

# Victorian regulation of the use of ionising radiation in human research

Noel Cleaves

Manager, Legionella & Radiation Safety

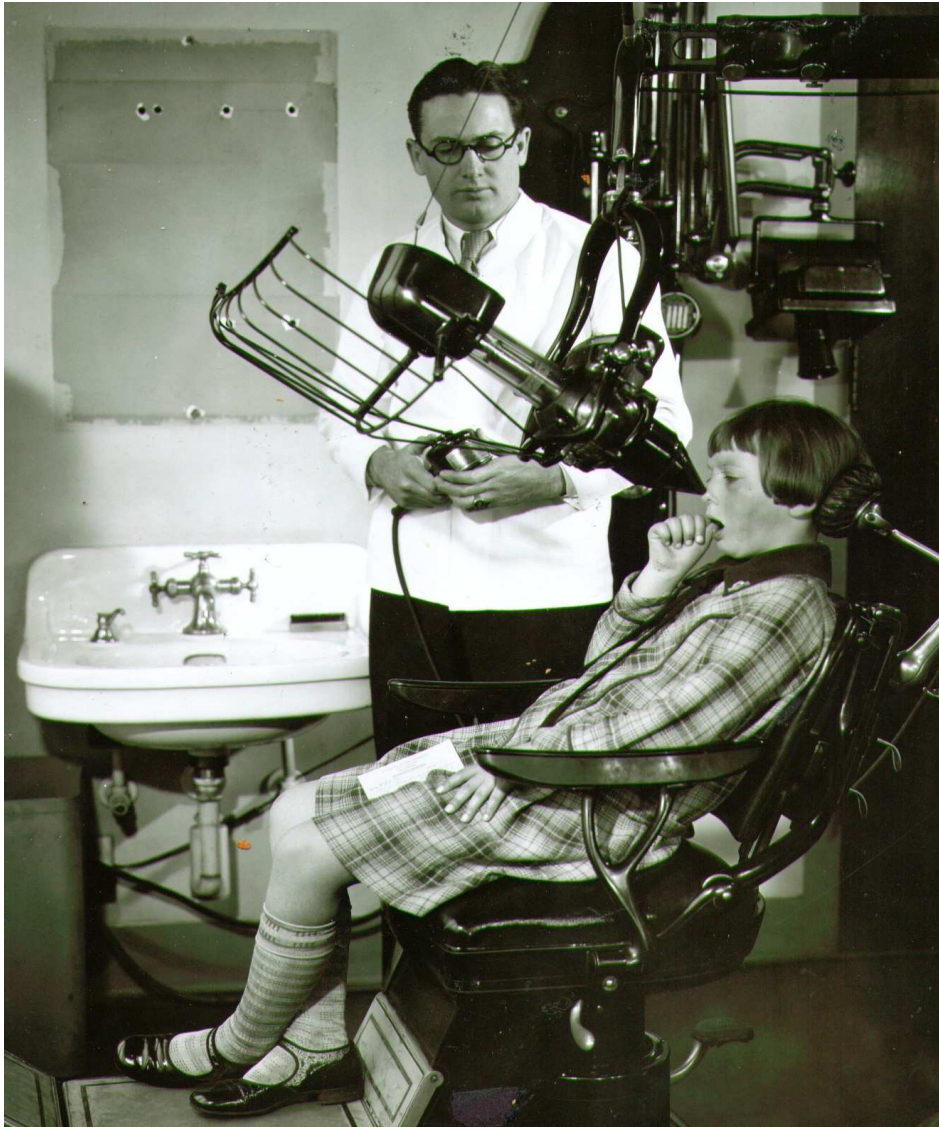
# Radiation Act 2005

- Commenced on 1 September 2007 replacing the previous legislation that regulated radiation safety
- Purpose is to protect the health & safety of persons & the environment from the harmful effects of radiation
- Creates a framework for regulation both of organisations and of individuals:

# Radiation Act 2005

- A part of the regulatory framework is a licensing system
  - organisations conducting ‘radiation practices’ must be authorised through a ‘Management Licence’ (~ 2,500)
  - actual use of a radiation source by an individual must be authorised by a ‘Use Licence’ (~ 10,000)

# What are radiation practices?



## What are radiation practices?

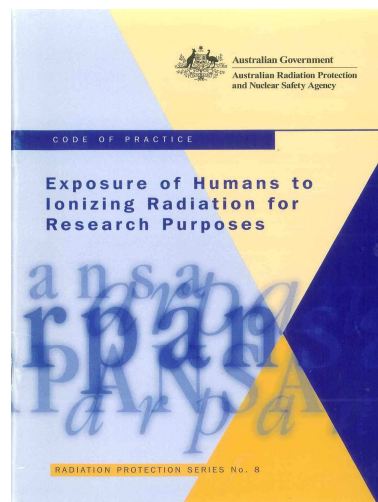
- The definition in the Act of radiation practices includes ‘procuring or arranging research involving the irradiation of persons’
- This definition means that a management licence must be held by an organisation prior to undertaking such a practice

# Management licences

- Issued to the legal entity conducting the practice e.g. the hospital group - 'XXXXX Health'
- Authorises all of the radiation practices conducted by the entity, often at many sites
- Typically has a range of schedules which detail the various radiation sources (e.g. a CT or a type of radioactive material) which may be possessed for a purpose stated in the licence
- Typically has many conditions which define the regulatory requirements
- Typically these conditions include compliance with a nationally agreed Code of Practice

# Management licences authorising research

- Require compliance with the 'Code of Practice for the Exposure of Humans to Ionizing Radiation for Research Purposes' published by ARPANSA
- Code was published in 2005 and was implemented in Victoria later that year through the then radiation licensing laws



# Victorian Radiation Advisory Committee

- Victorian Radiation Advisory Committee established in law by Radiation Act (and previous laws)
- Appointed by Minister
- Meets monthly
- In late 2008 the Victorian Radiation Advisory Committee considered information provided to them in relation to the Victorian approach to research issues and endorsed a series of changes to clarify the requirements relating to research

# What is the new approach?

- Licence still required
- Change to the management licence format to introduce a specific schedule relating to research.
- The new schedule will not list any specific research projects but rather will provide the general authorisation including the following:
  - Where dose constraint **not proposed to be exceeded**, a **notification** of the project title and the name of the lead researcher **only** will be required i.e. no need to wait for approval from Department
  - Where dose constraint is **proposed to be exceeded** the licence holder will need to:
    - » seek a second independent assessment of the doses and risks from a medical physicist not involved in the original assessment
    - » **apply to the Department for a specific authorisation for the project.** This authorisation when given will be via a letter rather than a varied licence.
- DH may audit licence holders periodically

# How will the Department assess a proposed project proposing to exceed the dose constraint?

health

- Radiation Safety Team will do a preliminary assessment and then list the project on the agenda of the next Radiation Advisory Committee meeting
- RAC focuses on the doses and the risk statements
- If satisfied then RAC will endorse the project
- DH then will advise the licence holder and the lead researcher in writing that the project is authorised and can now proceed
- RAC may sometimes ask the DH to seek additional supporting information about the project before it will endorse the project

## When will the changes take place?

- Soon!
  - Final drafting of the new licences and conditions ~ one month
  - New licence schedule ~ one month

# Issues?

- **Issue 1:** Not always clear in large organisations who is authorised to lodge applications, including for research or for requests to vary an existing licence, on behalf of the organisation
- **Issue 2:** When applications come before the RAC, the most common issues that can stall or delay approval are usually issues of clarity, such as:
  - the method for estimating radiation doses
  - the radiation risk statement provided to the research participant
  - the explanation of standard medical care
  - the justification for certain ionising radiation procedures
  - the nature of the research participants' health status and their prognosis in studies involving research participants with cancer
  - differences between sites in relation to multi-site trials e.g. radiation doses or standard care