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:** 24–26 July 2019
	Report no: R19/08620

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 ANSTO Health Products' performance at Lucas Heights Science and Technology Centre against the selected Performance Objectives and Criteria (PO&Cs) in the following areas:

- Baseline Module 1 – Performance Reporting and Verification
- Baseline Module 2 – Configuration Control
- Baseline Module 3 – Inspection, Testing and Maintenance
- Baseline Module 5 – Event Protection.

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. The majority of work activities involve processing of various targets that have been irradiated in the OPAL reactor. 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 have ceased to produce molybdenum-99 now that this radioisotope is produced by the new ANSTO Mo-99 Production Facility (ANM) in an adjacent building (B88) under a different ARPANSA licence (F0309).

Health Products, under its previous trading name ANSTO Health, have been subject to enhanced regulatory oversight and enforcement actions following a worker contamination accident in August 2017 and a number of subsequent safety incidents. Whilst this inspection is not directly related to those enforcement actions, it does reflect on some of the learnings and actions that have been shown to be needed in order to improve safety of the operations, particularly in regard to worker safety.

The main codes and standards applicable to this facility are those that appear in section 59 of the Regulations. Additionally best practice is informed by:

- the International Atomic Energy Agency's (IAEA) GSR *Part 2 Leadership and Management for Safety*
- IAEA's GSR *Part 4 Safety Assessment for Facilities and Activities*

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- AS 2243.4-2018 *Safety in Laboratories Part 4: Ionising Radiation.*

Observations

ANSTO Health Products has developed a management system including procedures and instructions covering its operations. The documents are informed by, and lie under, the ANSTO site-wide safety management system. The inspection found that Health Products has a number of new initiatives designed to enhance safety management and safety performance. This included physical changes as well as some useful initiatives on communication such as morning production meetings, use of notice boards and increased interactivity of management in production areas.

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

Performance reporting and verification

The relevant safety performance of the facility has been appropriately reported to ARPANSA as stipulated by the facility licence. It has been observed that the management has generally increased their presence among the staff in the operational areas of the facility, particularly the Operations Manager. The nature of this presence was reviewed from both manager and front line worker perspectives and was found to be both inquisitorial and enabling. It was noted that this has had a positive impact among the front line workers and their supervisors as it gives the workers, among other things, an opportunity to raise any safety matters directly with the manager. When done well and applied in a graded manner by all levels of management, it is widely considered to be one of the prerequisites of strong safety culture.

The internal reporting system provides opportunities for continuous improvement. Health Products use the site-wide Governance, Risk and Compliance (GRC) system for registering, tracking events, logging identified causes, lessons learned, and rectification actions. It also enables generating reports for users on demand.

ANSTO Safety Incident Response procedure AP-2372 describes the requirements for reporting and investigation of safety incidents at ANSTO. This includes expectations for investigations of events with various levels of impact rating. A number of events reported in the GRC were found overdue for investigation. For example, GRC 3385 related to a blockage of a liquid waste pipe assessed with a potential major consequence which was logged into the system in September 2017. Although the event investigation claimed to be completed, the event was not closed in the system. This observation was noted during previous inspections.

Some events registered in the system did not include investigation details, causes or lessons learnt. For example, an event involving a minor Cr-51 intake with a potential moderate consequence that occurred in July 2018 was marked closed but the investigation was not completed, and causes and lessons learnt were not formally identified. According to AP-2372, the investigation for moderate impact rating should be completed within two weeks.

The event investigations are, at large, approved by the General Manager. If the General Manager rejects investigation findings and returns them to the investigator for further investigation, the GRC system does not show the event as overdue and automated event notifications are terminated. In effect the system stops tracking the event. This has been recognised to be a system imperfection by the GRC administrators but some managers were not aware of it. Nevertheless, these overdue events are captured in the relevant system report generated monthly for the ANSTO safety coaches. It was noted that a portion of overdue investigations were also found in this group of events. The prompt close-out of events is particularly important as visibility of the events, lessons learnt and actions taken are restricted during the reporting phase, which is likely to cause unnecessary delay in communicating safety information across the organisation and implementing necessary improvements.

These deficiencies in event investigation and following events through to closure represent opportunities for improvement.

The majority of events included details of the investigation. It was noted that investigations often did not identify the true root and contributing causes of incidents. This is not mandatory for minor or low significance events even though some useful learning could be identified from these. Other investigations could further ask 'why' something happened to get to the deep contributing causes of an event. This was also a finding of the October 2018 report from an independent review of safety at ANSTO Health that placed a high priority on finding the true root and contributing causes of incident investigations. The inspection also found that lessons learnt from the events were sometimes applied only locally instead of sharing the operational experience with other relevant ANSTO facilities. This may cause valuable learning opportunities to be missed. The improvement in the depth of investigations and the sharing of information between Health Products and other facilities (in both directions) is an aspect of organisational learning that should be improved.

The GRC system is considered to be a powerful tool for tracking and managing of events. Overall, the system is accessible by everyone on site. All causes and lessons learnt from events are made available to all users after the event is closed. This is important for learning across the organisation. However when there is an unnecessary delay in closing the event, as frequently observed, there is a delay in communication safety information that could be used to reduce risk elsewhere. ANSTO has recognised this shortfall and is currently working on enabling all users' access to opened events.

A number of events were found opened for an unnecessarily long period due to the person who owned the risk associated with the event no longer working for ANSTO. Although the GRC allows changing the respective responsibilities for events throughout the process, the system administrators have to be formally advised in that regard. It was indicated that in those instances the communication between the Health Products and GRC administrators was slow.

It was noted that Health Products are currently recruiting an additional three process specialists and a number of other staff. ANSTO advised that these resources will assist with closing the overdue events in a proper manner.

Configuration control

Safety margins are identified through the Health Products Safety Analysis Report and the systems most important for safety are the subject of Operational Limits and Conditions (OLCs). The OLCs have associated surveillance requirements that ensure that safety margins are not compromised. Each of these were checked and found to be in compliance.

In the course of the inspection a number of task instructions were seen. Some weaknesses were found in regard to the description of how tasks are undertaken and how the awareness of safety consequences are reinforced to front line workers. For example, GRC 6314 regards an internal contamination event in the Isotope Handling Bay. As a consequence of this event, a sixty minute delay has been introduced before a can cutting operation commences to allow off-gassing to take place. The current instruction does not raise awareness of why the delay is included or of the possible consequences if the delay is not applied. The usefulness of raising awareness of hazards to front-line workers in procedures and instructions was a lesson identified from an accident that occurred in August 2017 but which has not yet been applied to all operational areas. ANSTO explained that the standard of procedures and instructions is being improved. Some documents were now found to contain more details in safety warnings, cautions, safety instructions and visual aids that provide users important information.

However, the approach used to present this information in the documents varies between ANSTO facilities and there is no standard requirements or style at the overarching ANSTO organisation level. Currently it is largely left to individual business units to develop the style that they use. This point, which relates to the ARPANSA Performance Improvement cross-cutting PO&Cs, is an area for improvement.

Change control processes are important to understand the implications to safety of any changes and reduce the likelihood of a change unknowingly reducing an existing safety margin. The management of change at Health Products was reviewed during an inspection in November 2018. It was found that the Health Products' change control procedure was not applied consistently, particularly for quick changes. At the time of this inspection, Health Products has drafted an updated version of its change control procedure that was found to contain more clarity about the change process. A review of the draft change control process found that it may be strengthened by the inclusion of a post implementation review to ensure that changes, especially to work practices, are sustained in the long term. This procedure should be finalised and implemented as soon as possible.

One aspect of the new process is a smart form that workers will use to determine accurately and easily what they need to do to develop a change through to approval. This is an innovative approach to helping workers undertake change management processes. This aspect of the revised change control procedure is a good practice from which others at ANSTO or beyond may learn.

Walk-around visits of Buildings 23 and 54 were undertaken. No safety concerns were identified in either building. Each building appeared to be well maintained and there were no signs of ageing that raised concerns. Some upcoming modifications to equipment in Building 23 that will improve safety were discussed. Some of these address lessons learnt from events and investigations such as improvements to the ventilation system in the Isotope Handling Bay. Discussions with workers and management indicated that financial resources were available for safety improvements.

A certain amount of equipment clutter, including some heavy equipment, was found in Building 54. ANSTO is no longer licenced for production in this building but radioactive waste from the previous production process will be temporarily stored in it. The building is currently being maintained under the same safety arrangements as during operation. It is good practice in shut down nuclear facilities to progressively reduce clutter so that the building is moved towards a more 'passively safe' state. ARPANSA will continue to monitor the facility over future months and years.

Inspection, testing and maintenance

ANSTO Engineering Capital Projects (ECP) provide engineering and maintenance services for Health Products. The team consists of designated engineers and technicians permanently located in Building 23. In addition, there is an Asset Management Group that closely cooperates with ECP. The position of group leader that had been previously vacant for months has now been filled. Some engineering staff from other ANSTO groups have been seconded to support asset management, engineering and maintenance. This, together with additional staff recruitment, indicates that resources are being directed to improve safety and productivity at Health Products.

The schedule of maintenance for systems important to safety was examined. Details of the maintenance plans and work orders examined did not identify any deviation from safety requirements. The maintenance schedules were confirmed to be based on the valid OLCs.

Although some maintenance plans appeared to be overdue, the backlog was caused by inclusion of maintenance tasks within the plans that are not important to safety. Health Products are now in the process of reviewing the maintenance plans. One of the review objectives is to de-couple all non-safety important maintenance tasks from those important for safety.

The maintenance key performance indicators (KPIs) are parameters often used for reports generated by the computerised maintenance system. The set of KPIs included a number of lagging indicators e.g. 'percentile of maintenance completed up to date'. It was noted that the existing set of KPIs could be further improved with leading KPIs. It is considered to be good practice when a balanced set of lagging and leading indicators is implemented. For example, 'percentile of failed surveillance tests of systems/components important to safety' is known to be an effective leading KPI that is used elsewhere at ANSTO.

Selected recent breakdown maintenance tasks registered in the GRC system were examined. One task related to an autoclave water boiler that was found long overdue for inspection. Subsequent tests of the boiler valve failed. The causes were identified to be unspecified system ownership. The immediate actions included review of ownership of all other relevant systems under facility licence F0262. Health Products continues to progress the revision of maintenance strategies based on the event investigations and maintenance observations.

Management of temporary changes was explored through some events reported to the GRC system. One example was an event that resulted in personal contamination and intake of I-131 during an irradiated target transfer. Among other conclusions, the investigation identified that temporary controls had been introduced to address failures of components. There was no documentation available to verify that the temporary change had been appropriately assessed. The existing change control procedure describes the process for change control in general but there is no sufficient specific instruction how to manage a temporary change. Any temporary change should be undertaken in a similar process to permanent changes, including change categorisation, risk assessment and approval. Temporary changes should also be assessed for their long term effectiveness (useful life) and periodically reviewed to ensure that the effectiveness is being sustained pending a permanent alternative. These measures are important as the effectiveness of temporary changes tends to drop over time. As discussed previously, the improvement of the change control process in this regard constitutes an area for improvement.

Event protection

Buildings 54 and 23 were also inspected for effects of outside influences, internal fire prevention, and the fire system conditions and arrangements. In general, the buildings and their surroundings were free of clutter and unnecessary fire loads, and effective pest control was in place managed by the ANSTO ECP through the computerised maintenance management system. Building wardens are required to undertake an annual pre-season bushfire check which will be due a few weeks after the inspection. A few trees encroaching the roof outside the north-west and south-east corners were noted. ANSTO undertook to have these pruned.

Findings

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

1. The event investigation process does not always follow ANSTO AP-2372 Safety Incident Response procedure. The causes of events, including deep contributing causes, should be identified and event investigations completed in a timely manner.
2. Relevant lessons learnt have not always been, but should be, shared with other ANSTO facilities.
3. The newly revised change control procedure should be implemented as soon as possible. The amendments to the procedure should include a process for managing temporary changes.
4. ANSTO has no organisational standard for structuring and writing procedure content. This should be developed and promulgated through the organisation to ensure the consistent preparation of high-quality, best-practice procedures.

The inspection revealed the following **good practice**:

1. A change management smart form that assists workers to understand their obligations has been developed. It is considered to be an innovative approach from which ANSTO as a whole, as well as other ARPANSA licence holders, may benefit.

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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