Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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Inspection report

Licence Holder: ANSTO (ANSTO Health)	**Licence Number:** F0262
Location inspected: Lucas Heights Science and Technology Centre, Sydney	**Date/s of inspection:** 12-15 June 2018 **Report No:** R18/07456

An inspection was conducted as part of ARPANSA's augmented inspection process to assess compliance with the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act), the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the Regulations), conditions of ANSTO Health Facility Licence F0262 and performance against applicable ARPANSA Performance Objectives and Criteria(PO&C).

The inspection was initiated following an event involving a spill of molybdenum-99 (Mo-99) quality control product at the facility on the 7 June 2018. The inspection included an assessment of the safety performance of ANSTO (ANSTO Health) at its radiopharmaceutical production facilities and, in particular, of the safe work practices of the Quality Control Section. The inspection consisted of a review of records, interviews, and a physical inspection of the facility.

Background

ANSTO Health manufactures radiopharmaceuticals for national and international markets. Mo-99 is extracted via a chemical process from targets irradiated in the OPAL reactor, and purified. The Mo-99 is then packaged and despatched for use in hospitals and clinics. To ensure the quality of the product meets the required standard, samples are taken from the bulk product and tested.

The event occurred when a wheel of the trolley used to transport quality control samples between laboratories unscrewed and detached from the trolley. This resulted in the trolley tilting, causing the lead pot containing a closed vial with the Mo-99 quality control sample to fall from the trolley and spill the vial contents on the floor. The analyst quickly recovered the pot and placed it back on the trolley. Minor contamination was detected on the worker's personal protective equipment, although the worker's skin was not contaminated and no abnormal external or internal dose was received.

The inspection was not an investigation of the event. The inspection was planned to obtain accurate information on the circumstances under which the event occurred with consideration of human, organisational and environmental contributions.

On 9 June, ARPANSA issued an approval to ANSTO to recommence Mo-99 production, based on a set of corrective actions being implemented following the event.

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Observations

At the time of the inspection, ANSTO had carried out an event investigation. The corrective actions identified for immediate rectification had been implemented, and others were in the process of being implemented to reduce the risk of a recurrence.

The personnel interviewed were considered by the ARPANSA inspectors to be engaged in the process to identify and make safety improvements to work practices. ANSTO management was supportive and actively facilitating these improvements.

An improvement was observed in applied protocols during the event. In addition to the standard safety protocols for a spill, ANSTO notified both ARPANSA and Comcare of the event prior to the scene being released for decontamination and recovery. ARPANSA visited the preserved scene and made their own observations before the area was cleaned.

Procedures and Instructions

ANSTO Health uses a business management system that covers document change control. The relevant quality control procedures were updated as a result of corrective actions from a previous event which occurred on August 2017. These quality control procedures identified for improvement are already recorded in the ARPANSA augmented inspection report dated 12 December 2017.

ANSTO issued a first set of updated *Good Laboratory Practice* procedures in April 2018. The improvement in procedures and instructions development was noted by the ARPANSA inspectors. The quality of these documents is considered to have improved, particularly by considering human factors in the processes and inclusion of clear information on risks related to individual tasks. However, considering the significance of the August 2017 event, the ARPANSA inspectors formed the view that the process of improving procedures and instructions have not taken place in a timely manner.

The laboratory processes that manage handling of radioactive samples within the laboratories are described in detail in the relevant procedures and instructions. These protocols are often sequence sensitive, which requires step-by-step work instructions. In addition to these processes, there are transfers of the samples, and sample storage and disposal that are also addressed in the procedures. All these protocols should form an effective system to manage safety and security of the radioactive samples throughout their entire pathway through the facility.

However, the safety aspects for sample transfers were considered by the ARPANSA inspectors to contain insufficient details compared to the laboratory processes. For example, the procedure *Good Laboratory Practice: Radioactive Sample Handling* generally describes the need to transfer samples between laboratories on a trolley but specific requirements or guidance were not included e.g. the required type of trolley to be used, any checks of the trolley condition, the possible layout of equipment on the trolley etc.

In addition, preliminary *QC Operational Safety Checklist F-7312* included a section on QC sample transfer but this did not include any requirements for the type of transfer equipment needed. At the time of the inspection this document was noted to be still in draft.

In this regard, safety of the transfer of the radioactive quality control samples within the building is not considered to have been captured effectively in the document control system and therefore the safety aspects are not managed effectively.

Training

Training of operators involved with the Quality Control (QC) processes is completed in sessions with the trainee staff member being taught by a suitably qualified and experienced operator. The number of sessions required to achieve competency is not fixed. The training progresses in stages of handling/involvement from the operators starting with full supervision and working towards trainees' independency. While competency is determined by the supervising experienced operator, the verification of training effectiveness is not always carried out.

Following on from the August 2017 accident, some of the lessons learnt had been observed to be implemented in the updated *Good Laboratory Practices* (GLP) documentation which had been issued in April 2018. Although this documentation had been readily available on the Business Management System (BMS), staff had not been formally trained until the week following the June 2018 event. From the training records supplied, it was noted that a key GLP document, Radioactive Sample Handling, was absent from the list of GLP documents that staff were trained in. Therefore, the staff remained untrained in the updated GLP practice for more than a month.

Specific refresher Radiation Safety training had also been provided to area staff on seven different occasions between March and May 2018. Some scenarios were covered during this training, including response to spills. The analyst involved in the June contamination event had been able to demonstrate an understanding of the appropriate response to an event but had not participated in this refresher training. Therefore, the training is considered to be inconsistent in this regard. The lack of training combined with human factors is deemed to be a contributing factor to the analyst's decision to retrieve the vial and lead pot following the spill.

The analysts are trained to use the work instructions and not to deviate from them. The supervisors and managers enforce adherence to the instructions and procedures. Regarding the quality of the product, any deviation from the procedures would be evident from the test results and easily recognisable by the supervisors. However, there is no formal procedure adherence program that would provide management an indication of the level of compliance with the protocols, including the sample transfer.

In order for ANSTO to continue the production of Mo-99, certain conditions were stipulated by ARPANSA. One of these was that staff had been trained and inducted in the relevant temporary procedure issued immediately after the June spill. This procedure included an independent check of the vial bung and that the lead pot was correctly latched. This training was verified to be carried out starting Sunday June 10th.

Equipment

In the investigation report provided to ARPANSA, ANSTO identified that the trolley used for the transport of the QC sample was not fit for purpose. It was originally purchased as a mobile workbench but was not intended to transport samples between rooms. However, over time it had become the dedicated trolley involved in the process.

Prior to this incident, trolleys had not been considered to require maintenance. There were no specific design requirements, ownership of the equipment was unclear and no pre-operational checks were conducted by the users. Immediately following the investigation, actions were put in place to periodically inspect the equipment, create a maintenance plan, and determine if the equipment currently used is fit for purpose. The trolleys unfit for use were quarantined and tagged as such. In addition, the trolleys were designated to their specific tasks, a temporary procedure has been put in place and a transport equipment checklist has been introduced. This is intended to be incorporated in the standard operating procedures.

Following the August 2017 event, where the previous design had an easily removable lid, the current pot has a latch mechanism which allows the operator to lock the lid to the pot base. This was considered to improve the pot shielding integrity. However, the drop tests of the shielded pots that were carried out in June showed that the lid could separate from the pot base on impact when dropped. This would likely result in the contents of the vial being spilled.

The provisions for defence in depth were found to be degraded for the Mo-99 quality control sample transfer between laboratories. The failed trolley and the shielded pot are considered the components of degraded defence in depth.

Event reporting

A good reporting culture and consistent appropriate event investigation with timely action implementation are considered by ARPANSA to be among the signs of a learning organisation as reflected in the PO&C. The ANSTO investigation report identified that events involving a failure of a trolley wheel had occurred previously. However, no such events have been reported into the ANSTO-wide action management and tracking system and personnel interviewed during the inspection did not recall any knowledge of such events. This inconsistency emphasised a need for the reporting and investigation of near misses. This was also previously identified in the ARPANSA augmented inspection report in November 2017.

Human performance and safety culture

ANSTO Health showed improvements in some human performance related attributes. For example, the operational environment of the laboratories has improved since August 2017, e.g. the refinement of processes and information available to analysts in laboratories. Some improvements in training and tools minimising human errors were also observed. For example, the shielded pot design has improved, even though the event showed its weak points.

However, consideration of human factors has not been applied systematically to all processes. The transfer process design did not fully appreciate human abilities and limitations. . The importance of the trolley design for the transfer of Mo-99 quality control samples was considered by ARPANSA inspectors to have been underestimated.

The inspection findings, particularly when considered in the light of other recent events, may indicate deterioration in some safety culture attributes. It was discussed in Procedures and Instructions above that some safety aspects were not integrated into all parts of the process. In addition, the trolley that failed which was deemed to be unfit for purpose had been used in the process for a long time without any personnel or management questioning the suitability of the trolley design. Considering that personnel are well aware of the risks associated with the task, this lack of questioning attitude may be a sign of risk normalisation and complacency in the work place.

Findings:

The inspection revealed the following **potential non-compliance** with:

1. Regulation 49 of the Regulations – the licence holder must take all reasonably practicable steps to manage the safety on the facility. The safety of the process involving quality control sample transfer using the trolley was not managed effectively.

The inspection revealed the following **areas for improvement**:

1. Implementation of safety related improvements in a timely manner.
2. Timely provision of training and training effectiveness verification.
3. Integration of safety into procedures and instructions needs to be considered for all parts of a process.
4. All parts of a process should be adequately covered in procedures.
5. Systematic application of human factors into process, and equipment design.
6. Safety culture attributes.

It is expected that improvement actions will be taken in a timely manner.

In response to any potential non-compliance, the licence holder must carry out its responsibilities under regulation 45

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