



# Inspection report

<b>Licence holder:</b> ANSTO Health	<b>Licence number:</b> F0262
<b>Location inspected:</b> Lucas Heights Science and Technology Centre, Sydney	<b>Date/s of inspection:</b> 24-26, 31 July 2018
	<b>Report no:</b> R18/09619

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 Australian Radiation Protection and Nuclear Safety Regulations 1999, and conditions of the Facility Licence F0262.

The scope of the inspection included an assessment of ANSTO Health's performance against the selected Performance Objectives and Criteria (PO&Cs) in the following areas: Performance Reporting and Verification, Configuration Management, Inspection Testing and Maintenance and Event Protection. The inspection consisted of a review of records, interviews, and physical inspection of the facility.

## Background

ANSTO Health is a nuclear installation that produces radiopharmaceuticals for hospitals and clinics. The majority of products involve processing of various targets irradiated in the OPAL reactor. The targets are chemically dissolved, the solution is then purified and the product is tested for quality before despatching.

The main codes, standards and guides applicable to this facility under the scope of the inspection are: the International Atomic Energy Agency's (IAEA) *GSR Part 2 Leadership and Management for Safety*, *GSR Part 4 Safety Assessment for Facilities and Activities* and AS 2243.4-1998 *Safety in Laboratories Part 4: Ionising Radiation*.

## Observations

In general, ANSTO Health follows the site-wide system to manage safety. The individual facilities developed specific procedures and instructions for activities at each location. Safety margins of the processes and facilities were found to be maintained within the constraints of the safety cases. The inspection identified a potential non-compliance related to Operational Limits and Conditions (OLCs) surveillance requirements with neither posing actual safety consequences nor reduction of defence in depth. Some areas for improvement were also identified.

## Performance reporting and verification

ANSTO Health event investigation follows the ANSTO site-wide protocol. Events and other issues identified are entered into the Governance Risk and Compliance (GRC) system that tracks the entries and

keeps records, e.g. investigation progress, lessons learnt and actions raised. Triage officers assess the events for general safety, radiation safety and determine the actual and potential impact of an event. They use the ANSTO risk matrix to determine the actual and potential severity of the event, on which the required level of investigation depends. A more significant consequence will require a more thorough and structured investigation. If the severity level is assessed to be moderate or higher the investigation involves the Ishikawa methodology covering multiple areas of contributing factors such as equipment and maintenance, processes and procedures, people and human factors, environment, leadership among other including the 5 Why's methodology.

Improvement in reporting, recording and analysing of information from near misses was observed recently. The analyses that include this information are discussed monthly at the management meetings, quarterly management review meetings and during all staff meetings. The interviewed personnel positively reflected on this improvement.

A number of events were examined during the ARPANSA inspection. They were all tracked in the GRC system, lessons learnt were recorded and actions arising from them had been logged. The low safety significant events were found to be investigated locally by respective supervisors as required by the ANSTO protocol.

The events assessed to have a greater impact were found to follow the Ishikawa and 5-Why's methodologies. Some events with moderate and higher consequences were found to be investigated into a reasonable depth whereas other investigations lacked the analysis warranted by the actual or potential safety implications. For example, a near miss event that involved processing a quality control sample with approximately nine times higher radioactive concentration than required by procedures was triaged to have a 'severe potential impact'. The Ishikawa method used for the investigation covered all required areas of contributing factors. However, the depth of analysis of some contributors was found to be inadequate. Human factors were clearly involved in the event but the records did not show an investigation level that would be warranted by the potential impact. This is considered a missed opportunity to learn valuable lessons from the event and therefore an area for improvement.

### **Configuration management and maintenance**

The examination of configuration management of ANSTO Health included verification that the facility complies with requirements of the OLCs. The OLCs outline the safe operation envelope demonstrated in the Safety Analysis Report. Part of the OLCs are surveillance requirements that comprise actions that verify certain parameters and conditions of the facility and which must be completed with the required frequencies. Condition 4 of licence F0262 states that:

*"The licence holder must ensure that the facility complies with the Operational Limits and Conditions approved by the CEO of ARPANSA."*

The surveillance tasks are entered in the ANSTO site-wide Computerised Maintenance Management System SAP. Based on the master data, the system will automatically generate work orders to carry out the required works which includes the OLC related tasks. General maintenance schedules for buildings 23 and 54 were examined. Samples of two individual OLCs for each building were examined in detail. The majority of the OLC surveillance activities were found completed on time. However, one surveillance task of an OLC for building 54 was found to be missed in July 2017. Therefore, on that occasion, the respective surveillance requirement was not conducted in accordance with the mandatory annual frequency. This constitutes a potential non-compliance with licence condition 4.

In July 2017, ANSTO was in the process of transitioning from the older SAP system to a new version of the program. The transition required that certain data to be entered into the new SAP version manually. During the process, all maintenance tasks including the OLC surveillances were correctly transferred from

the old to the new program version. However, the task notification for the OLC for building 54 examined above was inadvertently closed in the program before the corresponding work order was issued.

The affected OLC surveillance consists of three individual tasks each covered by a separate work order. In 2017, two of those three surveillances and respective work orders (the calibration of pressure transducers and function alarm test) were successfully completed. The third task, which involved an inspection and service of a mist separator, was not conducted at that time.

The subsequent inspection of the mist separator was scheduled by SAP for July 2018 and was completed in time. This maintenance inspection did not identify any performance degradation of the component.

It is noted that ANSTO Health immediately committed to verifying that the other OLC surveillance requirements for both buildings 23 and 54 were not affected by a similar error.

Much of the surveillance works are conducted by the production staff within buildings 23 and 54. These require completion before each run or batch has begun and is documented in either a batch record or through pre-start checks. The rest of the OLC surveillance works are carried out by ANSTO Facilities Management.

The Facility Maintenance Group conducts some of the maintenance work for ANSTO Health according to the Service Level Agreement. All surveillance requirements not covered by the operational arrangements are managed by Facility Management via the SAP system. SAP generates respective work notifications and work orders for those staff responsible and who have the required knowledge and skills to complete the work.

The licence holder's Operations Management have good oversight of the surveillances managed through the operational arrangements. They also effectively manage all the maintenance work in their facilities through which the rest of the surveillance requirements are completed. However, it was observed that the management, both in building 23 and 54, did not have clear oversight of the OLC surveillance schedule, particularly for the tasks carried out by the Facility Management. As such it was not straightforward for them to identify the status of the OLC surveillance related tasks when they are due or overdue. This represents an opportunity for improvement.

It was noted that the Facility Management immediately set up a page of OLC related maintenance plans in the SAP system that now gives the Operations Managers and Supervisors a good overview of the status of the relevant maintenance tasks.

## Findings

The inspection revealed the following potential non-compliance:

1. Licence Condition 4 of the licence for F0262 - the licence holder must ensure that the facility complies with the Operational Limits and Conditions approved by the CEO of ARPANSA. A surveillance requirement, which forms part of the OLCs for building 54, was missed in 2017, and hence ANSTO did not comply with the mandatory annual frequency on that occasion.

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

1. Inconsistent level of event investigation of all potential contributing factors as per the Ishikawa methodology, including human and organisational factors.
2. Management oversight of the maintenance task schedule associated with OLCs.

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

*In response to any potential non-compliance, the licence holder must carry out its responsibilities under Regulation 45*