conjunction with ARPANSA and regulators. It will be a requirement of the new medical radiation code of practice (see below) that patient doses be monitored and comparisons made with DRLs. ARPANSA has facilitated a multi-partite group to determine dosimetry quantities and national DRLs. This work has progressed slowly as the medical professions have taken time to appreciate the concept of DRLs as guidance levels rather than dose limits. The group is now in a position to publish DRLs for nuclear medicine, mammography and general radiology. DRLs for CT present difficulties both in the definition of suitable dosimetry quantities (for new technologies) and in the defining of routine procedures. Work is proceeding on these issues.

INTERVENTIONAL RADIOLOGY

The Council report touched upon this area and it is related to recommendation 6 in the Council report. The main risk from radiation exposure during interventional radiology is the occurrence of radiation damage or burns to the skin at the site of entry of the x-ray field. These injuries, although rare, can have serious medical consequences. Whilst it is recognised that the majority of interventional procedures in cardiology are for the treatment of life threatening conditions, most radiation injuries, and all of the serious injuries, can be prevented without compromising the efficacy of the procedure.

The main measures that will lead to a minimisation of the risk of injury are well summarised in the recommendations of the International Commission on Radiological Protection, Report 85, *Avoidance of Injuries from Medical Interventional Procedures*. Training, appropriate equipment and procedures are seen as the main methods of reducing the incidence of injuries. Appropriate training is now a condition of licence in many State jurisdictions.

The value and priority of a specialized Safety Guide on intervention radiology may be revised after the currently proposed medical Code of Practice and Safety Guides have been completed. ARPANSA has assisted the Cardiac Society of Australia in producing a survey for its members to determine the nature of equipment and procedures and, in particular, the level of training of practitioners with respect to radiation protection. The progress of this survey has been particularly slow. The highly clinical and dynamic nature of interventional radiology makes dosimetry and surveying difficult for an organisation such as ARPANSA.

RESPONSE TO THE COUNCIL RECOMMENDATIONS

In general ARPANSA supports and accepts the Council recommendations.

ARPANSA believes that its traditional roles remain a high priority and it will need additional support, in particular, to complete a major survey of dose to patients from CT. ARPANSA is also looking to develop its role in supporting radiotherapy dosimetry by purchasing and operating a medical Linac in order to respond to demands for greater accuracy in the dosimetry of practical treatment beams.

A number of the recommendations of the Council would require that ARPANSA significantly increase its interaction with the relevant professions and undertake a variety of

training and educational activities in support of the optimisation of medical exposures. ARPANSA would need additional resources to effectively carry out the wider roles recommended by the Council.

The specific recommendations made by Council are:

1. *ARPANSA directly engage in a process of consultation with professional bodies and regulators to discuss appropriate training for persons working in the medical radiation field. This may be assisted by medical colleges or professional organisations. In some cases training may need to be linked to a requirement for authorisation to operate radiation equipment.*

This recommendation is supported in principle, subject to available resources.

A general requirement for training is a part of the draft Codes of Practice for radiation protection in medical exposure to ionizing radiation. It is further addressed in the accompanying draft Safety Guides for radiotherapy, diagnostic and interventional radiology and nuclear medicine. The working groups that have assisted in developing these documents have included relevant medical specialists, regulators and representatives of the various professional organisations. As an example, the draft nuclear medicine Safety Guide stresses the training needed for radiation health professionals, other health professional groups and staff involved in radionuclide therapy.

The linkage of training to the authorisation to operate radiation equipment is being addressed in the *National Directory for Radiation Protection* through the definition of 'competency requirements' to be defined in Schedule 6. The first edition of the *National Directory* indicated that such competency requirements would be defined for occupations related to medical uses of radiation. It included requirements for diagnostic radiographers, radiation therapists in radiotherapy and nuclear medicine technologists. Edition 2 of the Directory will include requirements for X-ray operators in rural and remote areas.

Because ARPANSA is an advisory body with limited clinical expertise and resources, it would not, in general, be in a position to provide training and would view the professional colleges, in particular, the ACPSEM as major training agents. If ARPANSA is able to acquire a medical linac, that may be able to be used for training in radiotherapy.

2. *ARPANSA directly engage with professional bodies in relation to the issue of managing the increasing radiation dose to patients by offering to present papers and participate in panel discussions at conferences organised by medical colleges and professional organisations.*

This recommendation is supported in principle, subject to available resources.

ARPANSA has limited capacity at present to prepare the necessary materials to support these activities. ARPANSA has undertaken nation-wide targeted surveys of radiological fields that are of dosimetric significance and has reported the findings to conferences of appropriate professional organizations and to international forums, and it continues to do so. Significant statistical information is gathered that requires dosimetric expertise available within ARPANSA to interpret and put the information into a relevant form.

3. *ARPANSA expedite publication of the draft Codes of Practice on radiology, radiotherapy and nuclear medicine.*

This recommendation is accepted and ARPANSA will work closely with the Radiation Health Committee to achieve publication of the documents; with the aim of having drafts for public comment, together with a regulatory impact statement, available in the final quarter of 2006 and final publication in the first quarter of 2007.

The documents relating to the three modalities have been developed separately to date. The Radiation Health Committee reviewed them together at its recent meeting. It is now working on a single Code of Practice for radiation protection in medical exposures to ionizing radiation. This will contain the regulatory requirements applying across the board for medical exposure. The Code will be supported by three Safety Guides addressing good practice in each of the modalities.

The Regulatory Impact Statement (RIS) for the Codes is in advanced preparation.

4. *ARPANSA consider the development of a range of information on radiation protection to assist the medical profession, including:*

- *Preparation of articles for general practitioner publications/magazines. The articles could provide information that would help general practitioners in understanding radiation dose aspects of procedures for which they may write referrals. This would assist in selecting the most appropriate procedure to request.*
- *Collation of information on relevant Standards, Codes and Guidance on medical radiation protection, both within Australia, and internationally that may assist in further consideration of medical radiation issues.*
- *Utilising the ARPANSA web site to draw together sources of information on optimisation techniques and the dose reductions that can be achieved, particularly for CT and paediatric CT scanning.*

This recommendation is supported in principle, subject to available resources.

ARPANSA is in a position to develop articles about the health effects and risks associated with the doses of radiation relevant to medical procedures. The more detailed work on medical radiation protection, especially on optimisation techniques, will require working closely with the relevant professions and the development of training materials, brochures, web publications etc.

The publication of an advisory brochure for doctors and patients on radiation dose in diagnostic radiology is included as a priority in the ARPANSA 2005-08 Corporate Plan. General information of this type will be useful for referrers in the selection of a medical radiation procedure, in particular in the need for the procedure to be justified in terms of benefit versus risk.

ARPANSA has the facilities to collate national and international information on medical radiation protection, dose reduction and optimisation. The ARPANSA website would provide an easily accessible, centralised one-stop repository for this information, and for some ARPANSA commentary. Already for radiotherapy, dosimetry fact sheets and interpretative documents are posted on the ARPANSA website for professional guidance.

5. *ARPANSA maintain a watching brief on studies both domestically and internationally relating to paediatric doses.*

This recommendation is accepted.

Paediatric radiation doses are of particular concern as children are more sensitive to the detrimental effects of radiation and have a longer prospective life. ARPANSA will continue to monitor the results of studies of paediatric doses.

6. *ARPANSA encourage medical associations whose members sometimes use radiation to develop and use their own Codes of Conduct on the use of ionizing radiation. Council notes the recent Code of Conduct for Orthopaedic Surgeons prepared by the Australian Orthopaedic Association.*

This recommendation is supported subject to further clarification of what is meant by a “code of conduct”. Council itself could play a role in this activity.

ARPANSA would not support organisations developing their own “codes” in the sense of the regulation of radiation protection. ARPANSA would be willing to assist organisations in the development of a general approach to radiation safety plans and other radiation protection issues such as shielding. It is, however, noted that care must be taken to separate Code of Conduct issues in relation to ethical conduct, such as in the doctor-patient relationship, from issues relating to the conduct of a procedure and the associated justification and optimisation of that procedure in relation to radiation risk/benefit and radiation protection.

7. *ARPANSA consider undertaking a survey of doses from multi-slice CT scanners. Council noted the earlier survey, “Radiation Doses from Computed Tomography in Australia” (TR123 Nov 1997), which covered doses from single slice CT scanners. Council sees benefit in undertaking a further survey of doses, as the technology has changed.*

This recommendation is supported. The undertaking of such a survey is included in the ARPANSA Corporate Plan 2005-2008, and initial planning has commenced.

ARPANSA does not see multi-slice CT in isolation from other significant changes that have occurred in CT technology. It is proposed to perform a national survey of all CT centres and procedures to determine organ doses and effective doses. It is intended that the results be stratified by patient parameters (age, sex etc), equipment, practice types and technology (e.g. multislice, spiral, ‘smart-beam’ etc).

The survey is in the early design stage. The new CT technologies present some challenges in defining what needs to be measured (dosimetry quantities) and how to accomplish these measurements in a practical way. For example, equipment that modulates the beam current during rotation will present significant difficulties in the assessment of effective dose. Like all surveys, there will be the need to make the balance between the accuracy of dosimetry and the practical measures that make the aim achievable. It would appear that there is only limited standardization in the techniques used for a given procedure and one of the difficulties will be in defining the procedures for which data are required, in a way

that is understood by the practitioner. This will be particularly difficult in dealing with multi-phase examinations. On the more positive side, ARPANSA has completed the development of its mathematical phantom and Monte Carlo computer codes to compute organ and effective doses once the patient parameters and CT x-ray beam quality and intensity have been defined.

With current resources, a survey on the basis of simplified dosimetry could be completed within 18 months to 2 years. Such a survey would probably not accurately reflect the impact of new technology because the beams would be inaccurately 'modelled' in terms of the traditional methods (slices with constant current). A more detailed approach to the dosimetry, which is considered to be necessary, still needs to be developed and will result in a more complex survey that will take longer to complete. Additional staff resources, once the survey has entered the implementation phase would reduce the time for completion.

ATTACHMENT – ADDITIONAL INFORMATION

Nuclear Medicine

The use of positron emission tomography (PET) continues to grow rapidly. There are currently about 15 PET scanners in clinical use; in 2004-05 the Australian Government funded about 12,700 PET services. The application of PET radiopharmaceuticals to the diagnosis of dementia and to post-therapy monitoring is expected to increase significantly. The development of new specific PET radiopharmaceuticals is a major research area. The Medical Services Advisory Committee (MSAC) is currently examining data on PET in order to provide further advice to the Australian Government on the clinical and cost effectiveness of this technology. PET is one area of nuclear medicine practice in which there is the potential for significant exposure to medical staff in the preparation and care of patients. The key to minimizing these doses is in the careful design of the facility and good procedures for the management of patient flow through the facility.

Cyclotrons are now in operation in most State capitals, principally to produce ^{18}F for the manufacture of fluoro[^{18}F]-deoxyglucose for diagnosis. It is noted that cyclotrons are expensive to install and maintain, and that a reliable source of PET radionuclides is essential to ensure that benefit of PET scanners is maximised.

The total number of diagnostic nuclear medicine procedures has increased from 382,000 annually in 1999 to about 435,000 in 2005. This does not include the carbon-14 urea breath test, which results in a minimal radiation effective dose to the patient (2-3 μSv). ARPANSA has made estimates of the population dose from diagnostic nuclear medicine using the survey data on doses from Smart and Towson, and surveying the number of each type of procedure. The per caput effective dose from Nuclear Medicine in 1999 was 0.15 mSv, and this has risen to 0.17 mSv in 2004 as a result of the increased number of procedures. In general, doses for a given nuclear medicine procedures at different centres do not vary greatly and it is not expected that population doses will change significantly in the near future. A common nuclear medicine diagnostic procedure, the administration of Technetium[$^{99\text{m}}\text{Tc}$] Medronate Injection for a “bone scan” results in an effective dose of 4.2 mSv to the adult patient, whilst the administration of Thallous[^{201}Tl] Chloride Injection for myocardial imaging results in an effective dose of 18 mSv.

Therapeutic nuclear medicine continues to grow modestly, with 3,661 Medicare services in 2000 and 4,128 services in 2005. The radionuclides used have largely remained I-131, P-32, Sr-89, Sm-153, Y-90 and In-111. It is expected that the use of Y-90 will experience rapid growth. In general, the high hopes that were once held for specific antibodies labelled with therapeutic radionuclides have been only partially realised. There is, however, the potential for a breakthrough in the use of therapy radiopharmaceuticals based on α -emitting radionuclides. Boron neutron capture therapy (BNCT) creates little interest.

Diagnostic Radiology

This is an area that is being driven by rapid technological changes in equipment and data processing, and there are likely to be major further advances in the next 5-10 years. The RHSAC paper has highlighted the areas that may need to be addressed in the near future, in particular the balance between benefit and risk and the optimisation of radiation protection.

ARPANSA has had a long history of development of dosimetry and computational techniques for monitoring patient doses in Australia. The first national survey of doses from

general radiation was performed in 1978. Since then, ARPANSA has performed national surveys of doses from mammography (1990), computed tomography (CT) (1995), nuclear medicine (1991, 1999) and general radiology (2004), and updated CT doses to cover the period 1994-2004.

Mammography is significant because of the large number of asymptomatic women who receive modest doses from the screening program. The technology has not changed significantly over the past 15 years. Digital imaging has now become a reality and claims of significant dose reduction are being made. ARPANSA will keep a watching brief and will reassess the population dose from these procedures, if appropriate, when the new technologies become widespread. A driver of the survey may be to determine whether lower dose technologies should be mandated. ARPANSA's current estimate of the per caput effective dose from mammography is 0.02 mSv. The average mean glandular dose for a two-view mammographic examination for the National Screening Program is about 4 mGy.

A comprehensive national survey of radiation doses from general radiology in 2004 has been completed. General radiology is a modest contributor to the collective dose from medical procedures. The results indicate that, as expected, there are wide ranges of dose from a given procedure at different practices, indicating the continuing need for good quality control, including the monitoring of patient doses and the use of diagnostic reference levels (DRLs). The average doses for procedures are, however, similar to those found in other developed countries. The per caput dose from general radiology was estimated from the survey to be 0.13 mSv. The average effective doses for procedures range from 0.03 mSv for a single film chest exam through to 1 mSv for an abdomen or lumbar spine exam and 4 mSv for an IVP.

At the time of the survey, computed radiology (CR) (non film image receptors) was increasing. Survey results indicate only a marginal reduction in patient doses from CR. ARPANSA will maintain a watch in the literature for evidence of 'exposure creep' where doses increase without a concomitant improvement in diagnostic efficacy.

Over the past decade CT has undergone significant technological changes which have significantly altered the dosimetry and have enabled the modality to be used in new areas of diagnosis. This has been accompanied by a rapid increase in utilization. From the 1995 survey, ARPANSA estimated that CT was the major contributor to population medical radiation dose. The average effective dose was 2 mSv for a head exam, 5 mSv for a lumbar spine and 17 mSv for a complete abdomen exam. The survey data have been updated for changes in the numbers and types of procedures and it was estimated that the per caput effective dose from CT was of the order of 0.85 mSv in 2002. This is about 70% of the total dose resulting from all uses of radiation in diagnosis. This estimate does not include the changes in procedure doses resulting from new technology nor does it take into account new types of procedures. The dominance of CT as a contributor to population dose makes it a clear candidate for a new study.

Summary of population doses from diagnostic procedures.

From its surveys, ARPANSA estimates that the total per caput dose from diagnostic procedures is currently about 1.25 mSv. This is made up of CT (70%), nuclear medicine (12%), general radiology (11%), fluoroscopy (5%) and mammography (2%).