



## RADIATION PROTECTION IN THE MEDICAL APPLICATIONS OF IONIZING RADIATION

### REGULATORY REQUIREMENTS AND GOOD PRACTICE

#### Background to the System of Radiation Protection in Australia

The system of radiation protection that is applied in Australia derives from the recommendations of the International Commission on Radiological Protection (ICRP). The overall system was most recently set out by the ICRP in 1991 in its *Publication 60.1*

The ICRP 60 Recommendations form the basis for the *International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources* (the BSS) developed and promulgated by the International Atomic Energy Agency (IAEA). The BSS takes the system recommended by ICRP and sets out how they are applied in regulatory requirements.<sup>2</sup>

In Australia, the system established by ICRP 60 and the BSS is reflected in the ARPANSA publication *Radiation Protection Series 1: Recommendations for Limiting Exposure to Ionizing Radiation and National Standard for Limiting Occupational Exposure to Ionizing Radiation* (RPS 1).

The Australian Health Ministers' Conference endorsed the development of the *National Directory for Radiation Protection* in August 1999 as the means of achieving uniformity in radiation protection practices and legislation between jurisdictions. The Conference agreed that the *National Directory* would be prepared by the Radiation Health Committee for approval by the Conference. Upon consideration and approval of the provisions of the Directory, the Ministers agreed that regulatory elements of the Directory shall be adopted in each jurisdiction as soon as possible, using existing Commonwealth/State/Territory regulatory frameworks.

The first edition of the *National Directory* was published in August 2004. That edition 1 establishes the framework for the ongoing development of the Directory. Section 5 of the Directory refers to national adoption of Codes and Standards. The Directory states:

*Codes and Standards referenced in this directory must be adopted by Authorities within their regulatory frameworks. This should be done preferably by direct reference to a Code or Standard in the regulations of an Authority, but may be achieved by using a Code or Standard as conditions of licence and/or registration issued by an Authority.*

The Directory also allows for adoption of extracts from Codes and Standards.

Thus a 'Code of Practice' developed by the Radiation Health Committee and intended to be adopted by reference into the *National Directory for Radiation Protection* contains the regulatory

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- 1 A new set of recommendations has now been finalised for publication by the ICRP during 2007. There are no significant changes with regard to radiation protection in medical exposures.
  - 2 The BSS establishes general requirements and requirements that apply to applications of ionizing radiation. Detailed requirements for medical exposures are included in Appendix II to the BSS.

requirements that will be referenced in Commonwealth/State/Territory regulations or as conditions of licence or registration.

The Radiation Health Committee also develops 'Safety Guides'. These are documents that are not regulatory in nature but that provide activity-specific guidance on achieving the requirements set out in the Codes of Practice. They are non-prescriptive in style using 'should' statements to recommend good practices.

### **The System of Radiation Protection and Medical Applications of Radiation**

The system of radiation protection deals with exposure to radiation in three classes: occupational, medical and public. *Occupational* exposures are incurred at work and principally as a result of working directly with radiation; *medical* exposure is the exposure of patients as part of their medical diagnosis, to assist with a medical intervention or as direct treatment; *public* exposure covers all other exposures arising from a particular activity using radiation sources.

The medical applications of ionizing radiation – diagnostic and interventional radiology, nuclear medicine and radiotherapy – involve exposures of all three classes.

The general principles that are applied in the system of radiation protection are referred to as 'justification', 'optimisation' and 'limitation'. In brief, an activity involving the use of ionizing radiation needs to be justified to ensure that benefits from using ionizing radiation outweigh the detriment that exposure to radiation may cause; the radiation protection and safety involved needs to be optimised so that individual doses, the number of people exposed and the likelihood of exposure are all kept as low as reasonably achievable (ALARA), economic and social factors being taken into account; and the radiation doses to individuals from all justified activities fall below defined limits.

These general principles are then applied in any activity using radiation sources through regulatory requirements that define responsibilities of the persons undertaking the activity, establish management requirements, technical requirements for equipment and measurement, and processes for verification of radiation safety and source security. The achievement of the goals of radiation protection requires that the regulatory requirements be met in the context of good radiation protection practice.

As noted, the medical applications of ionizing radiation involve *occupational* and *public* exposures. The principles are applied and the activities are managed through regulatory requirements and good practice in much the same way as for other applications of ionizing radiation.

The radiation protection of patients from *medical exposures* raises some different issues. A medical exposure is intended to achieve some diagnostic or therapeutic purpose and thus cannot be reduced below a level where the purpose of the exposure is not achieved. Hence, the notion of applying dose limits to medical exposures does not apply.

The justification of medical exposure occurs on three levels. First, at the broadest level, the use of ionizing radiation to assist with medical diagnosis, to treat conditions directly and to assist with other treatment generically is a justified activity. Second, medical exposures undertaken in various specific diagnostic, interventional and therapeutic procedures is justified through adoption of good medical practice in a similar way to which other medical procedures are

established, for example through guidelines issued by appropriate professional bodies. Finally, the exposure of a particular individual to diagnose or treat a specific condition needs to be justified.

The optimisation of medical exposures involves the management of exposure so as to achieve the medical purpose, but otherwise to achieve a radiation dose that is as low as reasonably achievable (ALARA).

For diagnostic purposes, an established tool of optimisation is the comparison of the doses received by patients in various standard procedures with 'diagnostic reference levels'. These levels are set after surveys of doses and they should reflect what good practice achieves.

In the case of radiotherapy, doses to non-target tissue should be ALARA.

**Proposed Radiation Protection Series documents – a *Code of Practice for Radiation Protection in the Medical Applications of Ionizing Radiation (Regulatory requirements)*; three *Safety Guides on Radiation Protection in Diagnostic and Interventional Radiology; Nuclear Medicine; Radiotherapy***

The Radiation Health Committee is proposing to prepare these documents in consultation with the appropriate medical and allied professions.

The purpose of the *Code of Practice* is to establish regulatory requirements. It is planned that the *Code of Practice* when completed will be adopted into the *National Directory* and applied by the Commonwealth, States and Territories as described above.

The purpose of the *Safety Guides* is to describe good practice in each of the three different modalities to achieve the regulatory requirements established in the *Code of Practice*.

Thus, for example, the *Code of Practice* will set requirements for the radiation protection to be achieved by design and shielding of apparatus or radioactive source stores. It will do so by establishing public and occupational dose constraints below which the radiation protection achieved must be optimised. Each *Safety Guide* will describe good practice in how the constraints can be met and optimisation of protection achieved for design and shielding of equipment and radioactive source stores relevant to the three modalities.

The *Code of Practice* establishes the radiation protection principles and assigns responsibilities for achieving the outcomes flowing from the principles to the *Responsible Person* – the person having overall management responsibility for, and overall control of the medical practice; to the *Medical Practitioner* – the practitioner responsible for the overall conduct of the procedure involving the exposure of the patient to radiation; and to the *Operator* – the person who actually administers the radiation to the patient. The Code also requires the provision of expert advice from a qualified expert.

The *Code of Practice*, in particular, requires the preparation of, and adherence to, the Radiation Management Plan being the overall safety management plan for the practice that assists in ensuring that all the players meet their responsibilities.

The *Code of Practice* is planned to cover the three modalities. The intent behind this approach is to emphasise that the radiation protection principles apply to all exposures to radiation arising from medical applications, regardless of the nature of that application. In particular, that justification and optimisation are fundamental issues for medical exposures. Similarly, the basics of the responsibilities that are assigned to the Responsible Person, the Medical Practitioner and the Operator and the need for expert advice are fundamentally very similar across the three modalities. The *unified Code of Practice* is imparting an important message in this respect. It is likely to be a message of growing importance as technologies and modalities merge in yet unforeseen ways. It is noted that a single regulatory instrument, drawn from an EU Directive, applies in the UK.

It is recognised by the Radiation Health Committee that there must also be proper reflection of the differences between the modalities. These particularly arise in formulating the more detailed descriptions of the responsibilities and for technical requirements. The *Code of Practice* must incorporate these differences so that it is a practicable working document for regulators and for the people engaged in the medical practice.

Given that the *Safety Guides* address issues of good practice in detail, it is appropriate that there be separate *Safety Guides* for each of the three modalities to ensure that good practice is properly reflected in an accessible document.

ARPANSA  
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