Gemma Larkins

From: Tone Doyle
Sent: Monday, 18 June 2018 4:54 PM
To: LEHRMANN, Bruce
Cc: $ARPANSA Parliamentary Correspondence
Subject: ANSTO Health incident update [SEC=UNOFFICIAL]

Follow Up Flag: Follow up
Flag Status: Completed

Hi Bruce

Firstly, thank you so very much for your help with our exco papers, we are beyond grateful.

I've put together some dot points on the latest ANSTO Health incident – see below. It's looking very likely that Carl-Magnus will issue a formal direction (the first by ARPANSA). I'll keep you updated on how its progressing but would be grateful for your advice as to when you think we should formally brief the Minister. Perhaps CM can call her directly? Or meet with her in Canberra? Or we can get an information brief up this week.

- As previously advised, there was an incident at ANSTO Health on 7 June 2018 when a spill of Mo99 occurred from a trolley in Building 23.
- ARPANSA immediately requested that ANSTO provide an investigation report and a list of corrective actions for review before ANSTO could restart its Mo99 production (nuclear medicine).
- On 9 June ARPANSA received and reviewed the investigation report from ANSTO, which included a list of corrective actions. ARPANSA was satisfied that Mo99 production could safely recommence on 10 June subject to conditions.
- ARPANSA conducted an augmented inspection on 12 June to:
    - conduct interviews with personnel involved in the incident on 7 June,
    - verify the conditions on ANSTO stipulated in the letter of 9 June had been met ;and
    - witness some operational tests related to the incident.
- At a meeting with the CEO of ANSTO on Friday 15 June, Carl-Magnus advised ANSTO that a direction under s41(1A) of the ARPANS Act is the most likely outcome.
- The decision to issue a direction is based on the fact that this is the 4th incident at ANSTO Health in 10 months. Events include:
    - the serious accident (hand contamination) that occurred in August 2017,
    - followed by two near miss events during the Quality Control process (with potentially similar root causes); and
    - a regulation change with potential significant safety implications under Regulation 51 that was implemented without prior approval.
- Carl-Magnus is working to finalise the direction by the end of this month. As soon as possible after giving the direction, CM will provide a copy to the Minister. The Minister must then cause a copy of the directions to be tabled in each House of the Parliament within 15 sitting days of that House after the directions have been given.

Let me know if you need any more info – I've kept it pretty high level for now.

T

Ms Tone Doyle
Chief of Staff
Office of the CEO

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Gemma Larkins

From: Tone Doyle
Sent: Friday, 22 June 2018 11:08 AM
To: LEHRMANN, Bruce
Cc: $ARPANSA Parliamentary Correspondence; Nathan Wahl; James Wheaton
Subject: RE: ANSTO Health incident update [DLM=For-Official-Use-Only]

Hi Bruce

Confirming CM **will** issue a direction under section 41(1A) of the ARPANS Act. Likely end of next week.

Decision to issue a direction is based on recent safety events. CM has reason to believe that there is a risk of serious injury to personnel involved in quality control processes at Building 23, and also, by inference, at Building 2. Incidents include:

- Skin exposure exceeding a statutory dose limit, 22 August 2017
- ANSTO Health high activity concentration event for nuclear medicine Quality Control samples, 3 March 2018
- Implementation of a relevant change with significant implications for safety without prior approval in Building 23, 2 May 2018
- Event involving spillage of a solution containing Mo-99 in Building 23, 7 June 2018

The direction will likely include:

a) undertake an independent investigation of the safety of processes and operational procedures associated with quality control of Molybdenum-99 (Mo99) samples in Building 23 as soon as practicable;

b) appoint an external independent investigator, and a corresponding ANSTO investigation team as necessary;

c) support the investigation in any way necessary, including, but not limited to, providing access to facilities, documentation, staff and arrangements that enable staff to interact openly with the investigation team without restriction;

d) implement recommendations from the independent investigation to the Building 23 Quality Control process, unless by agreement with ARPANSA that alternative actions and arrangements could achieve comparable outcomes; and,

e) implement recommendations from the independent investigation, as relevant, to the quality control process in the Building 2 Active Laboratory.

We are preparing a sub as the Minister will need to table it within 15 sitting days.

Will it be possible for CM to call the Minister next week to verbally brief her, in addition to the Sub?

I will call you this arvo.

T

From: Tone Doyle
Sent: Monday, 18 June 2018 4:54 PM
To: 'LEHRMANN, Bruce' <Bruce.Lehrmann@health.gov.au>
Cc: $ARPANSA Parliamentary Correspondence <Parliamentary@arpansa.gov.au>
Subject: ANSTO Health incident update [SEC=UNOFFICIAL]

Hi Bruce

Firstly, thank you so very much for your help with our exco papers, we are beyond grateful.

I've put together some dot points on the latest ANSTO Health incident – see below. It's looking very likely that Carl-Magnus will issue a formal direction (the first by ARPANSA). I'll keep you updated on how its progressing but would be grateful for your advice as to when you think we should formally brief the Minister. Perhaps CM can call her directly? Or meet with her in Canberra? Or we can get an information brief up this week.

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Let me know if you need any more info – I've kept it pretty high level for now.

T

Ms Tone Doyle
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Gemma Larkins

From: Maryanne Macnamara on behalf of $ARPANSA Licence Administration
Sent: Friday, 29 June 2018 2:36 PM
To: Adi Paterson (adi.paterson@ansto.gov.au)
Cc: Carl-Magnus Larsson; Jim Scott (Jim.Scott@arpansa.gov.au)
Subject: Facility Licence F0262 - Letter of Direction [SEC=UNCLASSIFIED]
Attachments: Letter of Direction to ANSTO Facility Licence F0262 - June 2018.pdf

Good afternoon

Please find attached letter regarding Facility Licence F0262 as signed by the CEO of ARPANSA.

Kind regards

Licence Admin
Regulatory Services Branch

Australian Radiation Protection and Nuclear Safety Agency
Level 2 38-40 Urunga Parade Miranda NSW 2228 AUSTRALIA

licenceadmin@arpansa.gov.au
www.arpansa.gov.au

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[4] 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[5] 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[6] 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 (a 'near miss') 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 near miss 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.

[4] 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.

[5] 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."

[6] 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 7 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 has 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[1] 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***

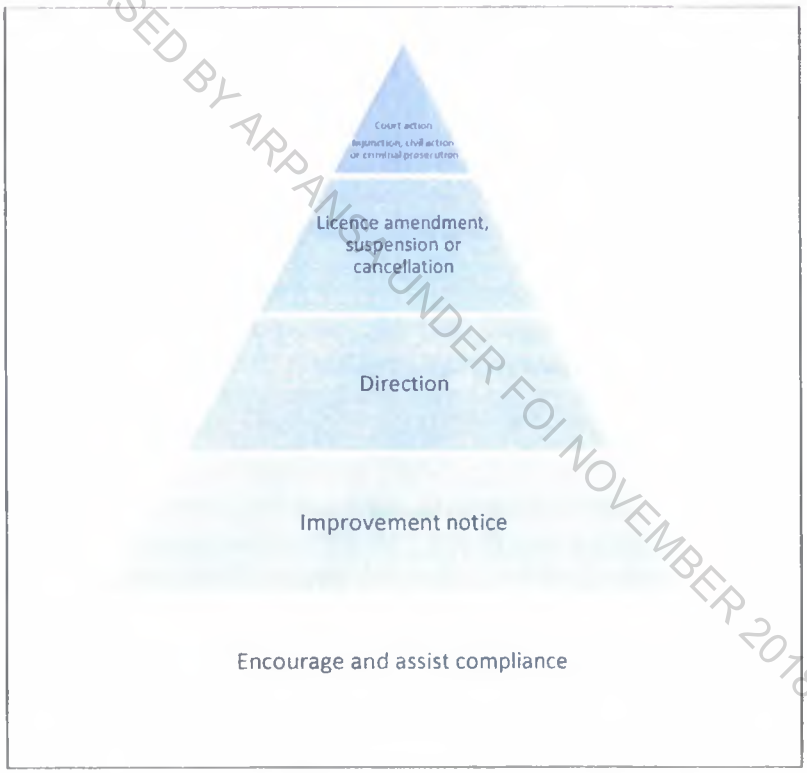

Figure 1. Schematic illustration of the escalation of enforcement actions.
From ARPANSA's Regulatory Guide: *Graded approach to dealing with licence holder non-compliance* v3, March 2017

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.

[1] 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[1].

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[2] 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

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

[2] 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.

Gemma Larkins

From: Nathan Wahl
Sent: Friday, 29 June 2018 3:37 PM
To: MGC Policy and Operations
Cc: $ARPANSA Parliamentary Correspondence; Carl-Magnus Larsson; Tone Doyle; Jim Scott
Subject: MS18-001400 - Tabling of Direction to ANSTO [DLM=For-Official-Use-Only]
Attachments: Attachment A - ANSTO direction.pdf; Attachment D - arpansa_s61 _report_-_radiation_exposure_of_a_worker_at_an....pdf; Ministerial Submission - Direction to ANSTO 28Jun18 - final.docx

Dear MGC,

Please find attached a MinSub seeking Minister McKenzie's permission to table a direction which has been issued to ANSTO today. This MinSub has been cleared by Carl-Magnus Larsson, CEO of ARPANSA.

Note Attachments B & C are in the word document.

Kind regards,
Nathan

Nathan Wahl
Assistant Director
Government and International Relations
Office of the CEO

Australian Radiation Protection and Nuclear Safety Agency
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Australian Government
Department of Health

UNCLASSFIED
FOUO
Ministerial Submission – Release of Report
MS18-001400 Version (1)
MPF to complete **Date sent to MO:<dd/mm/yy>**

To: Minister McKenzie
cc: Minister Hunt
Subject: TABLING OF DIRECTION TO AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION (ANSTO)

Critical Date: 16 July 2018 – To enable tabling in Parliament in a timely manner and in accordance with legislative requirements (see timing below).

Recommendations:

1. Approve the release and tabling in Parliament of the CEO of ARPANSA's letter of direction to ANSTO (Attachment A).	**1. Approved / Not approved**
2. Sign the transmittal letter to the President of the Senate at Attachment B, presenting the direction for tabling.	**2. Signed / Not signed**
3. Sign the letter advising ANSTO's Minister of tabling (Attachment C)	**3. Signed / Not signed**

Signature: ..... **Date:** / /

Comments:

Contact Officer:	*Nathan Wahl*	*Assistant Director, Government & International Relations*	Ph: (03) 9433 2322 Mobile: s 47F - privacy
Clearance Officer:	*Carl-Magnus Larsson*	*CEO of ARPANSA*	Ph: (02) 9541 8501 Mobile: s 47F - privacy

Report Details: The CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Dr Carl-Magnus Larsson, has issued ANSTO with a direction under section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) which applies when:

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

The CEO of APRANSA decided to issue the direction following four separate events with safety implications at ANSTO's Lucas Heights facility in less than 10 months. The first and most significant incident was the contamination accident of a staff member's hand on 22 August 2017. Subsequent to that accident, the CEO of ARPANSA found ANSTO in breach of the Act and, due to its severity, tabled a report in Parliament on 26 February 2018 under section 61(1) of the Act summarising the event and corrective actions (Attachment D).

The other three events, which occurred on 23 March, 2 May and 7 June 2018, demonstrate failures in safety protocols and procedural inadequacies.

While only one event has resulted in actual harm to staff, the systemic nature of these safety related events at ANSTO has led the CEO of ARPANSA to believe there is a risk of serious injury to ANSTO staff, in particular those involved in quality control processes for the production of molybdenum-99 (Mo-99).

The direction to ANSTO requires it 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; and

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.

The four events are outlined in the letter of direction, and are the subject of ongoing investigations. Further enforcement actions under the Act may follow.

Timing: The proposed timing to publicly release the report via tabling in Parliament is 17 July 2018 when the Senate is not sitting. Section 41(5) of the Act requires the Minister to cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of receiving the report. Tabling the report prior to the community votes in South Australia, referenced below (see 'Community Awareness'), will help mitigate the risk of any public perception of information relevant to the vote being withheld.

Community Awareness: Community votes on the proposed National Radioactive Waste Management Facility (NRWMF) are scheduled to occur in Kimba and Hawker on 20 August 2018. Therefore, this direction and the incidents at ANSTO may affect public or media perceptions of ANSTO given its significant involvement in the waste management project.

Impact on Rural and Regional Australians: No direct impact on rural or regional Australia. However, the communities around the towns of Kimba and Hawker in South Australia are involved in the community vote mentioned above.

Consultations: The Department of Health and ANSTO were consulted in the lead-up to the decision to issue a direction.

Attachments:

A. ANSTO Health – Facility Licence F0262 – direction under Section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*
B. Transmittal letter to the President of the Senate
C. Letter advising ANSTO's Minister of tabling
D. 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*

Senator the Hon Bridget McKenzie
Deputy Leader of The Nationals
Minister for Rural Health
Minister for Sport
Minister for Regional Communications
Senator for Victoria

Ref No: MS18-001400

July 2018

Senator the Hon Scott Ryan
President of the Senate
Parliament House
CANBERRA ACT 2600

Dear Mr President

Pursuant to standing order 166, relating to the presentation of documents when the Senate is not sitting, I present to you a direction from the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency to the Australian Nuclear Science and Technology Organisation (ANSTO).

Yours sincerely

Bridget McKenzie
Minister for Rural Health, Minister for Sport

Encl (1) ANSTO Health – Facility Licence F0262 – direction under Section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*

Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

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*

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

arpansa

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*

Further information about this publication

If you would like to know more about the content of this publication please contact ARPANSA on 1800 022 333 or **info@arpansa.gov.au**. Further information can be found on the ARPANSA website at **www.arpansa.gov.au**.

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.

Printed by:

CanPrint Communications Pty Ltd
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Fyshwick ACT 2609

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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

Senator the Hon Bridget McKenzie

Deputy Leader of The Nationals
Minister for Rural Health
Minister for Sport
Minister for Regional Communications
Senator for Victoria

Ref No: MS18-001400

Senator the Hon Michaelia Cash
Minister for Jobs and Innovation
Parliament House
CANBERRA ACT 2600

Dear Minister

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has submitted to me a direction to the Australian Nuclear Science and Technology Organisation (ANSTO), provided to them on 29 June 2018. I propose to table the direction in Parliament on 17 July 2018 via the President of the Senate while the Senate is not sitting.

The direction, issued under section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*, contains details of four separate events with safety implications at ANSTO's Lucas Heights facility in less than 10 months. The first and most significant incident was the contamination accident of a staff member's hand on 22 August 2017. The other three events, which occurred on 23 March, 2 May and 7 June 2018, also demonstrate failures in safety protocols and procedural inadequacies.

While only one of the recent events has resulted in actual harm to a staff person, the systemic nature of these safety related events has led the CEO of ARPANSA, Dr Carl-Magnus Larsson, to believe there is a risk of harm to ANSTO staff and an urgent need to reduce that risk.

The direction requires ANSTO to initiate an independent review of its approach to occupational radiation safety, and subsequently provide a plan with timelines to implement actions in response to any recommendations from the review's report.

ANSTO were consulted in the lead-up to the decision to issue a direction. If you require further information, please do not hesitate to contact my office.

Yours sincerely

Bridget McKenzie
Minister for Rural Health, Minister for Sport

cc: Senator the Hon Matt Canavan;

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Contact Officer Nathan Wahl
(03) 9433 2322
s 47F - privacy

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Division/Branch Australian Radiation Protection and Nuclear Safety Agency

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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.

Gemma Larkins

From: Jim Scott
Sent: Friday, 6 July 2018 4:20 PM
To: Vaz Mottl
Subject: FW: CVs of potential independent reviewers [SEC=UNOFFICIAL]
Attachments: AK_CV_3TSC.PDF; DJCV1b.pdf; LYNN WILLIAMS NuclearCC - CV.PDF; TUCK Matt CV.PDF; CV Wilson Sarah_for Adam.pdf; CV Marshall Julie_for Adam.pdf

Hi Vaz

Please put in HPREM.

Regards
Jim

From: GRIFFITHS, Hefin <hwg@ansto.gov.au>
Sent: Friday, 6 July 2018 12:59 PM
To: Jim Scott <Jim.Scott@arpansa.gov.au>
Cc: BERGHOFER, Paula <pbz@ansto.gov.au>
Subject: CVs of potential independent reviewers [SEC=UNOFFICIAL]

Jim,

In accordance with the direction issued by ARPANSA, I attach for review the CVs of the proposed personnel to undertake the review. The contractual arrangements have not been finalised as yet, but in order to expedite the response to the direction, I would like ARPANSA's endorsement of the capability of the review team.

The team will be led by David Jones, who has 40 years' experience in the nuclear industry in both the UK and French regulatory regimes. Dave will be supported by Matt Tuck, (Radiation Protection specialist), Lynn Williams (Safety culture and organisational capability) and Sarah Wilson (Human Factors / ergonomics). These 4 will visit Australia, with reach back to Adam Kilborn and Julie Marshall in the UK.

Resource	Company	Role	
David Jones	3TSC (Associate)	Overall Co-ordination, review of HAZID, Hazard Analysis, safety management	
Matt Tuck	Matom	Radiation Protection Specialist	
Adam Kilborn	3TSC	Project Management, Hazard Analysis review	
Lynn Williams	Nuclear cc	Nuclear Baseline, Quality Systems, Safety Culture	
Sarah Wilson	3TSC (Associate)	Human Factors, Ergonomics	Endorsed on linkedin by Stuart Parr
Julie Marshall	3TSC (Associate)	Human Factors, Safety Culture	Endorsed on linkedin by Stuart Parr

The company profiles are:
http://www.3tsc.co.uk/
http://www.matom.com/
http://nuclearcc.co.uk/

https://www.ergonomics.org.uk/marshallwilson

Hefin Griffiths
Chief Nuclear Officer
Office of the CEO

Australian Nuclear Science and Technology Organisation

Tel +61 2 9717 3295
Mobile 0458474599
Email hwg@ansto.gov.au
Web www.ansto.gov.au

3T SAFETY CONSULTANTS

Adam Kilborn - Curriculum Vitae

QUALIFICATIONS: BSc Chemical Engineering (Birmingham Univ.) - 1987
CEng MIChemE - 1993
MSc(Eng) Process Safety & Loss Prevention (Sheffield Univ.) - 1994
NEBOSH Certificate - 1996

SECURITY: SC

PROFILE:

A chartered chemical engineer with an MSc in Safety and Loss Prevention. Has over 25 years' experience in safety and risk management within the nuclear industry for a wide variety of clients on projects including new build, major modification, continued operation and decommissioning. Extensive experience in the production of safety case documentation and management of major safety case projects and programmes.

RELEVANT EXPERIENCE:

Feb 2009 - Present **3T Safety Consultants Ltd**

- Seconded Magnox safety case intelligent customer for the SGHWR core segmentation design and build
- Production and verification of documentation in support of the LC15 periodic review of the Silo safety case for DSRL
- Safety Case Manager for Shaft and Silo Retrievals Project for DSRL (including production of Concept Design PSR and Scheme Design PCSR)
- Seconded Safety Case Project Manager for all safety case support to RSRL (now Magnox) Winfrith site
- Management of production of overarching Decommissioning Safety Case for Dragon Reactor at RSRL (now Magnox), Winfrith
- Production of overarching Decommissioning Safety Case for SGHWR at RSRL (now Magnox), Winfrith and production, management or review of all subsequent modifications (including the modification of the SGHWR Primary Containment Deplanting and the PSR for SGHWR Remote Core Decommissioning)
- Production of re-categorisation modification and safety case HAZANs for B459, RSRL (now Magnox), Harwell
- Production of various modification safety cases to the Operational Safety Case for B462, RSRL (now Magnox), Harwell
- Production of significant HAZANs and safety case management role of all other HAZANs for the D3900 PCSR for DSRL, Dounreay
- Peer review of modification safety cases for RSRL (now Magnox), Harwell
- Preparation of radiological HAZAN training

Aug 2001 – Feb 2009 **DGP International Ltd / Scott Wilson Ltd**

- Manager of Safety and Risk Management Department (including tender production and management of £2.5M P&L account).
- HAZAN author for Windscale Pile 1 Decommissioning Safety Case.
- Safety case manager for production of D3900 PCSR for the BAND Alliance and lead safety case author for the subsequent DSRL/Nuvia Design Authority.
- Nominated peer reviewer for DRDL submarine fuel handling safety cases.
- Production of Plant Ancillaries Workshop Continued Operation Safety Report for Urenco Capenhurst Ltd..
- Production of safety justification in response to NII improvement notice for cell line interlocks at GE Healthcare.
- UKAEA Dounreay Safety Case Project Manager for D2700 (DCP) Modern Standard Safety Case, D3000 (LLLETP) Modern Standards Safety Case, DCP Import Export Facility PCSR.
- Production of D8570 (WRACS) Modern Standards Safety Case and input into D2900 (EMDC) Modern Standards Safety Case for UKAEA Dounreay.
- Argon dispersion modelling and reliability assessment for fire suppression system for Active Vault Waste Retrieval project for Magnox, Berkeley
- Independent member of the UKAEA Dounreay Waste Management Group Safety Working Party.
- Consultancy to UKAEA Harwell: specification of approach to ALARP prioritisation of actions arising from Site Periodic Safety Review (PSR); advice regarding the implementation of engineering substantiation; review of process for management of modification in response to NII inspection; preparation of working instruction addressing arrangements for extending the validity of safety cases; advice of DBA/SIL targets for proposed shielded cell line interlock arrangements; reliability assessments for various new plant in B459 and B462; management and production of numerous PSR/PCSR/PCmSR for projects within B459 and B462.
- Specification of Decommissioning Safety Principles for British Energy.
- Specification of key safety features for UKAEA Windscale Pile 1.
- Lead Safety and Risk Management consultant on B38 Alliance for BNFL

Aug 1999 – Aug 2001 **AEA Technology Consulting**
Senior Project Manager

- Project management of range of safety/risk consultancy contracts totally in excess of £1.5M per year for UKAEA, Dounreay; responsibility for technical delivery, financial performance, identification and development of business.
- Safety Case Project Manager on behalf of UKAEA Dounreay for Fast Reactor Fuel Reprocessing Plant, Low Level Liquid Effluent Treatment Plant and MTR Raffinate Cementation Plant; responsibility for satisfactory technical delivery against agreed timescales and costs.
- Independent member of Waste Management Group Safety Working Party (Dounreay).

Aug 1991 – Aug 1999 **AEA Technology**
Senior/Principal Safety Consultant

- Project management and production of safety case documentation for a wide variety of civil and military nuclear customers (UKAEA, DML, MoD, AWE, US DoE).
- Hazard assessment (including HAZOP studies, consequence analysis, fault/event tree analysis).
- Preparation of peer reviews.

- Preparation and delivery of training courses.
- Membership of UKAEA Safety Working Parties (including representing UKAEA Director of Safety).
- Project risk management.
- AEA Technology representative on worker risk industry working group.
- Management of Y2K consultancy project for UKAEA, Dounreay (>£0.5M).

Mar 1989 – Aug 1991 **Deeside Titanium Ltd. (Rolls-Royce)**
Process Engineer

- Responsible for various development projects associated with the improvement of titanium product quality.
- Study into the statistical process optimisation of a high temperature reaction process.
- Technical and economic feasibility study into an integrated production facility for titanium.

Nov 1987 – Mar 1989 **Elgar Phosphors (Thorn Lighting Ltd.)**
Chemical Engineer

- Production support.
- Design, installation and commissioning of various chemical engineering capital projects (including continuous process plant for firing of phosphors, phosphor milling processes, liquid reagent mixing and reaction plant, automatic unloading of bulk raw materials).

DAVID JONES

Security Clearance: DV (A&P)

Date of Birth: 04 January 1957

Education: BSc (Hons) Chemistry
Bristol University, 1978

Languages: English (mother tongue)
French (fluent)

SUMMARY

Dave has worked in the nuclear industry for approximately 40 years in a variety of technical and management roles. He is a highly experienced manager of departments and teams with a proven track record in the nuclear safety and risk management consultancy field. He has considerable programme and complex project management experience including change and transition management and the development and implementation of business management systems. In addition, he has extensive experience in strategic development and the application of both the UK and French nuclear regulatory systems.

He was heavily involved in the management of the production of safety cases developed in support of licensing of UKAEA, Devonport and AWE nuclear sites. He has been closely involved with the management of nuclear projects and safety case programmes and the production and review of safety cases for nuclear operators for approximately 30 years including the sites at Dounreay, Windscale, Harwell, Winfrith, Devonport, Amersham (GE) and Aldermaston. More recently, he has worked on nuclear projects in the area of nuclear safety and risk management for Devonport Dockyard, ITER, AWE, SCK-CEN, EdF (new build) and NDA RWM. Of particular relevance are the following:

- Management and production of the safety case and safety assessment methodology manuals for several licensees including:
  - The UK Nuclear Decommissioning Authority's Radioactive Waste Management department responsible for the future geological disposal facility for the UK's legacy and future radioactive waste
  - Management and production of GE Healthcare Safety Case and Assessment Manual for the Amersham, Harwell and Cardiff licensed sites
  - Member of technical team developing safety case and assessment methodologies and procedures for inclusion in Agility management system for the Devonport nuclear licensed site
  - Review and gap analysis study for EdF on the requirements for LC14 arrangements and the supporting safety case manual/assessment methodologies required to support the commissioning and operation of the Hinkley Point C PWR
  - Member of technical team responsible for the development of procedures for the UKAEA Safety Assessment Handbook and its implementation through training courses on all UKAEA sites
- Management of the GE Healthcare "modern standards" safety case update programme which required the management of mixed contractor and GE teams to deliver a challenging safety case programme which included the Drytec Mo-99 generator production facility, the F-18 radiopharmaceutical production facility, the site ILW storage facility, cyclotron facilities, shielded cave production facilities, glove box/fume cupboard production facilities and legacy material storage facilities.

He was a member of the team managing and producing the Drytec facility operational safety case and has extensive experience in the management of projects requiring cooperation between several different contractors and the associated stakeholder management. In addition, he is a recognised trainer in the field of safety management and safety assessment techniques.

RELEVANT EXPERIENCE

JD Solutions (August 2014 – Present), Partner

Technical consultant to nuclear industry including the following projects:

- Project Manager and leading technical consultant for the NDA RWM Nuclear Operational Safety Manual development for safety case content and safety assessment approaches including development of systems engineering approach including integration of design and safety for future implementation
- Independent oversight/expert adviser (peer review) and further development of the 2016 update of the geological disposal facility operational safety case including the preliminary REPPIR assessment and HAZANs for radioactive waste streams/packages
- Support to development of RWM technical programme in the areas of nuclear site licensing and safety case submissions
- Technical support to development of a methodology for determination of design basis external hazards for a future geological disposal facility
- Delivery of a training programme for AWE on the French nuclear regulatory system
- Independent member of an AWE Safety Assessment Panel for the joint UK/French project and technical advisor on nuclear safety requirements and independent assurance function for safety reports
- Nuclear safety advice and assistance to AREVA TA project team for the MYRRHA research reactor, Mol, Belgium
- Ongoing support to the site wide Periodic Review of Safety (including post Fukushima) for the Devonport nuclear site
- Benchmarking review of LC14 arrangements and implementation through Safety Case Manuals on behalf of EdF NNB for the Hinkley Point C reactor project
- HAZOP chair for range of projects for ITER, DRDL and AREVA
- Provision of training courses for UK nuclear organisations on nuclear safety and safety assessment techniques including AWE, DSRL, DRDL, AREVA

AREVA TA (June 2009 to August 2014), Senior Technical Consultant, Level 1 AREVA Expert

Senior technical consultant within AREVA TA providing technical consultancy to the following projects:

- Management of key sections and review of other sections of the Rapport Préliminaire de Sûreté (RPrS) for the ITER fusion facility at Cadarache
- Lecturer for the provision of a training programme for ITER on the French nuclear regulatory system
- Management of project for the safety assessment of the vacuum window confinement system for the ITER Ion Cyclotron Heating and Current Drive system
- Assistance to AREVA TA project team for the Hanford Mobile Hot Cell retrievals project including provision of consultancy on NaK handling and disposal
- Provision of training courses for UK nuclear organisations on nuclear safety and safety assessment techniques including AWE, DSRL, DRDL
- Lead Periodic Review of Safety (PRS) author for Devonport site wide safety management and infrastructure systems including consideration of post Fukushima accident requirements and responses to ONR considerations
- Safety Manager for the Near Surface Repository for intermediate level waste for the Ignalina reactor site in Lithuania
- Project Manager and leading technical consultant for Devonport safety assessment methodology for safety case content and safety assessment approaches for inclusion in new Agility management system
- Project Manager and leading technical consultant for the NDA RWMD Nuclear Operations Safety Manual development for safety case content and safety assessment approaches
- Finalisation of Operational Safety Strategy for the UK deep geological disposal facility.
- Senior safety engineer for the concept design of the MYRRHA Gen IV fast reactor in Mol, Belgium
- Lecturing on safety assessment, contract management and specific contracts (e.g. NEC3)

SCOTT WILSON (incorporating DGP International Ltd), Feb 2001 to June 2009, Director, Nuclear Services

Technical Director of Scott Wilson Ltd with management responsibility for the nuclear business unit since December 2006 following acquisition of DGP International. This comprises a team of over 80 staff

in the nuclear engineering and safety and risk management technical areas. Responsible for the development and implementation of Scott Wilson's nuclear business plan which is targeted with growing the nuclear business from a £5.3M pa business in 2006 to a £10M pa business in 2010. Key technical experience includes:

- Principal lecturer/facilitator for training courses on safety and risk management and management consultancy skills including nuclear technologies, nuclear safety, hazard identification, nuclear safety cases, liquid metals technology, commercial awareness, general health and safety, nuclear site licensing and nuclear facility manager's responsibilities
- Independent peer review of major safety case justifications for nuclear facilities at Devonport and Dounreay nuclear sites
- Project Director for Dounreay Fast Reactor Residual NaK Removal Design and Safety and Environmental Project
- HAZOP Chair for range of nuclear projects across UK
- Programme management of major modern standards safety case project for GE Healthcare's Amersham nuclear site including development of safety case manual and assessment methodologies and production of operational and decommissioning safety cases for facilities on the Amersham site including Drytec, the MHC ILW store, cyclotron facilities, F-18 production facility, legacy cave and glovebox production facilities and legacy radioactive material storage facilities
- Development of design & safety management process for Devonport Dockyard and GE Healthcare including facilitation of stakeholder workshops and review meetings

AEA TECHNOLOGY 2000 to Feb 2001, Department and Business Manager, Devonport and Dounreay Projects

Responsible for management of a £9-13M pa business unit including a resource team of 40 staff and 30 sub-contractors providing safety and risk management consultancy on a project basis for nuclear clients plus technical support work in the following:

- Lecturer and training courses on safety and risk management
- External membership of AWE Safety Committees
- Peer review of safety cases and generic documentation supporting operations on nuclear licensed sites for AWE, UKAEA, Vulcan and Devonport
- Project management of safety documentation for nuclear operations
- HAZOP Chairman for hazard identification studies for nuclear, oil and gas, rail and process industries
- Provision of nuclear safety advice to team of engineers and safety consultants reviewing facilities compliance with legislation and best practice at AWE sites
- Development of methodology to assist in prioritisation of safety improvements for rail industry including investigation of safety performance of UK rail industry and comparison with other industries using historical data to assist in developing model for prioritisation for safety improvement projects
- Membership of UKAEA licensing team assisting in development of safety management system for licensing by NII in 1990 including independent peer review of safety cases, development of company safety arrangements to meet site license condition requirements and advising Plant Operators on implementation and support to development of safety documentation standards.

UKAEA/NNC Risley 1979 to 1989

Seconded to UKAEA Risley Nuclear Power Development Laboratories providing expertise in liquid alkali metal operations and safety requirements for the UK Fast Reactor Programme. Principal duties included:

- Plant manager for major alkali metal facility, responsible for the aspects of safe operations and liaison with experimental staff and final decommissioning
- Responsible for experimental work in support of Prototype Fast Reactor including impurity monitoring and control, decontamination operations, structural materials performance and decommissioning.

LYNN WILLIAMS

Managing Director, Nuclearcc

MBA, Professional Diploma in Management, BA Psychology, Dip. English Law

Nuclear cc
Futureproofing your company

Key Skills

- Over 21 years' experience of Nuclear Safety & Quality Systems within the Nuclear Industry
- Implementation of Nuclear Safety Management Systems
- Detailed knowledge of: ONR/OCNS/ASME/GS-R/RCC-M/IAEA/NQA-1/CGD/CDM
- ISO 19443 Assessment & Implementation
- Assessor of GDA and Safety Case Management for Nuclear New Build on UK EPR and AP1000 Reactors
- Nuclear New Build - TAG77 Assessor
- ITPIA Safety Cases
- ONR LCs/DNSR ACs & FACs
- 3rd Party Certification Auditor - qualified to Nuclear Industry EAC11 for ISO9001/14001/OHSAS18001 & NQA-1
- Supply Chain Management Assessments
- Project Quality Management
- Authored Nuclear Baselines and Control of Organisational Change iaw LC36
- Regulatory Interaction and Licensing - Existing Plant and Nuclear New Build

Professional Training, Activities and Membership

- Human Reliability Analysis
- Nuclear Safety Foundation Course
- Nuclear Submarine Quality Assurance Course
- Warships in Harbour
- ISO 9001, 14001, 18001, 9100, NQA-1 Lead Auditor
- Six Sigma – Black Belt
- EA/SEPA - Procedures and Awareness
- Certificate – NEBOSH
- HNC – Quality Management
- Certificate of Explosives Safety
- ISO 19443 – UK Working Group participant

- **Member:**
- PCQI - Chartered Quality Institute Nuclear & Defence Special Interest Group
- BPS - British Psychological Society
- CIPD - Chartered Institute of Personnel Development
- Safety Directors Forum - Nuclear Industry Code of Practise (NICoP) Working Group
- Nuclear Industry Association (NIA)
- Nuclear Institute (NI)
- Non-Executive Directors

Nuclear cc
your company

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Selection of Project Experience

April 2015 – December 2017

Nuclear cc - Providing Nuclear Specialist Knowledge on NAMRC Civil Nuclear Sharing In Growth (CNSIG) Programme

Providing nuclear specialism to the Nuclear AMRC. CNSIG an intensive business support programme to help manufacturers compete for work in the civil nuclear industry, which aims to develop the UK manufacturing supply chain to successfully compete for work in the nuclear industry.

Nuclear cc assesses clients' organisational capability and nuclear organisational baseline to meet the UK, and global, nuclear regulatory requirements ie: ONR SAPs, TAGs, NQA-1 *et al.*, and implementing forward action plans to address identified shortfalls.

Following the implementation of ISO19443 management systems, clients have successfully won contracts worth over £100m having been able to demonstrate capability and compliance against nuclear industry codes and standards.

2010 – present

Nuclear cc – Managing Director

Provide guidance and advice to Nuclear Licensees, MoD, Category 1 Service Providers, and Tiered Supply Chain on Quality Management Systems and Nuclear Safety Arrangements under the auspices of UK and IAEA requirements.

Assessed the organisational capability of NNB GenCo against TAG77 - *Supply Chain Capability for procurement of Long Lead Items*. Issued report for ONR to verify issuing of Nuclear Licensee Certificate may be granted.

Conducted ITPIA under the requirements of the Office of Nuclear Regulation TAG 77, to include Supply Chain procurement of Goods & Services, Equipment & Material, for design, procurement, manufacture, construction and operation of UK NPP stations.

Working closely with SQEP stakeholders on Nuclear Supply Chain Management, providing guidance on the implementation of new ISO 19443 requirements.

Provide focus on LC36 Organisational Capability, to adequately meet Statutory, Regulatory, and Legal requirements et al., within Civil and Defence Nuclear.

Third Party Lead Auditor for Tier 1 Service Providers within Defence/Civil Nuclear, Aerospace & Marine under contract with Bureau Veritas.

Conduct Gap Analysis on Business Management Systems and advise on implementation to required standards. Leading Quality, Safety, and Project Teams on the implementation of Civil Nuclear Business Management Systems together with Nuclear Safety Culture training.

Implemented Management System within Nuclear New Build leading a Project Quality team of 17, interfacing and influencing Senior Management including Project Mangers, Divisional Directors, Architect Engineers and CEO. Principal interface with Stakeholders and Supply Chain to accommodate both ISO-HSEQ and ONR requirements under the umbrella of the IAEA & EFQM Framework.

Produced individual Project Execution Plans (PEPs), Procedures, and Processes, documented under the auspices of a bespoke Business Management System. Integrating Internal, External, Stakeholder, and Supply Chain correspondence, further linked to KPIs and Performance Management to ensure the transparent assessment of Business Risk is managed in accordance with the requirements of the Nuclear Industry.

Producing Internal Assessment Framework documenting the following Business requirements:

- Quality Assurance Programme & SQEP/Competency
- ITPIA – Safety Case
- Project Management Plan
- Supply Chain Assessment
- Nuclear Safety Management Arrangements (NSMA Level 1-3 including Duty Holders)
- Organisational Capability

Using the guidelines of: Safety Assessment Principles (MS.1,2,3,4, EHF.5,8), Technical Assessment Guides (16,27,33,49,65,77,79), Licence Conditions (6,10,12,14,17,19,28,36); ensuring both Internal and Stakeholder Management is fully documented and transparent.

Providing ISO19443 training to increase organisational capability within the global nuclear market. Training covers regulatory requirements of: IAEA, ONR, TEPCO, FANR, NRC-CFR, CNNC HAF 604, etc

By introducing a Nuclear Baseline in accordance with the NICoP Principles, and conducting ITPIA within Nuclear Supply Chain, clients can demonstrate a clear and definitive organisational control capability.

Lead Investigations on Nuclear Site Incidents.

2012 – June 2013

UK Head of Quality and Compliance – SPX ClydeUnion

Supplier of Nuclear pumps for Power Stations, including but not limited to: UK - Hunterston, USA – OPPD & GE Hitachi, China - CNPC, EU - KRSKO. Responsible for all Quality requirements from Bids and Bill of Materials, to complete compliance and verification of product. Site Principal contact for PQP's and Customer interface.

Conduct ITPIA on Supply Chain for verification of organisational capability and KPI measures. Leading team of 9 Quality Engineers, 9 Document Controllers, and 32 Quality Inspectors, ensuring Regulatory, Statutory, Legal, and Customer requirements are implemented, managed, and maintained, within both OE and Aftermarket.

Implementation of Project Policies, Procedures and Processes in accordance with: ISO 9001, ASME NQA-1, RCC-M, GS-R-3, CDM, DNSR Authorisation Conditions, ONR Safety Assessment Principles, et al.

Responsible for NDE, Hydrotest, DyePen, X-Ray, Pickle/Passivate, PMI, Ultrasonic, et al Inspection team

Accountable for the implementation of BMS, Project Quality Plans, Design Specification/Reviews, ITPs, PEPs, Supplier Audits, Business Management System, Internal Audits, NCRs, Corrective Actions, Preventive Actions, Continuous Improvement, Lean Techniques, Root Cause Analysis.

2010 – 2011

UK Senior Quality Consultant – Serco Technical Services (Defence, Science and Nuclear)

Leading a team of 8 Quality Consultants to provide support across a range of regulatory activities related to both the UK Defence and Civil Nuclear Industry on the implementation, management and monitoring of Nuclear Baselines and Management of Organisational Change.

Author of MoD AbbeyWood Nuclear Baseline, Level 1 Nuclear Safety Management Arrangements (NSMAs) (including Duty Holders), Conducted Technical Review and updated NSMA Level I & 2.

Provided guidance to New Build Design Authority and Utilities with EDF, Areva, Hitachi, Westinghouse, and NNBGenCo on ONR Regulatory requirements for Management of Plant Safety and Operation using SAPs, LCs, UKAS, and GS-R-3 guidelines.

Provision of advice on policy, Quality review of safety submissions in support of Contract/Project operations, regulatory inspection of safety arrangements, and monitoring of the quality and relevance of independent safety advice within both the Defence Nuclear, and Civil New Build GDA disciplines.

Author of Westinghouse Electric Company AP1000 GDA Safety & Quality Chapter for PCSR Safety Case. Responsible for provision of regulatory review of safety and operational documentation, incidents, and investigations.

Strategic Safety Support to Nuclear Licensee, including development and implementation of Company Safety Procedures and process improvement of Site License Condition Arrangements.

2009

UK Head of Quality – AMEC Nuclear

Developed and maintained an effective and efficient Quality Management System. Prepared Project Quality Management Plan for proposal bid of EDF/AREVA PCSR.

Advised on the implementation of key performance indicators to direct and inform the overall quality programme. Ensured the current and continuing quality and performance improvement capability. Educated and informed at all levels in the business on Nuclear Quality Management and performance improvement. Brought best practice in quality management and performance improvement to the business engaging at all levels in the business to consult on and deliver innovative programmes for continuous improvement in performance. Provided support and advice as necessary for bids and business development.

Lead team on key clients and Supply Chain to ensure understanding of quality management and improvement programmes enabled opportunities to support and enhance current practise.

2008 – present

Nuclear CC - Bureau Veritas Certification Auditor

Lead Assessor responsible for conducting Stage 1-3 audits in accordance with UKAS standards as confirmation and authority for Accreditation against ISO 9001/14001/18001/9100.

Provide consultancy advice, conduct pre-certification analysis within the Nuclear, Marine, Defence, Civil and Submarine industry on Quality Management Systems prior to audit.

Bureau Veritas Nuclear Technical Consultant - Author of Nuclear Quality Manual for BV Nuclear Division under the EFQM Framework.

Produced gap analysis to Senior Management teams on shortfalls against requirements of ONR, ISO and regulatory requirements for implementation within the relevant disciplines.

Conduct phased Assessment on NNB GenCo for Nuclear Licensee Certificate on procurement of Long Lead Items against ONR requirements for Hinkley Point C.

2008-2009

Site Safety Case (Programme) Engineer - Babcock Marine HMNB Clyde

Acted as HMNB Clyde representative at local and Naval Nuclear Propulsion Programme (NNPP) community meetings in Safety Case Staged Improvement Programme (SC SIP) work. Represented Clyde views at Regulatory Interface Forums (RIFs).

Assisted in the maintenance and development of the HMNB Clyde Site Safety Case (SSC) and relevant Nuclear Site Safety Justification (NSSJ) documentation to ensure continued permissioned operation of the Nuclear Powered Warship (NPW) at the designated Facilities within the Authorised Site.

SJG Business Support in the management and development of systems to monitor the Site Safety Justification Teams (SSJT) tasks, programme and deliverables. Monitored progress against set objectives and reported regularly to relevant stakeholders on the maintenance of the departmental project management plan including risk register.

Provide support to the Site Safety Justification Manager (SSJM) in the programme and project management of the Safety Justification Department and the maintenance and development of the suite of NSSJ documentation. Secretariat of Vessel & Crew Support Operational Working Group, responsible for the maintenance and development of the VS Hold Point Control Logic & Deliverables Schedule. Assisted the SSJM in the development and maintenance of a fully compliant Nuclear Site Safety Justification Process.

2004-2008

Senior Quality Advisor (Nuclear) - Babcock Marine HMNB Clyde

Leading team of Quality Advisors, accountable for the development, implementation and continuous improvement of appropriate policies and processes. Carry out inspections and conduct audits against Authorisation Conditions. Lead Member of DNSR SQEP review panel. Single point of contact for DNSR on Inspection and Exercise findings held within the Clyde Management System. Secretariat for the Change Review Board (CRB), responsible for Organisation Change Proposals. Leading member of the Nuclear Accident Response Organisation Sub-Committee.

Lead Assessor in Audit programmes to assess the continued adequacy, effectiveness and implementation of policies, processes and safety cases to meet a range of customer, regulatory and business requirements. HMNB Clyde QA representative in Investigation Reports relating to Nuclear, Radiological, Environmental and Safety related events; reporting to DNSR, HMNB Commodore, 2nd Sea Lord, and Secretary of State for Defence

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matom

CURRICULUM VITAE

Matt Tuck

CRadP

Employment Status: Managing Director **Base:** Conwy
Responsibilities: Commercial, Technical, Health, Safety and Quality.

SUMMARY OF EXPERIENCE

Matt is the Managing Director of Matom. He is a chartered radiological protection professional with over 25 years of experience with hazardous and radioactive materials in advisory, management, and operational capacities. He is currently appointed onto the Nuclear Industry Council (NIC) as a member, advising on the nuclear future as part of an energy mix, and is also Chair for the Wales SME Steering Group on behalf of the NDA. He also represents BSI on an ISO Technical Committee for Societal Security (CBRN specialist) and has presented technical papers on CBRN Counter Terrorism at conferences in the UK and military/public audiences across India and the US/Canada. His extensive operational background provides unique expertise when advising on the application of resource and technology for radiological protection.

EXPERIENCE

Managing Director, Matom
As the Managing Director of Matom, Matt has day-to-day overall responsibility for all aspects of the company performance. Specific responsibilities include UK and international marketing, special projects (e.g. international nuclear/CBRN), and the Matom UK consultancy services. In addition, he has Board level responsibilities for the Matom Integrated Management System (IMS) that addresses compliance with the international standards ISO 9001, 14001, 18001, and the safety of staff in Hazmat environments.

Matt has been appointed lead radiological/Hazmat adviser for a range of high risk projects on UK nuclear decommissioning sites, and also on behalf of international pharmaceutical organisations. He was the advisor on many of the first stage nuclear power plant decommissioning activities, providing input to engineering design, radiation exposure control and limitation, and waste management.

As part of the Matom support to the Government Decontamination Service (GDS), Matt was central to the business recovery operations for the Millennium Hotel, Mayfair, London, and the Litvinenko family house, following the attack on Mr Alexander Litvinenko with Polonium 210.

Matt was involved in a long-term contract to GE Healthcare (Cardiff) working as Project Manager for bioscience and radiological matters. He also input to the development of a site specific aerial and terrain discharge dispersion model that was acceptable by the Environment Agency.

He was radiological safety adviser for a range of site investigation projects in the UK and overseas. Major projects included support to Exxon Mobil in the Cheleken peninsula, Turkmenistan, for seismic investigation, and advising to Halliburton in UK on radiologically contaminated land issues.

Matt was appointed as Radiation Protection Advisor (RPA) to Swan Hunter Ltd. for work with offshore oil and gas platforms, including advising on levels for control of exposure to classified and non-classified operatives.

matom

Technical Manager (Nuclear), Nukem
Technical manager for environmental operations (radiological and chemical land contamination etc.).

Matt was also involved in commissioning of new hazardous materials process plant for UKAEA at the Dounreay site, including early seabed survey methods and equipment.

Principal Consultant, Pinnacle Operations
RPA to Swan Hunter Ltd. responsible for advising and implementing arrangements for decommissioning of offshore module process plant, and decontamination and disposal of LSA (Hazmat) contamination. Set up environmental monitoring programme to ensure adequate protection measures for staff and public.

Managing Officer for UKAEA for the site investigation of the Southern Storage Area, Harwell, monitoring compliance of contractors with contract methods and risk assessments for hazardous materials, occupational safety, and also programme. Also appointed as technical advisor/RPA for refurbishment work of Low Active effluent treatment lines at AWE Aldermaston.

Senior Consultant, Vectra Technologies
Worked for Nuclear Electric (Magnox) providing operational support health physics to UK nuclear power plants during outage maintenance operations. Involved in routine heat exchanger maintenance operations and non-routine operations. Main role was Contract Operational Health Physics Manager and Shift Manager.

Contracted to Baker Hughes, managing an operational health physics team involved in the decontamination of the Maersk Gallant (operating drilling platform) in the Norwegian sector of the North Sea.

Managed a team of health physics and safety engineers providing procedures and management control documentation covering radiological, environmental, conventional safety and site licensing requirements for the commissioning of THORP at BNFL's Sellafield site.

Responsible for preparing radiological protection and safety procedures and health physics input to method statements required for refurbishment of a plutonium facility at AWE Aldermaston.

Involved in shielding assessment work for BNFL for the design of new plant at Sellafield e.g. EP2, SETP, principally using the gamma shielding code Rankern, and to a lesser extent McBend.

EMPLOYMENT HISTORY

2000 – Present	Managing Director	Matom Ltd
1997 – 2000	Technical Manager	Nukem Ltd
1995 – 1997	Principal Consultant	Pinnacle Operations
1989 – 1995	Senior Consultant	Vectra Technologies
1988 – 1989	Deputy Head of Dosimetry	Rolls Royce Nuclear
1987 – 1988	Assistant Health Physicist	Nuclear Services Group

QUALIFICATIONS, PROFESSIONAL MEMBERSHIPS & TRAINING

CRadP Chartered Radiation Protection Professional

Institute of Leadership and Management level 5

Human Factors Specialist

Sarah Wilson BSc (Hons), MSc

Position with current employer:	Director, Marshall Wilson
Profession:	Human Factors Consultant
Years with organisation:	11 years
Years of experience:	20+ years
Normal base:	North West

Qualifications and membership of professional institutions

- BSc (Hons) Human Psychology
- CIEHF, Chartered Member Institute of Ergonomics and Human Factors
- DV Security Cleared
- Marshall Wilson is a Registered Consultancy with CIEHF

Summary of skills and experience

Sarah has 20 years' experience in the assessment of peoples' actions and behaviours within safety critical industries. Her work is targeted at the optimisation of task environments to improve human performance and reduce human error ensuring user needs are met in a practicable manner, and to meet regulatory requirements. She works across all safety critical industries, including nuclear, rail and defence. Sarah has delivered recent human factors assessments for Sellafield Ltd., BAE Marine Systems, Magnox, UKAEA, AWE, Westinghouse (Springfields) and Rolls Royce. Sarah can provide effective HF support to a wide range of projects including safety case assessments and reviews; HF Walkdowns, HAZAN support; design support and integration; resolution of operational issues, task analysis, qualitative and quantitative HRA.

Her relevant, recent SL experience includes updates to process and methodologies across the system lifecyle, HF substantiations for new, existing Safety cases and modifications throughout Plutonium Operating Unit, High Level Waste Plants, Magnox Reprocessing, and Evaporator D. This includes project with political importance, reporting regimes and programme requirements.

Relevant career experience

HF Technical Lead Support
Sellafield Ltd.
2015 - 2018

Human Factors Technical Lead Support / Human Factors Operations Support

Works as part of lead team for HF in SL to refresh processes and methodologies, includes liaison with regulator and senior process owners, supporting junior staff in developing methodologies, leading HF assessment teams and undertaking HF assessment for operational modifications and additions. Process upgrades address HF integration across lifecycle, to define, implement and test operator roles to support operational and safety requirements. Projects range from new design with engineered reliance to ageing plants with high operator reliance and legacy constraints. Development of in house resource and IC for range of business unit project.

Alarms and Warnings Design for Successor
BAE Systems
2010-2015

HF Support to HMI and Alarm rationalisation for Successor

Specification of alarm management process to manage cross system inputs to a complex alarm handling system with software functionality. Includes managing the inputs specified from diverse systems, for normal and abnormal scenarios, through to

specification of browser functionality. Specialist design review and assessment of alarms and warnings system, usability testing. Manage associated human error inputs to safety case, and detailed assessment approaches Task analysis, multi discipline review, operator trials to develop touch screen HMIs for alarms and warnings and process for managing alarm system content according to EEMUA 191. Working closely with software specialists, system specialists, HMI experts, and past and future users.

HF Support for Safety Case Review
Sellafield Ltd.
2009 - 2015

Human Factors Support to Safety Case Review for Storage and Finishing Plants

Review of updated HAZANs to identify key areas for assessment. Plant walkthroughs to assess and substantiate the human reliability and operational claims throughout the Safety Case HAZANs, in a manner where assessment in proportionate to risk. Develop practical solutions to issues raised through series of shortfalls and recommendations.

HF Support for Safety Case Review
RSRL.
2012 - 2013

Human Factors Support for Safety Case for Source move (CAT A MOD) and Vault Store complex

Review of updated HAZANs to identify key areas for assessment. Plant walkthroughs to assess and substantiate the human reliability and operational claims throughout the Safety Case HAZANs, in a manner where assessment in proportionate to risk. Develop practical solutions to issues raised through series of shortfalls and recommendations.

HF Design Support
Sellafield Ltd.

HF Design Support for Evaporator D

Design assessments and reviews, safety assessment and HEP reviews, ONR Liaison.

HF Peer Review
AWE
2012

Peer Review for Human Factors of Decommissioning Safety Case

Review of HF inputs to a Decommissioning safety Case against AWE Company Standards and Processes and ONR standards and expectations.

HF Support for Safety Case Review
Sellafield Ltd.
2010 - 2012

Human Factors Support to New Design Safety Case for NEW Highly Active Liquor Storage Tanks

Develop HFIP; Attend HAZOPs, Review HAZANs, Develop Task Assessment . Integrate with HF Design support. Develop practical solutions to issues raised through series of shortfalls and recommendations.

HF Integration
Magnox
2011

HF Integration to FED New Build Project

Develop and deliver HF Integration plan for structured integration of HF within a design safety case. Process includes design guidance to support FED Encapsulation safety case submissions.

Westinghouse
2010

Site Wide Control Room Assessments.

Structured audit of 6 control room arrangements against Ergonomic Guidelines in response to action from Nuclear Directorate. Provision of practicable shortfalls/recommendation against structured assessment of consequences.

HF assessment
UKAEA
2009

HF Assessment of ATL

Human factors (HF) assessment to support the detailed design and pre-construction safety case for a new intermediate level waste (ILW) transfer facility. The active transfer line (ATL) is part of the new Dounreay intermediate and waste immobilisation, encapsulation and storage plant (D3900).

HF integration
UKAEA
2009

HF Integration to New Design Project

At the pre-construction safety report stage to provide integrated design support and human reliability analysis against comprehensive review of safety critical tasks.

Ergonomist UKAEA 2000 to 2002	**Ergonomic Substantiation of Nuclear Plant (including D1208)** As part of modern standard safety case. Major technical contribution to development and application of the method, and project management of a site-wide assessment programme. This included a range of plants with diverse nature of operations including local plant operators, shielded tasks, control room operations and systems, crane movements and maintenance tasks.
HF Safety Case Review Assessment Sellafield Ltd 2007 to 2008	**HF Walkthroughs** Assessment of safety critical tasks for a cross section of representative tasks within THORP. This was carried out in support of LTPR and involved examination of task environment and equipment, talk throughs with operators and supervisors and analysis of procedures and other managerial controls to ensure that human error was reduced to ALARP levels.
HF Assessment Sellafield Ltd 2007	**HF Assessment of the Proposed New Panel Design** HF assessment for B215 evaporator B was carried out in support of current engineered modifications aimed at providing additional protection associated with evaporator B on B215 highly active liquor evaporation and storage plant at Sellafield. Assessment took account of national and international standards, together with task requirements and consistency with existing site/plant conventions.
HF Integration Magnox 2011	**HF Integration for new Encapsulation Plant** Develop and deliver Human Factors Integration Plan for new encapsulation plant. Deliver HF assessments to support the design and safety case, in a manner acceptable to Magnox and regulators, and proportionate to risk.
HF integration AWE 2009	**HF Integration to New Design Project** HF integration for the active transfer line to provide integrated design support and detailed task oriented assessment of safety critical tasks.
Ergonomist AWE 2008	**Ergonomic Substantiation** Ergonomic substantiation of key safety related engineered items across existing facility for PSR review. Detailed task analysis of safety critical aspects of operational and maintenance tasks that impact reliability of safety engineered kit.
HF assessment AWE 2007	**HF and Human Reliability Assessment of Core Decommissioning Safety Case** Screening of tasks, application of qualitative and quantitative analysis across generic tasks, including: decontamination of plant items; airline suit working; filter changes; MSC checks, maintenance activities and emergency responses.
HF peer review AWE 2008	**Human Factors Peer Review** Peer review of HF safety case methodology and associated technical submission against modern safety case standards.
HF assessment BNG 2007	**Safety Critical Task Assessment and Design Support for Mobile Platform Operations** HF assessment of tasks to be undertaken from mobile platform. Assessment against Manual Handling Regulations and key ergonomic standards to provide design input and change to planned operations.

Human factors specialist

HF assessment British Energy 2007 to 2008	**HF Design and Safety Substantiation Support** Support of design modification for NSP crimping on the existing Dungeness B fuel route. Integration of design advice iterative user trials to optimise error reduction and human reliability assessment.
HF assessment GE Healthcare 2006	**HF Assessment of Cell Operations and Door Opening Interlock and Alarm System** This assessment included task analysis, site assessment and human error quantification.
HF assessment GE Healthcare 2006	**Human Reliability Assessment of Castell Key Interlock Arrangements** Including a detailed task analysis and site assessment of critical operations and maintenance activities.
Ergonomist British Energy 2006 to 2007	**Ergonomic Assessment of Heysham and Hartlepool Reactor Control Room Controls and Displays to Support PSR2.** Involved screening of tasks to identify most risk significant operator actions, identification of related control and displays, ergonomic assessment at plant and on simulator accompanied. Findings were reviewed with operators, HF and safety representatives to agree final recommendations and input to PSR2.
HF assessment Devonport Marine 2002	**Qualitative Analysis of Human Errors** Review of human errors leading to loss of heat sink in 10 dock submarine refit activities.
HF assessment UKAEA 2000 to 2002	**Baseline Assessment of Staffing Arrangements (including D1208)** As part of modern standard safety case. Contribution to development and application of site wide assessment programme, applied across diverse range of plants including local and control room based tasks.
HF assessment BNG 1996 to 2000	**HF Commissioning Support to Sellafield MOX** This project involved a varied workload managed effectively under tight time constraints through strategic application and prioritisation, and multi-disciplinary team working, to integrate human factors throughout the project. Guidelines, checklists, evaluations, ad hoc support and advisory guidance were all deployed. Work was reviewed and implemented through management of safety committees.
HF assessment BNG 1996 to 2000	**Systems Interface Design for Alarm, Process Control, CCTV and Security Systems** Role included user requirement definition and design guidance for system presentation, structure, layout, colours, symbols, sizes and navigation tools. Contribution to specification, review and modification of user interfaces, as part of multi-disciplinary team.
HF assessment BNG 1998	**THORP Control Room Refurbishment** HF role in a team of operators, designers and managers to refurbish THORP central control room layout and workstation equipment. Seminar paper/presentation, safe and reliable control room operations.
Virgin, Sept 2009	**Fail to Call Research**. To identify the nature of the error, identify and appraise mitigation strategies with consideration of the wider impact on drivers. Focused on review of event data, task analysis and qualitative human error assessment.
Delta Rail, 2009	**Human Factors Delivery Manager for renewal of Piccadilly 7A Points**. Management of HF issues across design and safety aspects of the project to assure maintainability and

	optimal control of human error, in a manner that net Company Standards.
DeltaRail / Transys, 2007 - 2009	**Human Factors Assessments for GSM-R Cab location studies.** Examination of cab layouts via drawings or depot visits to carry out structured HF assessment and make justified recommendations for equipment positioning options.
Westfield, May - Sept. 2009	**Human Factors Assurance Manager** Review of the human factors integration work carried out during the design and build of Wood Lane and Shepherds Bush Underground station refurbishment. Packaging of evidence for Operational Readiness to demonstrate that in all public and staff areas, user needs were met to facilitate safe and efficient use of the stations.
DeltaRail, 2008 - 2015	**Ergonomic input to Signalling Management System (IECC Upgrades)** Ergonomic lead for design input to style and detailed design decisions. Structured functional and user requirement assessments, error assessment and ergonomic substantiation to Network Rail Company Specification RT/E/P/24040, RT/E/G/00027, RT/E/S/24017. Included existing system upgrades and new Advanced Virtual Networks.
Scott Wilson, Jan - June 2008, Jan 2009	**East London Line Modifications: Ergonomic technical lead for signal box modifications** Project was to accommodate changes at Three Bridges and Victoria Signal box. The work involved user consultation, technology optioneering, task analysis, equipment inventory, integrated ergonomic advice to design options, formal user trials and identification of training requirements. Delivered to meet programme requirements.
HMRI, 2005	**Professional Head Concept and Role Definition** Comprehensive review of existing professional head roles across industry to model conflicting and congruent goals. Defined task requirements, systems and processes to align the new role with (and take account of) activities in current re-organisation project. Also involved comprehensive skill/competency requirements capture for effective professional head role to interface effectively on standards matters across the industry.
Railway Safety, June 2006	**Research into expected Human Behaviour when trapped on HOT Trains** Human factors analysis for procedure when to evacuate trains based on ambient temperatures. Research and interviews with staff and passengers of trains that have experienced power loss in hot weather. Human factors representation for procedure, design advice and consultation to industry on response to potential future incidents.
Siemens, Sept 2005 - June 2006	**GSM-R Interface Design** Human factors technical lead for user requirements capture, design evaluations and iterative reviews, design requirements specification and substantiation for driver interface. Also, GSM-R cab positioning, human factors technical lead for evaluation of cab positioning options, audit and reporting of fitment decisions.
Tubelines, 2004	**Human Factors Delivery Manager for introduction of 7th car on Jubilee Line.** Develop and run HF Integration Plan to LUL Engineering Standard E1035/A1 and Manual of Good Practice M1035, and BS EN ISO 11064 - Ergonomic Design of Control Centres.
HMRI, 2002	**Safety Assessment Guidelines to guide approvals process against new European Directives.** Focused on stations and tramways following consultation with experts and analysis of data in risk based workshops.
DRS, 2002	**Preparation of Safety Case and supporting assessments, part of a team focused on**

	Safety Management Sections and Risk Assessment to Railway Safety Case Regs 2000. Audit and Revision of Management of Change procedures for staffing, structure, organisations and management. Supporting risk assessment matrix and guidance notes. Also used to assess changes to Booking On arrangements
Network Rail, 2001	**ERTMS National Implementation Strategy Part of a group of Human Factors specialists and train drivers developing a strategy** Project to manage human factors issues for the national implementation of ERTMS. More specifically the role included identifying and quantifying risks and the most appropriate strategies to manage those risks associated with ergonomic requirements for train cabs, training and competence for drivers and transition management.
Tubelines, 2004	**Task and Error Analysis of weed control operations** to identify risk reduction measures and assess acceptability of procedural changes.
Thames Trains, 2003	**Quantified Risk Assessment for the use of hammers in Class 165 trains.** Findings were applied in a fault tree approach and cost benefit analysis using equivalent fatalities.
LU, 2002	**Ergonomic review of the 630V overhead supply system** to identify improvement required to achieve safe and efficient interface and use by train staff.
HSBC, 2000	**Ergonomic review of emergency egress from rolling stock** Project included assessment of egress routes, barriers and hazards; internal layout; provision and operability of tools and equipment; signs and instructions, and the environment. Recommendations took specific account of expected human behaviours in emergencies and provided for improvements tailored to five different cab layouts.

Human Factors Specialist

Julie Marshall BSc (Hons), MSc

Position with current employer:	Director, Marshall Wilson
Profession:	Human Factors Consultant
Years with organisation:	11 years
Years of experience:	20+ years
Normal base:	North West

Qualifications and membership of professional institutions

- BSc (Hons) Applied Psychology
- MSc Occupational Psychology
- NEBOSH General Certificate
- DV Security Cleared
- Marshall Wilson is a Registered Consultancy with CIEHF
- 'List N' approved Offices

Relevant services capabilities

Applied human factors for risk and safety case assessment - HF Process development and improvement - HF strategy design, lead and delivery - Human reliability - HF peer review - Excellent oral and written communicator - Strategic safety management and organisational change management

Summary of skills and experience

Julie has extensive experience in the assessment of human error and violation within safety critical industries. She works across all safety critical industries, focusing largely on nuclear, and has worked for most UK licensees delivering work that is regulated by ONR.

Human factors integration is one of Julie's specialist areas. She has been project manager of numerous projects in which the human contribution to risk has been identified, measured and managed. During her work Julie has delivered HF processes and strategies; and lead and supported others in delivering task analysis, task screening, hazard analysis, error identification, human reliability assessments, qualitative error and task substantiations, design reviews, workshops, plant assessments, user consultations, workshops event analysis, training and research.

Julie has recently lead a team of HF specialists delivering revised systems, processes and methodologies for the BAe site as well supporting the successful integration and improvements to facilities required to improve COMAH implementation arrangements.

Relevant career experience

HF IC for BAE System	**HF IC for BAE**
Currents role	Providing peer review and support, as well as supporting development of working processes and methodologies, across a range of projects. Including ONR Liaison.

Human factors specialist

HF IC for Magnox Current role	**HF IC for Magnox** Providing peer review and support, as well as supporting development of working processes and methodologies, across a range of projects. Including ONR Liaison
HF assessment Sellafield Ltd	**Human Factors Walkthrough Assessment of the Flask Maintenance Facility** A Human Factors (HF) walkthrough assessment of the Flask Maintenance Facility was carried out in support of the Safety Case Long Term Periodic Review (LTPR). A HF walkthrough approach was used to review tasks which have significant operator involvement and where failure of the actions performed by the operator had the potential to give rise to a nuclear safety consequences. The walkthrough was carried out to identify any HF deficiencies which could adversely affect the reliability of operator performance and increase the likelihood or consequence of potential faults. The walkthrough assessment was carried out to meet the requirements described in the Safety and Risk Management (S&RM) Technical Manual
HF assessment Sellafield Ltd	**Human Factors Assessment of Triple Stacking and Upgrade of B311 Skip Handlers** Human Factors issues associated with Triple Sacking Skips in the Fuel Handling Plant (FHP). To identify the Human Factor (HF) issues that would be influenced by the planned Skiphandler Refurbishment A Human Factors (HF) walkthrough assessment of Skiphandler Machine (SHM) operations was carried out in support of the SHM Refurbishment Project. A Human Factors walkthrough approach was used to review specific safety related tasks which have operator involvement, particularly where human actions or errors have the potential to give rise to significant nuclear safety consequence.
HF assessment Sellafield Ltd	**THORP Human Factors Walkthrough (Package 2)** A Human Factors (HF) assessment of a selection of nuclear safety significant focus areas was carried out within THORP in support of the Periodic Safety Report (PSR) process. These tasks were reviewed to identify any Human Factors deficiencies which could adversely affect operator reliability and increase the likelihood of incidents. Where shortfalls were identified potential improvements are recommended.
HF assessment Sellafield Ltd	**Review of compliance document referenced in B80 Operating Rule Compliance Checksheet** A Human Factors (HF) walkthrough assessment of the Waste Monitoring and Compaction Plant (WAMAC) was carried out in support of the Safety Case Long Term Periodic Review (LTPR).
HF assessment Sellafield Ltd	**Sellafield Drypac Plant (SDP) Staffing Levels, Skill Levels and Training/Selection Programme Identification** Design of a programme of work to identify the numbers and skill levels of personnel and their selection and training needs to effectively man the plant. This project involved a task analysis of the proposed operations and maintenance activities.
HF Integration Magnox FED Storage Vaults at Hinkley Point A	**HF Integration to FED Storage Project** Develop, lead and deliver HF Integration plan and provide HF input for the project, currently safety case support and HAZOPs and design reviews.
HF Integration Magnox Bradwell Interim Storage Facility	**HF Integration to FED Retrievals Project** Develop, lead and deliver HF Integration plan for a FED retrievals project. Including Safety Case support, substantiation, design review and commissioning support.

HF Integration Magnox Trawsfynydd	**HF Integration to Design Modification to existing Decommissioning Process** Develop and deliver HF Integration plan for structured human error assessment within the safety case and design modification process. Process includes task analysis and design substantiation to support FED safety case submissions.
HF Integration DSRL	**HF Lead Shaft and Silo Project** Decommissioning Design project involving Design Support and Safety case input
HF Safety Case BAE Systems	**Methodology for HF Safety Assurance for Successor Submarine Project** Develop, lead and deliver a strategy and methodology for the systematic identification and assessment of human error within the safety case assurance and design process for the Successor project. Strategy has been aligned with the safety case assessment process and takes account of a proportionate assessment according to risk. Leading the HF aspects of the safety case the role involves technical review of oothers work, delivering training and support to others undertaking human reliability assessments and other HF inputs and claims.
HF Support for Safety Case RSRL	**HF Support for ILW Safety Case** Review and input to HAZANs and plant assessments to provide holistic safety case.
HF Support for Safety Case RSRL - now Magnox	**Two safety case projects HF support** HAZAN review and development of HF support file for: Contact Handled Intermediate Level Waste (CH-ILW) & Low Level Waste (LLW) Operations Safety Case (OSC) and Dragon Waste Transfer Modification.
HF Input to a Crane Replacement Project UUK	**HF Integration to URENCO UK Ltd** Lead HF aspects of the design of a control room and control stations to remotely operate two new semi-automatic Goliath cranes on cylinder storage Rafts, which are to be extended.
HF Integration Plan Development Rolls Royce	**HF Integration Plan** Develop a HFIP for PSR. This included integration with both the design and safety teams and regulatory liaison. The HFIP supports the PSR including detailed engineering substantiation.
HF Hazop Support Rolls Royce	**HF Support to HAZOPs** Structured identification of human errors within a rolling hazop programme, carried out to support safety case review. Develop HF Integration Plan for safety case review and engineering substantiation process.
Human factors (HF) assessment UKAEA	**HF Assessment of Active Transfer Line** Human factors (HF) assessment to support the detailed design and pre-construction safety case for a new intermediate level waste (ILW) transfer facility. The active transfer line (ATL) is part of the new Dounreay intermediate and waste immobilisation, encapsulation and storage plant (D3900).
HF integration UKAEA	**HF Integration Management** For a new design project at the preconstruction safety report stage to provide integrated design support and human reliability analysis against comprehensive review of safety critical tasks.
HF safety case UKAEA	**HF Support to Dounreay Safety Cases** HF support was provided to 1202, 1203 and 1208 in terms of safety critical task assessment and human reliability.

Site operating instruction review UKAEA	**HF Operating Instruction Review** Operating instructions were reviewed and advice provided concerning shortfalls. Plant staff were provided with two-day training in task analysis and writing operating instructions. Staff were subsequently supervised in rewriting the operating instructions to the new approved standard.
Baseline assessment UKAEA	**LC36 Baseline Assessment** Baseline assessments were carried out for numerous plants across the Dounreay site following the introduction of LC36. This involved the development of baseline methodology and consultation with NII.
HF methodology UKAEA	**HF Safety Case Methodology Development** A HF safety case methodology was developed. This included HF input to: engineering substantiation, hazard assessment, operational review and safety management sections of the safety case. This work also involved NII consultation.
HF safety case Atomic Weapons Establishment	**HF support to Safety Case (VIPER)** High level analysis of the operations performed in the facility to provide justification as to why specific tasks need to be (or have been) analysed in detail. Completion of technical HF assessments to support safety functional requirement updates, the development of the fault schedule and subsequent risk assessments.
HF Integration Atomic Weapons Establishment	**HF Integration Delivery Manager FWPS** Management of HF integration to both the design and safety justification processes. At the pre-construction safety report stage to provide due consideration of HF. This task included leading a team of HF personnel in supporting the project, assurance of their technical delivery.
HF peer review Atomic Weapons Establishment	**Peer Review (ARTL)** Peer review of HF methodology and associated technical submissions against modern standards for HF in safety case assessment.
HF engineering Atomic Weapons Establishment	**Ergonomic Substantiation for Key Safety Related Engineered Items** This involves definition of the task requirements, cue, action and feedback, review of the interface against national, international standards and site/plant conventions.
HF strategy development Devonport Marine Ltd	**HF Strategy Development** Support to client in the identification of HF requirements for inclusion in a HF strategy document for nuclear installations inspectorate review. Including HFI, HF in safety assurance and human engineering.
HF training AMEC NNC	**Human Reliability Training Course** Design and co-delivery of a tailored training course on human reliability.
HF assessment BNG	**HF Walk Through B80** Review of generic plant HF and identification of targeted improvements.

HF assessment Devonport Marine Ltd	**HF Support to Nine Dock Safety Case** Human reliability assessment of re-fuelling operations including a review of the training and competency assurance process.
HF assessment Atomic Weapons Establishment	**Human Factors and Human Reliability Assessment in Support of Burghfield Facility Safety** Screening of faults, application of qualitative and quantitative analysis across three buildings of key tasks, including: lifting and transfer operations, maintenance tasks, and x-ray tasks.
HF assessment United Kingdom Atomic Energy Authority	**Review of Flask Receipt Tasks** Focusing on flask receipt health physics tasks the review aimed to assess potential for human error.
Virgin, Trains January	**HF Integration Plan for PDA use by Drivers.** To identify the HF issues associated with use of PDAs by Drivers and to write and manage a HF Issues log as part of a wider HF Integration Plan.
Virgin, Trains Sept	**Fail to Call Research.** To identify the nature of the error, identify and appraise mitigation strategies with consideration of the wider impact on drivers. Focused on review of event data, task analysis and qualitative human error assessment.
Virgin Trains	**Assessment of Driver Safety Consequences of Increased Route Modernisation Training -** Review of the driver workload associated with training demands due to route modernisation. This project reviewed potential consequence of Driver overload.
Carillion / Balfour Beatty	**Hazard Log Manager and HAZOP Chair** - for the East London Line Project. This project included Hazard Log management, HF Hazard identification and HAZOP report delivery.
Metronet	**HF Training Course Delivery** - Human Factors and compliance with the London Underground Integration Standard (Client: Metronet).
AMEC NNC	**Human Reliability Training Course** - Design and Co-delivery of a tailored training.
AEA Technology and Engineering link	**Acquisition Management** - As part of the due diligence process existing organisational structures were reviewed for two merging organisations. New organisational structures were validated, and the workforce was involved in change decisions. Key objectives included ensuring that vital 'on the job' experience was captured, the structure was 'workable' and workforce 'buy in' to the change was maintained.
Porterbrook	**Independent Review of Rail Passenger Information System** - This review involved an Independent Ergonomic Usability Review of Internal Passenger Information System (PIS) Displays. The review assessed a proposed PIS against Rail Vehicle Accessibility Regulations (RVAR) relating to PIS Characteristics.
RIFFA	**Rail Emergency Response Management** - AEA Technology Rail in association with Rail Industry First Aid Association (RIFAA) designed a four phased programme of activity which aimed to fully co-ordinate Emergency Response arrangements, this included: (1) Emergency Response Training, (2) Testing of Independent Incident Response Functions, (3) Table Top testing of the Incident Response Plan and (4) Live Exercise Testing.
Railway Safety	Investigative research of hazards and concerns regarding stations.
Eurocontrol	**Personnel Profiling of Aeronautical Information Services** using task analysis to inform

	decision-making concerning work organisation, staffing, training, human error reduction. This research was carried out across all the European Member states.
Westminster Public Safety Committee	**Crowd Safety Review and Management for a Major Outdoor Public Event** - Observation and analysis of crowd safety for the Millennium crowd safety study for Trafalgar Square and surrounding areas. This contract lasted over the three years.
HSE	**HSE Crowd Safety Risk Assessment Methodology Peer Review** - Strategic peer review of the developing methodology, in the HSE report entitled Managing crowd safety in public venues: a study to generate guidance for venue owners and enforcing authority inspectors. ISBN 0 11 882132 6

Gemma Larkins

From: Nathan Wahl
Sent: Monday, 16 July 2018 5:10 PM
To: bruce.lehrmann@health.gov.au
Cc: $ARPANSA Parliamentary Correspondence; Tone Doyle
Subject: ANSTO Direction - proposal for ARPANSA announcement [DLM=For-Official-Use-Only]

Follow Up Flag: Follow up
Flag Status: Completed

Hi Bruce,

Thanks for the chat earlier today. Noting that with the Minister on annual leave we may not be able to table the direction in our preferred timing, we would like to proceed with making a public announcement in the coming days. With the formal approval of the auditors about to occur, it is good timing to speak publicly about it. In terms of content of the news release, it will give some basic insight around why the CEO of ARPANSA issued it and refer to the fact that the direction will become publicly available once tabled in Parliament in line with the procedures under our Act.

Our hope is this will assist by taking the pressure of everyone, managing risks of delays in publicly revealing it, particularly given ANSTO will soon announce it publicly themselves. However we will still abide by the parliamentary procedures not to publicly release documents prior to tabling.

Grateful if you could confirm this approach is satisfactory.

Regards,
Nathan

Nathan Wahl
Assistant Director
Government and International Relations
Office of the CEO

Australian Radiation Protection and Nuclear Safety Agency
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Australian Government
Department of Health

UNCLASSFIED
FOUO
Ministerial Submission – Release of Report
MS18-001400 Version (1)
Date sent to MO: 29/06/18

To: Minister McKenzie

cc: Minister Hunt

Subject: TABLING OF DIRECTION TO AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION (ANSTO)

Critical Date: ~~16 July 2018~~ – To enable tabling in Parliament in a timely manner and in accordance with legislative requirements (see timing below).

Recommendations:

1.	**Approve the release and tabling in Parliament of the CEO of ARPANSA's letter of direction to ANSTO (Attachment A).**	1. **Approved / Not approved**
2.	**Sign the transmittal letter to the President of the Senate at Attachment B, presenting the direction for tabling.**	2. **Signed / Not signed**
3.	**Sign the letter advising ANSTO's Minister of tabling (Attachment C)**	3. **Signed / Not signed**

Signature: ..... **Date:** 23/8/2018

Comments:

4 spills / 8 mls – good decon

Contact Officer:	*Nathan Wahl*	*Assistant Director, Government & International Relations*	Ph: (03) 9433 2322 Mobile: s 47F - privacy
Clearance Officer:	*Carl-Magnus Larsson*	*CEO of ARPANSA*	Ph: (02) 9541 8501 Mobile: s 47F - privacy

Report Details: The CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA), Dr Carl-Magnus Larsson, has issued ANSTO with a direction under section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act) which applies when:

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

The CEO of APRANSA decided to issue the direction following four separate events with safety implications at ANSTO's Lucas Heights facility in less than 10 months. The first and most significant incident was the contamination accident of a staff member's hand on 22 August 2017. Subsequent to that accident, the CEO of ARPANSA found ANSTO in breach of the Act and, due to its severity, tabled a report in Parliament on 26 February 2018 under section 61(1) of the Act summarising the event and corrective actions (Attachment D).

The other three events, which occurred on 23 March, 2 May and 7 June 2018, demonstrate failures in safety protocols and procedural inadequacies.

While only one event has resulted in actual harm to staff, the systemic nature of these safety related events at ANSTO has led the CEO of ARPANSA to believe there is a risk of serious injury to ANSTO staff, in particular those involved in quality control processes for the production of molybdenum-99 (Mo-99).

The direction to ANSTO requires it 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; and

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.

The four events are outlined in the letter of direction, and are the subject of ongoing investigations. Further enforcement actions under the Act may follow.

Timing: The proposed timing to publicly release the report via tabling in Parliament is 17 July 2018 when the Senate is not sitting. Section 41(5) of the Act requires the Minister to cause a copy of the report to be laid before each House of the Parliament within 15 sitting days of receiving the report. Tabling the report prior to the community votes in South Australia, referenced below (see 'Community Awareness'), will help mitigate the risk of any public perception of information relevant to the vote being withheld.

Community Awareness: Community votes on the proposed National Radioactive Waste Management Facility (NRWMF) are scheduled to occur in Kimba and Hawker on 20 August 2018. Therefore, this direction and the incidents at ANSTO may affect public or media perceptions of ANSTO given its significant involvement in the waste management project.

Impact on Rural and Regional Australians: No direct impact on rural or regional Australia. However, the communities around the towns of Kimba and Hawker in South Australia are involved in the community vote mentioned above.

Consultations: The Department of Health and ANSTO were consulted in the lead-up to the decision to issue a direction.

Attachments:

A. ANSTO Health – Facility Licence F0262 – direction under Section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*
B. Transmittal letter to the President of the Senate
C. Letter advising ANSTO's Minister of tabling
D. 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*

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.

[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.

KEEP WITH FILE COPY
- DO NOT DISPATCH-

Contact Officer Nathan Wahl
(03) 9433 2322
s 47F - privacy

Clearance Officer Dr Carl-Magnus Larsson
(02) 9541 8501
s 47F - privacy

Division/Branch Australian Radiation Protection and Nuclear Safety Agency

KEEP WITH FILE COPY
- DO NOT DISPATCH-

Senator the Hon Bridget McKenzie
Deputy Leader of The Nationals
Minister for Rural Health
Minister for Sport
Minister for Regional Communications
Senator for Victoria

Ref No: MS18-001400

Senator the Hon Scott Ryan
President of the Senate
Parliament House
CANBERRA ACT 2600

Dear Mr President

Pursuant to standing order 166, relating to the presentation of documents when the Senate is not sitting, I present to you a direction from the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency to the Australian Nuclear Science and Technology Organisation.

Yours sincerely

Bridget McKenzie

Encl (1)

Senator the Hon Bridget McKenzie

Deputy Leader of The Nationals
Minister for Rural Health
Minister for Sport
Minister for Regional Communications
Senator for Victoria

Ref No: MS18-001400

Senator the Hon Michaelia Cash
Minister for Jobs and Innovation
Parliament House
CANBERRA ACT 2600

Dear Minister

The Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) has submitted to me a direction to the Australian Nuclear Science and Technology Organisation (ANSTO), provided to them on 29 June 2018. I propose to table the direction in Parliament on 17 July 2018 via the President of the Senate, while the Senate is not sitting.

The direction, issued under section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*, contains details of four separate events with safety implications at ANSTO's Lucas Heights facility in less than 10 months. The first and most significant incident was the contamination accident of a staff member's hand on 22 August 2017. The other three events, which occurred on 23 March, 2 May and 7 June 2018, also demonstrate failures in safety protocols and procedural inadequacies.

While only one of the recent events has resulted in actual harm to a staff person, the systemic nature of these safety related events has led the Chief Executive Officer of ARPANSA, Dr Carl-Magnus Larsson, to believe there is a risk of harm to ANSTO staff and an urgent need to reduce that risk.

The direction requires ANSTO to initiate an independent review of its approach to occupational radiation safety, and subsequently provide a plan with timelines to implement actions in response to any recommendations from the review's report.

ANSTO were consulted in the lead-up to the decision to issue a direction. If you require further information, please do not hesitate to contact my office.

Yours sincerely

Bridget McKenzie
cc: Senator the Hon Matthew Canavan, Minister for Resources and Northern Territory

Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

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*

Australian Government

Australian Radiation Protection and Nuclear Safety Agency

arpansa

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*

Further information about this publication

If you would like to know more about the content of this publication please contact ARPANSA on 1800 022 333 or **info@arpansa.gov.au**. Further information can be found on the ARPANSA website at **www.arpansa.gov.au**.

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.

Printed by:

CanPrint Communications Pty Ltd
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Fyshwick ACT 2609

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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

Gemma Larkins

From: Nathan Wahl
Sent: Wednesday, 18 July 2018 9:52 AM
To: bruce.lehrmann@health.gov.au
Cc: $ARPANSA Parliamentary Correspondence; Tone Doyle; Minister McKenzie DLO
Subject: RE: ANSTO Direction - proposal for ARPANSA announcement [DLM=For-Official-Use-Only]
Attachments: News Article - ARPANSA issues direction to ANSTO Health-17Jul18.docx

Follow Up Flag: Follow up
Flag Status: Completed

Hi Bruce,

Per the below and our discussion, we have come up with the attached news article to announce the direction to ANSTO. This way we aren't reliant upon tabling to make it public.

We are hoping to release it tomorrow on our website, so grateful if you can review this today and let us know if you have any concerns with it going up.

Regards,
Nathan

From: Nathan Wahl
Sent: Monday, 16 July 2018 5:10 PM
To: bruce.lehrmann@health.gov.au
Cc: $ARPANSA Parliamentary Correspondence <Parliamentary@arpansa.gov.au>; Tone Doyle <tone.doyle@arpansa.gov.au>
Subject: ANSTO Direction - proposal for ARPANSA announcement [DLM=For-Official-Use-Only]

Hi Bruce,

Thanks for the chat earlier today. Noting that with the Minister on annual leave we may not be able to table the direction in our preferred timing, we would like to proceed with making a public announcement in the coming days. With the formal approval of the auditors about to occur, it is good timing to speak publicly about it. In terms of content of the news release, it will give some basic insight around why the CEO of ARPANSA issued it and refer to the fact that the direction will become publicly available once tabled in Parliament in line with the procedures under our Act.

Our hope is this will assist by taking the pressure of everyone, managing risks of delays in publicly revealing it, particularly given ANSTO will soon announce it publicly themselves. However we will still abide by the parliamentary procedures not to publicly release documents prior to tabling.

Grateful if you could confirm this approach is satisfactory.

Regards,
Nathan

Nathan Wahl
Assistant Director
Government and International Relations
Office of the CEO

Australian Radiation Protection and Nuclear Safety Agency
619 Lower Plenty Road, Yallambie VIC 3085 AUSTRALIA

Phone +61 3 9433 2322 **Mobile** s 47F - privacy
Email nathan.wahl@arpansa.gov.au
www.arpansa.gov.au

ARPANSA issues a direction to ANSTO

On 29 June 2018, the CEO of ARPANSA, Dr Carl-Magnus Larsson, issued the Australian Nuclear Science and Technology Organisation (ANSTO) with a direction under section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act).

The direction requires ANSTO to take immediate steps to initiate an independent review of its approach to occupational radiation safety of processes and operational procedures at its nuclear medicine facility, ANSTO Health (Lucas Heights, NSW), in particular those associated with quality control of molybdenum-99 (Mo-99) samples.

Dr Larsson decided to issue the direction following four separate events with safety implications at ANSTO Health in less than 10 months. The first and most significant event was the contamination event of a staff member's hands on 22 August 2017. After that event, the CEO of ARPANSA found ANSTO to be non-compliant with licence conditions and, due to its severity, tabled a report in Parliament under section 61(1) of the Act. Three further events including the latest event on 7 June 2018 indicate ongoing safety issues at ANSTO Health.

In line with the direction, ARPANSA today approved ANSTO's appointment of an external review team to undertake the review at ANSTO. This review will provide recommendations to improve safety practices, along with a plan and associated timelines to implement any actions.

ARPANSA will make the direction including the complete statement of reasons publicly available once tabled in Parliament.

Gemma Larkins

From: LEHRMANN, Bruce <Bruce.Lehrmann@health.gov.au>
Sent: Wednesday, 18 July 2018 10:24 AM
To: Nathan Wahl
Cc: $ARPANSA Parliamentary Correspondence; Tone Doyle
Subject: RE: ANSTO Direction - proposal for ARPANSA announcement [DLM=For-Official-Use-Only]

Follow Up Flag: Follow up
Flag Status: Completed

Hi Nathan,

That looks great, all fine with me. Thanks for giving me the heads up and for the teams ongoing understanding in terms of getting these subs handled etc.

Cheers,
Bruce

Bruce Lehrmann | Acting Senior Adviser
(Preventive Health, Food, Tobacco, Drugs, Alcohol, Chemicals & Nuclear Protection)

Office of Senator the Hon Bridget McKenzie
Deputy Leader of The Nationals
Minister for Rural Health
Minister for Sport
Minister for Regional Communications
Senator for Victoria

Suite M1.48 Parliament House Canberra ACT 2600
Phone 02 6277 7495 | Mobile s 47F - [redacted]
Email: bruce.lehrmann@health.gov.au

From: Nathan Wahl [mailto:nathan.wahl@arpansa.gov.au]
Sent: Wednesday, 18 July 2018 9:52 AM
To: LEHRMANN, Bruce
Cc: parliamentary@arpansa.gov.au; Tone Doyle; Minister McKenzie DLO
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Regards,
Nathan

Nathan Wahl
Assistant Director
Government and International Relations
Office of the CEO

Australian Radiation Protection and Nuclear Safety Agency
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Gemma Larkins

From: BERGHOFER, Paula <pbz@ansto.gov.au>
Sent: Wednesday, 18 July 2018 5:58 PM
To: $ARPANSA Licence Administration
Cc: PATERSON, Adi; Jim Scott
Subject: Request for approval - External review team and terms of reference [SEC=UNCLASSIFIED]
Attachments: 180718_Letter_Out-Direction_Review_Team_Terms_of_Reference.pdf

Good Afternoon,

Please find attached letter requesting approval of an external review team and terms of reference in relation to the direction received on 29 June.

Kind Regards,
Paula

From: Maryanne Macnamara <Maryanne.Macnamara@arpansa.gov.au> **On Behalf Of** $ARPANSA Licence Administration
Sent: Friday, 29 June 2018 3.36 PM
To: PATERSON, Adi <apz@ansto.gov.au>
Cc: Carl-Magnus Larsson <Carl-Magnus.Larsson@arpansa.gov.au>; Jim Scott <Jim.Scott@arpansa.gov.au>
Subject: Facility Licence F0262 - Letter of Direction [SEC=UNCLASSIFIED]

Good afternoon

Please find attached letter regarding Facility Licence F0262 as signed by the CEO of ARPANSA.

Kind regards

Licence Admin
Regulatory Services Branch

Australian Radiation Protection and Nuclear Safety Agency
Level 2 38-40 Urunga Parade Miranda NSW 2228 AUSTRALIA

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Nuclear-based science benefiting all Australians

18 July 2018

Dr Carl-Magnus Larsson
Chief Executive Officer
ARPANSA
PO Box 655
MIRANDA 1490

Dear Dr Larsson, Carl-Magnus

Appointment of reviewers and terms of reference following the ARPANSA CEO direction to undertake an independent review into ANSTO Health Building 23

I refer to your letter of direction of 29 June 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 the quality control of molybdenum-99 samples. In that letter, you indicated that the external reviewer and supporting experts must be considered suitable for the task by ARPANSA before being appointed by ANSTO, and that the terms of reference for the review must also be approved by ARPANSA.

Proposed external review and supporting experts

An external reviewer and six supporting experts have been identified to undertake the review. Each member is distinguished in their respective field, and the team as a whole contains the breadth and depth to provide a thorough and thoughtful review in line with the terms of reference. Table 1 lists the specialists we are proposing to undertake the review.

Table 1: ANSTO's proposed expert review team

Role	Name	Expertise
Lead Reviewer	David Jones	Overall co-ordination, review of HAZID, Hazard Analysis, safety management
Supporting Expert	Adam Kilborn	Project Management, Hazard Analysis review
Supporting Expert	Julie Marshall	Human Factors, Safety Culture
Supporting Expert	Lynn Williams	Nuclear Baseline, Quality Systems, Safety Culture
Supporting Expert	Brent Rogers	Radiation Protection Specialist
Supporting Expert	Andrew Hopkins	Applied Sociology in Environmental and Occupational Health and Safety
Supporting Expert	Peta Miler	Human Factors / Ergonomics

Proposed terms of reference

The following terms of reference are proposed for the review:

Engagement objective (scope)

The overall engagement objective is to review:

- the current safety culture within ANSTO Health, including the appropriateness and utilisation of the existing mechanisms for reporting of incidents
- the person-machine interface within nuclear medicine production
- the current and revised ANSTO Health processes for safety assurance to ensure (1) responsibility and authority is delegated to appropriate persons, and (2) correct enterprise oversight is in place, with independent processes for escalation
- the current processes in ANSTO Health for conducting hazard identification and consequence and risk assessments
- the organisational capability to support nuclear medicine production, both within ANSTO Health and ancillary services within the wider ANSTO
- the optimisation of risk control measures within ANSTO Health
- the effectiveness of measures introduced by ANSTO subsequent to the August 2017 event

Review philosophy

The review should be conducted by an independent and competent reviewer based on the principles of trust, learning and accountability, consistent with a learning or 'Just Culture'. Observations and recommendations should be based on ARPANSA and/or IAEA Standards.

Engagement approach

The above objective should be satisfied through the performance of the following:

1. Safety culture

   The current safety culture within ANSTO Health should be assessed by means of a fit-for-purpose tool that will measure all major dimensions of safety and quality specific to the ANSTO environment.

   The tool should be able to be applied with appropriate utility and granularity to identify any differences in safety culture within different sections of ANSTO Health and also be appropriate for future application across the ANSTO group.

2. Human factors

   The review should assess the person-machine interface within nuclear medicine production, particularly related to Molybdenum-99 and associated Quality Control activities. Factors which can affect human performance, both positively and negatively, should also be reviewed.

3. Safety assurance

   Review the current and revised ANSTO processes for safety assurance to ensure that the responsibility and authority is delegated to the appropriate persons within the organisation. The review should also assess whether the correct enterprise oversight is in place, with independent processes for escalation within the organisation.

4. Hazard ID and risk/consequence assessment

Review the current processes for conducting hazard identification and consequence and risk assessments across ANSTO Health. Assess the robustness (process owner identified, inputs and outputs identified, key stakeholders identified etc.) of these processes and suitability for the ANSTO Health environment. The review should also assess the escalation process for 'high risks' within the organisation and compare the current processes against international practice, particularly with reference to deterministic assessment and identification of required levels of control.

5. Organisational capability / nuclear baseline

The review should examine the organisational capability to support nuclear medicine production, both within ANSTO Health and ancillary services within the wider ANSTO.

6. Optimisation

The optimisation of control measures within ANSTO Health should be reviewed, recognising the age of the facility. The effectiveness of measures introduced by ANSTO subsequent to the August 2017 event to date, in terms of reducing potential consequences of incidents and thereby risks, should also be assessed.

Those terms of reference are, in my view, sufficiently broad to allow the team to explore whatever issues may appear relevant to their review. The review team will use the above terms of reference to develop a detailed work plan that ANSTO will review prior to commencement of the review. The work plan will include details of the persons to be interviewed and documents to be reviewed, amongst other aspects.

Progress report

As directed, ANSTO will provide ARPANSA with a progress report 30 days after commencement of the review. This report will contain information on the progress against the terms of reference, and describe any hurdles or challenges that may affect the completion of the final report within the given timeframe.

Final report

As directed, ANSTO will provide ARPANSA with the final report, including any recommendations of the review and ANSTO's response to those recommendations, within 60 days of commencement of the review.

A draft of the final report will be provided to ANSTO to allow us an opportunity to provide comments around ensuring the report achieves the required scope of the review. The sharing of the draft will also allow ANSTO an opportunity to provide correction with respect to factual accuracy of the content. The review team will make an independent determination as to the incorporation of any of our proposed changes.

ANSTO will stipulate that participants must not be able to be personally identified in the report in any way. This is to promote frank, open and honest discussions. We reserve the right to amend the report to ensure this anonymity.

ANSTO will not be provided with access to any primary documentation generated during the review, including review notes or interview transcripts.

The final report will be provided from the review team to ANSTO. ANSTO shall then, prior to 60 days from commencement of the review, provide that report to ARPANSA on an unamended basis. At this time, we will also provide a separate document containing ANSTO's response to the recommendations.

Request to commence

ANSTO hereby requests ARPANSA approval of the aforementioned review team and terms of reference. Based on your approval, we also seek that 6 August is deemed the date of commencement of the review, as this is in line with the arrival date of the international experts.

If you require any further information regarding this matter, please contact the Regulatory Affairs Manager, Paula Berghofer on (02) 9717 3754 or via email paula.berghofer@ansto.gov.au

Kind regards,

Dr Adi Paterson
Chief Executive Officer

Gemma Larkins

From: Maryanne Macnamara on behalf of $ARPANSA Licence Administration
Sent: Thursday, 19 July 2018 11:49 AM
To: Adi Paterson (adi.paterson@ansto.gov.au)
Cc: Carl-Magnus Larsson; Tone Doyle; Jim Scott (Jim.Scott@arpansa.gov.au)
Subject: Facility Licence F0262 - ANSTO Health - Approval of external review and terms of reference [SEC=UNCLASSIFIED]
Attachments: Outgoing letter to F0262 ANSTO Health - Approval of external review team and terms of reference.pdf

Good morning

Please find attached letter from the CEO of ARPANSA regarding the above.

Kind regards

Licence Admin
Regulatory Services Branch

Australian Radiation Protection and Nuclear Safety Agency
Level 2 38-40 Urunga Parade Miranda NSW 2228 AUSTRALIA

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Australian Radiation Protection and Nuclear Safety Agency

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19 July 2018 **Ref: 2018/00820**

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

Dear Dr Paterson

ANSTO Health – Facility Licence F0262 – Direction under Section 41(1A) of the *Australian Radiation Protection and Nuclear Safety Act 1998*

Thank you for your letter of 18 July 2018, informing me of your proposed arrangements for an independent review of the approach to occupational radiation safety of processes and operational procedures in Building 23, pursuant to my direction of 29 June 2018.

I have reviewed the arrangements as regards:

- *Proposed reviewer and supporting experts.* The nominated persons are either known to ARPANSA or their CVs have been reviewed by ARPANSA. I am of the view that the team comprises a balanced and appropriate mix of competence and experience.
- *Terms of reference and other arrangements.* I consider these to be satisfactory.

Based on the above, I approve your request to commence the review on 6 August 2018.

Yours sincerely

Carl-Magnus Larsson
CEO of ARPANSA

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Gemma Larkins

From: Nathan Wahl
Sent: Thursday, 19 July 2018 12:37 PM
To: bruce.lehrmann@health.gov.au; Minister McKenzie DLO
Cc: $ARPANSA Parliamentary Correspondence; Tone Doyle
Subject: ANSTO Direction - News announcement live [SEC=UNCLASSIFIED]

Hi Bruce and Aaron,

I just wanted to give you a heads up that our news article on the ANSTO direction is now live.

https://www.arpansa.gov.au/news/arpansa-issues-direction-ansto

If anyone does ask however, please do ensure that they understand this direction and the four accidents we reference are unrelated to the current outage impacting ANSTO and which is generating Ministerial Corro.

Regards,
Nathan

Nathan Wahl
Assistant Director
Government and International Relations
Office of the CEO

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Australian Government
Australian Radiation Protection and Nuclear Safety Agency

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ARPANSA issues a direction to ANSTO

6 September 2018

On 29 June 2018, the CEO of ARPANSA, Dr Carl-Magnus Larsson, issued the Australian Nuclear Science and Technology Organisation (ANSTO) with a direction under section 41(1A) of the Australian Radiation Protection and Nuclear Safety Act 1998 (the Act), which was tabled in Parliament on Friday 24 August.

The direction requires ANSTO to take immediate steps to initiate an independent review of its approach to occupational radiation safety of processes and operational procedures at its nuclear medicine facility, ANSTO Health (Lucas Heights, NSW), in particular those associated with quality control of molybdenum-99 (Mo-99) samples.

Dr Larsson decided to issue the direction following four separate events with safety implications at ANSTO Health in less than 10 months. The first and most significant event was the contamination event of a staff member's hands on 22 August 2017. After that event, the CEO of ARPANSA found ANSTO to be non-compliant with licence conditions and, due to its severity, tabled a report in Parliament (/about-us/corporate-publications/reports-parliament/report-parliament-radiation-exposure-worker-ansto) under section 61(1) of the Act. Three further events including the latest event on 7 June 2018 indicate ongoing safety issues at ANSTO Health.

In line with the direction, ARPANSA today approved ANSTO's appointment of an external review team to undertake the review at ANSTO. This review will provide recommendations to improve safety practices, along with a plan and associated timelines to implement any actions.

See our Significant regulatory activities (/about-us/corporate-publications/significant-regulatory-activities) page for the tabled direction and other updates.

*This article was originally published on Thursday 19 July 2018 and updated on Thursday 6 September 2018.

ARPANSA

Gemma Larkins

From: BERGHOFER, Paula <pbz@ansto.gov.au>
Sent: Wednesday, 5 September 2018 5:36 PM
To: $ARPANSA Licence Administration
Cc: GRIFFITHS, Hefin; PATERSON, Adi; Jim Scott
Subject: Progress Report - External Review ANSTO Health Building 23 [DLM=For-Official-Use-Only]
Attachments: External Reveiw - Progress Report.pdf

Good Afternoon,

Please find attached a progress report pertaining to the external review of the approach to radiological safety of processes and operational procedures in ANSTO Health Building 23.

This relates to the ARPANSA direction for ANSTO to provide ARPANSA with a progress report 30 days after commencement of the review.

Best Wishes,
Paula

Paula Berghofer
General Manager Waste Management Services
Nuclear Operations

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Email pbz@ansto.gov.au
Web www.ansto.gov.au

SAFETY CONSULTANTS

Document Reference: AS001-REP01
Issue: 1

PROGRESS REPORT FOR THE INDEPENDENT SAFETY REVIEW OF THE AUSTRALIAN NUCLEAR SCIENCE AND TECHNOLOGY ORGANISATION'S OPERATIONS WITHIN BUILDING 23 AND WITHIN THE ANSTO HEALTH BUSINESS

Prepared by:	Signature:	Date:
D G Jones (Lead Reviewer)	DGJ	23/08/2018

SAFETY CONSULTANTS

Document Reference: AS001-REP01
Issue: 1

Independent Safety Review Progress Report

Introduction

The Australian Nuclear Science and Technology Organisation (ANSTO) operates a number of facilities with a potential nuclear/radiological hazard at its Lucas Heights site. Following a series of incidents with radiological safety implications within the B23 licensed facility (facility licence F0262) over a 10 month period, the Australian nuclear regulator, Australian Radiological Protection and Nuclear Safety Agency (ARPANSA) has issued a direction to ANSTO to obtain an independent review of the approach to radiological safety of processes and operational procedures in B23. In particular the review is to examine processes and practices associated with the quality control processes of molybdenum-99 (^{99}Mo) samples. ANSTO has arranged this review through a team of independent consultants and the review includes a number of programmed deliverables, one of which is a progress report 30 days after the commencement of the review.

This document provides the progress report for the independent review.

Progress Report Against the Work Plan

A detailed work plan has been issued to ANSTO for onward transmission to ARPANSA and this progress report is based upon the finalised work plan. The review has been split into 3 distinct phases comprising:

- An initial desk based review phase which entailed detailed review of ANSTO processes, procedures, records and information either provided initially by ANSTO and then as requested by members of the review team.
- A site visit comprising an accompanied tour of the relevant facilities at Lucas Heights and a series of interviews with managers and staff.
- Production of the review study report.

Desk Based Review

The documentation provided by ANSTO, both at the commencement of the project and following specific requests by members of the review team have been reviewed by the team members. No difficulties have been experienced with the provision of documentation and other information to support the first phase of the review. The only exceptions to this were confidential information which had been requested and was provided to the team at the start of the site visit phase. All requests for information were dealt with rapidly and efficiently by ANSTO.

Site Based Review

The site based review was completed over the period of 6th to 13th August 2018; other visits by the Australia based members of the team have been undertaken following the formal site visit to clarify certain questions and issues. The visit included meetings with ARPANSA, members of the ANSTO Executive, managers and staff; all discussions with managers and staff were held on the basis of full confidentiality and anonymity. The interviews were arranged and coordinated by the ANSTO Regulatory Affairs Manager and this sole route operated very efficiently and effectively. As a result, all managers and staff who had either requested to speak with the review team or had been nominated by the review team were interviewed within the time period.

Subsequent to the site visit, an additional task has been initiated. This task involves inviting the ANSTO Health employees to complete a voluntary survey to inform the review report over the period 17th to 24th August 2018 using the People at Work (PAW) psychosocial risk assessment tool with a number of additional questions. The survey is underway and many responses have been received and the output from the data will be analyses and added to the body of evidence in the review study report.

Study Report

Work has commenced on the first draft of the study report and is currently programmed to be completed in line with the agreed schedule, namely:

- Issue draft report to ANSTO 17 September 2018
- ANSTO review 17-21 September 2018
- Issue final report to ANSTO 27 September 2018