



Inspection Report

Licence Holder: Australian Radiation Protection and Nuclear Safety Agency (ARPANSA)	Licence Number: F0046
Location inspected: ARPANSA Medical Radiation Services (MRS)	Date/s of inspection: 15 -16 May 2017
	Report No: R17/05465

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 the Facility Licence F0046.

The scope of the inspection included an assessment of the performance of the Medical Radiation Services (MRS) branch of ARPANSA against the Performance Objectives and Criteria (PO&Cs). The inspection consisted of a review of records, interviews, and physical inspection of facilities.

An officer from the Queensland radiation regulatory authority (Queensland Health) participated in the inspection to provide additional independence.

Background

ARPANSA holds a licence under Section 32 of the Act to operate linear accelerators and a teletherapy laboratory. ARPANSA currently operate one linear accelerator which provides photon and electron beams, in the range 4 -25 MeV, covering both kilovoltage X-rays and megavoltage photons. The teletherapy laboratory includes a Co-60 source and a Cs-137 source which are used to maintain primary standards and provide calibration services.

Observations

In general, the safety and security of the facilities were found to be satisfactory. Staff operate well-maintained equipment with a due consideration for operational safety and security. However, some areas for improvement were identified, including documentation and change management processes.

Radiation Protection, Facility and Record Maintenance

Facilities and equipment were observed to be well maintained with controls such as physical barriers, key interlocks and warning lights. Records of maintenance and testing were observed. General housekeeping was in good order and improved since the previous inspection.

Handheld monitoring equipment was observed to be present, calibrated and in good condition. In addition to the use of area and portable monitors, doses are monitored using personal dosimetry badges. Badges were observed to be in use, and badges which are not in use were stored at a clearly labelled badge board. However, it was noted that the control for the badges was not stored at the badge board.

Records showed that annual doses received by workers were very low and well within the ARPANSA annual dose constraint of 2mSv.

Records of training and authorisations were reviewed. However, there was no clear staff induction pathway outlining required training for new staff, or staff in new roles.

Performance Reporting and Configuration Control

Plans and arrangements have been regularly reviewed by the relevant section staff and the Radiation Safety Committee. These reviews identified that updates are required. While some documents were recently updated, a significant number of documents were reviewed as requiring changes but had not been updated for a number of years. Documentation had not been updated to reflect changes to requirements (e.g. such as references to outdated codes and standards), organisational changes, and drift in actual practice from recorded practices.

In some cases, local or lower level, procedures and work instructions were found to be in conflict with organisation wide, or higher level, policy and procedures. For example, a 'radiological work authorisation' is required for each operational procedure involving a radiation hazard, under OHS-RSM-IRSP-SOP-001. However the permit to work procedure (OHS-RSM-IRSP-SOP-008) stated that the SOP could be signed by the workers instead of this requirement. This reflects current practice, but does not include the required radiological work authorisation by the branch head and RSO.

Waste and disposal considerations in the plans and arrangements do not currently cover final disposal or transfer of high activity sources. The disposal process was well understood by staff, but there is no description of the current preferred disposal option in the documentation.

It was noted in a previous inspection in November 2015, that 'the review and update of plans and arrangements for the safe operation of the linear accelerator has not always been effective in ensuring an accurate description of the current operations. While some progress was noted, this issue has not been fully resolved. This evidence suggests that focus on maintaining safety related procedures could be improved.

Risk Assessment and Event Reporting

IAEA Safety Standards Series No. GSR Part 4, Safety Assessment for Facilities and Activities is considered international best practice in risk assessment. Using a graded approach, risk assessment for minor changes require a level of detail different to that for more significant changes, while in routine operation, procedures and policies support informal risk assessment.

A documented procedure was observed for the formal risk assessment, through the use of the Hazard Identification, Risk Assessment & Management (HIRAM) process. However, no formal process for change management, including the requirement for approval from or notification to the regulator in accordance with Regulations 51 & 52, was observed. While risks for changes appear to be assessed by individuals, and relevant controls are put in place for tasks and procedures, this process is not documented and not subject to any formal review. The assessment of safety significance and the determination of the requirement to notify the regulator of such changes could not be verified.

It is considered good practice that organisations show curiosity, an effort to understand deviations and share operational experience. Evidence was observed that abnormal events, such as a worker receiving slightly more dose than similar workers, are investigated and learned from. However, these events are

not captured as part of a formal system. Regular internal recording and reporting of near misses within MRS's own procedures were not observed. While there was evidence that information sharing on such matters occurs via the Radiation Safety Committee, during the inspection this could not be confirmed through documentation. Any such learning or events have not been included in the quarterly reports to the regulator.

Security

A security plan (v1.0) was endorsed by an accredited person, as required by the Code of Practice for the Security of Radioactive Sources (2007) [RPS11]. While subsequent revisions (v1.3) were reviewed by an accredited person, it was not clear to inspectors if these changes were also endorsed by an accredited person.

Physical security measures observed were in accordance with the security plan. However, there was no evidence that the annual security checks, in accordance with the plan and RPS 11, were carried out in the last 12 months.

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. **Documentation.** MRS safety related documentation has not always been maintained to accurately reflect current facility practices.
2. **Change Management.** MRS formal processes on change management and the assessment of risks (safety significance) were not clearly documented at the time of inspection.
3. **Security Checks.** MRS security checks in accordance with the plan and RPS 11 have not always been performed on an annual basis.
4. **Safety Culture.** MRS procedures which support considering very minor abnormal events and potential opportunities for learning were not evident at the facility.

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