



Australian Government

# **TWGRR Meeting**

# **Australian Regulation of**

# **Radiopharmaceutical**

# **Production Facilities**

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# Overview of presentation

- Framework for regulation of safety of research reactors and production facilities in Australia
- Transition to a new research reactor and new Mo 99 production process – Australian experience
- Impact of issues arising out of recent international meetings (ASN and NEA)
  - Harmonisation of safety standards – further advanced for RRs than production facilities?
  - Next steps

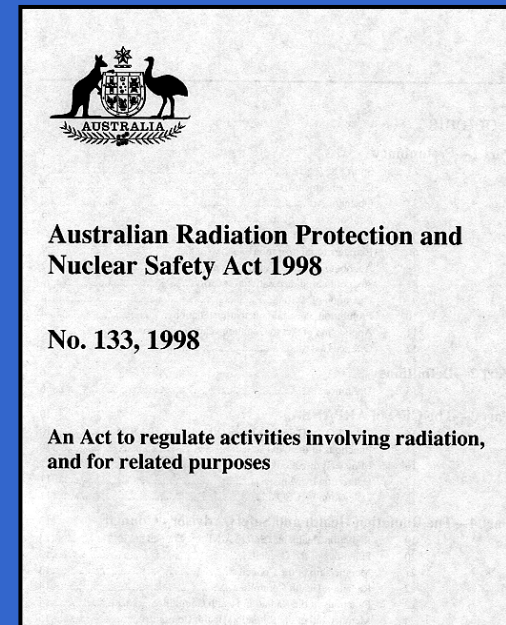


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# ARPANS Act

## — The *Australian Radiation Protection and Nuclear Safety Act 1998*

- Object – “to protect the health and safety of people and to protect the environment from the harmful effects of radiation”
- Created Australian Radiation Protection and Nuclear Safety Agency
- Framework for regulation of safety of RR and RPF





# ARPANSA Regulatory Framework

- Is based on
  - IAEA Safety Requirements GSR 1
  - International Basic Safety Standards for Protection Against IR and the Safety of Radiation Sources
- Incorporates then IAEA Regulations for Safe Transport of Radioactive Material
- Under the ARPANS Act the regulator must take into account international best practice in radiation protection and nuclear safety when making decisions



# ARPANSA regulatory framework

- ARPANS Act regulates each stage of the life of a facility (both RR and RPF) with a separate authorisation for–
  - Preparation for siting,
  - Construction,
  - Operation and
  - decommissioning
- Each licence stage requires information to be provided on plans and arrangements for managing safety including:
  - Effective control
  - Safety management
  - Radiation protection
  - Radioactive waste management
  - Emergency plans
  - Security plans



# Regulation of RR and RPF

- Research reactors and radioisotope production facilities are licensed separately as facilities (nuclear installations) under the ARPANS Act.
- The Australian Nuclear Science and Technology Organisation is the only operator of nuclear facilities in Australia
- The HIFAR reactor operated for 50 years until it was finally shutdown in 2007
- The OPAL reactor has replaced HIFAR as Australia's only research reactor and has recently completed hot commissioning
- ANSTO is also in the process of hot commissioning a new Mo 99 production process, under regulatory supervision.



# LEU Mo99 Production process

- New Mo99 production process currently being hot commissioned
- Characterised as a relevant change with significant implications for safety rather than a new licence application
- New Mo 99 process requires separate approval by ARPANSA prior to routine operation.
- New safety case required and demonstration of appropriate operating procedures
- Also requires separate approval by the Australian Therapeutic Goods Administration



# Issues for regulator

- As radiopharmaceutical production involves:
  - RR operation (irradiation of target)
  - Transfer to the production facility
  - Production within a separate facility
  - Waste processing and storage
  - Dispatch and product transport
- Challenge for the regulator:
  - To assure itself of consistency of safety across all stages
  - To assure itself that all interfaces between operational areas are well managed, responsibilities well understood, communication protocols are established etc
  - EG Recent process review by ANSTO prior to hot commissioning of the new moly process



# Regulatory response

- Promote the role of regulators in the assurance of safety
- Respond appropriately to incidents and accidents and to assess the extent to which operators subsequently have used the incident to improve safety (lessons learned)
- Take positive regulatory steps to encourage the continuous improvement of the performance of the licensee
- Ensure maintenance of communication with the public



## Challenges identified at recent international meetings

- Harmonisation of safety of RRs much further advanced compared to RPFs – an example status of application of Code of Conduct of Safety Management of Research Reactors
- Production imperatives competing with safety at the plant level?
- Is the global demand for supply putting pressure on safety regulators to place supply above safety?



## Next Steps

- Continued knowledge sharing and networking
- Identification of areas of progress in other aspects that could be applied – Code of Conduct?
- Development of an action plan for regulators
- Action!
- Assessment of the efficacy of those actions on a regular basis