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5 October 2018

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

Dear Dr Larsson,

RE: Facility Licence F0262 ARPANSA direction of 29 June (your reference R18/07432)

The independent review of the *approach to occupational radiation safety of processes and operational procedures in Building 23* that ANSTO was directed to undertake is complete.

ANSTO has received the final report from the independent external reviewer and supporting experts. Redacted and unredacted copies of the report are enclosed.

There are three sections in the report which do not meet the anonymity requirements agreed between ARPANSA and ANSTO prior to the review commencing. ANSTO will not compromise this very important principle. As such, these sentences have been redacted in all versions of the report that will be accessible to staff and the public. ANSTO requests that you consider the materiality of the redacted sections to ARPANSA's regulatory purposes, and whether the conclusions and associated recommendations are affected. If you consider that the redacted paragraphs are not material to ARPANSA, ANSTO would request that you restrict access to the unredacted version within ARPANSA to a need to know basis, in order to protect ANSTO staff who would be identifiable. ANSTO understands that the redacted version will otherwise be used consistent with the anonymity principles.

The report contains important areas for improvement and many sound recommendations. The experts have identified practices and behaviours which can be improved for the ANSTO Health business, which it is acknowledged is operated from a relatively old legacy facility, and some of which may also be applicable to other ANSTO divisions. ANSTO respects and values each and every view expressed in the report, and the value that the experts have contributed to providing ANSTO with a holistic overview of areas for improvement and of issues present in ANSTO Health.

ANSTO is pleased that the expert reviewers recognised both the unique nature of ANSTO Health in producing life-saving nuclear medicines to the tight schedules required by the nuclear medicine communities across Australia and the very nature of the product, and also the extraordinary commitment of the staff and management in ANSTO Health in fulfilling this vital mission.

In accordance with your letter of 4 October (your reference R18/11936) we will provide to ARPANSA within 60 days a full and complete response to the recommendations and a comprehensive action plan for the implementation of actions responding to these recommendations.

Review Recommendations and development of action plan

There are 85 recommendations arising from the review that the expert reviewers have categorized as High, Medium, Low and Area for Improvement in accordance with their expert opinion. We are committed to undertaking a full and proper review, in consultation with staff, of each individual recommendation in order

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to determine the best course of action to achieve sustainable, evidence-based and appropriately resourced outcomes. For this purpose, set out below are some of the key principles and considerations that will be adopted by ANSTO in developing its comprehensive action plan. Other principles will be developed throughout the development of the action plan.

- 1. Change will be sponsored from the ANSTO executive, with input, guidance and directions from all levels:** The ANSTO executive appreciate the significance and severity of the issues raised. It understands the need to sponsor, and have a leadership role in implementing, changes for these matters at the highest level. However, it will do so whilst involving and valuing the contributions needed from all levels of the organisation to ensure productive and appropriate actions with the necessary ownership and engagement.
- 2. ANSTO will continue to make improvements and also acknowledge the work already underway by many people at ANSTO to address these recommendations:** Many recommendations are being addressed through improvements ANSTO had initiated prior to receiving the report. ANSTO will ensure that the solid basis of these improvements and the hard work already completed is not overshadowed and is integrated smoothly into the action plans developed. ANSTO is also pleased that the review has highlighted the strong current ongoing work that ANSTO Health has undertaken in many of these areas, and the dedication by ANSTO Health staff and management to doing everything they can to safely and reliably support the production of nuclear medicine for Australia and overseas. It is clear from the report that it is important for ANSTO to implement changes, and in some cases, quickly. At the same time, ANSTO will not lose sight of the hard work and experience within ANSTO Health and ANSTO, and will ensure that those areas continue to be strengthened.
- 3. ANSTO recognizes that the report was developed during a difficult period. Awareness of the stress, workloads, and emotional burden faced by ANSTO Health staff will remain at the forefront:** The review was undertaken at a time which was one of the most challenging for ANSTO Health; during an outage of ANSTO Health's main nuclear medicine production facility caused by mechanical failure of the Tc-99m generator line in June. As noted in the report, in accordance with TGA requirements, the production site had to be thoroughly sterilised and then had to be left undisturbed for 14 days before being tested for microorganism contamination prior to recommencing production. Meanwhile patients were waiting for their doses, and many of the ANSTO Health staff involved at the time perceived that there was pressure exerted to shorten the waiting time. The decision was taken, in conjunction with production staff, to delay the return to production to address emerging safety issues to ensure compliance and therefore the ongoing sustainability of production once commenced. This period was and has continued to be immensely stressful on ANSTO Health staff and management, emphasised by the deep emotional reactions and profound levels of the commitment of ANSTO Health staff reported during the review interviews. As with all 'point in time' reviews, ANSTO is alert to this issue and the impact it will have had on the review. It is also identified in the report itself. It will be important to ensure that the action plans are developed so as to be well suited to the most difficult of periods, such as this, but also be developed so as to apply during business as usual periods.
- 4. ANSTO will delve deeper into the concerns and issues raised to ensure a thorough and complete basis for improvements and actions:** A large part of this review was based on the content of interviews held at ANSTO Health and support areas. In total, 41 interviews were held: 18 with employees from either central technical functions or ANSTO management, and 23 with ANSTO Health/ANM employees. Throughout the report, it is clear that many of the conclusions associated with ANSTO Health are based on those interviews with ANSTO Health staff. ANSTO Health (including B54/ANM) has 126 staff. The views provided by all or some of those interviewed are important, and from the report display honesty and transparency that we welcome. They are essential to ANSTO's understanding of the nature of issues facing ANSTO Health. However, in implementing the recommendations due regard will be paid to the fact that not all staff were interviewed and, whilst many have, ANSTO expects that not all views, issues or concerns have made it into the report. In order to develop the most effective response to the report, ANSTO needs to ensure it has a thorough and complete understanding of the concerns within ANSTO Health, and will delve deeper into understanding these.

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5. **ANSTO will not rush into a “one size fits all” approach:** ANSTO will take into account that other parts of ANSTO operate differently, sometimes significantly so, due to their different mission. Actions adopted will need to be mindful of different mission, time-constraints, cultural, behaviour, workforce planning and resource issues faced by these other parts of ANSTO as compared to ANSTO Health. Accordingly, one of the key tasks of ANSTO in implementing the recommendations will be to further investigate and review the issues identified to determine whether and to what extent they apply in other parts of ANSTO, and ANSTO as a whole. It is critical to ensure that the actions adopted are proportionate, are appropriate and appropriately tailored where practicable, take into account all relevant issues and are based on detailed examples and evidence. Importantly, it is also fair to ensure that the work done in other areas is reflected in a balanced and proportionate action plan. For example, OPAL has a highly sophisticated, well audited, system in relation to safety approvals. It would be inappropriate to expect the same types of actions of OPAL staff as might be required of ANSTO Health. This said, ANSTO prefers organisational consistency and transferability, so the ability to have consistent processes and procedures and in particular management systems will be a priority.
6. **There are some recommendations that require input beyond ANSTO Health:** It is recognised that input from other parts of ANSTO is also required to ensure that actions implemented work well for all parts of ANSTO; not just for ANSTO Health. Input from areas outside ANSTO Health (such as engineering and WHS) will be important, and in some cases, input from stakeholders outside ANSTO will also be important. This is not just so that the actions have had input from all key areas of expertise, but also so that in addressing issues in ANSTO Health others are not inadvertently created in support functions.
7. **Involvement and engagement are key:** Given the significance and importance of the report and its recommendations, all action plans will be developed in consultation with appropriate staff. Dedicated workgroups bringing together expertise across the organisation, each led by a member of the executive, will be formed to develop the action plans. This does not mean that everyone will need to be involved in every solution. It means that careful thought will be given to developing the right involvement at the right levels so that engagement and ownership of the actions is as high as possible.
8. **ANSTO will look at relevant options, but will not over-burden staff with too many solutions:** Some of the recommendations have significant breadth, particularly those relating to management systems. This is expected and fair given the short time frame for the review, the limited number of people interviewed and the inability of the experts to review ANSTO's systems and procedures per se. Recommendations which are broad are valuable, but ensuring a clear approach to the actions required can take more time. It is important in a resource-constrained environment that the tasks taken are appropriate, necessary and proportionate. In some cases, a full review of the management system will not be warranted or may be phased. ANSTO will seek to understand in more detail the issues with the system in order to fully advance improvement options in a proportionate, systematic and appropriate manner.
9. **ANSTO will be mindful that people's days are already full and stress levels are elevated:** The review identifies, on a number of occasions, the stress levels and resource constraints being faced by ANSTO Health. It identifies concerns held by staff that they need to work longer hours than should be expected, or that they are unable to take leave. It also identifies concerns raised by staff on change management. This causes ANSTO concern, and addressing these matters will be a top priority of ANSTO. However, this stress also needs to be taken into account when implementing (and even in preparing) a comprehensive action plan. ANSTO will take into account the timing for action to ensure those actions of highest impact and highest priority are implemented soonest, with appropriate consideration of resourcing requirements. It will be important to integrate the actions *into* rather than *on top of* people's existing work. .
10. **Change is difficult. ANSTO realises this.** ANSTO has spent recent years developing change management processes for personnel changes. ANSTO is conscious of the stresses that recent executive management changes may have had on both ANSTO Health and radiation protection services, particularly the latter who integrated into the People, Culture, Security and Safety group only in September 2017. It will be important to ensure that any further change or clarifying of roles or reporting lines is implemented through a robust change management process. This is also a recommendation of the report.

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Other comments on the Report

As noted above, ANSTO fully respects all the issues, concerns and improvements identified in the report, and will deeply consider each and every recommendation. However, there are some aspects of the report that ANSTO would also like to comment on at this stage. This is not done in the spirit of criticising the report; rather, as the report acknowledges, the review was undertaken in a compressed time frame and the report consequently omits mention of some important organisational initiatives in recent years.

Strong Safety Record:

The report recognises that notable improvements in safety have occurred in recent years in ANSTO Health, and we are committed to improving upon the good work that has been done. Ensuring that ANSTO's operations have a strong and robust safety culture has in recent years been a fundamental part of ANSTO's values, driven by the CEO. As part of this, ANSTO regards as first and foremost the need to value, look after, and nurture its people and its infrastructure.

ISO 45001 is an ISO standard for management systems of occupational health and safety, published in March 2018. The goal of ISO 45001 is the reduction of occupational injuries and diseases. ANSTO has recently passed a stage 1 ISO 45001 audit as we progress our mission to gain accreditation against this important standard. The scope of this recent audit covered all areas of the organisation, including production and use of radioisotopes, isotopic techniques and nuclear radiation for medicine, science, industry, commerce and agriculture.

This said, all recommendations for improvements to safety and safety management are welcomed. In particular, ANSTO will reconsider its structured training program to determine whether or not there is sufficient training in relation to areas such as regulatory expectations and requirements, and radioactive hazards in particular (as well as any other areas).

ANSTO will also ensure ANSTO Health learns from the robust and successful OPAL reactor operation to identify and implement improvements.

Core to many recommendations is the need to focus on the culture and morale within ANSTO Health, which has battled numerous recent issues. Ensuring that the recommendations are implemented in a manner which improves and does not increase levels of stress, anxiety, high workloads and time pressure is critical to the approach ANSTO will implement the recommendations. In particular, consideration of the need to increase or improve training and to update documentation will be implemented with principal focus on the need to do so in a controlled, sustainable, valued and positive manner. This will mean, for example, that it is not the case that all staff will be required to do all training, and nor will all documents need to be fully reviewed in a short time period. ANSTO will take a proportionate response to these matters to ensure that no additional undue workload is placed on staff.

Serious allegations were raised in the report in relation to potentially inappropriate workplace behaviours. Whilst such allegations had not been previously raised with ANSTO, it will ensure it promptly investigates all such allegations and implements changes to ensure that staff feel comfortable to report such behaviours, which are unacceptable to ANSTO, and to ensure that there are improvements to reporting and investigation processes in relation to such issues.

ARPANSA Relationship:

ANSTO regards highly the regulatory relationship that it holds with ARPANSA. Over the last 5 years the increased engagement and regulatory oversight through frequent site visits and a long term inspection program has fostered an open and honest relationship. ANSTO welcomes the opportunity to increase the detailed procedures as to this working relationship and to improve widening interfaces at many levels.

ANSTO Health workforce:

ANSTO welcomes the findings in relation to the strong dedication and passion of the ANSTO Health workforce and management - in particular, their dedication to the customer and to the nuclear medicine community which they serve. ANSTO strives to achieve excellence in its ability to safely, capably and sustainably support patients with medical technology that is critical to diagnosis and treatment of many Australians.

A number of initiatives in ANSTO Health over the years have focused on collegial ways of working and enhancing local leadership. Most notably, the Wayne Pearce Program was designed to furnish leaders with the skills and support to engage and inspire their people to improved and sustainable levels of performance. This was then built on through the Engaged Team, Engaged Leadership and Leadership Development Centre programs that were implemented in both ANSTO Health and other business units. These programs assisted staff to better understanding their strength and personality traits and how to better relate to their colleagues. We will continue to ensure that these programs are strengthened whilst focusing on other areas for improvements.

Communication and engagement between managers and their staff:

One of the recommendations to ANSTO is to improve the communication to this dedicated workforce. ANSTO intends to seek insights from what is happening on a regular day to day basis and how this affects patterns of safety, performance and satisfaction, despite unexpected and challenging circumstances.

Nuclear Science Technology and Landmark Infrastructure (NSTLI) are currently piloting the Career Management System (CMS) for ANSTO. Part of this CMS is to enable all staff with techniques for courageous conversations. This is a full day training course with many practice sessions; NSTLI has to date trained more than 450 of its staff. The Steering Committee have decided to start to roll out the CMS training to the broader ANSTO, including ANSTO Health, with the intention of improving communication on difficult issues.

New facility and biomechanical risks

The report identifies that the existing ANSTO Health facilities are operating in the lifecycle phase where ageing and obsolescence are major factors. ANSTO, and its management and ANSTO Health staff, have a resolute commitment to ensuring the continued production of nuclear medicine for Australia in a safe and sustainable manner. ANSTO will continue to explore with the Government opportunities to rectify some of the issues identified through the development of a replacement nuclear medicine facility, recognising that there are various options by which this may be achieved, each of which take time. Irrespective of these potential options, ANSTO will continue to focus on improvements to the current facility operations and asset management which can support the existing facility for as long as is feasible.

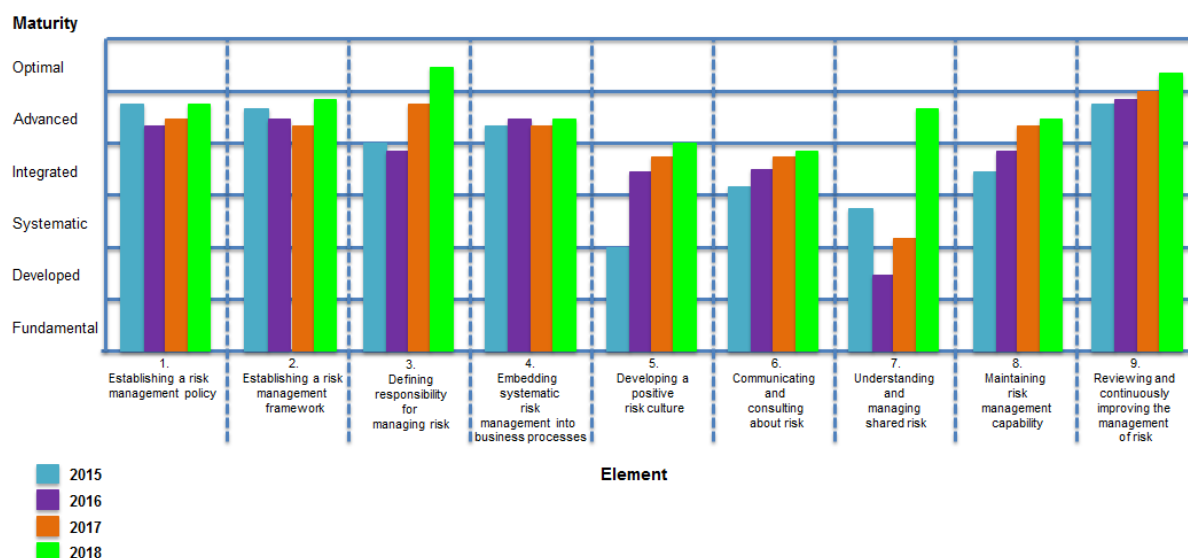
ANSTO recognises the view among ANSTO Health staff that facility and asset maintenance have not been sufficient to address all the issues they face working in such an ageing facility. In the short term, ANSTO's actions will focus on hazard identification and rectification as well as addressing issues raised as to musculoskeletal discomfort reported by some staff during the review. In addition, ANSTO will develop a nuclear baseline for the ANSTO Health facility which will assist ANSTO to develop and reflect the strong capability and capacity ANSTO has in operating the facility.

Non-reporting of incidents

Between 2012 and 2014, ANSTO implemented a new, more comprehensive, integrated GRC solution to facilitate risk and compliance management, incident management, assurance and the tracking of actions. However, the report indicated that the reviewers felt that there was under-reporting or a fear of reporting within ANSTO Health – which is a matter of concern to ANSTO. ANSTO is an organisation which is continually developing its "learning from experience" (LfE) and reporting culture. ANSTO will pay more attention to the matters which are preventing prompt and accurate reporting, and will strive to increase the LfE culture of ANSTO Health.

Risk management

Important recommendations have been made to re-assess ANSTO’s risk management focus, and in particular its focus on residual risk. Since 2011, ANSTO has gradually increased its risk management maturity through a range of targeted actions. As a corporate Commonwealth entity, its risk management maturity is measured annually through the Comcover Risk Management Benchmarking Program (developed by Deloitte). This program benchmarks ANSTO’s risk management performance against nine key elements as outlined in **Graph 1** below. This graph also depicts ANSTO’s maturity relative to each of these elements.



Graph 1: ANSTO Risk Management Maturity: 2015 - 2018

It is clear from the above graph that ANSTO has shown gradual improvement across most elements in recent years - most elements are at the 'advanced' or 'optimal' maturity levels.

ANSTO is currently implementing a new Enterprise Risk Management (ERM) Framework that was approved by the ANSTO Board in August 2017. This is a comprehensive framework that addresses all of the above elements and beyond. In addition, the framework has a strong focus on auditable risk management performance expectations and defines the roles and responsibilities specific to each element of the framework. These will form the basis of risk management assurance activities going forward.

Building on the enhanced ERM Framework, ANSTO has also developed a much improved Risk Appetite Framework (Element 1 – ERM Framework) that was approved by the ANSTO Board in June this year. That Framework clearly stipulates the boundaries within which ANSTO must operate (risk appetite) and articulates specific risk tolerances. This framework stipulates ANSTO’s risk acceptance criteria generally, but also specific to safety and radiation risks.

The development of the above frameworks was informed by a range of factors, including relevant risk management benchmarking models, ISO 31000 Risk Management standard, COSO ERM Framework, Commonwealth Risk Management Policy, stakeholder expectations, contemporary management thinking (e.g. unconscious bias, organisational culture, and change management) and experiences of the Risk Function over many years.

The ANSTO Risk Management Process is currently being implemented across ANSTO and incorporates some of the latest thinking (e.g. focus on critical controls – see *Critical Control Management* by International Council on Mining and Metals) and provides for an ANSTO-developed three dimensional approach to risk analysis. This approach provides us with unique insights, as we consider a range of factors (e.g. risk velocity, uncertainty, complexity, ambiguity, controllability and interdependency) in addition to traditional risk management approaches.

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Prior to the adoption of the enhanced ERM Framework and Process, ANSTO's risk management approach was aligned with relevant risk management standards and characterised by, amongst other, a common risk language and risk analysis basis (ANSTO Risk Analysis Matrix), defined roles and responsibilities, online risk management training, a risk culture assessment and board risk workshops. ANSTO will build upon these in implementing the recommendations included in the report.

Safety assurance process

The report credits ANSTO for initiating a project to review and revise the ANSTO safety assurance process based on increasing line management's level of responsibility and accountability for safety. The revised safety assurance process will also focus less on the categorisation of the modification at the start of the process. The focus will shift to the identification and control of hazards holistically and appropriately, and the output of the process will determine the classification of the change i.e. once controls have been optimised. The SAC process as currently operated has relied on the objective independence of the subject matter experts who act as assessors. The effectiveness of the independent challenge is evidenced by the robust and comprehensive assessment documents produced by the assessors. ANSTO will consider how the current culture of independent challenge can be formalized.

Change management process

ANSTO was awarded by Comcare in 2016 for its Change Management toolkit, which is widely used for a full range of change management actions, including systems, processes, organisational change, workforce change and major projects. We see appropriate application of this toolkit as critical to the implementation of the recommendations highlighted in the report.

The ANSTO Enterprise Agreement 2017-2020 provides for consultation on major workplace change, and ANSTO will ensure compliance with that requirement when developing and implementing the improvements to be adopted following this review.

Beta dose measurements

ANSTO has the capability to measure beta radiation in the form of thin end window contamination monitors. There are various designs available in B23. They are often used by operators and RPS to search for contamination and assess surface concentrations on objects and people. Although the practice of using dose rate meters that measure penetrating (gamma) radiation but not beta is common within ANSTO RPS, there are seven portable radiation monitors (Ion Chambers) available at ANSTO that are capable of monitoring for beta dose rates. These monitors 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). In most circumstances, insufficient information is known about the radiation field to quantify dose rates accurately, and any beta dose rate measurement is used for indicative purposes only. Beta radiation exposures to the operator's body and hands are measured (retrospectively) by the use of TLD's.

Asset Management (ISO55000)

ANSTO is implementing the ISO55000 Asset Management Model across its businesses. Through the rollout ANSTO is focusing its resources on a number of critical issues i.e.: Sites Management, Spatial (master) Planning, Property and Tenancy Management, Change Management initiatives leveraging key assets, Facilities and Active Maintenance Services, and Refurbishment and Production Workshop Services. In ANSTO Health, the initial focus has been on ensuring the delivery of predictable, repeatable and reliable facilities and active maintenance services. The recent ARPANSA audit evidenced the high level of performance being achieved in these areas across ANSTO Health. In the next phases of the rollout, the focus will be on the efficient and prudent use of capital and non-financial resources to achieve the business's strategic objectives.

Staff Engagement

The introduction of Pulse surveys across ANSTO is enabling business unit leaders to quickly and regularly obtain feedback and engage their staff on matters of concern to them. Most recently the Asset

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Management Services Group (AMSG) completed its first survey using the new tool. Significant improvements have been made in all but one of the 15 factors surveyed. AMSG management are now focusing on not only addressing the one area of concern staff identified but also in improving further staff engagement across the other 14 factors. The use of such tools across ANSTO including ANTO Health will form part of our suite of measures to address the issues identified in the review.

Accountability and disciplinary action

ANSTO appreciates the feedback by some of the staff interviewed that there is a concern that ANSTO Health does not fully reflect a "no blame" or a "full accountability" culture. ANSTO will focus significantly on the recommendation to implement a "just culture" policy which enables decisions around accountability, performance management, discipline, and human error adjustments to be better aligned. ANSTO's CEO has openly stated his commitment to a 'no blame' culture, but that this is effectively a compact between the organisation and staff members, where 'no blame' comes with an obligation for 'full disclosure' on behalf of staff. It is only on this basis that the full *Learning from Experience* can be gained.

Finally, ANSTO restates that the report contains important areas for improvement and sound recommendations. Through the thoughtful and measured approach to tackling the report and its valuable recommendations, ANSTO will continue the journey in improving both safety and staff engagement in ANSTO Health as well as improve systems across ANSTO as a whole.

If you would like any further information please don't hesitate to contact the coordinator of the review, Paula Berghofer on paula.berghofer@ansto.gov.au or (02) 9717 3754.

Yours sincerely,



Shaun Jenkinson,
Acting Chief Executive Officer, ANSTO

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