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INDEPENDENT REVIEW TEAM AND REPORT GENESIS

1. Who was on the independent review team?

The review panel comprised five national and international experts headed by David Jones, who has extensive experience in management and production of safety cases and assessments for nuclear facilities in the UK and Europe. The full list of people on the team and their resumes is available on Page 18 of the Report.

- Who appointed and approved the team? The independent regulator, ARPANSA, directed that ANSTO appoint the Independent review team, and approved the experts who comprised the panel.
- What was the scope of the review?
 The scope was an independent review of safety at Building 23 and related operations. A full outline of the scope is on Page 17 of the Report.

How did the independent team conduct their review? The Team conducted its review through a combination of in-person interviews,

documentation reviews, a site inspection visit and report preparation.

5. Which staff were interviewed as part of the review process? How many?

Interviews were based on a combination of requested interviewees provided by the review team in advance, together with staff who had expressed a desire to speak with the review team. In total, 41 interviews were held. Around 20 per cent of ANSTO staff involved in medicine production either came forward to be interviewed or were selected. An additional 18 employees were interviewed from the wider ANSTO organisation.

6. What happens with the recommendations from the independent review now?

As the Report states on Page 15 "The findings of this Report, are therefore not exhaustive, but are designed to provide recommendations to support improved safety, health and organisational effectiveness". Some 85 recommendations have now been received, and they will be carefully considered over the 60 days from when the report was submitted to ARPANSA.

7. What were the overall concerns the review heard from staff?

ANSTO will let the Report speak for itself but does note that it says: "This conclusion needs to be balanced against the notable improvements in safety that have been achieved by ANSTO Health and the corporate organisation in recent years. For example, while production at ANSTO Health has significantly increased over recent years, annual average doses to the operators have shown a downward trend. This demonstrates that safety improvements, both physical changes and changes in management and operations practices have delivered improved radiological safety." (Page 10)

- 8. Why was the August 2017 incident designated a Level 3? What does this mean? According to the International Atomic Energy Agency (IAEA) International Nuclear and Radiological Event Scale (INES), a Level 3 on the seven-level scale is equivalent to an exposure causing non-lethal radiation effects (tissue reactions) on a single worker. As publically confirmed in December 2017, this event was the only Level 3 (and above) rated incident reported worldwide last year, and the only one ever reported at ANSTO.
- **9.** How has ANSTO changed its safety procedures since the incidents of the past year? The report acknowledged the good work that has already happened in this area: *"The implementation of actions from incidents and opportunities for improvement has resulted in significant improvements since the incidents referred to, that led to this review. Those improvements have all been documented through appropriate change control processes. These have included, but not limited to changes to additional people resources, upgrades to equipment, process and documentation improvements" (Page 59). We are now reviewing the recommendations of the independent review and will develop a comprehensive action plan around what else can be done to make ANSTO's operations safer.*

PHYSICAL AND POLICY SAFETY IN BUILDING 23 AND AT ANSTO

- **10.** Is ANSTO meeting modern standards approaches with regard to safety in Building 23? No. Although building 23 has had five major upgrades in the past 30 years, it is now coming to the end of its life. While it has operated safely for decades, the safe operation of the facility increasingly relies on administrative controls rather than modern standards engineered controls. As the report identifies, this is not unusual within the nuclear industry, but does challenge the long-term sustainability of the B23 facility and the nuclear medicine it produces. ANSTO will now consider the 85 recommendations from the Report, and develop an action plan that addresses nuclear, radiological and conventional safety improvements. Central to our response to the recommendations will need to be a plan to upgrade the ageing infrastructure on which production of Australia's nuclear medicine currently relies.
- **11.** What safety training do staff at ANSTO Health undertake? How regularly is this training updated?

Since 2015, staff working within ANSTO Health have completed on average 144 hours of training per person per year. This equates to 20 days. In the past financial year, ANSTO Health staff completed almost 10,000 training modules and spent, on average, 155 hours of training per person, or 21 days.

12. Is the OPAL reactor involved?

No. The OPAL reactor is a separate building. OPAL is one of the world's safest, most regulated and most reliable multi-purpose reactors, and consistently operates for more than 300 days a year. It is independently regulated by Australia's nuclear regulator, ARPANSA. The Report notes that *"The OPAL safety management system is a well-established system commensurate with the operation of a nuclear facility which includes sufficient technical staff to support ongoing operations, changes and safety issues"* (Page 31).

13. Is ANSTO's risk reduction process in line with modern nuclear standards?

Yes. That said, the Report found: *"It is understood that the safety assurance and risk management and acceptance processes are currently under revision to reflect changes in the ANSTO business processes and to further embed these processes within the ANSTO management system"* (Page 87).

14. Is the "Just in Time" approach at the expense of employee safety? Are some safety decisions in B23 being taken in order to meet production deadlines?

No. Every ANSTO staff member needs to both be safe at work, but also know that the management of this organisation has no higher priority than their safety. As the Report outlined, there is a "balance between availability of life-saving medicines, product safety and worker safety that is the key aspect of operations within ANSTO Health" (Page 29). The Report made recommendations in this space, and those recommendations will certainly be considered.

15. Are there gaps in ANSTO's radiation protection systems?

Whilst ANSTO always seeks to continuously improve in all areas, including radiation protection, its current systems are robust and were subject to a specific inspection by ARPANSA which recognised the quality of the service provided.

16. Why doesn't ANSTO measure beta radiation?

ANSTO does measure beta radiation. Building 23 has various instrument designs available, which have the capability to measure beta radiation in the form of thin end window contamination monitors. They are often used by operators and RPS to search for contamination and assess surface concentrations on objects and people. There are seven portable radiation monitors (Ion Chambers) available at ANSTO that are capable of monitoring for beta dose rates, and these have been used widely in the assessment of beta doses during the return to generator production (which is probably why the team did not see any of these instruments in the general area of B23). Beta radiation exposures to the operator's body and hands are also measured (retrospectively) by the use of TLD's.

STAFFING, MANAGEMENT & SAFETY CULTURE

17. How is ANSTO's safety culture being improved?

Constantly. As the Report says, "ANSTO has a well-developed safety assessment approach culminating in the management, production and assessment of safety cases as the presentation of the totality of the safety argument" (Page 7). It is further noted that "ANSTO is currently progressing its 10-year periodic review of safety and security within the licensed facilities at ANSTO Health and the OPAL reactor which is examining safety assessment methodologies and the associated standards" (Page 10). However, ANSTO recognises the concerns raised by some ANSTO Health staff, and as a result of the Review, there are now 85 recommendations to further strengthen safety in Building 23 and across ANSTO more broadly. Those recommendations will be considered and responded to in the action plan currently being developed.

18. How does ANSTO management communicate corporate safety requirements to its staff?

Throughout the Report there are several reported instances where communication could be improved between the front line and ANSTO management, and there were recommendations to that effect, which are being considered and will inform the development of our action plan.

19. Does ANSTO promote a "no blame" culture

Yes. ANSTO is committed to a 'no blame' culture, with an obligation for 'full disclosure' on behalf of staff. However, recommendations have been made to improve a "Just Culture", and those will be considered in detail during the development of the action plan. The Report acknowledges that "ANSTO as an organisation is developing its "learning from experience" culture and approach in line with nuclear industry norms and this process should be accelerated" (Page 7).

20. Is ANSTO Health adequately resourced?

Like any public service organisation or business, ANSTO always works to ensure that we have the right balance between people, safety and production. The report made recommendations that relate to staffing in certain areas of ANSTO Health, and those recommendations will be considered. All ANSTO staff have access to a range of policies, services and information that support employee wellbeing. Central to this suite of programs is the Employee Assistance Program, an independent counselling and advisory service for ANSTO staff members and their immediate family members. This service can be accessed 24/7 via a free call number.

- 21. On average how many training hours do ANSTO Health staff undertake each year? Since 2015, staff working within ANSTO Health have completed on average 144 hours of training per person per year. This equates to 20 days. In the past financial year, ANSTO Health staff completed almost 10,000 training modules and spent, on average, 155 hours of training per person, or 21 days.
- 22. How many staff work in Building 23 for ANSTO Health?84 staff work for ANSTO Health across B23 and B54.

23. What medicines are produced or supplied by ANSTO Health?

The ANSTO Health business operates a number of facilities related to the production of radioisotopes for therapeutic and diagnostic use including:

- a. Molybdenum-99 (⁹⁹Mo) and its decay product, Technetium-99m (^{99m}Tc), which is used worldwide in nuclear medicine for diagnostic imaging.
- b. Chromium-51 (⁵¹Cr) which is used as a diagnostic radiopharmaceutical agent to determine the red blood cell volume or mass, study the red blood cell survival time and evaluate blood loss.
- c. Iodine-123 (¹²³I) meta-iodobenzylguanidine (MIBG) which is used to confirm the presence of tumours called neuroendocrine tumours and is used as a therapy for brain cancers, almost always paediatric.
- d. Iodine-125 (¹²⁵I) which has uses in biological assays, nuclear medicine imaging and in radiation therapy as brachytherapy (i.e. the placement of a sealed radioactive source inside or adjacent to the region that requires treatment) to treat a number of conditions, including prostate cancer, uveal melanomas and brain tumours.
- e. lodine-131 (¹³¹I) which is a nuclear medicine treatment for an overactive thyroid and also may be used to treat thyroid cancer.
- f. Samarium-153 (¹⁵³Sm) which is used to help relieve the bone pain that may occur with certain kinds of cancer (e.g. prostate cancer).

- g. Lutitium-177 (¹⁷⁷Lu) which is a recent development for the nuclear medicines industry but could become one of the most widely used therapeutic radionuclides and is currently undergoing patient trials for therapy of prostate cancer metastases.
- h. Gold-198 (¹⁹⁸Au) which is used in some cancer treatments and for treating other diseases and is being investigated as an injectable treatment for prostate cancer.
- i. Iridium-192 (¹⁹²Ir) which is used as a source of gamma radiation for treating cancer with the application of brachytherapy.
- j. Yttrium-90 (⁹⁰Y) which is used to treat liver cancer.
- k. Gallium-67 (⁶⁷Ga) which is used to locate and examine tumours and specific inflammations, especially of the lung.
- I. Thallium-201 (²⁰¹TI) which was the main substance for nuclear cardiography before the adoption of ^{99m}Tc and is still used for stress tests for risk stratification in patients with coronary artery disease.
- **24.** What impact do the nuclear medicine products from ANSTO Health have on Australians?

ANSTO delivers over 10,000 patient doses of nuclear medicine to around 250 hospitals and clinics every week, and has done so for many years. The primary use of these medicines is in diagnosis, and as we all know, early and accurate diagnosis can be critical to survival rates. There is also an increasing use of new nuclear medicines in treating and curing life-threatening diseases. This potentially life-saving medicine will be, on average, needed by one in two Australians in their lifetime.

25. According to the Report, both Buildings 23 and 54 are old 'legacy' facilities and therefore do not meet modern standards of nuclear design, nuclear safety and operational workflows. How can ANSTO, therefore, justify its current commercial use of the building?

The Report acknowledges that "A number of additions and improvements have been made over the years which have added capacity and capability but the facilities are now operating in the lifecycle phase where ageing and obsolescence are major factors, both in terms of operational effectiveness and the nuclear safety case" (Page 29). The fact is that work is already being finalised on the ANM project to replace Building 54. And central to our forthcoming response to the report will be a plan to upgrade other ageing infrastructure on which production of most of Australia's nuclear medicine currently relies.