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# **YOUR RESPONSIBILITIES UNDER THE ARPANSA SOURCE LICENCE**

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***Introduction to RPS 14 - Code of  
Practice for Radiation Protection  
in Medical Applications of  
Ionizing Radiation***

**For Defence Personnel – March 2009**



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## Presentation Outline

- ARPANSA Legislation Overview
- Licence Requirements
- Accidents and incidents
- Defence Source Licence
- Licence Conditions
- Inspections
- RPS 14 – *Code of Practice for Radiation Protection in Medical Applications of Ionizing Radiation*



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# Australian Radiation Protection And Nuclear Safety Act 1998

Objective is *“To protect the health and safety of people, and to protect the environment, from the harmful effects of radiation.”*

The Act prohibits controlled persons from undertaking:

- certain activities (facilities) or
- certain dealings (controlled apparatus and materials)

Unless they are:

- licensed, or
- the dealing is exempt



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## Provisions of the ARPANS Act (cont)

‘Controlled Person’ is defined as a:

- Commonwealth contractor
- Commonwealth entity (includes Commonwealth employee)
- Person in the capacity of an employee of a Commonwealth contractor

To ‘deal with’ is defined in the Act as:

- possess, or have control of, the apparatus or material
- use or operate the apparatus, or use material
- dispose of the apparatus or material



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## Controlled Apparatus

- Is defined by the Act as:
  - an apparatus that can produce ionizing radiation when energised (e.g X-ray apparatus)





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# **Australian Radiation Protection And Nuclear Safety Regulations 1999**

- **Prescriptive**
  - Further defines controlled sources and prescribed radiation facilities
  - Sets out exemptions for low hazard radioactive subs
- **Licence conditions**
  - Compliance, plans and arrangements, reviews and approvals
- **Practices to be followed**
  - dose limits, codes of practice, standards



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## **Plans and Arrangements for Safety**

When an organisation applies for a licence they provide details known as plans and arrangements

- Maintaining effective control
- Safety management plan
- Radiation protection plan
- Radioactive waste management plan
- Security plan
- Emergency plan



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## **Conditions of Licence**

Comply with S 35 of the Act (allow entry for inspections)

Comply with Licence Conditions in Part 4 Division 4 of the Regulations

Comply with the Practices listed in Part 5 of the Regulations

Comply with Conditions imposed by the CEO in Schedule 2 of the Licence



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## **Conditions of Licence (cont)**

Regulation 45 – Investigate suspected breaches

Regulation 46 – Prevent, control and minimise accidents. Notify within 24 hours and written report within 14 days

Regulation 49 – Follow plans and arrangements

Regulation 50 – Review and update plans and arrangements at least once every 12 months

Regulation 51 – Prior approval for relevant changes that will have significant implications for safety.

Regulation 52 – Make changes unlikely to have significant implications for safety – advise in quarterly report.

Regulation 53 – Tell CEO about movement of controlled apparatus and materials. Prior approval for disposal.



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# Radiation Incident

## Definition from the NDRP:

“Any unintended or ill-advised event when using ionising radiation apparatus, specified types of non-ionising apparatus or radioactive substances, **which results in, or has the potential to result in, an exposure to radiation to any person or the environment, outside the range of that normally expected for a particular practice**, including events resulting from operator error, equipment failure, or the failure of management systems that warranted investigation.”



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# Defence Source Licence S0042



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S0042

## Source Licence

Under Section 33 of the *Australian Radiation Protection and Nuclear Safety Act 1998*, (the Act) I, John Loy, Chief Executive Officer of ARPANSA issue a Source Licence to:

### Australian Defence Force and Department of Defence

that authorises the persons identified below to deal with the Controlled Apparatus and Controlled Material described in Schedule 1, subject to the following:

1. Conditions in Section 35 of the Act
2. Conditions in Part 4 Division 4 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999*, (the Regulations)
3. Practices to be followed in Part 5 of the Regulations
4. Conditions in Schedule 2

Persons covered by this Licence are the Licence Holder, employees of the Licence Holder, Commonwealth Contractors and employees of Commonwealth Contractors.

ISSUED at SYDNEY, this *twenty third* day of *December* 2005.

John Loy  
CEO of ARPANSA

This licence continues in force until cancelled or surrendered



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### Schedule 1

## Controlled Apparatus & Controlled Material

Group <sup>2</sup>	Item <sup>2</sup>	Kind of Controlled Apparatus or Controlled Material
Group 1	1	Sealed source for calibration purposes of activity of 40 MBq or less
	2	Sealed source in a fully enclosed analytical device
	10	Conventional dental x-ray unit
	13	Fully enclosed x-ray analysis unit
	<b>15</b>	<b>Mobile or portable medical x-ray unit</b>
	16	Magnetic field non-destructive testing device
	17	Induction heater or induction furnace
	19	Radiofrequency plasma tube
	22	Optical source, other than a laser product, emitting ultraviolet radiation, infra-red or visible light
	23	Laser product with accessible emission level more than the accessible emission limit of a Class 3B (Restricted) laser product, set out in Australia/New Zealand Standard AS/NZS 2211.2:1997
Group 2	25	Sealed source for calibration purposes of activity of more than 40 MBq
	26	Sealed source in a partially enclosed analytical device
	28	Sealed source in a mobile gauge
	<b>33</b>	<b>Industrial radiography x-ray unit</b>
	<b>34</b>	<b>Fixed medical x-ray unit, including a unit used for fluoroscopy, tomography and chiropractic radiography</b>
	35	Partially enclosed x-ray analysis unit



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## Schedule 2: Licence Conditions

1. Maintain up-to-date inventory
2. Render Quarterly Reports of Compliance
3. Ensure persons who deal with controlled sources are properly trained
4. Ensure persons who repair and maintain controlled sources are properly trained
5. Document, approve and maintain work procedures
6. Comply with codes of practice
7. Ensure controlled apparatus used for medical/dental purposes have compliance testing



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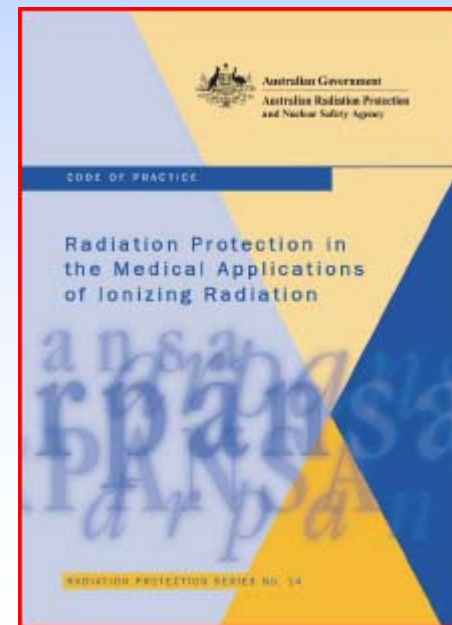
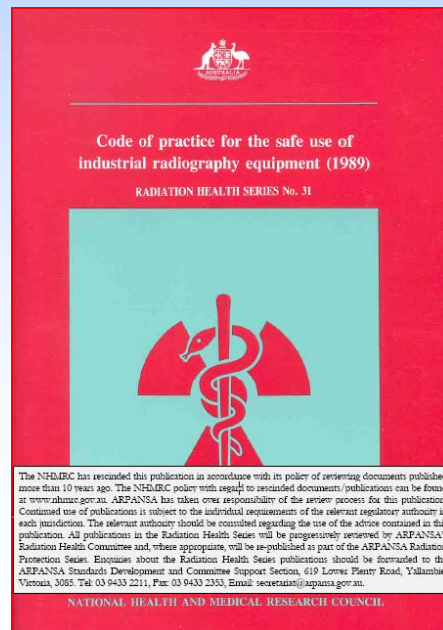
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## Schedule 2: Licence Conditions

***Licence Condition 6 applies Codes and Standards to Items from Schedule 1.***

*RPS 14 - Code of Practice Radiation Protection in the Medical Applications of Ionizing Radiation (2008)*

*RHS 31 - Code of practice for the safe use of industrial radiography equipment (1989)*





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## **Powers of Inspection**

- Empowered under Sections 62-82 of the Act
- Inspectors are authorised via ARPANSA Identity Card
- May search and seize in regard to an offence
- Can result in enforcement action
  - Reporting of breach – to Parliament
  - Directions by CEO - restrictions or suspension of operation  
(Reviewable under principles of natural justice)
  - Injunctions or prosecutions



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## **Conduct of Inspections**

- Types of Inspection
  - Compliance
  - Incident
- Objective is to gather evidence on compliance with Act, Regulations and licence conditions
- Inspectors make preliminary conclusions
  - copy of report to licence holder
- CEO is the decision-maker regarding breach and/or enforcement action



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## **Inspection Process**

- Coordinated by DRSA (LA Branch)
- Requires preparation from work place (Hazards Checklist)
- ARPANSA Inspector and DRSA Representative will conduct Entry and Exit Brief with Base/Unit staff
- Inspectors will review documentation, physically inspect plant/equipment, interview personnel
  - Almost certainly a requirement for photography
  - Inspectors may request copies of documents
- Representatives are briefed on findings before departure



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## Summary

- Defence holds an ARPANSA radiation licence
- The licence has conditions attached
- Includes the use of controlled apparatus (X-ray units)
- You are covered by this licence and must meet the conditions
  - Follow plans and arrangements
  - Comply with relevant Codes of Practice
- Your site may be inspected



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## New Medical Code

*Code of Practice Radiation Protection in the Medical Applications of Ionizing (2008)* has been in the pipeline for about **five years**.

- RHC working group
- several drafts circulated for public consultation
- conference in October 2008
- discussions with relevant professional bodies – AIR, ANZSNM, RANZCR etc





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## How does this affect Defence Medical Imaging Technologists and Radiologists?

*It will be **mandatory** for you to meet this code of practice **no matter where you work** within Australia or **what regulatory regime** you are under !!!*

*Will be adopted as a condition of the Defence source licence from 1 July 2009.*



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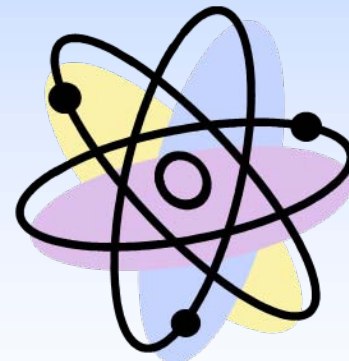
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## What does the code cover?

Regulatory requirements – the **MUSTs**

Mostly things you are already doing – aligned with radiation protection principles.

- **Justification**
- **Optimisation**
- **Limitation**





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## **1. Introduction**

## **2. Radiation Protection Principles**

- 2.1 Justification
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- 2.3 Dose Limits

## **3. Responsibilities**

- 3.1 The Responsible Person
- 3.2 Radiation medical practitioner
- 3.3 Operator

**Schedule A      Radiation Management Plan**

**Schedule B      Protection of an Embryo or Foetus**



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## **Major components**

- **Radiation Management Plan (RMP)**
- **Roles and responsibilities of responsible person**
- **Roles and responsibilities of radiation medical practitioner**
- **Roles and responsibilities of operator**



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## Radiation Management Plan

- Work practices and protocols
- Design and shielding
- Training and qualifications
- Personal monitoring and PPE
- Managing incident/accident/emergency
- QA program
- Management and review of RMP



Schedule A of the code describes 20+ things it must cover



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## **3.1 Responsible person**

**Overall management** responsibility for radiation sources and their use.

In this case Defence – rather than an individual person.

Responsible for ensuring all appropriate systems and documentation are in place to meet requirements of RMP and principles of optimisation, justification and limitation.



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## Things to note...

Optimisation of protection, limitation and recording of radiation doses.

A record is to be kept for a type of diagnostic radiology procedure:

- sufficient information on the procedure or exposure parameters that would allow the radiation **dose to a patient to be estimated**; or
- the radiation dose administered to the patient.

Ensure doses to occupationally exposed persons and public are within limits of RPS1 and **ALARA**.



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## Things to note...

Program to ensure that radiation doses administered to a patient for diagnostic purposes are:

- periodically compared with **diagnostic reference levels (DRLs)** for diagnostic procedures for which DRLs have been established in Australia; and
- if DRLs are consistently exceeded, review to determine whether radiation protection has been optimised.



Ensure training of occupationally exposed persons

Ensure radiation sources are accounted for,  
maintained and tested, appropriate documentation  
kept



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## 3.2 Radiation medical practitioner

The person responsible for the justification and optimisation of the procedure involving the exposure of the patient to ionizing radiation, **either for each individual patient or by way of protocols** specific for the procedure.

- Usually the Radiologist in charge of the practice/dept
- For Defence this may be someone who has been involved in designing the protocols – not necessarily on site
- Must be authorised by relevant regulatory body



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## Radiation medical practitioner (Cont'd)

- Must comply with RMP
- Gives authorisation for procedure
- Determines net benefit (justification)
- Considers dose to potentially pregnant patients
- **Approves procedures**
  - must not undertake or approve a procedure without written referral
  - must specify procedure or have generic written guidelines



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## 3.3 Operator



Things you must do.....

- Be authorised by relevant regulatory body to administer radiation
- Comply with RMP
- Wear personal monitor and PPE provided
- Report equipment faults and not override safety interlocks
- Report radiation incidents to responsible person and medical practitioner **within 24hrs**



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## **Operator (cont'd)**

Responsible for the delivery of medical radiation procedure:

- Correctly identify the patient
- Not expose person unless procedure approved
- Follow protocols
- Ensure exposure to others is minimised
  - lead aprons
  - only necessary persons in room
  - close doors
  - beam collimation



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## Operator (cont'd)

- Ensure protection of patient is optimised (dose ALARA)
  - tailor exposure factors for procedure and patient (e.g. high kV, low mA)
  - limit number of views
  - keep track of screening time
  - consider source to skin distance
  - appropriate receptors (film/screen or II field size)
  - suitable digital image processing parameters
  - use ABC, pulsed fluoro
  - patient immobilisation
  - grids as applicable



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## Advice and guidance - the SHOULDs

Three separate **Safety Guides** for radiation protection in radiotherapy, diagnostic and interventional radiology, and nuclear medicine inform **best practice** in each of these medical applications of ionizing radiation. They provide useful radiation protection information to the medical community.

RPS14.1 *Safety Guide for Radiation Protection in Diagnostic and Interventional Radiology*



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## **Implementation ?**

The code and safety guide are available on ARPANSA website [www.arpansa.gov.au/publications](http://www.arpansa.gov.au/publications)

- Review Defence policies and procedures to ensure the requirements of the code are taken into account
- Promulgate new procedures as necessary and ensure all relevant personnel are aware
- Include in site quality and/or accreditation management systems
- Be prepared for this to be part of future ARPANSA inspections



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# Questions?

