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# **The Regulatory Impact Assessment and Process for Code Development**

**for the**

**Code of Practice for Radiation Protection in the Medical  
Applications of Ionizing Radiation**

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**Standards Development & Committee Support Section  
ARPANSA**

*National Conference on Radiation Protection in Medicine, 3 October 2007, Melbourne*



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# ARPANSA

## Radiation Protection Series

- **Priorities:** set by RHC for review of each of the NHMRC RHS publications and Nuclear Codes as well as any new work
- **Scoping groups:** set up to review particular areas, and to identify priorities and existing gaps, including medical radiations



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# **ARPANSA**

## **Radiation Protection Series**

- **Developed by working groups appointed by the RHC.**
- **Working group members typically include:**
  - regulators (eg Members of RHC);
  - industry representatives;
  - professional nominations selected for their expertise;
  - community representatives, where relevant to a particular working group.



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# **ARPANSA**

## **Radiation Protection Series**

### **4 levels of publication**

- **RADIATION PROTECTION STANDARDS**
- **CODES OF PRACTICE**
- **SAFETY GUIDES**
- **RECOMMENDATIONS**



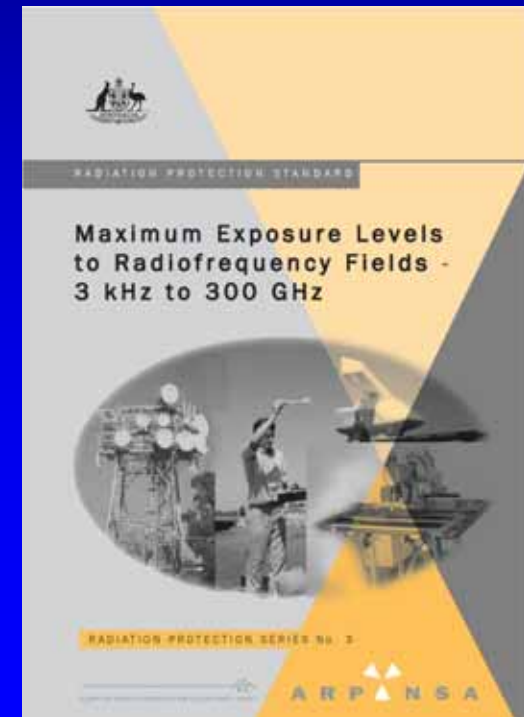
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# ARPANSA

## Radiation Protection Series

- **RADIATION PROTECTION STANDARDS**
- Regulatory in style (able to be directly adopted by regulators)
- Set fundamental requirements, such as dose or exposure limits  
eg. Limiting exposure to ionizing radiation, Limiting exposure to RF Fields



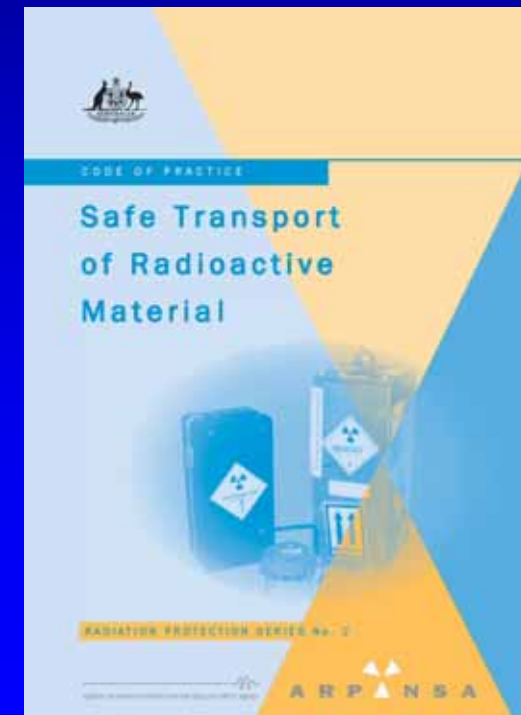


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# ARPANSA Radiation Protection Series

- **CODES OF PRACTICE**
  - also regulatory in style
  - more practice-related
- eg. Safe Transport of Radioactive Materials, Safe Use of Portable Moisture/Density Gauges





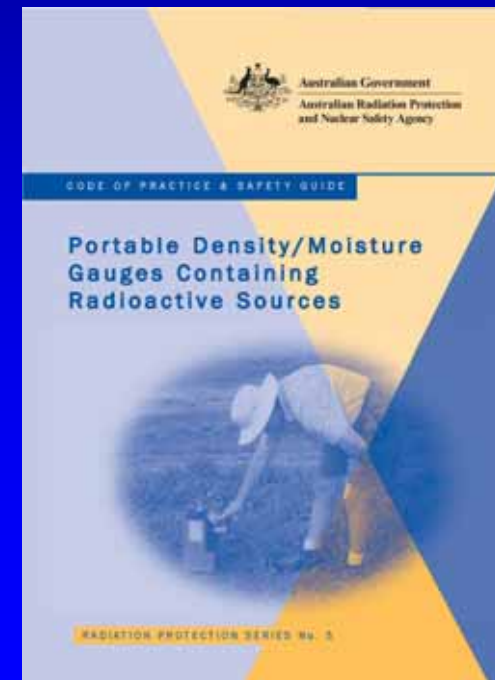
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# ARPANSA

## Radiation Protection Series

- **SAFETY GUIDES**
- provide practice-specific, non-regulatory guidance on achieving the requirements of Standards and Codes
  - eg. Radiation Protection in Veterinary Science, Radiation Protection in Dentistry





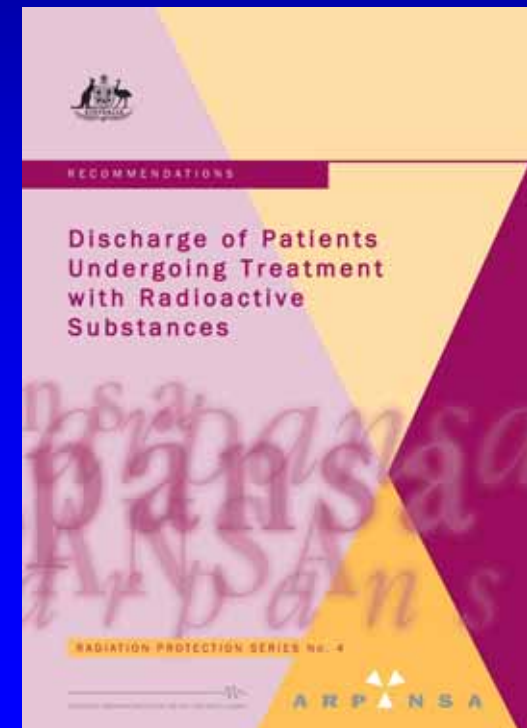
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# ARPANSA

## Radiation Protection Series

- **RECOMMENDATIONS**
- advice on best practice
- usually cover areas where there is no comparable Radiation Protection Standard or Code
  - eg. Intervention in Emergency Situations involving Radiation Exposure, Discharge of Patients undergoing Treatment with Radioactive Substances





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# **1994 Report to COAG of Committee on Regulatory Reform**

## **Key issues in setting national standards**

- **Impetus from Mutual Recognition Agreement**
- **Need for sufficient scrutiny to guard against unnecessary regulation & excessive requirements on business**
- **Need to move away from overly prescriptive standards towards performance based standards**
- **Desirability of avoiding duplication in the impact assessment procedures of different jurisdictions**



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# The COAG Principles and Guidelines

- Originally endorsed by COAG in 1995
- Latest edition is June 2004
  - Describes the features of good regulation
  - Recommends a set of principles for standard setting and regulatory action, including RIS
  - Requires that major costs and benefits are adequately identified and where appropriate quantified
  - Requires that analysis is commensurate the impact of the proposed regulatory measures



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# ARPANSA

## Radiation Protection Series

- Process for development of Codes & Standards must meet **COAG** requirements for National Standard setting
  - i.e. Codes & Standards must undergo a **regulatory impact assessment** including cost-benefit analysis, assessment of other regulatory or non-regulatory options, and public consultation.

COUNCIL OF AUSTRALIAN  
GOVERNMENTS

*Principles and Guidelines for National  
Standard Setting and Regulatory  
Action by Ministerial Councils and  
Standard-Setting Bodies*

Endorsed by COAG April 1995

Amended by COAG November 1997

NOVEMBER 1997



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# Elements of a Regulatory Impact Statement

- The **problem** or issues requiring action
- The desired **objective**
- The **options** that may achieve the objective
- Assessment of **impact** on consumers, business, government & community of each option
- A **consultation** statement
- An evaluation leading to a **recommended option**
- A strategy to **implement & review**



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# The RIS Process

- The RIS must be cleared by the Office of Best Practice Regulation (OBPR) before being released for public comment
- The OBPR must be satisfied that the level of analysis is adequate for consultation purposes
- A **final** RIS dealing with the issues raised in submissions
  - must be cleared by OBPR
  - forms part of the papers submitted to decision makers with the final Code
- OBPR reports annually to the National Competition Council on compliance by Australian Government Departments and Agencies with the COAG Guidelines



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## **The “Consultation RIS”**

- **Information was sought from a variety of sources, including all State and Territory radiation protection regulators**
- **Cost-Benefit Analysis prepared by The Allen Consulting Group**
- **Cleared by OBPR**
- **Released for public comment along with Code and Safety Guides until 26 October 2007**



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# The RIS

- **Background**
  - **Describes the industry in general terms.**
- **Problems**
  - **Information Asymmetry (outdated legislation for radiation protection)**
  - **Externalities (off-site effects (eg carers, public transport users))**
- **Objective**
  - **Cost-effectively improve the health outcomes of patients and to protect workers, public & environment from the harmful effects of ionizing radiation.**



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## The RIS (cont'd)

- **Statement of Possible Options**
  - ***Status quo* (rely on current legislation)**
  - **Self-regulation (industry sets its requirements)**
  - **New Code & Safety Guides**
- **Impact Analysis**
  - **Affected parties (medical industries inc radiology, nuc med, radiotherapy, medical workers, patients, Government regulators (State, Territory & Commonwealth), the community)**



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## **The RIS (*Status Quo*)**

- **Impact Analysis for Status Quo**
  - **Benefits**
    - **Current regulations are resulting in health and safety outcomes that are better than no regulations**
  - **Costs (admin)**
    - **Existing regulatory regime costs sunk**
    - **Monitoring and enforcing existing Codes (low)**
    - **Training (low – no more than for staff turnover)**



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## **The RIS (*Status Quo*)**

- **Impact Analysis for *Status Quo***
  - **Costs (compliance)**
    - **Lack of uniformity**
    - **Different skill sets and training requirements across Australia**
    - **Absence of specific regulator or set of regulations**
    - **Some existing regs are outdated, do not incorporate “best practice”**
    - **Grey areas within some regulations**
    - **Omissions in some regulations**



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# The RIS (Self-Regulation Model)

- **Self-Regulation Model**
  - **OBPR lists 3 criteria that should apply for a successful self-regulatory model:**
    - 1. No major public interest concern; no major health and safety concern**
    - 2. Problem is low risk; the consequences of self regulation failing are small**
    - 3. Incentive for industry to develop and comply with self regulation requirements**



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## The RIS (Self-Regulation Model)

- **Self Regulation – Conclusion**
  - *Given the nature of the risks to human health and the nature of the industry, self regulation does not provide a workable alternative to regulation in the fields of nuclear medicine, radiotherapy and radiology.*



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# The RIS (Proposed Code)

- **Impact Analysis for Proposed Code**
  - **Costs (admin)**
    - Amending regulations, training regulatory staff
    - Monitoring costs small as already undertaken
  - **Costs (compliance)**
    - Justification of medical procedures – required in Qld, implicit in some other jurisdictions
    - Optimisation of medical procedures
    - Preparation and review of radiation protection plans (required in some jurisdictions already)
    - Procedures for when an embryo or foetus is inadvertently irradiated
    - Formalisation of training



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# The RIS (Proposed Code)

- **Impact Analysis for Proposed Code**
  - **Benefits (health & safety)**
    - **Improved radiation protection awareness**
    - **Reduction of unnecessary**
    - **Formalisation**
    - **Tightening of occupational dose limits – Compliance with RPS1**
  - **Benefits (regulatory approach)**
    - **Uniformity**
    - **Dynamic Efficiency – changes can be effected over time through RHC, as necessary**
    - **International standing and consistency**



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# The RIS (Consultation)

- **Consultation**
  - **1 month for public comment during the 2 month public comment period for Code and Safety Guides (end 26 October 2007)**
  - **Notified a wide range of industry, Government and other stakeholders**
  - **Code, Safety Guides and RIS made available via the ARPANSA web site**



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# Summary of CBA conclusions

- **Proposed Code provides best option**
  - Up-to-date radiation protection information
  - Exposure limits consistent with other sectors
  - Uniform national set of requirements for occupationally exposed, carers, patients, public and the environment
  - Reduced uncertainty & enhanced regulatory consistency
  - Some costs associated with limits, RMPs, training
    - but some already carried out under State/Territory licensing so costs are low



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## Submissions commenting on RIS

- **Invitation in RIS:**
  - *Stakeholders who disagree with the conclusions above are urged to substantiate their view with a description and quantification of costs to apply, implement, administer or enforce the proposed ARPANSA Code of Practice or Safety Guides.*
  - *Stakeholders are also invited to provide input with relevant information that could add value to the Regulatory Impact Statement.*
- **All comment will be taken into account in preparation of the final RIS**



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# Thank You

