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:** 28 August - 6 September 2019
	Report no: R19/09834

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. This was an augmented inspection following an accident at the ANSTO Nuclear Medicine (ANM) facility in June 2019.

The scope of the inspection included an assessment of the ANM's performance in the training relating to the Molybdenum Production Process. The inspection consisted of interviews and examination of training records.

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 an accident occurred during which the hands of three staff members were exposed to radiation 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 the helium leak station. Surface contamination was detected at the helium leak station during a routine check performed for all packages. In attempting to decontaminate the DU container the extremity dose to two operators exceeded the annual statutory limit of 500 mSv. Following the accident ANSTO undertook corrective measures to prevent recurrence of contamination incidents while transferring material from the hot cell through the cell face area. These corrective measures included some operator training and revision of a number of instructions used for training purposes.

ARPANSA undertook this augmented inspection to ascertain the current status of training for the Mo-99 production process. The inspection was planned and implemented using ARPANSA's inspection Performance Objectives and Criteria (PO&C) for training. Broadly, these look to establish if there is a systematic approach to training, i.e. that training programs are the result of analysis of training needs, design and development, effective implementation and evaluation of outcomes. Training should ensure that all workers are suitably qualified and experienced so that the controlled activity is undertaken safely and securely. Leadership should be actively engaged in ensuring that training supports high standards of human performance.

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Observations

ANM training is documented in the ANM Training Procedure (P-50009). This procedure outlines the arrangements and responsibilities for training. These responsibilities are clearly defined from the operator, through line management up to the level of the operations manager. ANM training is supported part time by a Learning and Development Advisor. ANSTO is in the process of recruiting a Training Officer. P-50009 Training Procedure describes the elements of the training system at ANM which includes induction, work-specific area, on-going, refresher/remedial, job-change and competency-based training. Supervisors are responsible for reviewing the training compliance of workers and take relevant actions to ensure compliance is maintained.

ANM workers are assigned an individual training plan, comprising curriculums based on their job responsibilities. All workers have the responsibility to ensure that their training is kept up to date. Operators can view the status of their training and curriculums via the Learning Management System (LMS). Inspectors noted that IAEA GSR Pt 2 Para 4.23 states: "*Senior management shall ensure that competence requirements for individuals at all levels are specified and shall ensure that training is conducted, or other actions are taken, to achieve and to sustain the required levels of competence…….*"

P-50009 Training Procedure has no requirement for training above the level of operations manager and there is no other training specified for upper management in the facility plans and arrangements. Since senior executives are responsible for sign off on operational safety documentation and provision of resources important for safety this is identified as an area for improvement (AFI 1).

Senior management has the responsibility to provide resources for safety including to identify and provide the safety training required by their workers that ensures safe conduct associated with particular tasks, roles or areas. Training requirements are specified for the operational and middle management levels in the form of a work procedure (P-50009) but there is no high-level strategic document that articulates ANSTO's strategic approach to training ANM staff or its alignment to organisational objectives for nuclear safety and radiation protection. This is an area for improvement (AFI 2).

Radiation Protection Services provides radiation safety training. The High Reliability Team is responsible for providing ANM facility- specific hazard training. Training responsibilities and shared responsibilities are not clearly defined for the High Reliability Team and Radiation Protection Services. This is an area for improvement (AFI 3).

ANM is discussing ways to improve the ANM system with the OPAL Reactor Operations Group. ANM is currently working on a training matrix for operational staff.

ANSTO Nuclear Services' workers play an important safety role as experts on radiation protection practices. Health Physicists (HP) and Health Physics Surveyors (HPS) are recruited with the necessary knowledge, skills and experience or are trained and authorised within ANSTO. ANSTO Nuclear Services Division provides radiation safety training and radiation protection workshops to ANM workers under a service level agreement (refer to Q-50083 Radiation Protection Plan). Any workers required to do specialised tasks are provided with task-specific training prior to their assignment to the job. ANSTO Nuclear Services Division provides radiation training and conducts refresher training to support staff competency when working in radiological areas. However despite having expertise in radiation protection practices, Radiation Protection Services do not sign off on work instructions and training material which have important radiation protection controls. This is an area for improvement (AFI 4).

Work instructions and batch records are used by production workers to make a quality product, safely. These instructions and batch records are used as primary training material for on-the-job training. ANSTO explained that training is provided on both the instruction and batch record but that only the batch record is used during production. Each contain instructions, some of which do not provide

completely precise instructions or aligned messaging. For example the instruction (I-50223) provides the instruction to reduce surface contamination on the DU container to less than 4 Bq/cm^2 whereas the same step in the batch record states that if contamination is found, to halt the process and seek advice (although no guidance in the instruction is provided to those giving the advice). This is the step that led to the June 2019 accident. In terms of task performance, the simultaneous use of batch records and instructions is problematic, especially when differences between the two exist. It may lead to an increased rate of mistakes, lapses and slips (errors with unintended consequences). In a first instance ANSTO needs to identify and address inconsistencies between these documents. In terms of manufacturing safety the use of separate batch records and work instructions may be best avoided. This is an area for improvement (AFI 5(a)).

Instructions and batch records contain steps which require the operator to understand and mitigate risks. Batch records were found to have been amended since the June 2019 accident and now contain improved warnings for operators. However, there is an absence of information relating to the degree of harm that may be caused by hazardous steps in the batch records. There are scarce warnings in the work instructions. Hence from a training perspective this aspect of the instructions and batch records could be improved. Radiation protection training for operators was also provided after the accident but this was found to be not fully effective in providing the skills needed for operators to quantify the hazards they may encounter or the grading of response actions. For example, action levels are not always specified and there is mismatch of units between instructions and available instrumentation (e.g. Bq in the instructions and measurement units of CPS on instrumentation). Therefore, although the risk awareness of workers was not directly tested during the inspection, it was concluded that the combination of instructions, batch records and training could be further improved to enhance risk awareness. This is an area for improvement (AFI 5(b)).

Expected behaviours of operators are not reinforced through training material. For example, neither the required response to radiation alarms nor the requirement to follow the Stop, Think, Act, Review (STAR) principle, both of which were issues in the June 2019 accident, are provided in the training material. ANSTO stated that some training material was being developed on the response to alarms and safety drills and that there was regular work place observations by supervisors and management. The reinforcement of expected behaviours during training is an area for improvement (AFI 6).

Inspectors viewed a number of records in the LMS. The training records are maintained in a database management system and this facilitates record retrieval and usage. Some operator training is overdue particularly in regard to self-paced learning that is frequently used to update workers of procedural changes. Workers are nominally given two weeks to complete this training but records indicated some had not been completed for more than four months. It is not clear if overdue training curricula are important to safety. Management visibility of safety importance of particular training needs and of worker training status through the LMS is problematic and requires significant effort to find important information. The timely completion of learning activities and visibility of status details to enable managers to ensure its completion is an area for improvement (AFI 7).

Workers undertaking high reliability and specific hazard training complete an evaluation form at completion (AT-5835). However, generally ANM does not have a systematic structured training evaluation scheme that feeds back to the training needs evaluation. This is an area for improvement (AFI 8).

Operators have been accredited in recent months which is consistent with ANM routine operations commencing in May 2019. P-50009 Training Procedure sets out the requirements for training including how operators are initially accredited as an ANM operator. Most training is on-the-job and skills and knowledge are assessed by experienced operators that have completed the Cert IV in Training and Assessment. However, there is no operator reaccreditation process or effective system ensuring that learned knowledge will be maintained over time or updated where necessary, for example to reflect changes. This is an area for improvement (AFI 9).

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. The training plan and procedure has no requirement for training above the level of Operations Manager. This is unusual since Senior Executives have the responsible for sign off on operational safety documentation and provision resources important for safety.
2. There is no high-level strategic document that articulates ANSTO's strategic approach to training ANM staff of its alignment to organisational objectives for nuclear safety and radiation protection.
3. Training responsibilities and shared responsibilities are not clearly defined for the High Reliability Team and Radiation Protection Services.
4. Radiation Protection Services do not sign off on work instructions and training material which have important radiation protection controls.
5. Material used for training does not give sufficient awareness of risk and consequence:

   a) There is an absence in information relating to the degree of harm that may be caused by hazardous steps in instructions and batch records, both of which are key training resources. There are scarce warnings in work instructions and the correlation between instructions and batch records is sometime imprecise.

   b) Radiation protection operator training is not fully effective in providing the skills needed for operators to quantify the hazards they may encounter or the grading of response actions. For example action levels are not always specified and there is an unnecessary mismatch of units between instructions and available instrumentation (e.g. Bq in the instructions and measurement units of CPS on instrumentation).
6. Expected behaviours of operators are not reinforced through training material. For example neither the required response to radiation alarms nor the requirement to follow the STAR principle is provided in the training material.
7. LMS indicated that operator training for some operators is overdue. It is not clear if overdue training curricula are critical to safety. Management visibility of worker training status through the LMS is problematic and requires significant effort to find important information.
8. ANM does not have a systematic structured training evaluation scheme.
9. There is no operator reaccreditation process or effective system that ensuring that learned knowledge will be maintained over time or updated where necessary, for example to reflect changes.

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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