Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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Inspection report

Licence holder: ANSTO	**Licence number:** F0309
Location inspected: ANSTO, Lucas Heights	**Date/s of inspection:** 8 July 2019
	Report no: R19/09347

An inspection was conducted as part of ARPANSA's inspection program to assess compliance with the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act), the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations), and conditions of facility licence F0309.

The scope of the inspection included an assessment of ANSTO Nuclear Medicine's (ANM) performance in the following areas: radiation protection and configuration management. The inspection consisted of a review of records, interviews, and observation of the packaging and dispatch operations.

Background

The ANM facility is used for large scale production of Molybdenum-99 (Mo-99). Mo-99 is the precursor of Technetium-99m (Tc-99m) which used in 80% of all nuclear medicine procedures. The production process involves various steps including dissolution, purification, evaporation, dispensing and packaging of the product (Mo-99 solution). On 21 June 2019, three staff members were exposed to extremity doses while handling an inner container, namely a Depleted Uranium (DU) container, of a Type B(U) transport package containing the Mo-99 product. The inner container was transferred from the packaging hot cell to a helium leak station prior to dispatching to Building 23 for manufacturing Technetium generators. Contamination was detected on the inner container at the helium leak station during a routine check for contamination, which is performed for all packages. The extremity dose to two operators exceeded the annual statutory limit of 500 mSv. Following the incident ANSTO undertook corrective measures to prevent recurrence of contamination incidents while transferring material from the hot through the cell face area. At the time of inspection ANSTO had completed a preliminary investigation into the incident, but had not completed the investigation. ANSTO had prepared a revised risk assessment and procedures based on the incident, and was permitted to return to restricted operation with specific controls in place. ARPANSA undertook this inspection to follow up the implementation of the corrective measures including use of revised procedures for packaging and dispatch.

Observations

In general the management of safety at the ANM facility was satisfactory. In some cases, however, there appeared to be room for improvement with respect to radiation protection and configuration management.

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Radiation protection

ANM follows its Radiation Protection Plan based on site-wide radiation protection management plans, procedures and guidelines. The ANM Radiation Protection Plan describes the radiological hazards and controls at the ANM facility. This includes controls for exposure to radiation and potential contamination during transport and receipt of irradiated target plates from the OPAL reactor, and radiation and contamination hazards during routine maintenance tasks. ANM staff were trained on relevant radiation protection procedures.

Considering the contamination incident the inspection focussed on the procedures for radiation protection and contamination aspects in transferring the Mo-99 solution and the quality control (QC) sample from the packaging hot cell to the dispatch area. Such procedures included *Beatrice Containers: Loading and Loading, I-50223 (Rev. 6)* and *Dispensing of Sodium Molybdate (Mo-99] (fission) Solution, M-10914 (Rev. 7)*. The ARPANSA inspectors noted that some steps in the procedure were not consistent with the steps specified in the batch record (M-10914). This may have contributed to minor deviations from the procedure. For example, during the clearance process of the inner container, several contamination checks are required including a 'smear test' specified in the procedure and in the batch record. The inspectors observed the smear test step using a dedicated contamination detector located at the helium leak station before sending the product to the dispatch area was not performed, instead the only check was by the health physics surveyor using a direct measurement of the smear using a probe before releasing the sample from the controlled (blue) area. Both checks were identified as 'critical controls' in the updated risk assessment. The inspectors also observed that the health physics surveyor did not always perform the contamination check of operators' gloves before disposing into the waste bin.

In general, the inspectors found the health physics services provided by the Radiation Protection Services health physics were adequate. However, the inspectors consider that the radiation protection procedure particularly those related to contamination clearance should be clearly developed and consistently applied. This is particularly important where the risk assessment, and procedure, specifies multiple types of checks.

Configuration management

ANM follows documented procedures for processing Mo-99 at the ANM facility. This includes manufacturing batch records. During the inspection the inspectors observed the procedures and practices followed by the ANM operators for transferring the product from the packaging hot cell to the dispatch area. Following the incident on 21 June 2019, ANSTO introduced the presence of 'safety observers' during the production process to ensure that the operators properly follow the documented procedures. The inspectors observed that the operators appropriately followed the procedures including signing off the batch record by capturing relevant safety parameters specified in the procedures/batch records for the production process.

Though the procedure, I-50223, refers to the batch record for dispensing and packaging tasks it was observed that the steps described in this procedure were not properly harmonised with the batch record (M-10914) which may result in lack of clarity to the operators about the safety significance of each step. For example the order of operation, which procedure contained the detail, and the specific instructions, were not consistent across the documents.

The procedure, I-50223, cites the surface contamination activity (e.g. ≥4 Bq/cm^2 for beta-, gamma-contamination), which is adopted from the Code for Safe Transport of Radioactive Material 2019. This level may not be directly translated into the radiological risk to the operators since the operators measure the contamination in 'cps' (counts per second) rather than 'Bq' (Becquerel) without an apparent conversion.

In general, the ANM operating procedures reflect the configuration of the plant and material, and safety parameters are clearly described in the procedures. However, the inspectors consider that all procedures and the batch record should be properly harmonised to avoid confusion, and that the steps involved in these documents should be self-explanatory in terms of safety significance.

Findings

The licence holder was found to be in compliance with the requirements of the Act, the Regulations, and licence conditions.

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

1. Radiation protection processes, including contamination clearance, should follow clearly written procedures and guidance.
2. Relevant procedures (e.g. I-50223) should be properly harmonised to avoid any confusion in the steps involved in the procedure and to enhance the contamination control.
3. Safety significance and critical controls should be clear in the procedure to ensure that risk is understood by persons following the procedure.

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

No written response to this report is required

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