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Radiation exposure of a worker at ANSTO Health, Lucas Heights on 22 August 2017

Report to parliament

of the CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) under section 61(1) of the *Australian Radiation Protection and Nuclear Safety Act 1998*

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The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety. Our purpose is to protect the Australian people and the environment from the harmful effects of radiation, through understanding risks, best practice regulation, research, policy, services, partnerships and engaging with the community.

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Foreword

This report is tabled in both houses of Parliament pursuant to section 61(1) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the ARPANS Act), which states:

> *"The CEO may at any time cause a report about matters relating to the CEO's function to be tabled in either House of the Parliament".*

The matter considered in this report is a radiation exposure of a worker on 22 August 2017 at the Australian Nuclear Science and Technology Organisation (ANSTO) Health radiopharmaceuticals production facility at Lucas Heights, NSW, which exceeded the relevant statutory dose limit.

As symptoms of radiation injury developed over the weeks and months after the exposure event, it became clear that the exposure was considerably higher than original estimates provided by ANSTO. I have subsequently found ANSTO in breach of section 30(2) of the ARPANS Act for failing to comply with the Australian Radiation Protection and Nuclear Safety Regulations 1999, specifically regulation 46 (in relation to measures to prevent accidents) and regulation 48 (in relation to dose limits).

My view is that the seriousness of the accident justifies reporting under section 61(1) of the ARPANS Act and I have informed ANSTO of my intention to do so.

In accordance with section 61(3) of the ARPANS Act, I have provided a copy of this report to ARPANSA's Minister, Senator the Hon Bridget McKenzie.

Dr Carl-Magnus Larsson
CEO of ARPANSA

Executive summary

This report provides an overview of an accident leading to contamination of a worker at the Australian Nuclear Science and Technology Organisation (ANSTO), specifically ANSTO Health on 22 August 2017. The accident occurred during a routine quality control procedure and caused radiation exposure of the skin of the hands. The radiation dose was significantly underestimated in ANSTO's initial assessments. However it was acknowledged in the ANSTO report that the radiation dose could lead to tissue reactions. The scene of the accident was not preserved by ANSTO, which means that important information on contamination levels on personal protective equipment, which could further have informed the dose assessment, had not been gathered. Tissue reactions that subsequently developed on the worker's hands are compatible with a radiation dose about 40 times higher than the statutory annual equivalent dose limit to the skin. ANSTO has performed a separate internal investigation of the matter.

ARPANSA has reviewed information submitted by ANSTO and has carried out an investigation into the accident. ARPANSA's dose reconstruction confirms ANSTO's advice that an exposure corresponding to 40 times the annual equivalent dose limit to the skin is plausible, and compatible with symptoms of radiation injury on the analyst's hands. ARPANSA classified the exposure as a serious incident corresponding to Level 3 on the International Radiological and Nuclear Event Scale (INES). The INES scale ranges from zero (with no safety significance) to 7 (major accident).

Human and organisational factors identified as important contributors to the accident include:

- the risk was not well understood and underestimated by ANSTO
- a high risk task was accepted by management with no record of any mitigating measures implemented
- equipment and training of the worker was deficient
- learnings from previous 'near misses' were inadequate
- procedures for carrying out the quality control were insufficiently detailed.

ANSTO has been found in breach of subsection 30(2) of the *Australian Radiation Protection and Nuclear Safety Act* 1998 for failing to comply with the Australian Radiation Protection and Nuclear Safety Regulations 1999, specifically regulation 46 (in relation to measures to prevent accidents) and regulation 48 (in relation to dose limits). Further regulatory enforcement actions may be considered.

ARPANSA is monitoring ANSTO's actions to implement changes to internal processes to prevent a similar event reoccurring, at ANSTO Health or otherwise. ARPANSA has shared information on the event with Comcare.

1. Introduction

1.1 Purpose and scope of the report

This report provides an overview of events on and after 22 August 2017, relating to radiation exposure of a worker performing quality control procedures at the ANSTO Health facility. It summarises the circumstances surrounding the exposure event; information submitted by ANSTO; ARPANSA's assessment of the radiation exposure; and regulatory assessment and subsequent enforcement activities in relation to this event.

1.2 Background on ANSTO Health

ANSTO Health manufactures radiopharmaceuticals for the domestic and international markets. Production and distribution of radiopharmaceuticals occurs in a number of buildings at ANSTO's Lucas Heights facilities. In the molybdenum-99 (Mo-99) production plant, irradiated uranium target plates are received from the OPAL reactor. The Mo-99 formed in the target plates is extracted via a chemical process and purified. It is then packaged into Gentech® technetium-99m (Tc-99m) generators or packaged into containers for bulk export internationally in another building and despatched for use in hospitals and clinics for nuclear medicine procedures.

Mo-99 has a half-life of 2.7 days, and is a powerful emitter of beta radiation. A beta particle is an energetic electron, which originates from the decay of a proton in the nucleus of an atom. The radiation exposure of the worker was predominantly caused by beta radiation.

2. Information submitted by ANSTO to ARPANSA

2.1 The exposure event

At approximately 7 am on 22 August 2017, a quality control analyst was performing routine quality control of a solution containing Mo-99, to verify compliance with quality criteria set by the Therapeutic Goods Administration (TGA). The process involves manual handling of solutions containing high activities of Mo-99, including unsealing and sealing glass vials using a manually operated tool, drawing the liquid into pipettes, moving vials in and out of shielded pots using long tweezers, and moving the shielded pots with vials between rooms. The quality control procedure requires handling to occur within ventilated fume cabinets to reduce the likelihood of exposure to radioactive substances.

The analyst dropped a vial containing a solution of Mo-99 within the fume cabinet while de-capping the crimped seal on the vial. Some solution was lost from the vial and contaminated the inside surfaces of the fume cabinet and the analyst's gloves. Double gloves were worn on each hand. The analyst recovered the dropped vial from the floor of the fume cabinet and placed it in its lead pot, and then monitored the gloves for contamination. Contamination was detected on both the inner and outer gloves. Both pairs of gloves were removed and discarded in the nearby shielded waste bin.

The analyst then monitored their hands and discovered significant radioactive contamination on the skin of both hands. The analyst started washing their hands and called for assistance from colleagues in the next room. After a few minutes of washing hands with cold water in the laboratory, the analyst was moved to another room for further decontamination. The ANSTO Site Operations Centre (ASOC) was notified of the event by phone and asked to alert the on-call Health Physics Surveyor (HPS). There was no specialist Health Physics support on site at 7 am, the time of the event.

At approximately 7.30 am, after about 30 minutes of continuous washing, the radiation levels on the hands were still high. Further washing of the hands using soap and water as well as a special decontamination solution did not bring down the contamination to within the measuring range of the monitor.

At approximately 11 am, a significant portion of radioactive contamination from the most contaminated skin area had been removed, but some remained on one hand. Washing of the contaminated skin area continued at regular intervals throughout the day with the contaminated hand being covered with a nitrile glove to encourage sweating in-between washing. By the end of the day, only a small amount of contamination remained on the affected skin area of the right hand.

For the following days, contamination on the skin was measured and recorded, and periodic washing continued. The analyst wore a nitrile glove on the right hand during the day and overnight to encourage sweating in an effort to reduce the contamination levels further. By 28 August, no contamination could be detected.

The room and tools were decontaminated shortly after the event. Personal protective equipment used by the analyst as well as radioactive waste generated during the event were disposed of shortly after the event.

However, it was subsequently determined that the contribution to the dose from the contamination found on the skin was significantly less than the dose delivered by the contamination on the gloves prior to their removal and the washing procedures started.

2.2 Exposure assessment and symptoms of radiation injury

ANSTO reported the event to ARPANSA within 24 hours, in accordance with regulation 46(2)(c) of the Australian Radiation Protection and Nuclear Safety Regulations 1999 (the ARPANS Regulations).

ANSTO provided the preliminary event report to ARPANSA on 30 August 2017, in accordance with regulation 46(2)(d) of the ARPANS Regulations. ANSTO's estimate of the radiation dose incurred by the analyst indicated an equivalent dose to the analyst's hands of 0.85 +/- 0.25 sievert (Sv), which is in excess of the statutory annual limit of 0.5 Sv equivalent dose[1] to the skin. However, the analysis indicated that, depending on assumptions, the dose could potentially be up to 4 Sv, i.e. 8 times the statutory dose limit[2].

Radiation injuries, unless caused by extremely high exposures, do not normally produce immediately observable symptoms. The dose assessment at the time suggested that tissue reactions potentially could develop with time. Initially, the analyst was assessed by an occupational health nurse on a daily basis. After 15 days, the worker's hands started to show skin reddening and blistering typical of radiation exposure in excess of the tissue reaction threshold. An occupational health physician, specialist dermatologist and radiation oncologist have provided analysis and support after the event as the symptoms have developed. Since that time, ANSTO has regularly reported the injury progress to ARPANSA.

Based on the medical observations by the radiation oncologist in September 2017, the dose received by the worker was estimated to be approximately 20 times the statutory annual dose limit. The medical report of December 2017 suggested the dose received could be over 40 times the limit, i.e. in excess of 20 Sv compared to the annual equivalent dose limit to the skin of 0.5 Sv.

Additional independent advice to ARPANSA from a second radiation oncologist confirmed that the symptoms were consistent with an exposure of 20 - 40 times the statutory annual dose limit.

The injury has caused skin blistering, erythema and desquamation. Recent medical observations dated January 2018 showed that the tissue damage to the skin of both hands is ongoing. The healing will take months and there is a risk of longer term effects.

2.3 ANSTO's internal investigation

On 21 September, ANSTO supplied a report on its internal investigations of the event to ARPANSA. In summary, ANSTO's investigation concluded that:

- the specific radioactivity analysed that day was higher than the minimum required for carrying out the quality control task
- there was 'less than optimal' equipment and training

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[1] For exposures of the type and magnitude discussed in this report, it is more appropriate to use the basic physical quantity *absorbed dose*, with its special name gray (Gy). For the purpose of this report, the quantities *equivalent dose* (in sievert, Sv) and *absorbed dose* (in gray, Gy) can be used interchangeably. The report reflects the units used in the sources of information underpinning this report, i.e. the ARPANS Regulations, ARPANSA's dose assessment, and information provided by ANSTO.

[2] The annual equivalent dose limit to the skin applies to the average dose received by any 1 cm^2 of skin. Based on personal radiation monitoring and models used to calculate exposures, there is no indication that the annual dose limit for *effective dose* (20 millisievert averaged over 5 years; 50 millisievert in a single year) has been exceeded.

- the high risk associated with the task was accepted by management with no documentary evidence that additional mitigation measures had been implemented
- 'near miss' events of a similar nature had been under-reported
- the majority of the dose to the hands occurred in the short space of time the contaminated gloves were on the analyst's hands, and only a small fraction of the dose was received whilst the skin was being decontaminated by washing the hands
- the skin dose was likely to lead to tissue reactions, e.g. skin erythema and reddening.

The report included a list of immediate as well as longer-term actions that arose from the investigation.

Although the report covered the contributing causes to the event, it did not examine in detail the possible contribution by human and organisational factors.

3. ARPANSA's regulatory investigation

3.1 Dose assessment

Experts from ARPANSA's Radiation Health Services Branch conducted a dose reconstruction of the exposure event. Using reported conditions during the event, the study confirmed that the radiation dose could have been in excess of 10 times the statutory annual equivalent dose limit to the skin.

The ARPANSA assessment included additional scenarios and sensitivity analysis, where input parameters such as the time of exposure and the amount of liquid spilled were varied. The scenarios were grouped in two categories. Category 1 scenarios considered no contamination remaining on the skin surface of the fingertips, whereas category 2 scenarios considered direct contamination of the fingertips.

ARPANSA estimated that in the category 1 scenarios the skin dose ranged up to over 10 times greater than the statutory annual dose limit. Estimates from analysis of category 2 ranged up to about 40 times greater than the statutory annual dose limit for the first hour following the incident.

In summary, ARPANSA's dose reconstruction demonstrated that scenarios using different combinations of parameters such as amount of spilled substance, use of protective equipment, different skin thicknesses and exposure times could have led to radiation exposures consistent with the observed symptoms.

3.2 Regulatory investigation

ARPANSA found that the event met the definition of an *accident* for the purposes of the ARPANS Regulations.

ARPANSA assessed the accident as a *Level 3 Serious Incident* on the International Nuclear and Radiological Event Scale (INES) and notified the International Atomic Energy Agency (IAEA), who subsequently published it on their website. The INES scale ranges from Level 0 (zero) to 7, where Level 0 events have no safety significance, and Level 7 events correspond to major accidents such as the nuclear accidents in Chernobyl and Fukushima. ARPANSA's classification was based on the exposure causing non-lethal radiation effects (tissue reactions) on a single worker. Accidents with similar consequences involving several workers would

be subject to higher classification. This is the first time ARPANSA has classified an event among its licence holders at Level 3 on the INES scale. ARPANSA has previously reported an INES Level 3 event which occurred in another jurisdiction where a borehole logger received a significant exposure above statutory limits.

Since the event, officers from ARPANSA's Regulatory Services Branch have undertaken site visits and held a series of meetings with representatives of ANSTO, including with the worker sustaining the radiation injury. ANSTO has informed ARPANSA on progress of its internal investigation, immediate actions to prevent a recurrence of a similar event, and on progress of the worker's injury over time. ARPANSA's regulatory officers were satisfied the immediate changes made in relation to the quality control procedure had mitigated risks in the short term. Radiopharmaceutical production was then able to continue without interruption.

As part of its own investigation, ARPANSA undertook an augmented inspection[3] which focused on human factors, safety practices and organisational aspects that could have contributed to the event. The inspection identified that:

- practices for reporting low significance events, near misses and deviations from expected practice were not implemented effectively to identify improvements that may have prevented this accident or other serious incidents and accidents. Learning from events was limited to the immediate operation where each event took place. Related incidents did not trigger corrective actions and improvements to processes internally within ANSTO Health and across other divisions on the ANSTO site
- operational level worker knowledge of safety events and the level of risk associated with their work or related work was found to be incomplete
- current understanding of how the risk outcomes are derived was inadequate and workers considered that risks had been overstated. Communication of the basis for the risk assessment relating to quality control processes was not sufficient to result in ownership of risk by the workforce
- it was evident that the hazard associated with the particular task was significantly underestimated by ANSTO. This was confirmed by the difference between the actual dose received and dose estimated by the ANSTO risk assessment. The radiation dose symptoms (December 2017) indicated that the dose received was more than 20 times higher than the maximum dose postulated in the existing risk assessment
- the procedures and instructions in use in the ANSTO Health quality control laboratory did not consider the contribution of human factors to the variability in practices, performance and reaction of workers to unusual events. Prescriptive guidance on how to undertake specific tasks was not included in procedures or instructions. There were no warnings or cautions to highlight different levels of hazards associated with specific tasks
- current training systems that relate to the safety of operations are overly reliant on the teaching ability of the trainer, lack independent assessment of the trainee's performance, and do not provide an independent verification of the training effectiveness.

[3] ARPANSA's inspection reports are published on ARPANSA's website; https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/inspections/inspection-reports.

There were no immediate safety or operational reasons to disturb the scene of the contamination event. The laboratory was not required for use until the following day. ANSTO followed a procedure for clean up after a contamination event which is considered suitable for spills, but not fully applicable to accidents in that it does not allow for proper post-accident characterisation which could include measuring contamination levels on structures and personal protective equipment.

This lack of a clear approach to evidence preservation led to the discarding of the contaminated gloves, cleaning of the room and decontamination of the area without consideration of the implications for the subsequent investigation. Therefore, the ANSTO investigators and ARPANSA had to rely on personal accounts during the post-event investigation, without the support of physical evidence. This has prevented the ANSTO investigators and ARPANSA from fully understanding what happened in order to reconstruct the event, and to accurately estimate the radiation dose to the worker. The severity of the exposure was initially underestimated and this only became clear as symptoms of radiation injury gradually developed.

3.3 Breach decision

Based on preliminary assessments, ARPANSA informed ANSTO of its findings of potential non-compliance with regulations 46 and 48, and requested further information on matters related to the event. On 19 December 2017, taking account of all information available, the CEO of ARPANSA found ANSTO in breach of subsection 30(2) of the ARPANS Act for failing to comply with regulations 46(1) and 48(1)(a) of the Regulations.

The decision regarding regulation 46, which states that "*(1) the holder of a licence must take all reasonably practicable steps to prevent accidents involving controlled materials, controlled apparatus or controlled facilities described in the licence*", was based on evidence that ANSTO had many opportunities to prevent the accident, or reduce the likelihood of occurrence and/or severity of the accident consequence.

Regulation 48 states that "*(1) the holder of a facility licence must ensure that the following are complied with in relation to activities relating to the controlled facilities to which the licence relates: (a) the Planned Exposure Code...*" The code specifies the statutory annual dose limits for workers, as does regulation 62 of the ARPANS Regulations. There is clear evidence that the statutory equivalent dose limit to the skin has been exceeded as a result of the accident.

ARPANSA has shared information on the event and the breach decision with Comcare.

3.4 Actions requested

A corrective action plan requested by ARPANSA lists several actions that have already been completed and have been reviewed and verified by ARPANSA. A number of medium and longer term actions have been identified that will require ongoing review by ARPANSA, including:

- review of manual handling in the quality control process to redesign and potentially automate the process to further reduce the risk
- achieve further reductions in the concentration of the radioactive material in quality control samples, whilst still meeting the requirements of the TGA.

ANSTO will also perform a review and report on the outcomes of risk assessments of high risk operations using unsealed sources at ANSTO.

4. Concluding remarks

Radiation exposures in excess of statutory dose limits are rare and exposures causing tissue reactions in workers are exceptional. ARPANSA compiles incident data on a yearly basis involving radiation exposure from across the country in the Australian Radiation Incidents Register (ARIR) and publishes an annual summary report[4]. Out of almost 400 incidents that were reported for 2016, most result in low or very low exposures; however, their evaluation provides valuable feedback to regulators and licence holders about opportunities to improve safety practices. Properly implemented, such lessons learned should reduce the likelihood of events with severe consequences. In relation to events reported in the 2016 ARIR summary report, the accident dealt with here is exceptional and, as stated earlier, for the first time led ARPANSA to submit an INES Level 3 event report relating to its licence holders to the IAEA and to report it to Parliament under section 61 of the ARPANS Act.

ARPANSA has not made its final conclusions regarding the contributing factors to the accident, and when it does so, further enforcement actions may be necessary. However, ARPANSA's compliance monitoring is risk-informed where compliance history of the licensee is one of the determinants of regulatory priority. The prioritisation of compliance monitoring activities and objects is currently under revision and will take this accident into account.

Without pre-empting any remaining conclusions regarding the accident, ARPANSA emphasises the need for consideration of the people-technology-organisation interface and its contribution to safety among licence holders. ARPANSA uses the approach of 'holistic safety'[5] to address this interface. It focuses on technological, human, and organisational aspects—making sure the technology (plant, equipment, tools, apparatus, machinery, etc.) is safe to use; people perform tasks safely at work; and the organisation overall is managed safely. Performance objectives and criteria (PO&C) are used by ARPANSA inspectors to support a rigorous approach to inspection that is consistent with the risk of a facility, source or controlled activity. They provide a comprehensive list of features, controls and behaviours that contribute to safety. When considered with relevant codes and standards the PO&C assist the detailed planning and conduct of each inspection and support a qualitative assessment of safety. A review of ARPANSA's performance objectives and criteria[6] is planned, which will give further consideration to the holistic safety aspects.

[4] See ARPANSA's website, https://www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/australian-radiation-incidents-register/annual-summary-reports

[5] See ARPANSA's website, https://www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/holistic-safety

[6] See ARPANSA's website, https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/inspections/performance-objectives-and-criteria