Inspection report

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| **Licence holder:** ANSTO | **Licence number:** F0251 |
| Location inspected: Camperdown | **Date/s of inspection:** 28–30 November 2018 |
| **Report no:** R18/14409 |
| 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 in force at the time of the inspection) and conditions of the Facility Licence F0251. The Regulations in force at the time of the inspection were remade in December 2018. The remade regulations are the Australian Radiation Protection and Nuclear Safety Regulations 2018 (Regulations 2018).  The scope of the inspection included an assessment of ANSTO’s performance at the Camperdown facility against the Performance Objectives and Criteria (PO&Cs). The inspection consisted of a review of records, interviews, and physical inspection of the facility. Background ANSTO’s Camperdown facility houses a commercially available 18 MeV cyclotron used for the production of both 11C and 18F from irradiated targets. The facility also makes use of various hot cells, laboratories and other rooms which prepare radiolabelled compounds. This facility, which is primarily research focussed, collaborates with the University of Sydney’s Brain and Mind Centre. ObservationsPerformance reporting and verification It is a requirement that the licence holder provides the CEO of ARPANSA with a quarterly report which details information regarding their compliance with the Act, Regulations and any imposed licence conditions. This responsibility falls on the facility officer who supplies information including but not limited to airborne discharges, movement and acquisition of sources, items significant for safety and accidents or incidents. An important item considers the review and update of the facility’s Plans and Arrangements for managing safety, in line with requirements of Regulation 50 of the Regulations 1999 (now section 61 of the Regulations 2018)*.*  There was evidence that these Plans and Arrangements were in the process of being reviewed, however only minor changes had occurred. There was no evidence that an in-depth review such as the identification of updates to codes and standards, consideration of the consequence of changes to these codes and standards to Camperdown operations or analysis against ARPANSA’s guidance. Regardless of the scope or depth of the review, all of these documents have fallen outside of the period required for regulation 50 of the Regulations 1999 (now section 61 of the Regulations 2018) resulting in a potential non-compliance.  The culture of internal reporting at Camperdown has improved as a result of previous inspection findings and recent events at ANSTO. The nominee reviews all event reports, a customised report is generated for the facility for the purposes of trending and lower level incidents are being reported in greater numbers indicating that near-misses are being captured. In terms of investigating events at Camperdown, the triaging of events has been removed from the responsibility of the facility officer in order to remove conflict of interest and add independence.  Inspectors noted there was generally good communication of certain safety incidents that have occurred at Lucas Heights to Camperdown. Configuration management The aforementioned Plans and Arrangements, having only had a minor review conducted, contain a range of out-of-date information which diminishes their usefulness. Examples include reference to obsolete organisational names and structures, safety codes, standards and guidelines. In one instance (the emergency plan) reference is made to version five of the Safety Analysis Report (SAR). This revision of the SAR had never been implemented or ratified and thus the previous iteration (version four) is still in place.  Another plan (waste management) dated November 2014 highlights that packaged radioactive waste will be characterised and transported to Lucas Heights where it will enter the waste stream, yet the facility does not have the capability to perform this function. ARPANSA reiterates the finding from a 2015 inspection that current plans did not properly represent actual practices and arrangements at the Camperdown facility and that these need to be subject to further review and update.  ANSTO have contracted MSS Security for their services in relation to managing the security and emergency response at the Camperdown facility. MSS had drafted their own security plan for the facility in January 2017. This plan has been put in place as of September 2018 but has not yet been approved by ANSTO Security or reviewed as required by ANSTO internal procedures. This security plan has not been seen by Camperdown staff.  As previously mentioned, the current SAR in place is version four. This is a report that has been in place since the facility was commissioned in 2012. While approvals have been given to ANSTO for various operations to take place, this document does not completely reflect the current facility. Version five has since been skipped and development of version six has been in process for the past two years. ANSTO have advised that amendments with significance to safety would be submitted to ARPANSA for approval.  A general risk review for many ANSTO activities is ongoing. ANSTO’s Systems Safety and Reliability (SSR) team are currently working with Camperdown staff to review evidence supporting the worker risks and mitigation methods associated with licensed activities. This has contributed to a lengthy review process and halted the approval and implementation of the revised SAR.  There are other aspects of the out-of-date SAR whose implications on the safety case have not been stated to ARPANSA. These include the future refinement of the operating limits and conditions as parameters of surveillance requirements are currently not fully defined, as well as the maintenance requirements and scheduling of the cyclotron, hot cells and other equipment not being entered into the ANSTO SAP maintenance system. Only building services are managed via SAP. The Camperdown facility wishes to eventually have these requirements in SAP but is currently managed manually through a paper based system relying on individuals to organise maintenance activities. While the management of maintenance activities is not in-line with the SAR, there was no evidence that critical maintenance activities had not been performed.  The Camperdown facility has its own change control procedure (P-4084). The procedure states that all changes which may alter the current state of, for example, a piece of equipment, an item of plant or a process (including procedures and instructions), must follow the procedure and be recorded in the change register (F-4100). While this had been demonstrated for a modification to equipment, there was no documented change control process governing amendment and revision of management system documents, including Plans and Arrangements and the SAR. Other than tracked changes in draft revisions, there was no tracking of changes or information on the assessment of safety risk associated with those changes.  During the physical inspection, a fume cupboard was found to have been fitted with equipment to reproduce the same process for 18F as is currently performed in the hot cells but on a smaller scale. This equipment would be used by staff and PhD students with less experience. This equipment is not currently in operation but was operated a number of times to obtain dose rate and performance data. A Safe Work Method and Environment Statement (SWMES) was developed in consultation with Radiation Protection Services for the work in December 2015 and a proposal for the work was created in November 2016. In order to have enough data, the equipment was essentially hot commissioned by scaling up the amount of activity used to upwards of 5 GBq. The SWMES details a moderate risk is generated due to the <860 mSv extremity dose potentially received by the operator as the result of a contamination incident from an activity 50 MBq in 300µL. The statutory extremity dose limit, which ARPANSA uses as a threshold for triggering regulation 51 of the Regulations 1999 (now section 63 of the Regulations 2018) is 500 mSv and therefore this process should have been submitted to ARPANSA for prior approval. This process has not gone before the Safety Assurance Committee (SAC) and SSR, however ANSTO has indicated that it will in the future. ANSTO had also not completed a safety categorisation assessment from a regulatory standpoint and, as such, no request for approval has been submitted. However ANSTO indicated that a submission would be prepared and submitted to ARPANSA before the equipment is operated. This is a potential non-compliance with Regulation 51 of the Regulations 1999 (now section 63 of the Regulations 2018). Inspection, testing and maintenance Responsibility for maintenance falls on the facility officer. This performance of maintenance is then placed upon the on-site support staff. ANSTO’s asset management group are also involved at Camperdown and provide support when required. ANSTO employs contractors for maintenance of certain systems such as fire detection (Wormald) and its hotcells (Comecer and GMS). As it currently stands, the hot cells are maintained on failure but there is the intention to place the hot cells on a preventative maintenance schedule.  Cyclotron maintenance is currently performed by trained staff at Camperdown. Staff responsible for cyclotron maintenance have been certified by the original equipment manufacturer, IBA, and have previous experience at another ANSTO facility which operates cyclotrons. It is the future intent of the facility to have IBA on 24/7 remote support and potentially allow for an annual visit. Training for specific cyclotron maintenance will continue with staff to attend an advanced IBA course.  As previously indicated, while there are issues relating to the management of maintenance, it was evident that maintenance activities were still being performed. Training ANSTO uses its Learning Management System (LMS) to monitor, organise, schedule and deliver training. While the identification of training needs is not a formalised process, managers will assess the development needs of staff through analysis of Camperdown’s training matrix, which is not currently linked with the LMS and separate to ANSTO’s organisational training matrix, and its Annual Performance and Effectiveness Appraisals (APEA).  It is recognised that staff are employed based on pre-existing knowledge and expertise, however must still be trained to work in accordance with ANSTO’s safety objective. This is important to achieving the high level of safety that ANSTO wishes to demonstrate for its activities. While processes are described or demonstrated by supervisors and guided by instructions, specific detail on how to perform the task and its associated consequences is lacking.  Camperdown specific training is delivered by more experienced supervisory staff through on-the-job training. Currently those staff who provide the training are also responsible for its authorisation upon completion. This method of delivery heavily relies on the teaching ability of the trainer to instil safe work practices, lacks independent assessment and does not allow for independent verification of training effectiveness. Radiation protection Camperdown has both a lead and deputy Radiation Protection Advisor (RPA) and are supported by the Health Physics Surveyors (HPS). Support is provided through a mix of on-site and on-call services that includes radiation assurance surveys, clearances of items from radiological areas, and providing advice on radiological risk.  In the event of a radiological incident both the RPA and HPS will be contacted, the area will be cordoned off and the scene preserved. Radiation Protection Services (RPS) is currently developing guidance surrounding scene preservation. Staff should then follow ANSTO’s investigation methodology.  It is worth noting, depending on the radiological incident, that risks to staff can be mitigated by avoiding the area and allowing for decay due to the nature of short-lived radioisotopes. In the instance of contamination, decontamination procedure exists within ANSTO’s Work Health and Safety Management System and basic radiation safety training provided during induction. Recent events at ANSTO have highlighted the importance of quick and effective personal decontamination but no procedures for Camperdown are in place. If staff require personal decontamination they would then lean on their training, the area RPA/HPS would be contacted immediately and offer advice, if not on-site, or immediately attend to the person in question.  Clearance of items from radiological areas by non-RPS staff is limited to small personal items. A small number of staff at Camperdown have been certified by RPS to clear product from the facility, however given recent events at Camperdown, this arrangement may be handed back to HPS. Event protection Given the geographical location of the Camperdown facility and its design, inspectors found the measures in place in relation to event protection management to be sound. On physical inspection, pest control measures could be seen and records related to fire detection systems were able to be shown. Security For an extended period of time dating back to 2016, the Camperdown Security Plan had not been reviewed or endorsed by an ANSTO Security expert to ensure it aligned with the ANSTO Security Plan and to ensure it included up-to-date-information on threat assessment, personnel security, IT, among others. This document has only recently been reviewed and endorsed by ANSTO Security. While it was highlighted that this document would follow the ANSTO template, it could not be confirmed as to whether or not this document takes into account the IAEA’s Nuclear Security Series 14, Nuclear Security Recommendations on Radioactive Material and Associated Facilities.  While ANSTO adopts the attitude that everyone is responsible for security, the contracted MSS Security officer has specific responsibilities at Camperdown. Previously, ANSTO Security presence at Camperdown has only been on a quarterly basis with regular communication via email and telephone. Given current changes to ANSTO Security personnel, Camperdown is looking to have this presence increased with an even greater level of communication.  Security is also a standing agenda item at the weekly operations meeting which the MSS Security officer attends to inform or gather new security information.  Access to the site follows the standard ANSTO on-boarding process with authorisation of access ultimately residing with the Facility Manager. In regard to access, Camperdown has an emergency pass system and also a policy surrounding lone working. Lone working in the laboratory environment is not allowed, however special access can be authorised for desk work. Staff are required to carry a lone work radio and alert the ANSTO Site Operations Centre.  Overall, the security measures in place at Camperdown are deemed to be appropriate. Emergency preparedness and response ANSTO’s Camperdown facility is geographically disconnected from the main site at Lucas Heights. As such the ANSTO Emergency Response Team (ERT) has no real presence at Camperdown and the responsibilities fall on the Facility Manager and MSS Security Officer. Without the aid of the ERT, response to emergency situations is handled in communication with external emergency services such as local police and fire services.  Throughout the office areas there are facility maps showing fire exits, muster points, first aid boxes, fire extinguishers and emergency showers/eyewash stations are present. However, these maps are not present within the radiological areas of the facility. The maps also do not alert staff to the locations of spill kits. In the event of a spill, a specific radiological spill response document for Camperdown has not been developed. There is also no formalised audit process for restocking of spill kits.  The emergency procedure (P-4092) lists emergency posters that have been placed around the building. They describe the immediate actions to be takin in the event of fire, radioactive contamination, a general accident requiring ambulance, electric shock, or a major chemical spill or release. On inspection, they were not present within the facility and could not be produced when requested.  Inspectors noted that there was inconsistency between Camperdown’s Operations Management Procedure (P-4000) and the Emergency Procedure (P-4092). The first indicates exercises are to be performed every 12 months while the latter increases the frequency to biannual. It was then indicated to inspectors that exercises are conducted annually. Communication of lessons learnt from exercises between Lucas Heights and Camperdown was found to not be effective and therefore their relevance to Camperdown is unknown. Findings The inspection revealed the following potential non-compliance/s:   1. Regulation 50 of the Regulations in force at the time of the inspection (now section 61 of the Regulations 2018)– The holder of a licence must, at least once every 3 years, review and update the plans and arrangements mentioned in regulation 49 (now section 60 of the Regulations 2018) in relation to the licence. All of these documents have fallen outside of the 3 year period. 2. Regulation 51 of the Regulations in force at the time of the inspection (now section 63 of the Regulations 2018) – the holder of a licence must obtain the prior approval of the CEO if a change will have significant implications for safety. The statutory extremity dose limit is a threshold which triggers this section. The conduct inside the aforementioned fume cupboard was risked assessed to exceed this and was not submitted for approval prior to implementation.   The inspection revealed the following **areas for improvement**:   1. Review and update the Safety Analysis Report to reflect the current status of the facility. 2. Change management arrangements not adequately addressed. 3. Authorisation of trained workers is not independent. 4. Review and update of emergency arrangements, inclusive of response documentation and spill kit arrangements.   It is expected that improvement actions will be taken in a timely manner. | |

*In response to any potential non-compliance, the licence holder must carry out its responsibilities under section 57 of the Regulations 2018*

This report will be published on the ARPANSA website