Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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Inspection report

Licence holder: Australian Nuclear Science and Technology Organisation (ANSTO)	**Licence number:** F0309
Location inspected: Lucas Heights, NSW	**Date/s of inspection:** 19-20 August 2019
	Report no: R19/11731

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 involving interface of activities between ANM and ANSTO Health. The inspection consisted of a review of records, interviews, and observation of some aspects 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 is 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 higher than normal 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. Used empty packages, molybdenum product bottles (MPB) and inner product containers (IPC) are cleaned at ANSTO's Health Products facility and sent to the ANM facility for use. ARPANSA undertook this inspection to examine the contamination control measures in place for receipt and dispatch operations.

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.

619 Lower Plenty Road, Yallambie VIC 3085
+61 3 9433 2211
PO Box 655, Miranda NSW 1490
+61 2 9541 8333
info@arpansa.gov.au
arpansa.gov.au

Radiation protection

The interface activities between ANM and ANSTO Health are governed by a number of procedures to ensure that appropriate radiation protection procedures and practices are followed. The following key procedures are followed for interface activities related to receipt and dispatch activities for contamination control measures.

ANSTO Health Procedures

- Packaging and Despatch of ANSTO Health Products from Building 23A, R_032-01-00_I, Rev. 19, July 2019
- Packaging and Despatch Return of Imported B(U) Containers, R_032-10-00_I, Rev 3, November 2012
- Isotope Handling Bay Transport Containers: Loading and Unloading, R_043-03-00_I, December 2018

ANM Procedures

- Packaging and Dispatch and Return of B(U) Containers, I50234, Rev.2, August 2019
- Beatrice Containers: Loading and Unloading, I-50223, Rev. 6, September 2019
- Glassware Washer: Operating Instructions, I50107, Rev.4, May 2019
- Beatrice Transport Containers: Inspection and Maintenance Worksheet, F-50229, Rev.3, June 2019
- Glassware Washer: IPC and MPB Cleaning Log, F-50336, Rev.4, May 2019

Currently all returned empty packages are cleaned and washed at ANSTO's Health Products Facility following appropriate procedures and sent to the ANM facility. The cleaning procedures for packaging items are identical at both facilities. During the inspection examples of completed IPC and MPB logs were sighted and found up to date.

The dispatch of cleaned empty packages from ANSTO Health to the ANM facility are subject to health physics clearance and dispatch of an empty Type B(U) package from ANSTO Health to the ANM facility was witnessed during the inspection. Inspectors also observed that the dispatch operation was accompanied by appropriate documentation including contamination clearance certificates.

Contamination clearance steps at the Health Products facility for operators are clearly described in the packaging and despatch procedure (R_032-01-00_I) but have not been reproduced in the ANM procedure (I-50234). The inspectors consider that contamination clearance steps should be consistent across ANSTO facilities where similar tasks are undertaken. This has been identified as an area for improvement. Apart from this, the contamination clearance procedures were considered adequate.

Configuration management

Though ANM has a designated cleaning and washing area for receiving contaminated empty packages, it is yet to be operational as the equipment has not been installed. This cleaning and washing space is located in the empty packages receipt area and is currently classified, in accordance with ANSTO's AG-2509 (Classification of Radiation and Contamination Areas), as a radiological 'blue' (i.e. above background radiation levels) area. Currently all cleaned packages from the Health Products Facility are transferred through here.

Since no contaminated items can be cleaned in this area, it is essentially being treated as radiologically 'white' (i.e. nothing above a background radiation level) contamination area. However, the current radiological area classification ('blue') has remained in place in terms of both radiation and contamination and thus the practices to be employed in such an area must still be enforced (i.e. PPE). Staff were found to not completely adhere to the necessary controls required for the current area classification as highlighted on the area's safety hazard notice board. To avoid confusion, inspectors highlighted that a potential change to the area classification, in accordance with AG-2509, could be put in place to avoid this scenario. This is considered to be an area for improvement.

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. Harmonisation of contamination clearance procedure for operators
2. Adherence to requirements of safety hazard notice board and consideration of provisions of AG-2509

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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