DEVELOPMENTS IN RADIATION PROTECTION AND CLINICAL DOSIMETRY

The Australasian College of Physical Scientists and Engineers in Medicine

Australian and New Zealand Society of Nuclear Medicine

ICRP and ARPANSA New Guidance Publications

Richard Smart

Physics SIG Workshop 2004

International Commission on Radiological Protection

- 2005 Recommendations of the ICRP
- Publication 94:

  Release of patients after therapy with unsealed radionuclides (approved for publication in March 2004)
- Interim Radiopharmaceutical Reports

  Addenda 5-7 published 22 July 2004

  http://www.icrp.org/intrep.asp

2005 Recommendations of the ICRP

Main Changes from the Current Recommendations

- Justification is no longer included as a fundamental principle of radiation protection for consideration by radiation protection authorities (although it is retained for medical exposures).
- A change of approach with dose constraints. In ICRP 60 dose constraints were part of optimization and were prospective. In the 2005 recommendations dose constraints appear also to be retrospective (in that they relate to doses received) and regulatory. A number of "maximum values for constraints" are introduced.

2005 Recommendations of the ICRP

Main Changes from the Current Recommendations

- New terminology:
  "radiation weighted dose" to replace equivalent dose,
  "tissue reactions" to replace deterministic effects, and
  "cancer development and inheritable disease" to replace stochastic effects

- ICRP 2005 also includes a policy on the protection of non-human species.

2005 Recommendations of the ICRP

Proposed changes to the Tissue Weighting Factors

Tissue	w_T
Bone marrow, Breast, Colon, Lung, Stomach	0.12
Bladder, Oesophagus, Gonads, Liver, Thyroid	0.05
Bone surface, Brain, Kidneys, Salivary glands, Skin	0.01
Remainder Tissues	0.1

2005 Recommendations of the ICRP

The Remainder Tissues

- Adipose tissue, Adrenals, Connective tissue, Extrathoracic airways, Gall bladder, Heart wall, Lymphatic nodes, Muscle, Pancreas, Prostate, SI Wall, Spleen, Thymus and Uterus/cervix.

Foundation Documents from the ICRP

- Biological and Epidemiological Information on Health Risks Attributable to Ionising Radiation (ICRP Committee 1)
- Low Dose Extrapolation of Radiation-related Cancer Risk (ICRP Committee 1)
- Basis for Dosimetric Quantities used in Radiological Protection (ICRP Committee 2)
- The Representative Individual for the Purpose of Assessing Annual Dose to the Public (ICRP Committee 4)
- The Optimisation of Radiological Protection – Broadening the Process (ICRP Committee 4)

Probable Timetable

- Comments to ICRP by 31 December 2004
- Publication of Foundation Documents after March 2005 meeting of ICRP
- New draft Recommendations (? September 2005)
- ? second round of public comment

- Final Recommendations, probably in 2006

ICRP Publication 94

Release of patients after therapy with unsealed radionuclides

- 83 pages !!
- Almost essentially devoted to radioiodine therapy for thyrotoxicosis and thyroid cancer
- Half a page on antibody therapy
- No mention of labelled-Lipiodol or labelled microspheres
- Refers to the Australian Recommendations but mis-quotes them! (“25 µGy/h at 3 m”)
- Extensive use made of the Australian Code of Practice on Radioactive Corpses

ICRP Publication 94

- Re-emphasises the 5 mSv/episode dose constraint for relatives and caregivers and 1 mSv/year to infants, children and casual visitors.

- "Patients travelling after radioiodine therapy rarely present a hazard to other passengers if travel times are limited to a few hours"

ICRP Publication 94

- "sewer disposal of excreta from radiotherapy patients is well within both occupational and public radiation dose limits"
- Due to increased security devices at airports and train stations "it may be best to suggest that patients do not travel in major public areas unless they are willing to experience some inconvenience."

ARPANSA Publications

Already Published

- National Directory for Radiation Protection – Edition 1.0 (August 2004), RPS No. 6

Almost Published

- Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

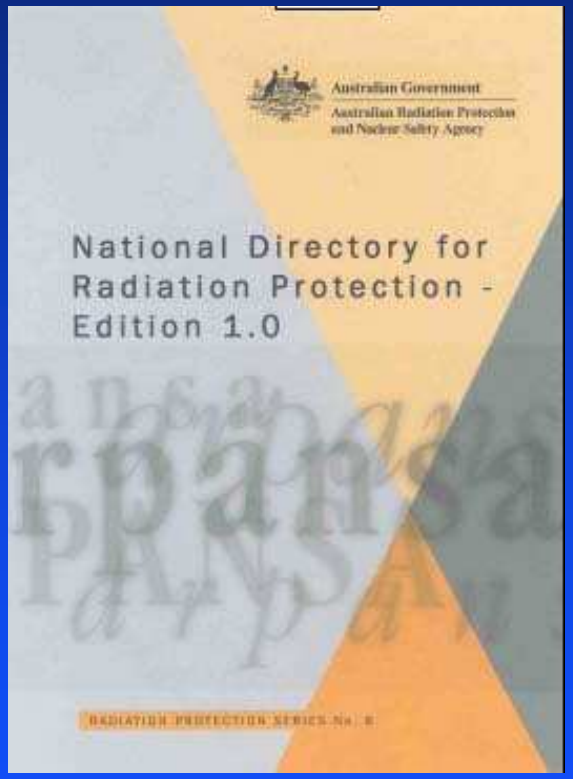
Almost ready for public comment

- Code of Practice and Safety Guide for Radiation Protection in Nuclear Medicine

National Directory for Radiation Protection – Edition 1.0

Purpose

- To provide an overall agreed framework for radiation safety, including both ionizing and non-ionizing radiation, together with clear regulatory statements to be adopted by the Commonwealth, States and Territories.



National Directory for Radiation Protection – Edition 1.0

Structure

- Part A sets out the agreed overall framework for radiation protection in Australia. It is expected that jurisdictions will adopt these principles as reviews of legislation come forward.
- Part B of the Directory contains the uniform regulatory elements, which are to be adopted by each jurisdiction, within its particular regulatory framework.
- Part C of the Directory contains guidance that will assist regulators in adopting consistent approaches, but is not regulatory in nature.

National Directory for Radiation Protection – Edition 1.0

- Part B provides for the national adoption of Codes and Standards
- Schedule 11 lists the Codes of Practice and Standards that must be adopted by all jurisdictions. It currently lists:
  - RPS 1 Recommendations and National Standard for Occupational Exposure
  - RPS2 CoP for Safe Transport of Radioactive Material
  - RPS3 Standard for Exposure to RF fields

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

- Issued for Public Comment in February 2004
- 23 submissions received
- 2 full day face-to-face meetings plus countless teleconferences
- Draft reviewed by Radiation Health Committee and by the Health Ethics Section of the NHMRC in November 2004
- Current draft sent to responders on 1 December 2004 – comments to be received by 24 December.

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

Purpose

- The purpose of this Code of Practice is to provide requirements which must be met for the exposure of humans to ionizing radiation for the purpose of research.
- This Code of Practice contains additional advice to that contained in the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* which addresses the ethical principles and values which govern research involving humans.

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

Scope

- This Code of Practice applies to research involving humans who are exposed to radiation which is in addition to that received as part of their normal clinical management.

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

Outlines the roles and responsibilities of:

- the researcher
- the medical physicist
- the Human Research Ethics Committee
- ~~the subject or guardian~~
- ~~the "responsible person"~~
- ~~the relevant regulatory authority~~

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

The medical physicist must:

1. independently verify the total cumulative effective dose and organ doses and radiation risk assessment which have been provided by the researcher, or
2. assess the expected total cumulative effective dose and organ doses which will be received by the research participant as a result of their participation in the research and the corresponding radiation risks ; and
3. where the dose constraints are exceeded, obtain verification of the dose assessment by a second medical physicist who must be independent of the researcher.

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

When undertaking the dose assessment or verification, the medical physicist must:

1. assess only those radiological procedures which are performed specifically for the research protocol and which are in addition to those received as part of the research participant's normal clinical management; and

2. take into account the technical specifications of the radiological procedures as detailed in the research protocol.

Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes

The medical physicist must prepare a written report, which includes:

1. the assessed or verified expected total cumulative effective dose and organ doses;
2. a statement as to whether the dose constraints in Table 1 are likely to be exceeded; and
3. an assessment of the risks associated with the expected radiation exposure; and
4. the proposed text on the radiation doses and risks to be included in the information provided to the research participants, consistent with Annex 2.

Definition of a Medical Physicist

- for the purpose of this Code, is a person who is qualified to perform the necessary dosimetric calculations, measurements and monitoring and has been approved by the regulatory authority to make estimates in the specialty relevant to the research project.
- A suitable person must be accredited by the Australasian College of Physical Scientists and Engineers in Medicine (ACPSEM) or have an equivalent level of training as determined by the relevant regulatory authority.

Dose Constraints for Adult Participants in Research

Participant Category		Dose Constraint
Cumulative effective dose	in any year	5 mSv
	over 5 years	10 mSv
Equivalent dose to skin	in any year	200 mSv
Equivalent dose to any other organ or tissue	in any year	100 mSv
Cumulative effective dose in adult with a life expectancy of less than 5 years	in any year	50 mSv

Dose Constraints for Adult Participants in Research

Participant Category		Dose Constraint
The following dose constraints apply when all the research participants are within the specified age limits:		
Cumulative effective dose for adult aged 60 years or more	in any year	8 mSv
Cumulative effective dose for adult aged 70 years or more	in any year	12 mSv

Dose Constraints for Children and Fetuses in Research

Participant Category	Dose Constraint
Cumulative effective dose to age 18 years, subject to:	5 mSv
Effective dose from conception to birth; and	0.1 mSv
Effective dose in any year from birth to 18 years	0.5 mSv
Cumulative equivalent dose to age 18 years to any organ or tissue	100 mSv

Other major changes to the Code

- The researcher must review the doses actually received for *novel uses of radiation*.
- Annex 1 now includes a table of age- and sex-specific risk factors (from Docs of the NRPB, 1993)
- Risk categories now uses the terminology of Calman, 1996
- Annex 2 added (*Communication of the Risk to the Research Participant*) based on the HURSOG guideline.
- Annex 3 added (*Recommendations to Assist in the Implementation of the Code*)

Code of Practice for Radiation Protection in Nuclear Medicine

- Introduction
- Justification
- Duties and Responsibilities
- Optimization of Protection for Medical Exposures
- Pregnancy and Protection of the Embryo/Fetus
- Breast Feeding and Protection of the Infant
- Quality Assurance
- Accidents and Incidents
- Occupational Exposure
- Environmental Issues
- Training

Duties and Responsibilities

- Responsible Person
- Referrers
- Nuclear Medicine Specialist
- Administering Person
- Nuclear Medicine Practitioner
- Radiation Safety Officer
- Radiopharmacist / Radiochemist
- Nuclear Medicine Physicist
- Nuclear Medicine Suppliers

Duties and Responsibilities of the Nuclear Medicine Physicist

- Take responsibility for all matters relating to image quality optimisation, patient dosimetry and equipment quality assurance.

- Provide advice to the nuclear medicine specialist on appropriate diagnostic and treatment techniques to ensure that staff radiation exposure is minimised and that patient radiation doses are optimized.

Quality Assurance

- All nuclear medicine practices must establish a comprehensive Quality Assurance (QA) program which places particular emphasis on image quality optimization and patient dose reduction as its primary and secondary goals, respectively.
- At initial installation, equipment must undergo acceptance tests
- Survey meters must be calibrated at least annually

Quality Assurance of Dose Calibrators

- Background – at least once each work day prior to the first assay
- Constancy – at least once each work day prior to the first assay (+/- 10%)
- Linearity – at installation and at least annually thereafter (+/- 10%)
- Accuracy – at installation and at least annually thereafter (+/- 10%)
- Geometry dependence – at installation and after repair or movement (+/- 10%)

Safety Guide for Radiation Protection in Nuclear Medicine

Expands on the topics covered in the Code and includes sections on:

- Prevention of mis/maladministrations
- Avoidance of conception after radionuclide therapy
- Advice to patients regarding the need to restrict close contact with children and/or the need to interrupt breast-feeding
- Patient activity surveys and DRLs

Advice to ensure that the infant receives no more than 0.3 mSv (a fretful, sick or demanding infant)

Radiopharmaceutical	Administered Activity (DRL) to mother (MBq)	Advice to patient concerning the need to restrict close contact with child	Advice to patient concerning the need to interrupt breast-feeding	Milk conc. at which breast-feeding can resume (kBq/ml)
^{18}F-FDG	400	Restrict contact for 1 h	7 h interruption	4
^{51}Cr-EDTA	8	Not required	Not required	Not required
^{67}Ga-citrate	400	Restrict contact for 10 days	Cessation	0.06
^{99m}Tc- aerosol or Technegas	40	Not required	Not required	Not required
^{99m}Tc-colloid	200	Not required	Not required	Not required
^{99m}Tc-DISIDA or HIDA	200	Not required	Not required	Not required
^{99m}Tc-DMSA	185	Not required	Not required	Not required

2004

Code of Practice and Safety Guide

Timetable

- Drafts to be submitted to the Radiation Health Committee in March 2005
- Regulatory Impact Statement to be prepared
- Released for Public Comment