The Implementation of Optimising ANSTOs Tc-99m Generator Assembly Process

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This poster aims to show the monitoring findings during optimisation of an approved process following the implementation of validated substitution and administrative controls, resulting in a dose reduction to workers.

Background and Understanding

Technetium-99m (Tc-99m) is a widely used radiotracer in nuclear medicine. However, its six hour half-life makes longer transportation times an issue. To overcome this, Molybdenum-99 (Mo-99), (sixty-six hour half-life) the parent isotope is delivered in the form of a generator.

Mo-99 is produced at the Australian Nuclear Medicine (ANM) facility at the Australian Nuclear Science and Technology Organisation (ANSTO). This is further processed at ANSTO Health Products and delivered to customers within shielded GENTECH™ generators. The ANSTO Health GENTECH generator production method is a justified process involving a series of steps executed at designated workstations, throughout which radiological conditions are monitored. As part of ANSTO's questioning attitude an inspection and review of the generator production process was conducted during a brief shutdown period. An augmented risk assessment updated the risk of potential skin exposure.

WHY?

In understanding a process, it is important to consider why particular steps and tools are used prior to administrating changes.

Things to consider include:

- It has "Always" been done that way
- Technology setbacks
- Non-apparent consequences
- Resultant from previous incident

Potential exposures identified

Table 1 shows the areas of improvement identified as a result of process review, production flow observation and standard operating procedure study.

The optimisation process for identifying potential exposures is further explained in Poster: **"The Re-evaluation and Optimisation of a Tc-99m Generator Assembly Process"** by H. Lake and P. Maharaj

Table 1: Potential identified exposures

Removal of dust caps from column lines (occurs at workstation 1)	Changing radiological conditions
• Mo-99 product placed into a partial generator with attached elution lines sticking out at either end, one line to elute product, the other to milk Tc-99m for medical use. • Dust caps protect the lines ends, they are removed and replaced with other apparatus at this stage. • Consistent occurrence of significant contamination observed on operator gloves post cap removal → suggesting transfer of contamination from the dust caps. • Identified as the main area of improvement for contamination reduction and dose optimisation.	• Pre-run room survey compared to post-run room survey data suggested a build-up of residual contamination on lifting equipment. • Self-monitoring is good practice and reduces the spread of contamination, this could have been difficult due to elevated dose rates. • To encourage understanding the risk of contamination and increased dose rates at certain steps of the process

Improved Process

Dust caps sent for gamma spectroscopy, main contaminants found to be Mo-99 and Tc-99m, activity range of 0.0268KBq to 54500KBq. The activities of the generators would range from 20 – 476 GBq at assembly time.

Observations highlighted potential scenarios that could result in workers receiving dose above the threshold for skin tissue reactions e.g. transient erythema, blistering.

Collaborate group controls to minimise this can be seen in table 2.

A special mention to; production subject matter experts, engineering group, ANSTO Health team, radiation protection services and the waste characterisation group without whom the implementation would not have been possible.

Table 2: Summary of new Process controls

Control type	Improvement	Pre-implementation
Substitution	• Introduction of tools to protect operators from high contamination levels and associated dose. • Minimise risk of contamination transfer onto operator gloves and hence potentially operators skin.	• Mock trials to test the usability of tools, the desired functions being holding a line and removing a dust cap. • Cleanroom validation to ensure suitability in TGA pharmaceutical grade production facility.
Administrative and PPE	• Teach and train self-glove monitoring techniques in elevated dose area → improve safety culture → reduce exposure • Teach and train workplace monitoring for contamination spread and dose rates.	Teaching plan discussed including: • Suitable placement of contamination monitors • Proper glove check techniques • Frequent glove changes incorporated into work instruction for radioprotection and GMP

Monitoring

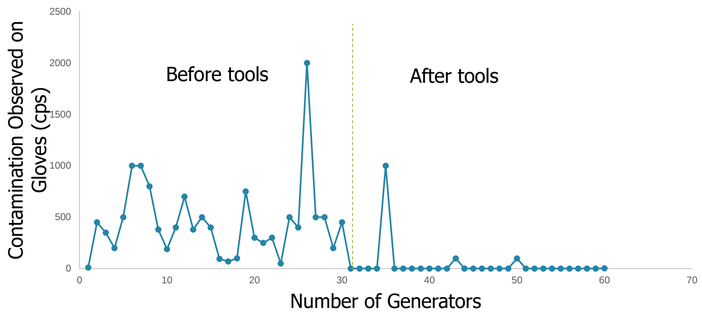
Program specific TLD results, activity on dust caps, and, radioactive contamination and radiation levels from different steps were monitored over seven weeks.

Monitoring duration to allow for familiarity with the use of tools and to capture changes as production was ramped up. The slow ramp up of use also ensured that no underlying effects were resultant from the new method.

Results & Conclusion

Overall use of tools have reduced the contamination on operator gloves. Figure 1 shows reduction in glove contamination from no tools (Generators 1-30) by 90% by using tools (generators 31-60). Random glove contamination is observed with tools, however this was found to be due to accidentally bumping the leads when re-adjusting the generator.

Fig 1: First 60 generators: Without tools vs With Tools



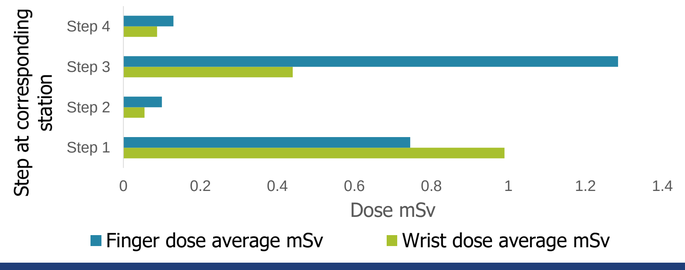
Average dose averted since introduction of tools in table 3, was mathematically modelled based on; dust cap activity data, 10% transfer factor, assumptions, cap dimensions, configurations and conversion factors drawn from IAEA document and ANSTO analysis.

Table 3. Potential dose equivalent to skin averted

Based on duration of task	1 min	0.5 min
Potential Average dose equivalent averted to skin received per generator (with tools)	~790µSv	~369µSv
Annual Potential Average dose equivalent averted to skin (with tools)	~356mSv	~178mSv

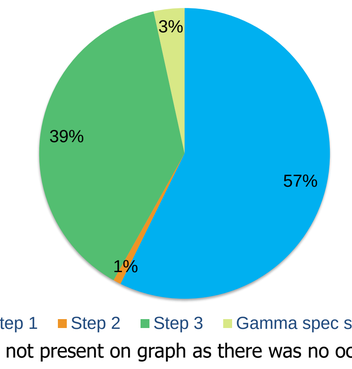
One month TLD data from the different steps can be compared in figure 2. Step 1 identified as the area for improvement had the highest wrist dose. This comparison also highlighted highest finger dose received in step 3 – due to closer proximity and more hand related work, step 3 in particular has a longer duration. This learning experience highlighted a future dose optimisation opportunity for step 3.

Fig 2: Average TLD Dose Comparison in One Month



Of the 117 contamination occurrences, the levels observed at step 3 were lower than that observed in step 1 (Fig 3), in which 72% were <20cps, 11% between 20-49cps and 17% ≥50 cps – this is opposed to approx 72% contamination ≥50cps in step 1.

Fig 3: Occurance of Contamination Observed from Assembled Generators



(Note: Station 4 not present on graph as there was no occurrences at this station)

Of the 342 generators assembled during a period following the improvements, monitoring observations showed an overall reduction in worker glove contamination occurrences. The data collected allowed for the dose averted to be modelled which revealed a reduction in potential extremity dose received.