Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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Inspection report

Licence holder: ANSTO Health Products	**Licence number:** F0262
Location inspected: Lucas Heights Science and Technology Centre, Sydney	**Date/s of inspection:** 4-7 May 2020
	Report no: R20/04132

An inspection was conducted as part of ARPANSA's baseline 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 F0262.

The scope of the inspection included an assessment of Health Products' performance against the selected Performance Objectives and Criteria (PO&Cs) in the following areas: Baseline Module 4 – Training, Baseline Module 6 – Security, Baseline Module 6 – Radiation Protection, and Baseline Module 6 – Emergency Preparedness and Response. The inspection consisted of a review of records, interviews, and physical inspection of the facility.

Background

ANSTO Health Products is an authorised nuclear installation that produces radiopharmaceuticals for the Australian and international market. Various targets that have been irradiated in the OPAL reactor are processed in the facility. The targets are chemically dissolved and the solution is purified in hot cells to produce product for the nuclear medicine industry. The product is tested for quality before dispatching. ANSTO Health Products no longer produces Molybdenum-99 as this radioisotope is produced by the new ANSTO Mo-99 Production Facility in an adjacent building under a different ARPANSA licence (F0309).

The main codes and standards applicable to this facility are those that appear in section 59 of the Regulations plus Australian Standard AS 2243.4-2018 Safety in Laboratories Part 4: Ionising Radiation.

Observations

Health Products has developed an integrated management system that covers the licensed operations. The system includes procedures and instructions specific to the facility. The documents are informed by the overarching ANSTO site-wide protocols and policies.

The facility continuously improves work and management processes for reasons including improved process safety. A number of initiatives were observed. One of them is implementation of recommendations identified by the independent safety review team in October 2018. The actions have been progressing and some of them are in the validation phase.

The inspection identified several areas for improvement which are discussed below.

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Training

The Health Products training system broadly aligns to the requirements of a systematic approach to training but has some weaknesses. Some of the weaknesses have been identified during previous inspections and are yet to be addressed. Despite these outstanding issues, it is recognised that ANSTO continues to make improvements and that it is in the process of finalising the recruitment of a training manager and trainer to cover Health Products and ANSTO Nuclear Medicine (ANM) to support improvements in training. It was also apparent that Health Products is now working more closely with the OPAL Reactor Operations team to determine if any of its experience in developing training may be of use to Health Products.

The training needs are systematically developed and periodically reviewed for all positions including those with safety and security responsibilities. In addition to the ANSTO general training requirements, Health Products curricula include training specific to the facility. It was noted that training programs have been set for Senior Managers. This was not in practice at the time of previous inspections.

Facility specific training is mainly on-the-job training under supervision of the production supervisor. The trainee is progressively taught certain techniques while responsibilities are gradually increased. The training is complete when the supervisor is personally satisfied that the trainee has acquired the required level of skills. As the task specific training forms a vital part in achieving the trainee's qualifications and competencies, the supervisor who sometimes delivers the training also assesses the trainee's performance. In such cases, the authorisation of the personnel is carried out by the same person that conducts the training and therefore the element of independent verification is lost. An independent verification can aid acceptable human performance and reduce the risk of passing on unsuitable practices. This weakness is a possible contributing cause of an accident that occurred in August 2017 and has been previously identified (Inspection Report R17/13159) but that has not been fixed. Therefore, the systematic independent training evaluation remains an area for improvement.

Work procedures and instructions are a key training resource for on-the-job training and are important to instruct safe work methods and to provide awareness of hazards. ANSTO continues to implement different approaches for the contents of these documents across its various business units even where similar activities are undertaken. It was noted that despite some recent work on the structure and content of work instructions, not all used in Health Products contain effective information on risk and consequence awareness (warnings) and others contain detailed risk assessment data without a clear rationale for why that data is useful in a work instruction. These issues have also been identified previously for a number of ANSTO facilities (Inspection Reports R17/13159, R19/06933, R19/08620) but remain an area for improvement.

Health Products' training follows ANSTO AP-2363 Work Health and safety Training Procedure and more specific facility procedure R 007-00-00 P Training at ANSTO Health. The latter procedure provides among other things clear descriptions of the training framework, Health Products training programs and curricula, and requirements for record keeping. Whilst the procedure outlines certain responsibilities for different levels of staff, it does not clearly formalise their accountabilities. Explicit inclusion of accountabilities into procedures in addition to responsibilities improves clarity of the document and helps to build organisational culture. This is an area for improvement.

The Health Product training is managed using the ANSTO site-wide Learning Management System (LMS). The system works with the position curricula, training needs and schedules. It also generates training reminders to staff and notifications to managers. However, contractor training records are not available in the system. Training of the Health Product staff is organised by the training co-ordinator, while contractors' training is managed by the contractor supervisor. The contractor training-related information is available to the Health Products managers on demand but the LMS does not seem to be updated for this kind of information. Therefore, the managers may not become aware of contractor

training lapsing in a timely manner. For instance, the system was interrogated for records of the contractor training for radiation protection related to hazards associated with the project for installation of the air sampling and area monitor above a hot cell in building 23. Although the training records were ultimately provided by Radiation Protection Services, this record was not available to the Health Products managers through the LMS. The managers' reduced overview particularly of the contractor training presents an area for improvement.

LMS training records for operating staff were examined. The ANSTO side-wide radiation protection refresher training has been delivered to all staff in the required frequency of five years. In addition to this mandatory ANSTO wide training, the Health Products group is committed to additional facility specific radiation training. The records showed that this safety training was overdue for several operators by up to 400 days. Some security training was overdue since 2018. This in an example where the clarity of accountabilities provided in Health Products' procedures may benefit from review. It appeared that the general training status is presented and discussed in the regular management meetings. However, management was not aware of the status of the training at an individual level. This could be contributed to the LMS notification restrictions that were initially introduced to prevent the system from generating an excessive number of notifications. The limited manager overview of staff training status is considered an additional area for improvement. It is acknowledged that by the end of the inspection Health Products' management issued a schedule for the radiation safety refresher training course to be delivered soon.

Security

The inspection examined the effectiveness of Health Products' arrangements to prevent unauthorised access or damage to, loss, theft or unauthorised transfer or unauthorised use of radioactive material or the facility. The documentation provided and discussions held with inspection participants did not identify any significant problems with the protection of facilities, operations and radioactive material. The plans and arrangements are developed based on the ANSTO overarching security policy and plans and arrangements. Health Products' management have a good understanding of why protective security is required, what the system comprises and how it should be implemented and tested for system effectiveness (performance), among other things.

Health Products assessed their security risks in 2019. While the risk assessment adequately covers the security risks across the facility, there was an area identified in the risk register that requires some further consideration. Specifically, some measures attributed to Health Products are measures captured by the broader ANSTO environment and not necessarily Health Products business. It is recognised that ANSTO Security is currently reviewing the security risk assessments across all licensed facilities to align with the new ANSTO risk assessment methodology and to ensure that mitigating measures are attributed to facility risk assessments appropriately. It is also understood that Health Products' management contributed to the security risk assessment for the licence, however there would be value added to the risk assessment if there was a range of additional staff across all operational areas of Health Products involved in the assessment.

ANSTO has appropriate response mechanisms in place to counter or mitigate against identified threats, minimising the impacts from potential security events. The AFP and ASOC are the main conduit for communications of security events from the licence holder perspective where relevant response personnel can be deployed as necessary. There have been no security events reported since the last inspection in 2018.

Health Products has a range of protective security measures in place, including the Health Products' plans and arrangements document that articulates a range of security requirements. Overall, the document that has been revised recently marks improvement in the quality of the security management plan. The security management plan forms an integral part of the document and has been historically considered to be endorsed by ARPANSA issuing the licence to Health Products. This does not fully meet

the RPS 11 requirements for endorsement of the security management plan by an assessor accredited for this purpose. ANSTO Security has recognised this shortfall and is currently undertaking a complete review of all security plans across ANSTO licence holders to ensure their consistency and that they meet all of the requirements. Therefore, this is considered an area for improvement that should be addressed as soon as possible.

There is evidence that suggests both safety and security are considered across the business. However, this could be further improved, particularly in the areas of the management system and training for example, so this is also included as an area for improvement. Such inclusion of security within the Health Products Plans and Arrangements would see medium to long-term tangible benefits in security culture.

The maintenance management program (SAP) used across the ANSTO site comprehensively captures the maintenance requirements of the Health Products buildings' protective security systems. ANSTO Security manages maintenance of the Health Products security system. Although Health Products are informed about the security system maintenance related issues, there is no formal reporting mechanism for ANSTO Security to communicate to Health Products on the performance of the protective security system on a regular basis. As the ANSTO CEO delegates the management of Health Products to the respective executive, Health Products are accountable for security of the facility. Therefore, a periodic performance report from ANSTO Security (an internal service provider) could improve Health Products' understanding, overview and ownership of the system's performance.

The accountancy and records management systems are appropriate whereby the daily process (or as per operational requirement) used to verify the inventory is captured by the SAP system. While the area and building access control measures are adequate, there is no formalised commitment to undertake a periodic review of the authorised access. Although the list of authorised personnel was audited within the last 12 months, there is no requirement in the Health Products' arrangements to carry out the review periodically and as needed for new or departed staff. This is an area for improvement.

The personnel security controls in place are appropriate. All vetting is conducted internally via ANSTO Vetting Officers. Where deemed necessary, the Australian Government Security Vetting Agency is used for security clearances where a greater level of scrutiny is required given the access to national classified information or access to sensitive areas. Importantly, it is understood that ANSTO Security will shortly start a program of security clearance revalidation assessments of approximately 600 staff who hold a current ANSTO security clearance.

While a detailed review of ICT elements was not conducted during the inspection, the documentation reviewed indicates relevant controls are in place to mitigate against the theft of information whether that be hard copy information or other.

Due to the COVID-19 pandemic, a physical inspection of protective security measures in place was not completed. This component of the inspection will be undertaken when appropriate to do so however it is understood that ANSTO Security has conducted their own assessment of the appropriateness of the security system across relevant Health Products' buildings to meet RPS 11 requirements.

Radiation protection

The staff with safety functions are inducted and periodically trained for radiation safety. Dedicated Health Physics Surveyors (HPS) and Radiation Protection Advisors (RPA) provide the facility personnel specialised radiation protection service. The HPS and RPA interact directly with Health Products personnel.

One of the basic radiation protection principles of ARPANSA Radiation Protection Series RPS C-1 Code for Radiation Protection in Planned Exposure Situations is optimisation to provide the highest level of safety that can reasonably be achieved. ANSTO's Radiation Protection Services developed a new document

G-1372 ANSTO Effective Local Dose Constraints in 2018 that gives guidance on how to determine the appropriate dose constraint specific to an area, practice or task. Health Products are currently progressing the development of their own set of specific dose constraints.

The quality of procedures and instructions has recently been improved such as R 106-00-00-P 2.4 Tonne Flask, Transfers Between OPAL and Building 23 Junior Caves. However, not all procedures and instructions have been amended to integrate hazards involved, safety warnings and cautions. As indicated in the training section above, there are still some safety-related documents that have been recently revised with little improvements in safety information. For example, procedure R 230-00-00 P Iodine Bulks Manufacturing Instructions revised in January 2019 includes only a few safety cautions and warnings. It is acknowledged that Health Products initiated a gradual review of all processes during which they will revise all activities and respective work documents.

In addition to involvement in identification, assessment and review of radiation hazards in the facility, RPAs participate in assessing the radiation safety implications of changes. They actively contribute to the review of the processes but they are not systematically involved in advising on radiation safety in the final stage of changes to the relevant procedures and instructions (this was also a finding from a recent inspection of Mo-99 Production Plant). The documents are also used for training purposes and therefore it is imperative that they include all appropriate safety information needed for hazard and consequence awareness. As the document modification process could introduce unintended variations, formal RPA involvement in the final stages of the process is useful to ensure that appropriate radiation protection information is included. Therefore this is an area for improvement.

Records of a number of recent modifications were examined. A significant project document that identifies specific task-related hazards and measures to mitigate the risks is the Safe Work Method and Environmental Statement (SWMES). Any contractors usually develop their own SWMES for their work but these documents may not fully cover all risks and measures specific to Health Products operation. Therefore, ANSTO produces its own SWMES to ensure that all radiation risks are identified. All participating personnel sign the SWMES including the contractors to acknowledge the risks. While the majority of documents were found to be signed, the SWMES associated with the air sampling monitor installation above a hot cell did not carry the involved contractor's signature. Other related records showed that the contractor had been properly trained and aware of the risks at that time. Therefore, the missing signature does not have a direct safety implication but the record keeping practice could be more consistent.

Molybdenum-99 generators are assembled within the Health Products' facility. The process includes a multistage check to ensure, among other things, that there is no surface contamination and generators are ready for shipment. Under the recently improved process, personnel now use tools for the contamination check which has resulted in a significant drop in extremity dose. The last contamination verification is a smear test at the despatch area previously conducted by the HPS. The despatch personnel have been recently trained and tasked to carry out the smear test themselves. The test was claimed to be based on a random selection of approximately 10% of generators. However, the actual selection practice or the percentage of smeared generators was not formalised. In addition, there was no formal assessment and justification showing that the random verification of generators at despatch was sufficient. This is an area for improvement.

All events or deviations from expected outcomes should be logged into the electronic system Governance Risk Compliance (GRC). A selection of event records was examined. Recent events have been closed in a progressively shorter timeframe and in this regard, an improvement is recognised. Several relatively older events have also been examined. Although a few of them have been awaiting formal administrative closure, the investigations have been completed and lessons to learn have been identified and actioned.

ANSTO has been operated with a limited staff level during the COVID-19 pandemic period. Radiation safety personnel have adopted a modified roster to accommodate the restrictions. However, the temporary changes have not had effect on radiation safety.

Emergency preparedness & response

The inspection did not identify any significant problems with Health Products arrangements for emergency preparedness and response. The local procedures are informed by the ANSTO site-wide emergency plans. It is recognised that the recently revised local government emergency plan which has been reflected in the ANSTO overarching emergency management plans and sub-plans are now cascaded into the Health Products' emergency management plans. Both the site and facility documents follow the IAEA General Safety Requirements GSR Part 7.

All emergencies are immediately reported to ANSTO Site Operations Coordinator (ASOC) who triggers the response. The Emergency Response Team (ERT) is deployed to the facility to assist the Health Products' staff. The team is equipped with PPE including HAZMAT suits and other specialised equipment. Team members are trained and familiar with facility specifics.

To deal with emergencies the Health Products' personnel use the set of emergency procedures and instructions. Training records showed staff are periodically trained to follow the approved process. PPE is used in the facility and spill kits are strategically located throughout the facility.

Facility personnel exercise emergency procedures periodically. Although the last emergency exercise was organised in 2018, there was a number of events in 2019 that also tested the emergency arrangements. Lessons to learn arising from both exercises and events are logged into the GRC system and appropriate actions are initiated. Health Products has developed a plan for upcoming exercises in 2020.

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. Lack of consistent requirements for independent training evaluation to ensure high level of human performance
2. Accountabilities are not clear in relevant procedures and instructions
3. Procedures and instructions are inconsistent in regard to approach to hazard and consequence awareness (including information on risk, hazard and consequence)
4. Managers and relevant personnel do not have an effective overview of training status for all groups and individuals to ensure the training is done when required
5. The security plan is not endorsed according to RPS 11
6. Plans and arrangements do not integrate security more broadly
7. Requirements for periodic and on-demand reviews of authorised access to the facility are not formalised
8. RPAs are not involved in endorsement of safety significant work documents in their final stage of the change process
9. There is no formal assessment and justification for random verification of generators at despatch

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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