Inspection report

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| **Licence holder:** ANSTO Health | **Licence number:** F0262 |
| Location inspected: Lucas Heights Science and Technology Centre, Sydney | **Date/s of inspection:** 7–9 and 15 November 2018 |
| **Report no:** R18/13262 |
| 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 1999 (the Regulations), and conditions of Facility Licence F0262.  The scope of the inspection included an assessment of ANSTO Health’s performance against the Source Performance Objectives and Criteria (PO&Cs) in the following areas: training, security, radiation protection and emergency preparedness and response. 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 work activities 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 2243.4-2018 *Safety in Laboratories Part 4: Ionising Radiation*. Observations ANSTO Health follows the site-wide system to manage safety. The individual facilities develop specific procedures and instructions for work activities at each location. The facility is responsible for the safety and security of operations with the radiation protection, emergency response and security functions mainly provided by the relevant ANSTO site-wide services.  The inspection did not identify any potential non-compliance. However, some areas for improvement were identified. Training In general, training and development at ANSTO Health uses a systematic approach and appears to be well-coordinated. The Learning Management System (LMS) software that manages training is a site-wide system. In addition to the site-wide training scheme that delivers the ANSTO training core curriculum, ANSTO Health has developed its own training program. The designated Learning and Development Adviser coordinates training for ANSTO Health.  All positions including those with safety and security functions have position descriptions developed. The position description requirements are covered by training curriculum which are periodically reviewed as per ANSTO procedure AP-2363.  Training of contractors is managed by the site contractor supervisors. General contractor training, such as radiation protection training, is required prior to granting site access. Training needs for contractors who provide ANSTO services on a regular basis is established and managed similarly to training of any ANSTO employee. Occasional contractors are supervised by ANSTO contractor supervisors at the ANSTO Health premises. In addition, ANSTO uses a third party company system to manage the interface between the contractor supervisor and ANSTO Health to record receipt of the induction training, possession of appropriate qualifications, licences and work permits among other.  The LMS sends e-mail notifications of training requirements to individual personnel. Every person is then responsible for self-managing the training to meet the expectations. The line managers are informed about their staff training status continuously via the LMS dashboard. At the moment ANSTO is in the process of developing key performance indicators that will also include the training requirements.  The ANSTO Health personnel training records indicated the training in radiation protection was largely met. Four persons whose training was overdue were either on extended leave or seconded to work outside of ANSTO.  In addition, the training records of a sample of seven staff members were checked in detail. The sample contained representatives from various work groups and hierarchical positions. The training required by their curriculums were met and no inconsistencies were identified.  Training for changes arising from the recent events was conducted in the timely manner. Periodic training sessions have been incorporated into the periodic refresher scheme. For instance, high-risk activity toolbox talks have been scheduled for every second month.  It is noted that the ANSTO based training is currently undergoing a review to improve the personnel training under the actions arising from the ANSTO Health independent review. Security No major inconsistencies were identified during the inspection. The ANSTO Security Policy is the overarching document for the entire Lucas Heights site which is the basis for the ANSTO Security Plan. This site plan informs individual facility security plans. The requirements for the facility security plan is specified in the Regulations and relevant security recommendations are found in the IAEA Nuclear Security Series document NSS-14, noting ARPANSA has adopted this as international best practice document. ANSTO Health has developed a document ANSTO Health Plans and Arrangements that includes, among other, information on security. However, this document fell short in providing details required by NSS-14. For example, the description of radioactive material and the environment for its use and storage, description of specific security concerns or description of security systems were not presented appropriately in the document.  ANSTO Health‘s security arrangements for access to both facility buildings is restricted by security systems requiring either swipe card or PIN-controlled access. The access rights are reviewed periodically. In addition, ANSTO Health staff undergo security checks, with the majority of staff cleared by the ANSTO vetting team.  The maintenance of the security system relies on either the facility maintenance management or the external contractor. This is achieved by using SAP system that feeds information into the asset management planning process. Any changes to the systems follow the ANSTO change control process. The security related contractors are managed using the site-wide contractor management system.  Arrangements to address risk mitigating measures for security equipment under maintenance are developed on a case-by-case basis. For example, the measures introduced during the access control system maintenance were found appropriate.  A vulnerability assessment of the facility was conducted in 2017. ARPANSA has been informed about the results of this assessment. Radiation protection The doses of ANSTO personnel are recorded and analysed periodically. The Radiation Protection Advisor (RPA) provides advice to the managers based on the analysis. Recently, the annual ALARA objective of the occupational dose of 2 mSv was removed from the ANSTO level documents. However, the dose of 2 mSv remains to be a threshold above which a quantitative dose assessment is carried out in addition to a qualitative assessment. The doses to the personnel are now assessed and optimised taking into account the personnel position and work activity involved. This improves the optimisation process.  RPAs are actively involved in identification, assessment and monitoring of radiation hazards in the facility. They are also involved in revision of processes and procedures related to the radiation protection.  Many of the ANSTO Health work procedures and instructions have now integrated warnings and cautions related to possible consequences involved. This has improved the safety related information presented to the procedure users in order to minimise human factor errors. ANSTO is committed to complete the process of revision of all relevant documents.  ANSTO Health has a mature change control process. The relevant procedure requires that this change control is followed to ensure that any change to plant and processes is appropriately assessed for safety, categorised, managed and approved accordingly. A similar requirement is also stipulated by the ARPANS regulation 49. In a case where a change is assessed to have the potential to be safety significant, regulation 51 of the Regulations applies and the proposed change must be submitted to ARPANSA for prior approval. This process should be followed even for changes that are introduced relatively quickly based on learning from events or other operational experience. However, records of changes implemented in September 2017 did not show that the formal change control process was applied consistently.  These inconsistencies pre-date the recent non-compliances with regulations 49 and 51 that ARPANSA recently issued to ANSTO Health. Therefore, the new findings are considered to be additional examples of the inconsistency previously identified. However, it emphasises the licence holders regulatory obligations particularly associated with the change control, safety assessment of the changes and internal review process.  Radiation protection equipment used for normal operation and emergencies should be appropriately maintained. The facility inspection identified that a small number of fixed area radiation monitors were found out of calibration. The maintenance of radiation monitors is normally managed using Computerised Maintenance Management System SAP. On this occasion, the periodic calibration was missed. Although this did not indicate a systemic shortfall, it represents an opportunity to improve. Emergency preparedness and response ANSTO Health’s emergency preparedness and response arrangements are generally considered to be satisfactory. The emergency response is scalable with the ability to escalate depending on the nature of the emergency. The overall ANSTO site-wide emergency arrangements are presented in the ANSTO Emergency Management Plan and relevant sub-plans. The facility emergency arrangements are based on these higher-level documents. Both the site and facility documents follow the IAEA General Safety Requirements GSR Part 7. It is noted that ANSTO has been actively involved in revision of the local government emergency plans.  In the case of an emergency the personnel notifies the ANSTO Site Operations Coordinator (ASOC) to trigger the response. The emergency response for ANSTO Health is provided on demand by the ANSTO Emergency Response Team (ERT). The team is equipped with proper personal protective equipment including the HAZMAT suits and other specialised equipment.  The ANSTO Health Spill Response procedure, for which all personnel are trained, covers the local emergencies. The spill kits are strategically located throughout the facility buildings. Building 23 spill kits were found to be marked on the emergency plans displayed and periodically checked, though no formal frequency of the inspection was established. The Building 54 procedures instruction for Mo-99 for maintenance and operation during the reactor shutdown includes a requirement to check the spill kits. However, their locations were not marked on the emergency plans displayed within the facility. One of the chemical spill kit was found opened with no content list present. These shortfalls constitute an area for improvement.  It is noted ANSTO Health immediately initiated rectification actions. The emergency plans have been updated and emergency kits in building 54 checked and replenished.  The facility carries out regular emergency drills and exercises. The recent one was conducted in October 2018 and involved evacuation due to loss of ventilation in a hot cell. Actions arising from the exercise have been initiated. 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. The facility security plan should follow the recommendations of NSS-14 2. Requirements for change control and safety significant change must be followed 3. Radiation equipment should be maintained periodically 4. The emergency equipment should be inspected and checked for completeness periodically   It is expected that improvement actions be taken in a timely manner. | |

*No written response to this report is required*