



Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Regulatory Challenges for Reactor Based Nuclear Medicine Production

Jim Scott
Regulatory Services
ARPANSA



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Background

In October 2012, ARPANSA received a licence application from the Australian Nuclear Science and Technology Organisation (ANSTO) to site a new molybdenum-99 (Mo-99) production facility at the Lucas Heights Science and Technology Centre.

The facility is a purpose-designed plant for extraction of Mo-99 from Low Enriched Uranium (LEU) targets irradiated at the Open Pool Australian Light water research reactor (OPAL). The technology is based on an alkaline fission product process which has been in use for many years at the existing ANSTO Health plant (now 'Health Products') and the NTP Radioisotopes Pty Ltd plant in South Africa.



New Mo-99 production facility



OPAL 20 MW research reactor



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



arpansa

Mo-99 Production Facility

The Mo-99 production facility consists of:

- hot cells for the processing of Mo-99 including dissolution, purification, dispensing and packaging
- a control room housing the process control and building monitoring systems
- a truck bay and crane for deliveries, despatch and removing waste and a plant room housing main switchboards, plant and equipment
- a system to ensure capture and decay of dissolver off-gases
- ventilation systems to supply clean air and extract potentially contaminated air from production equipment and areas
- laboratory activities which are integrated with existing laboratories on-site
- storage areas and active maintenance areas

ANSTO video on the new Mo-99 production facility can be viewed at <https://youtu.be/IO2DQ8gMcNI>



Front of hot cells



Rear of cells



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Licensing chronology

- October 2013. New Mo-99 production facility siting licence issued
- June 2014. New Mo-99 production facility construction licence issued
- April 2018. Operating licence issued for new Mo-99 production facility to cover hot commissioning
- May 2019. Licence condition removed to allow ANSTO to move to routine operations



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



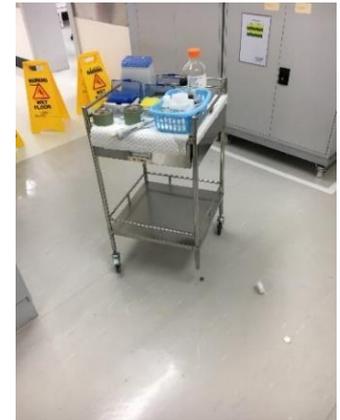
Safety events and ARPANSA responses which occurred at ANSTO during licensing of the new Mo-99 production facility (1)

- August 2017. A Quality Control Technician receives an estimated extremity exposure of 20 Gy whilst decapping a vial of Mo-99 at the older ANSTO Health facility (now 'Health Products'). This results in severe tissue reactions and is reported as an INES level 3 event to the INES database.
- February 2018. A special report is tabled in Parliament on the employee overexposure under Section 61(1) of the ARPANS Act which is the first such report prepared by ARPANSA
- Corrective actions requested and implemented included retraining, strengthened oversight, redesign of the process, and new risk assessment for scenarios with greater than moderate risk



Safety events and ARPANSA's responses (2)

- March – June 2018. A series of safety events then occur at the older ANSTO Health facility, including a near miss where a trolley fails and a vial containing Mo-99 is spilled
- June 2018. As a result, ARPANSA issues a direction instructing ANSTO to conduct an independent safety review using external experts
- August 2018. A team of 5 national and international experts is selected for the review team
- October 2018. A report is produced by the team which includes a series of 85 recommendations



Trolley with failed wheel and spilled vial





Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Safety events and ARPANSA's responses (3)

- December 2018. ANSTO provides ARPANSA with an action implementation plan to address the recommendations from the independent review
- June 2019. A contamination event occurs at the front of cells of the new Mo-99 production facility whereby two employees receive an extremity dose above the statutory limit (best estimate 1.4 Sv and 0.7 Sv) whilst transferring an inner container of a transport package. The event was reported as an INES level 2 event
- ARPANSA raises questions around safety culture. Are assessments carried out for the whole supply chain?



Packaging cell where contamination event occurred, with radiation monitoring station subsequently installed as a corrective action



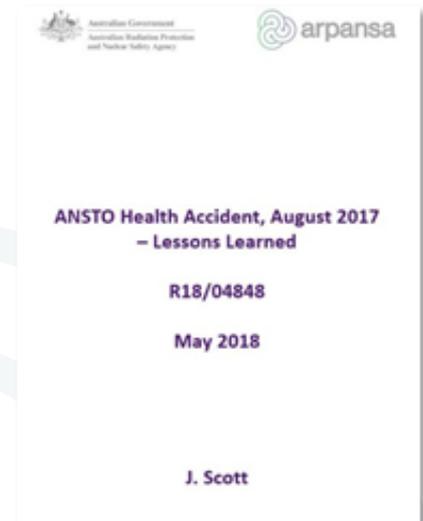
Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Lessons learned (1)

- It is highlighted that the radiological hazard from direct contact with Mo-99 solution from the dissolution process is extreme with skin dose limits potentially being reached in a matter of a few minutes
- The accident identified potential weaknesses in licence holder risk assessments, particularly human factor aspects. ARPANSA has since engaged its licence holders to ensure that their risk estimates do not underestimate likelihood or consequence





Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Lessons learned (2)

- It is important to preserve the scene of accidents to inform dose estimates. There was a high level of uncertainty in the estimated dose for the August 2017 accident due to the accident scene being cleaned up before the amount of activity involved in the spill was quantified. ARPANSA has since produced guidance on this topic for licence holders which can be found on its website at:

<https://www.arpansa.gov.au/sites/default/files/reg-com-sup-270k.pdf>

- A regulatory incident response procedure did not exist within the ARPANSA Quality Management System. It was considered that a procedure providing guidance to regulatory officers and inspectors from time of notification to closure of the incident would improve regulatory outcomes. A draft procedure has now been prepared by ARPANSA





Lessons learned (3)

Analysis of the accident in August 2017 at the ANSTO Health facility resulted in the following:

- The specific activity of the Mo-99 Quality Control samples was higher than needed, and was not optimal. This specific activity was reduced significantly after the accident
- The process for Quality Control testing could be improved and risks reduced by introducing semi-automation of some steps
- A new risk assessment was undertaken for the Quality Control process



Redesigned transport container lid with vial holder



For visualisation of amount of liquid spills contemplated in the risk assessment, drops of three sizes were placed on a nitrile glove

50µl drop

1µl drop

10µl drop



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**

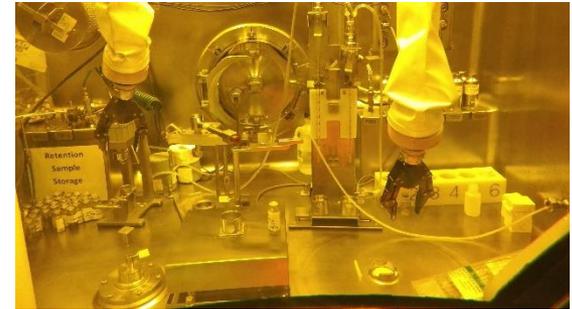


arpansa

Lessons learned (4)

Following the contamination event at the new Mo-99 production facility in June 2019, an investigation report was prepared by ANSTO which concluded the following:

- There was an over-reliance on the risk assessment process which led to a lack of questioning on whether contamination could occur where it was not expected
- Assumptions based on the risk assessment led to a false sense of security that contamination could not occur at a certain point which resulted in a lack of adequate radiation monitoring
- A need for better identification and education on potential contamination exposure during the process
- Further education and training needs to be provided to employees to ensure theoretical knowledge is embedded in a practical application with respect to monitoring and managing contamination



Manipulators in the dispensing cell of the new Mo-99 production facility



Contamination monitoring introduced after the event at the new Mo-99 production facility



Australian Government

**Australian Radiation Protection
and Nuclear Safety Agency**



Conclusions

ARPANSA has reflected on the recent events and has asked itself the following questions:

- Could a more effective regulatory approach have prevented this series of failures?
- Has ARPANSA done the right things, and have we done them right?

Thank you

Email: jim.scott@arpansa.gov.au

Website: arpansa.gov.au

Phone: +61 2 9541 8343



ARPANSAGovernment



ARPANSA



ARPANSANews