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 F0285.

The scope of the inspection included an assessment of ANSTO’s performance in the following areas: reporting and verification, configuration control, inspection, testing and maintenance and radiation protection for ANSTO Nuclear Medicine Facility (ANM Facility). The inspection consisted of a review of records, interviews, and visit to the facility.

**Background**

ANSTO has a licence to construct the ANM Facility. Construction is nearing completion with many of the safety systems and components within ANM undergoing acceptance testing. The ANM Facility will be used for large scale production of Molybdenum-99 (Mo-99). Mo-99 is the precursor of Technetium-99m (Tc-99m) which used in 80% of all nuclear medicine procedures.

The facility is designed considering the principle of waste minimisation. Only low and intermediate level solid and liquid waste will be generated from operation of the facility. Gaseous waste will also be generated and discharge will be subject to regulatory notification levels set by ARPANSA.

**Observations**

**Performance reporting verification**

In general, reporting to ARPANSA of required information by ANM management has been accurate and timely. Compliance reporting and applications for approvals were found to be comprehensive. Various key performance indicators were used to monitor the progress of the ANM construction activities.

**Configuration control**

Items at the ANM Facility important to safety are described in the Preliminary Safety Analysis Report (PSAR). This PSAR defines the safe envelope of operation of the ANM Facility and considers degradation of defence in depth and in operating safety margins. Safety margin degradation is also considered as part of the change control process. Changes to the facility are made in accordance with the ANM Change
Control Procedure (P-50003) and Project Change Procedure (Mo99_FACL_QUAL_PR0_0035_A). Apart from a formal system for managing and evaluating the impact of the proposed change the procedure also ensures that a complete history of project changes is recorded and maintained as evidence that changes throughout the design, construction and commissioning of the ANM Facility are being managed and controlled. Proposed changes are signed off by a responsible person and completed actions are then verified and signed off. Changes are communicated during regular ANM management meetings.

ANM change control procedure has been written to comply with: ISO9001, PIC/S Guide for Good Manufacturing Practice for Medicinal Products, PE009 (Part II) and IAEA-TECDOC-1226 Managing Change in Nuclear Industries (July 2001). Inspectors noted that the project change procedure did not currently reference the concepts for responsibly managing change in IAEA General Safety Requirement GSR Part 3 at paragraph 3.35(a). Referencing the current version of IAEA GSR Part 3 as a higher level document is seen an opportunity to enhance the change management procedure documentation. This was identified as an area for improvement.

**Inspection, testing and maintenance**

Since the construction of the facility is nearly complete the emphasis is on inspection and testing. For inspection and testing ANM follows a comprehensive program documented in accordance with the ANSTO Quality System. The inspection and testing arrangements and schedule for acceptance of structures, systems and components were sighted and found comprehensive and suitable. All safety related items require some form of Factory Acceptance Test (FAT), Site Acceptance Test (SAT) and/or installation checks and tests to satisfy functional operation.

**Radiation Protection**

The provisions for radiation protection, including engineering controls as constructed, were observed to be of high standard incorporating state-of-the-art instrumentation. The procedures for testing shielding of the hot cells and the test results were sighted and found to be comprehensive. Provision is made for results to be verified and signed off. The results showed that a few areas did not conform to the design objective therefore requiring rectification and further verification. This will be completed in accordance with the ANM acceptance testing schedule.

**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 **area for improvement**:

1. Reference to the IAEA GSR Part 3 in ANM Project Change Procedure (Mo99_FACL_QUAL_PR0_0035_A) would show consideration of international best practice with respect to safely modifying the ANM Facility.

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