Re-evaluation and Optimisation of a Tc-99m Generator Assembly Process

Henry Lake, Prashant Maharaj, Rani Sharma, Bronte Hoban, Joshua Reus-Smit, Andrew Popp

Radiation Protection Services, Australian Nuclear Science and Technology Organisation

An opportunity to closely examine the Tc-99m generator assembly process at ANSTO highlighted some potentially significant skin dose risks. This poster looks into the different stages and processes that were undertaken to optimise the generator assembly process with the introduction of preventative measures, ultimately leading to a reduction in radioactive contamination and the resulting skin dose.

A History of Optimisation

Optimisation is applied using the ALARA principle: to keep the likelihood of incurring exposures, the number of people exposed and the magnitude of individual doses As Low As Reasonably Achievable, taking into account economic and societal factors. Optimisation of protection is one of 5 radiation protection strategies used at ANSTO to manage radiation risks, along with Justification, Limitation, Defence in Depth, and Safety Culture.

ANSTO has manufactured Tc-99m generators for many years. It is a process that has undergone development, risk assessment, optimisation and approval over the years. The optimisation of protection by ANSTO is a forward-looking iterative process aimed at preventing or reducing future exposures and where review has shown an overall group reduction over the past decade.

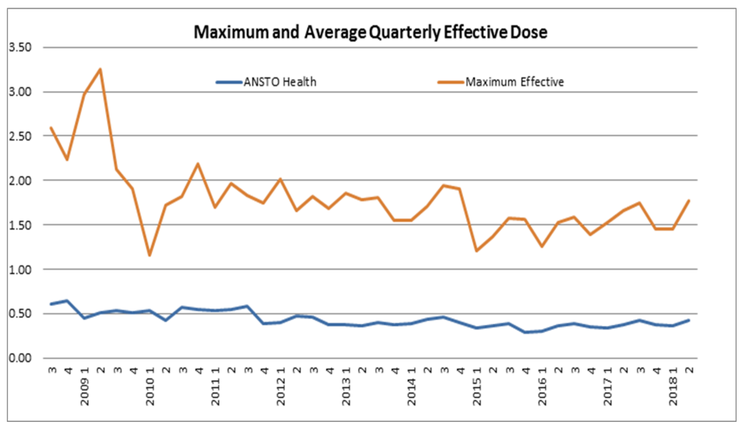


Figure 1: Maximum and average effective dose trends over the past decade indicate a reduction for the radiopharmaceutical business unit as a whole.

Opportunity for Improvement

In 2018 it was identified that this generator manufacturing process could be further optimised in terms of occupational exposures. An inspection and review of the process was instigated during an unplanned manufacture shutdown. Improved risk assessment methodology was utilised that involves the consideration of the techniques used in the manufacturing process, human factors in greater detail and an updated approach to the calculation of potential likelihood and consequence.

The review working group conducted a walkthrough of the working area to identify high risk process tasks. During the review workers reported variability in the levels of contamination observed on components. Subsequent assurance monitoring by ANSTO's Radiation Protection Services (RPS) identified significant levels of contamination on some components.

The revised risk assessment identified areas in the process where there was a risk of significant skin exposures if hands come into close contact to highly concentrated radionuclides of Mo-99 and Tc-99m that were detected on the generator components. Four generator manufacture activities were highlighted where the radiation exposure risks to skin were significant and is outlined in table 1.

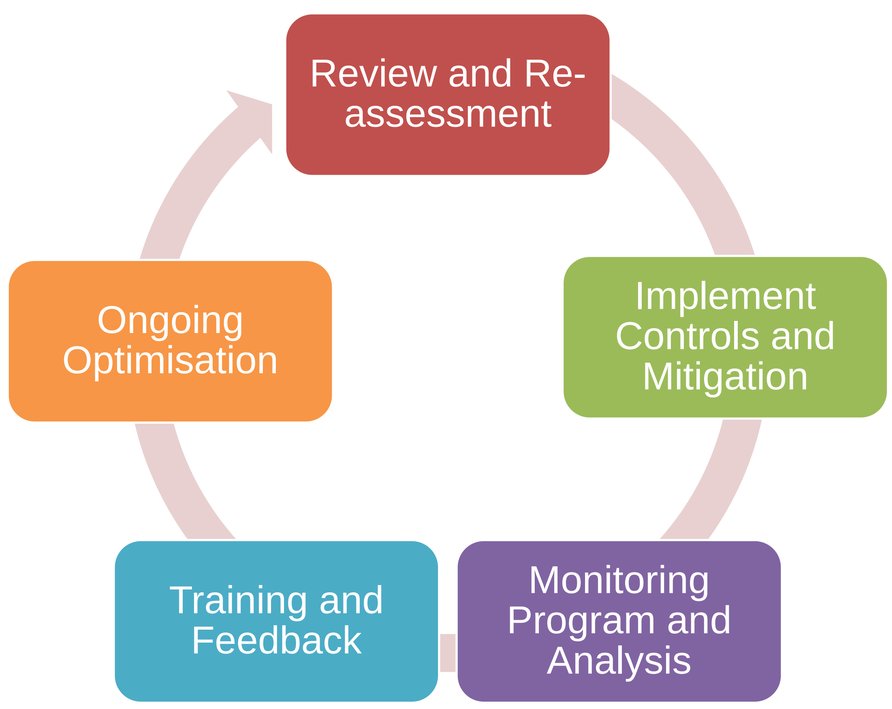
Activity with Significant Risk	Risk Scenario	Mitigation Strategy
Transfer of shielded generator pot	**Contact with unshielded generator vial or to the contents of vial due to drop of partially assembled generator**	Engineer method to secure pot lid during transfer, and modify lifting cradle Reinforce incident response procedures
Manual handling during generator assembly	**Contamination from handling of generator leads**	Additional contamination monitoring along the manufacture process to identify and act on contamination Frequent glove changes to reduce exposure time Alternate assembly methodology using tools to introduce distance between the fingers and hands and potentially contaminated generator components
Transfer of shielded elution pot	**Drop of elution sample in pot**	Vial redesign Pot redesign New generator process
Manual handling of elutions	**Handling errors leading to contamination**	Additional contamination monitoring along the manufacture process to identify and act on contamination Frequent glove changes to reduce exposure time

Table 1: Generator activities identified has having significant skin dose risks and the mitigation strategies

Optimisation

Possible improvements were discussed with the generator production business unit and chosen improvements ideas were trialled, timed and implemented in a mock cell. Production operators of varying levels of experience were video recorded undertaking the new process with feedback integrated into the improved process flow. RPS analysed the video recordings to generate approximate timings for dose assessments.

RPS utilised these inputs to generate a new training program tailored to the operators. The training program incorporated general radiation safety and monitoring skills during generator manufacture and provided reassurance about the levels of potential exposures.



The ongoing iterative cycle of optimisation

RPS implemented an intensive monitoring program, of which the objectives were to:

- collect data to feed into the risk assessment;
- re-inforce operator radiation and contamination monitoring techniques;
- confirm the likelihood of contamination transfer;
- introduce and refine in-process monitor techniques to key steps in the assembly process;
- collect data for dose assessments and lastly;
- provide assurance to staff, supervisors and managers that doses were optimised and skin dose risk reduced;

The monitoring program is further detailed in the poster: **"The Implementation of Optimising ANSTOs Tc-99m Generator Assembly Process**" by R.Sharma and B.Hoban.

What Worked and Why

The implementation of new controls and mitigation strategies proved effective in reducing the skin dose risk. The radiation and contamination monitoring program showed the significant potential skin dose that was averted by implementing these controls and mitigation strategies. Of the 342 generators assembled during the monitoring period led by RPS, monitoring observations showed an overall reduction in worker glove contamination occurrences and reduced contamination on generator components.

There was no increase in worker's effective and extremity doses to date, including during the periods of control implementation and gradual ramp-up of generator manufacture. Exposures can be deemed optimised since the potential skin dose risks were reduced significantly from the monitoring data analysis and theoretical modelling.

Optimisation would not have been successful without successful factors:

- A systematic data collection methodology to establish potential exposure levels before and after the implementation of mitigation strategies;
- A slow-down of throughput of the process as manufacture re-commenced and the operators were adapting and learning the new techniques and safety measures introduced;
- Ensuring the risks are communicated and understood by all;
- Open communication and feedback with regard to protection and safety with all stakeholders;
- Concurrent work to support changes affecting product GMP and compliance.

Review and optimisation continues with a feedback into ongoing process improvements.

+61 2 9717 3111 enquiries@ansto.gov.au www.ansto.gov.au

ICRP 2019