Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

29 June 2018 **Ref: R18/07432**

Dr Adrian Paterson
Chief Executive Officer
ANSTO
Locked Bag 2001
Kirrawee DC NSW 2232

Dear Dr Paterson

Re: Facility Licence F0262

Decision

For reasons summarised in this correspondence, I believe there is a need to exercise my powers under section 41 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) with regard to activities covered under Facility Licence F0262, issued to the Australian Nuclear Science and Technology Organisation (ANSTO) and carried out by ANSTO Health in Building 23, Lucas Heights Science and Technology Centre, NSW.

Therefore, under section 41(1A) of the Act I **direct** you to:

i) take immediate steps to initiate an independent review of the approach to occupational radiation safety of processes and operational procedures in Building 23, in particular those associated with quality control of molybdenum-99 (Mo-99) samples

ii) appoint an external reviewer and, as necessary, external experts to support the reviewer in carrying out their task including providing recommendations to ANSTO with regard to relevant practices at ANSTO

   a) the external reviewer and supporting experts must be considered suitable for the task by ARPANSA before being appointed by ANSTO

   b) the terms of reference for the review must be approved by ARPANSA

iii) support the review in any way necessary, including but not limited to providing access to facilities and documentation, as well as access to staff under arrangements that enable staff to interact openly with the reviewer

iv) provide ARPANSA with a progress report 30 days after commencement of the review

v) within 60 days after commencement of the review, provide ARPANSA with the final report, including the recommendations by the reviewer and ANSTO's response to those recommendations

vi) at the same time, provide a plan and associated timelines for the implementation of actions responding to the report's recommendations for ARPANSA's approval.

Statement of reasons

Recent events with safety implications

In less than ten months (22 August 2017 – 7 June 2018), four events with safety implications at Building 23 have come to ARPANSA's attention. The activities in Building 23 are carried out by ANSTO Health, under Facility Licence F0262, issued to ANSTO for a *controlled facility* (*nuclear installation*) as defined in the Act.

The events are summarised below. Attachment A provides a chronology of events, and a selection of regulatory interactions relevant to the events, since 22 August 2017.

1. Skin exposure exceeding the statutory dose limit, 22 August 2017

ANSTO advised ARPANSA on 23 August 2017 of an event leading to contamination of the hands of a quality control analyst during a routine quality control procedure at Building 23. The event involved the manual handling of a solution containing a high activity solution of Mo-99 (approximately 4.5 GBq) in a volume of less than one millilitre. Liquid was accidently spread on the surfaces of the fume cabinet and on the analyst's hands. Upon removal of the analyst's gloves, contamination of the skin was detected which was reduced through successive washing and decontamination treatments. However, tissue reactions (deterministic effects) subsequently developed that were not consistent with either the location or level of contamination as reported. The radiation oncologist treating the analyst subsequently estimated that the exposure would have been in the order of 20 Gy, or more, to parts of the skin; this estimate has been corroborated by ARPANSA's modelling of the event. The analyst's symptoms are, approximately 10 months after the event, still evolving.

ARPANSA's inspectors identified a number of shortcomings in the approach to safety that contributed to the event. ANSTO was found in breach of subsection 30(2) of the Act on 19 December 2017 for failing to comply with regulations 46 and 48 of the *Australian Radiation Protection and Nuclear Safety Regulations 1999*, which concern measures taken to prevent accidents and exceeding dose limits, respectively.

The event was rated by ARPANSA as Level 3 (serious incident) on the International Nuclear and Radiological Event Scale (INES)[1] and reported as such to the International Atomic Energy Agency (IAEA) INES Database. In light of the seriousness of the event, I tabled a report in Parliament under section 61(a) of the Act on 26 February 2018, summarising the event and corrective actions to that time. I also indicated that further actions including enforcement actions may be considered. A copy of this report can be accessed via the ARPANSA website at:

https://www.arpansa.gov.au/about-us/corporate-publications/reports-parliament/report-parliament-radiation-exposure-worker-ansto

2. ANSTO Health high activity concentration event for nuclear medicine quality control samples, 23 March 2018

On 23 March 2018, ANSTO informed ARPANSA about a potential non-compliance with Regulation 49 arising by not following its own procedures during the Mo-99 quality control process in Building 23. This resulted in a high activity concentration of 25 GBq per millilitre being prepared rather than the expected concentration of 2.7 GBq per millilitre, considerably higher than specified in ANSTO's procedures, which had been amended after the contamination event recounted above (No 1). No significant additional exposure was incurred by any operator as a result of the deviation; however, it constitutes a degradation of defence-in-depth and any event of a similar nature as event No 1 above could have resulted in even more serious harm.

[1] 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.

A preliminary investigation report was provided by ANSTO to ARPANSA on 3 April 2018 and a second investigation report on 29 May 2018. ARPANSA has issued ANSTO with a letter of potential non-compliance[2] with regulation 49 on 26 June 2018.

3. Implementation of a relevant change with significant implications for safety without prior approval which occurred on 2 May 2018

ANSTO notified ARPANSA on 3 May 2018 of a potential non-compliance with Regulation 51[3] which it became aware of on 2 May 2018. This potential non-compliance was in relation to a Regulation 51 application being assessed at that time by ARPANSA to modify the iodine-123 MIBG[4] process in Building 23. ANSTO reported that the modification had been implemented before approval had been received from ARPANSA. The ANSTO investigation report is currently being finalised and will then be provided to ARPANSA. Once ARPANSA has reviewed the investigation report, it will make a decision on whether a non-compliance has occurred.

4. Event involving spillage of a solution containing Mo-99, 7 June 2018

On the morning of 7 June 2018, while an operator was moving a trolley containing a Mo-99 solution between two rooms in Building 23, the trolley failed when a wheel fell off. The Mo-99 solution that was contained in a vial in a shielded lead pot spilled from the trolley, resulting in contamination of the floor. The solution comprised approximately 900 MBq of Mo-99 in 0.9 millilitres of solution and was part of the quality control process. The operator lightly contaminated their gloves, but no skin contamination was subsequently found by health physics surveyors. However, more significant contamination was present on their overshoes and one safety boot. It has been estimated by ANSTO, and agreed by ARPANSA, that the resultant radiation exposure to the operator was minor.

On 7 June 2018, ARPANSA undertook a site visit to examine the preserved scene. An augmented inspection was subsequently undertaken on 12 June 2018. The inspection report is currently being prepared which will report on any findings of potential non-compliance.

Since the event, an INES assessment has been made by ARPANSA. The potential for serious contamination causes the event to be classified at Level 1 (anomaly) on the INES scale.

Considerations

In December 2017 in relation to the accident in August 2017, ANSTO was found to be in breach of section 30(2) of the Act, as a result of not taking all reasonably practicable steps to prevent accidents involving controlled materials and significantly exceeding a statutory annual dose limit. However, despite having been issued these breach notices, a further set of three events has occurred in a period of less than ten months, including a contamination event, all of which *prima facie* would seem to constitute breaches of section 30(2) of the Act. The fact that these events continue to occur causes me to believe that the practices in Building 23 pose a risk for harm and that there is an urgent need to identify underlying shortcomings in ANSTO's approach to safety in order to minimise that risk.

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[2] A licence holder is given 28 days to advise ARPANSA whether the licence holder disagrees with the potential non-compliance and may during this period also provide supplementary information, before ARPANSA's makes a final determination regarding the potential non-compliance.

[3] Regulation 51 states that "The holder of a licence must seek the CEO's prior approval to do either of the following things if it will have significant implications for safety;

(a) change the details in the application for a licence;

(b) modify the source or facility mentioned in the licence."

[4] MIBG, meta-iodobenzylguanidine, is used for imaging tumours in nuclear medicine

I conclude that systemic issues related to the safety practices in Building 23 need to be reviewed in order to firstly identify shortcomings in the approach to occupational radiation safety of processes and operational procedures in Building 23, in particular those associated with quality control of Mo-99 samples; and secondly provide ANSTO with recommendations for improvement. On this basis, a plan of action must be developed by ANSTO for ARPANSA's approval. This plan must also address the safety of quality control procedures in Building 2 Active Laboratory carried out for the ANSTO Nuclear Medicine Mo-99 Facility, which received a licence to operate with conditions on 12 April 2018 (Facility Licence F0309).

I acknowledge that ANSTO has taken actions in relation to events No.1–4 above and has been forthcoming and responded to ARPANSA's requests for further action. ANSTO has also re-assessed risks and hazards, and the effectiveness of controls in relation to activities in Building 23. The actions have gone some way to reducing the risk for recurrence of similar events, but so far have not satisfactorily explored systemic issues. The nature of the events, which all broadly relate to the approach to safety, lead me to conclude that the safety objective[5] would be best served through an external and independent review.

ARPANSA exercises a graded approach to licence holder non-compliance. The escalation of enforcement actions is schematically illustrated below. A copy of ARPANSA guidance which outlines the escalation of enforcement actions can be found on ARPANSA's website at: ***https://www.arpansa.gov.au/sites/g/files/net3086/f/reg-com-sup-270j.pdf***

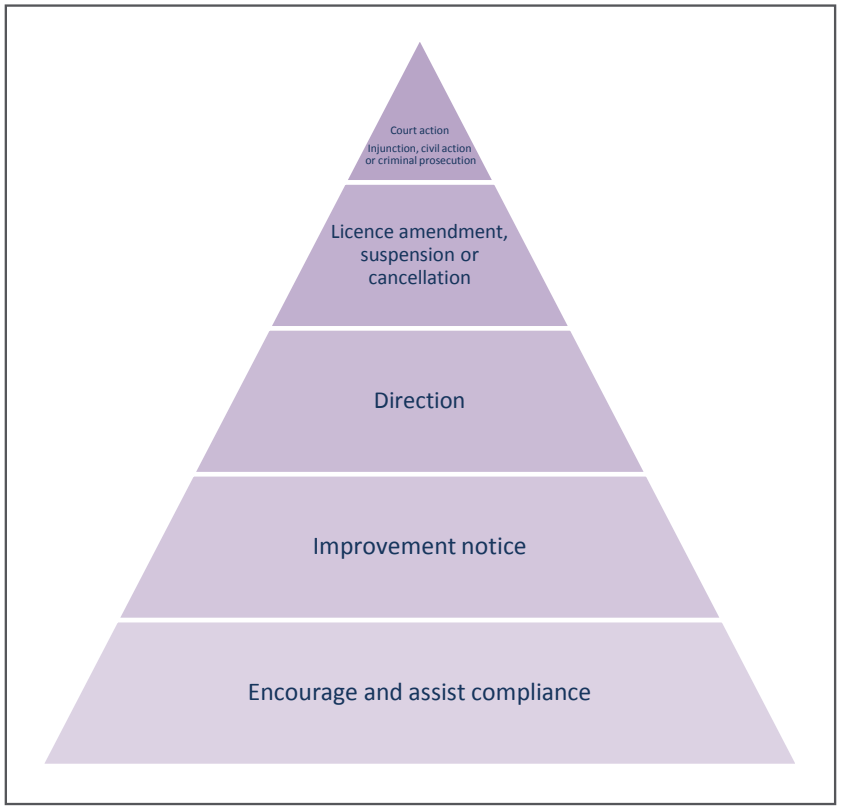

Figure 1. Schematic illustration of the escalation of enforcement actions.
From ARPANSA's Regulatory Guide: *Graded approach to dealing with licence holder non-compliance* v3, March 2017

Notwithstanding the actions taken so far by ANSTO, I consider that the systemic issues contributing to events in Building 23 and the fact that one such event has led to serious injury, and that other events have led to loss of defence in depth and potential for injury, indicate that enforcement actions below a direction would not suffice or be otherwise well suited to the circumstances.

[5] The object of the ARPANS Act is stated in section 3 of the Act: "The object of this Act is to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation."

On the higher end, amendment of the licence would not achieve the desired outcome, and suspension or cancellation of the licence would not be proportionate to the risk when also taking into account the potential impact on the global supply of Mo-99 and its decay product technetium-99m (Tc-99m) for nuclear medicine procedures[6].

I conclude that a direction is the most appropriate enforcement action under the given circumstances. Section 41 of the Act gives me the power to issue such direction to a controlled person. Section 41(1A) of the Act states that the CEO may give directions to controlled persons if:

(a) the CEO believes, on reasonable grounds, that there is a risk of death, serious illness, serious injury or serious damage to the environment, arising from radiation, in connection with a controlled facility, controlled material or controlled apparatus

(b) the CEO believes that there is an urgent need to exercise powers under this section in order to minimise the risk.

I consider section 41(1A) to be an appropriate basis for issuing ANSTO with a direction in relation to events and practices in Building 23.

This matter was discussed in detail by members of the Nuclear Safety Committee[7] at the Committee meeting held on 22 June 2018, where the members in attendance unanimously endorsed ARPANSA's enforcement approach, including issuing a direction, in relation to the events in Building 23.

How to seek review of this decision

As my decision is reviewable under section 42 of the Act, please note that you may make a request to ARPANSA's responsible Minister, the Minister for Rural Health, to reconsider my decision to issue this direction. Any such request must be made in writing and submitted to the Minister within 28 days of the date of this letter. The Minister must reconsider the decision and confirm, vary or set aside the decision. If a response from the Minister is not received within 60 days of the request, this is deemed to be confirmation of my decision. A request for review of the Minister's decision may, in turn, be made to the Administrative Appeals Tribunal.

Additional information

Pursuant to section 41(4) of the Act, I will provide a copy of the direction to the Minister for Rural Health. Section 41(5) requires the Minister to cause a copy of the direction to be tabled in each House of the Parliament within 15 sitting days of that House after the direction has been given.

The direction will be listed in ARPANSA's Quarterly Report for the 2nd Quarter of 2018 and in the 2017–18 Annual Report of the CEO of ARPANSA.

Yours sincerely

Carl-Magnus Larsson
CEO of ARPANSA

[6] The NTP Facility in South Africa is currently not producing Mo-99.

[7] The Nuclear Safety Committee is established under section 25 of the Act. Among the functions is to advise the CEO on matters relating to nuclear safety and the safety of controlled facilities. More information on the Nuclear Safety Committee is available at: ***https://www.arpansa.gov.au/about-us/advisory-council-and-committees/nuclear-safety-committee***

Attachment A

Chronology (selected)

Date	Action
22 August 2017	A Mo-99 contamination event occurred during a quality control procedure in Building 23.
23 August 2017	ARPANSA notified of Mo-99 contamination event in Building 23.
31 August 2017	ARPANSA receives a preliminary dose assessment of the event.
6 September 2017	ARPANSA undertakes a site visit to discuss event details.
21 September 2017	ARPANSA receives first photos from ANSTO regarding the employee's medical condition.
22 September 2017	ANSTO provides investigation report into the event.
4 October 2017	Letter of potential non-compliance under Regulations 46 and 48 is issued to ANSTO, also requesting responses to a set of questions.
4 October 2017	ARPANSA uploads details of the event on INES website at level 3 (serious incident).
4 October 2017	ARPANSA undertakes a site visit to ANSTO to verify corrective actions identified immediately after the event have been implemented.
1 November 2017	ARPANSA receives response to ARPANSA letter of potential non-compliance of 4 October.
8-9 November 2017	ARPANSA undertakes an augmented inspection to investigate human and organisational safety factors surrounding the event.
17 November 2017	ARPANSA receives independent advice on the nature of the employee's injuries.
19 December 2017	ANSTO are found in breach of section 30(2) of the ARPANS Act by failing to comply with regulations 46(1) and 48(1)(a).
24 January 2018	ARPANSA receives a report from radiation oncologist revising the dose estimate to at least 20 Gy.
29 January 2018	ARPANSA produces an independent dose reconstruction report confirming the magnitude of the estimated exposure (20 Gy).
31 January 2018	ARPANSA receives a corrective action plan from ANSTO to reduce the radiation risk in quality control operation in Building 23.
2 February 2018	ARPANSA undertakes site visit of Building 2 quality control laboratory.
5 February 2018	ARPANSA site visit of Building 23 to verify actions arising from the investigation report have been undertaken.
26 February 2018	The CEO of ARPANSA submits a special report to Parliament under Section 61(1) of the Act on the contamination event.

Date	Action
23 March 2018	ANSTO notifies ARPANSA of an event in Building 23 where activity concentration of quality control samples is found to be approximately 9 times higher than expected.
3 April 2018	ANSTO provides investigation report into high activity concentration samples.
6 April 2018	ARPANSA site visit to gather information on the high activity concentration event.
12 April 2018	ANSTO provides a review of high risk/high hazard tasks in Building 23.
1 May 2018	ARPANSA provides responses to ANSTO high risk/high hazard report.
3 May 2018	ARPANSA notified by ANSTO of a potential non-compliance in Building 23 under Regulation 51 for iodine123 MIBG production.
3 May 2018	ARPANSA site visit of Building 23 to review Health Physics records of event on 22 August 2017.
7 May 2018	ARPANSA site visit of Building 23 in response to potential non-compliance of Regulation 51 for MIBG process.
29 May 2018	ANSTO provides second investigation report into the high activity concentration samples.
7 June 2018	ANSTO notifies ARPANSA of Mo-99 spilled from a trolley, lightly contaminating an employee.
7 June 2018	ARPANSA undertakes a site visit of Building 23 to examine the scene.
8 June 2018	ANSTO provides investigation report and corrective actions into spilled trolley event, requesting permission to restart production of Mo-99 on 10 June 2018.
9 June 2018	ARPANSA provides letter to ANSTO granting permission subject to conditions.
11 June 2018	ANSTO provides updated high risk/high hazard assessment report incorporating ARPANSA comments.
12 June 2018	ARPANSA undertakes augmented inspection at Building 23, verifying that conditions in letter of 9 June have been met.
21 June 2018	ARPANSA provides preliminary INES assessment of spilled trolley event to ANSTO at level 1 (anomaly).
22 June 2018	ARPANSA's Nuclear Safety Committee meets and discusses the CEO of ARPANSA's proposed direction to ANSTO regarding recent events at Building 23, and endorse this enforcement approach.
26 June 2018	Letter of potential non-compliance is issued to ANSTO regarding the activity concentration of quality control samples that had the radioactivity concentration approximately 9 times higher than expected.