



2 November 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 R18/11936)

ANSTO is writing to provide the 30 day progress report regarding the development of the plan and timelines of the implementation of actions responding to the recommendations of the independent review panel (the Panel), as requested in your letter dated 4 October 2018. As you are aware the report made 85 recommendations. ANSTO is continuing to take into account the issues raised in our letter to ARPANSA of 2 October 2018 in its review of recommendations and development of applicable actions.

The recommendations are being grouped into programs of work to allow ANSTO to satisfy the intent of a number of recommendations in the one body of work. A number of relevant actions (improvements, process changes and associated interventions) are underway where these have practical utility and no direct regulatory impact or are corrective actions previously agreed with ARPANSA.

Our analysis of the recommendations has responded to:

- The original priority assigned by the Panel;
- The opportunity to group individual recommendations into (A) ANSTO programs, (B) Regulatory process and program improvements agreed with ARPANSA, (C) Joint actions with others, (D) Task assignments to responsible Executives or the CNO, and (E) Current ANSTO practice – to be documented for closure;
- (F) Some recommendations are inconsistent with our management approach and these will be addressed by demonstration that our plans and arrangements, governance and risk frameworks, and/or operational settings achieve substantially the same outcome.

Further consideration of each is included below with details relating to specific recommendations included in Appendices A – F.

Priority

Consideration of the priority assigned by the Panel is being taken into account in resourcing and scheduling the implementation plan. As discussed above a number of these recommendations will fall under programs of work. The programs identified as requiring the highest priority are the Safety Assurance Process Review (previously SAC), ANSTO Health Workforce Planning and ANSTO Health Change Management.

ANSTO Programs

Where one body of work is able to satisfy the intent of a number of recommendations they have been grouped into programs of work. 60% of the recommendations have been grouped into ten programs. Implementation plans will be provided for each program of work. ANSTO Programs and the recommendations are included in Appendix A.

Improvements Agreed with ARPANSA

Two recommendations were previously agreed with ARPANSA in the form of corrective actions. The improvements agreed and the recommendations are included in Appendix B.

Joint Actions

ANSTO will seek to transfer one of the recommendations to the Federal Government as it is directly related to funding of a replacement facility for B23. Five of the recommendations involve significant input and approval from ARPANSA before progressing. Discussions will be held on these prior to delivery of the detailed implementation plan. The recommendations related to joint actions are outlined in Appendix C.

Task Assignments

Recommendations which do not fit under a program of work have been assigned to a responsible Group Executive (GE) or the Chief Nuclear Officer (CNO). ANSTO officers are currently working with stakeholders and practitioners to finalise actions for our submission on [4] December 2018. The recommendations covered by task assignments are outlined in Appendix D.

Current ANSTO Practice

Recommendation 36 is considered substantially in place and will be documented for closure with the submission of the detailed implementation plan. The recommendation and further information is included in Appendix E.

ANSTO's Management Approach

Some recommendations are inconsistent with our management approach and these will be addressed by demonstration that our plans and arrangements, governance and risk frameworks and/or operational settings achieve substantially the same outcome. The related recommendations and further information is included in Appendix F.

Improvements already underway

Twenty-seven of the recommendations are being addressed through actions already in progress. ANSTO has been working on improvements initiated prior to, and since receiving the report. These improvements are being incorporated into the action plans to ensure work is captured to provide additional resourcing if required or marked as completed. Further detail on these improvements is included in Appendix G.

ANSTO recognises there is much work to be progressed in meeting the intent of the recommendations and is committed to delivering on plans that will improve both safety and staff engagement in ANSTO Health as well as improving systems across ANSTO as a whole. The full action plan addressing the recommendations and associated timelines will be provided to ARPANSA on 4 December 2018.

Unclassified

If you would like any further information please don't hesitate to contact Karen Wolfe, General Manager High Reliability on karen.wolfe@ansto.gov.au or 9717 3571.

Yours Sincerely,

A handwritten signature in black ink, appearing to read 'Adi Paterson', with a stylized flourish extending to the right.

Dr Adi Paterson
Chief Executive Officer, ANSTO

Appendices

- Appendix A: ANSTO Programs (existing or new)
- Appendix B: Improvements agreed with ARPANSA
- Appendix C: Joint actions
- Appendix D: Task assignments
- Appendix E: Current ANSTO practice
- Appendix F: ANSTO's management approach
- Appendix G: Improvements already underway

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Appendix A: ANSTO Programs (existing or new)

Where suitable, recommendations have been grouped into programs. This will allow ANSTO to satisfy the intent of a number of recommendations with the one body of work. The recommendations which are grouped under programs of work are summarised below.

The ten ANSTO Programs are: ANSTO Health Change Management; ANSTO Health Workforce Planning; Incident Management; Nuclear Baseline; Risk Management; SAC – Safety Assurance Review; Safety Culture; WHS Management System; Training; and Workplace Behavior.

ANSTO Program	#	Recommendation
ANSTO Health Change Management 2 recommendations	24	ANSTO Health implements a change management process for changes to systems, structures, people and process, taking due cognisance of quality, environmental, radiological, nuclear safety and workplace health and safety, together with the safety significance in accordance with applicable regulatory requirements.
	62	The change management process within the nuclear facilities should take due account of the nuclear modification process (i.e. assessment of the impact of an inadequately conceived or executed project and secondary impacts) as well as the GMP requirements. [Context is ANSTO Health]
ANSTO Health Workforce Planning 6 recommendations	20	ANSTO should consider the current resourcing situation for those who have responsibility for both nuclear and conventional safety and the hazards it brings and that the risks to personnel due to tiredness, fatigue and physical condition should be addressed as a matter for urgency. [Context is ANSTO Health]
	21	Senior management and/or responsible person(s) should conduct an assessment of their individual department/section and identify posts required to perform each activity. [Context is ANSTO Health]
	22	Each post should have a Role and Competency Profile (RCP) which includes clearly defined behavioural competencies, accountabilities, ownership and responsibilities. Senior management should determine the competencies and resource necessary to carry out the activities of the organisation safely and shall provide them. [Context is ANSTO Health]
	34	Workloads should be designed, as far as is reasonably achievable, to be manageable, that is without risk of harm during normal operating conditions and, in the event of crises and emergencies, to be as low as reasonably achievable/practicable. [Context is ANSTO Health]
	35	Staffing issues should be addressed to ensure all staff can take leave accordingly, without placing undue pressure on other employees. [Context is ANSTO Health]
	85	ANSTO needs to increase the number of operational staff who are certified to perform aseptic procedures, which the review team acknowledges is a very arduous process. At present, no scheme is in place to provide incentives for operators to achieve this certification which may be one solution that could be considered to achieve meeting adequate staffing levels.

ANSTO Program	#	Recommendation
Incident Management 5 recommendations	13	ANSTO should ensure its incident investigations get to true root causes in the area of leadership and policy.
	14	ANSTO needs to steer its reporting system in the right direction by identifying, celebrating and rewarding the most useful reports.
	15	ANSTO should place greater emphasis on routinely identifying the lessons contained in its incident database and communicating these lessons across the organisation including the collation, review and implementation of Learning from Experience, Safety Performance Indicators, Operational Excellence, Improvement Opportunities, Causal Analysis and sharing of best practice across the wider ANSTO audience.
	26	ANSTO instigates a review of the GRC system for the reporting of incidents to verify the system is accessible to all ANSTO personnel. A formal process should be implemented and owned by the CEO for the review of incidents and near-misses/hits and formally rolled out across the site.
	41	ANSTO Health should learn by exploring when things go right in "safety successes" despite unexpected and challenging circumstances.
Nuclear Baseline 3 recommendations	18	The ANSTO CEO implements and takes full ownership of the process to ensure adequate organisational capability for the provision of nuclear safety advice and independent challenge and the appropriate organisation, staffing and management of the nuclear safety advice and independent challenge capabilities.
	19	The Nuclear Baseline should be owned by the person who has full responsibility for the nuclear licence, the ANSTO CEO. The content of the baseline can be formally delegated accordingly, however, it should be emphasised that the ultimate responsibility remains with the CEO of ANSTO.
	23	The ANSTO CEO should identify and implement Technical Authority, Design Authority and independent nuclear safety positions, to include appropriate terms of reference (TORs) and include each into the management of change process TORs.
Risk Management 12 recommendations	25	The classification for change management of any physical change which could impact on nuclear safety, including changes to engineered or procedural safety measures, should be based on deterministic methods, complimented where appropriate by probabilistic methods and design/engineering judgement.
	32	Risk assessments should be holistic and systematically consider controls for each hazard category and then for the whole job and through the entire life cycle.
	33	Suitable techniques for risk reduction including cost benefit analysis and multi criteria decision analysis of control options should include all relevant potential life costs and benefits.
	37	Architects, engineers and others designing or procuring modifications to ANSTO facilities and equipment should accommodate relevant human factors including anthropometric ranges.
	63	The definitions, inputs and requirements associated with calculating inherent risk and residual risk should be made clear.
	64	ANSTO should modify its safety assessment approach to a deterministic assessment approach in line with relevant good international practice with the residual risk (probabilistic) calculations acting as a supporting analysis rather than primary analysis.
	66	The role of PSA should be clarified especially if the deterministic approach proposed earlier is adopted.

ANSTO Program	#	Recommendation
Risk Management (continued)	67	The hierarchy of risk control should also include the “prevent, protect, mitigate” priorities as well as the preference for passive over active and engineering over procedural.
	69	The SSC categorisation should be driven by deterministic safety demands rather than probabilistic.
	72	ANSTO risk reduction process should be made more robust and that the requirement for formal option studies and decision processes are included within the process as a specific requirement.
	73	ANSTO should remove the criterion that LOW/VERY LOW risk is acceptable and transition to a broadly acceptable criterion requiring further risk reduction unless it is grossly disproportionate in terms of reduced risk and cost.
	75	The forward actions arising from the safety assessment and safety case process should be formalised within the risk reduction process and a formal process for their implementation and close-out included within the ANSTO procedures.
SAC – Safety Assurance Review 13 recommendations	45	The arrangements for the assurance and due process associated with Category B proposals should be more clearly set out and implemented, including the terms of reference for the sub-committee to the SAC and SAC has at least a retrospective (perhaps quarterly) review of all Category B proposals as part of the auditing function.
	46	All changes which have a potential impact on nuclear safety (physical and organisational) should be independently reviewed in terms of categorisation through an appropriate independent authority such as the CNO or a change control committee.
	47	The safety assurance process should be based only on inherent risk (regardless of the residual risk claimed) as this allows the appropriate level of challenge at all levels and stages of the safety assessment process.
	48	The safety assurance (both nuclear/radiological and conventional) and risk management/acceptance processes should be integrated within the management process at “arrangements” level rather than as guidance as they all form part of the mandatory assurance and due process for the organisation.
	49	The SAC arrangements should clarify who is the licence holder and who the committee is formally advising and who in the organisation approves Category A/B activities for implementation such that it is made clear given that safety is actually an executive management responsibility.
	50	ANSTO should examine how to ensure that true independence between authors and reviewers can be maintained for the “goodness” of the independent challenge function.
	51	The arrangements for deputising for named members of the SAC should be more formally recorded including demonstration that the nominated deputies are suitably qualified and experienced.
	52	Regulatory interactions should be included within the assurance and due process arrangements level documents.
	53	ANSTO should take forward changes to the safety assurance process including a full programme of engagement with the businesses and with ARPANSA to ensure that all stakeholders are content with any revised arrangements and that these arrangements are formally documented .
54	The CNO (or SAC) should initiate a retrospective audit of all changes/modifications over a pre-determined time period (e.g. 3 years) to identify whether there are changes that have been under-categorised.	

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ANSTO Program	#	Recommendation
SAC – Safety Assurance Review (continued)	55	ANSTO should investigate further the possibility of including Reg. 51 submissions within the definition of Category A for inherent risk.
	56	ANSTO should examine the possibility of a differentiated categorisation system to define management and organisational changes and that the safety assurance and due process arrangements for organisational changes are set out and fully documented.
	58	The arrangements for the review and update of safety assessments and safety cases should be set out formally and that the status of this work forms part of the annual reporting cycle to the executive for each nuclear facility on the site.
Safety Culture 2 recommendations	16	ANSTO should seek opportunities to identify what the safety culture is rather than how good or bad it is through a combination of structured interviews with a selection of staff across the facility, observations of work at different times of the day, review and benchmarking of procedures and processes and investigation trending/analysis tools and findings.
	17	ANSTO management, at all levels within the organisation, should consistently and openly demonstrate support and promote attitudes and behaviours that result in an enduring and strong safety culture.
WHS Management System 2 recommendations	27	ANSTO undertakes a full review of its safety management system to ensure clarity and traceability and undertakes a review of the individual process documents to ensure that they meet the required quality standards.
	68	The relative roles of ALARA and ALARP should be made clear in the procedures and guidance.
Training 2 recommendations	4	OPAL management and staff are consulted and involved in the process of identifying and implementing any improvements within ANSTO Health where their procedures, training and experience is relevant.
	77	ANSTO should include basic information about the health effects of radiation exposures within their radiation safety training modules.
Workplace Behaviour 4 recommendations	8	The ANSTO PCSS function should find a way to more effectively deploy their resources in the arena of conflict resolution.
	38	A causal analysis approach should be used when investigating and responding to alleged poor workplace behaviour including bullying.
	40	ANSTO should initiate a programme of active promotion of and adherence with the ANSTO whistleblowing procedures.
	43	Staff who have experienced harm arising from recent events should be offered easy access to appropriate support to assist their recovery.

Appendix B: Improvements Agreed with ARPANSA

Two recommendations are related to previously agreed actions with ARPANSA.

#	Recommendation
42	Training documents should be user-friendly and include explicit hazard warnings and cues in the text to alert operators around safety or quality issues. [Context is ANSTO Health]
74	The risk assessments involving operator errors should be re-examined to take into account human performance limiting values and dependencies.

Appendix C: Joint Actions

Recommendations which require approval or input from others to progress are shown below.

Stakeholders	#	Recommendation
ANSTO and Government	1	The Australian government should commit to a replacement facility for B23 as soon as is practicable through either providing additional funding or endorsing an alternative funding strategy that that will enable ANSTO to plan for the future more effectively.
ANSTO and ARPANSA 5 recommendations	3	ANSTO and ARPANSA engage in a working arrangement to set out specific principles to be applied to ANSTO Health facilities to ensure a graded approach is applied to any improvements arising from this review.
	5	ANSTO, in conjunction with ARPANSA, should institute a process of Learning from Experience within their management processes, including extending the network to include overseas experience.
	29	Both ARPANSA and ANSTO should develop documentation that offers guidance on the interpretation and implementation of ARPANSA Licence Conditions and which take due cognisance of the suite of documents available through international bodies such as IAEA, WENRA and relevant good international regulatory practice e.g. UK, France, US, etc.
	30	Nuclear safety management arrangements, as demonstrated within IAEA Safety Fundamentals, are implemented which should document the interface arrangements between ANSTO and ARPANSA, taking due cognisance of the recommendation for a project lifecycle and gate review process.
	57	A more formal structure and programme of interface meetings and other interactions should be put in place between ARPANSA and ANSTO as part of both organisations' arrangements.

Appendix D: Task Assignments

21 recommendations do not fit under a program of work outlined in Appendix A and have been assigned to responsible ANSTO Officers who are Group Executives (GE) or the Chief Nuclear Officer (CNO). These have been grouped related to Subject Matter Experts.

Subject Matter Expert Group	#	Recommendation
Customer Advocacy & Value Chain (CAVC)	2	ANSTO senior management commits to regular engagement, dialogue and communication with ANSTO Health staff regarding future projects.
	28	A series of specific Safety Performance Indicators should be developed and implemented to include both nuclear and conventional safety and organisational risks in order to drive safety improvements and to provide a clear demonstration of leadership and management for safety in accordance with IAEA principles. [Context is ANSTO Health]
	31	WMSD risks for staff remaining in ANSTO Health should be controlled as a matter of urgency in order to ensure they are ALARP.
	70	The maintenance, inspection and test requirements for each facility should be formally documented from the safety analysis claims and supported by a suitable strategy. [Context is ANSTO Health]
Transformation & Engagement (T&E)	9	ANSTO should introduce a carefully considered walk-around policy and train its managers in how to do this effectively.
Chief Nuclear Officer	44	ANSTO should develop suitable controls related to the procurement of systems performing a safety function which reflects their safety classification.
	59	The safety case formats should include a section on how ageing and obsolescence are to be addressed through the hazard identification, safety analysis and the deductions arising from the analysis.
	60	The safety case format documents should include a format for change/modification submissions.
	76	ANSTO should consider the production of a safety case manual/safety assessment handbook.
Engineering and Capital Programs (ECP)	61	Any future projects, in particular changes or modifications within existing facilities, should have sufficient time and resources allocated to the hazard identification studies and that this step should act as a gate to prevent any further progress on the change if this requirement is not met.
	65	ANSTO should consider the inclusion of suitable tabular schedules within the facility SARs as the record of traceability and auditability of safety provisions and their suitability against relevant hazards.
	71	ANSTO should examine its claimed procedural safety measures to identify whether any could be classed as related to compliance with the safe operating limits and conditions i.e. "Operating Rules" and whether the associated procedures are robust enough from a quality assurance, training, implementation and human factors substantiation viewpoint.

Subject Matter Expert Group	#	Recommendation
People, Culture, Safety & Security (PCSS)	7	ANSTO needs to reflect further on how it deals with its licence holders and other authorized persons in terms of technical challenge.
	10	ANSTO should consider introducing 360 degree appraisals for its senior staff to ensure that the voice of subordinates is heard.
	78	ANSTO should implement a training scheme to include proper measurement of beta radiation for all RPS personnel.
	79	ANSTO RPS should set up an experiment to ensure the Perspex glasses used as splash protection for the eyes also provides sufficient protection from beta radiation.
	80	The ANSTO RPS roster staff to ensure health physics coverage when high risk activities are taking place.
	81	ANSTO undertake an assessment and validation of the clearance procedure of high risk items, such as flasks, by non-health physics persons.
	82	ANSTO come to a final decision on the total dose assigned to the QC analyst who suffered a hand burn due to beta radiation exposure in August 2017 and ensure that this dose is added to their 2017 dose record. A discussion with the REAC/TS group at Oak Ridge is suggested, where it can be determined if there is enough remaining evidence to provide a proper dose assessment. Additionally, ANSTO should consider enrolling a member of the RPS staff to the REAC/TS course to gain knowledge and experience with dealing with medical management of radiologically contaminated persons.
	83	ANSTO review their procedures to ensure proper uses of physical units and amend them based on the review.
84	ANSTO review the staffing and workload of the RPS unit, with consideration that accepting many of the recommendations of this review will result in a higher workload for an already lean staff.	

Appendix E: Current ANSTO Practice

The recommendation below is considered substantially in place and will be documented for closure with the submission of the detailed implementation plan.

#	Recommendation	Comment
36	Workloads should be reviewed and monitored and effectively managed during organisational change and controls to manage workload documented in the change management plan. [Context is ANSTO Health]	ANSTO's has a well-documented change management toolkit for use during organisational change.

Appendix F: ANSTO’s Management Approach

Some recommendations are inconsistent with our management approach and these will be addressed by demonstration that our plans and arrangements, governance and risk frameworks and/or operational settings achieve substantially the same outcome.

#	Recommendation	Comment
6	ANSTO should appoint an Executive Manager for safety who has nuclear competence and experience.	ANSTO does not have a position equivalent to Executive Manager for safety but has suitably qualified and experienced General Managers and Subject Matter Experts who can cover the scope of this proposal.
11	Relevant functional staff should be described as “embedded” in the host business. They should have a dotted reporting line to someone in the host business.	This is a very detailed recommendation. We will give substantive effect to this but may not retain the exact phrasing proposed by the expert panel. The nature of the reporting lines will be reviewed in line with the recommendation.
12	ANSTO should adopt a no-blame policy in responding to serious incidents and reserve the disciplinary process for behaviour that has been identified as problematic but has not led to any specific incident or accident.	The full expression is "no blame with full disclosure". This is the ANSTO process and we will continue to use it. If this test is not met then disciplinary processes are used.
39	Unacceptable behaviours including bullying and harassment should be included in the incident register with the appropriate anonymity protections.	The incident register may not be the correct mechanism since it is based on "no blame with full disclosure". ANSTO has a range of alternative mechanisms to document and respond to unacceptable behaviours.

Appendix G: Improvements already underway

There are twenty-seven recommendations which have actions in progress and have been grouped under common themes. These actions (improvements, process changes and associated interventions) are underway where these have practical utility and no direct regulatory impact or are corrective actions previously agreed with ARPANSA.

External stakeholders

Six recommendations require ANSTO to work strategically with partners in government. Recommendation one relates to funding options for a new Facility: a proposal requesting \$18M over 2 years has been submitted to government.

Recommendations three, five, 29, 30, 57, all relate to the ARPANSA and ANSTO working relationship and discussions have commenced.

Communication

Recommendation 2 relates to communication between senior management and ANSTO Health staff. The CEO and senior management have met directly with ANSTO Health staff to discuss the proposals put to government and provide a forum to discuss the Independent Review. Further review for future communication protocols is continuing.

Training and Documentation

The OPAL workforce has been recognised as having good procedures and training in place and recommendations four and 42 consider improvements that could be made in ANSTO Health would benefit from consulting with OPAL staff. A project reviewing training in ANSTO Health commenced in August 2018 and relevant OPAL staff have been consulted to incorporate learning from their experience. Documents are currently being updated to include hazard warnings and consideration is being given to have technical writing support to expedite the process.

Safety culture, performance and lessons learnt

Recommendations 15, 16, 27 and 28 have partly been addressed through a deep dive into safety culture in ANSTO Health undertaken by High Reliability; safety empowerment is measured through the ANSTO Pulse Survey. The CEO receives a monthly briefing with the WHS performance analyst and the GE PCSS. ANSTO issues site wide safety alerts with learnings from significant incidents. Safety coaches representing each group meet monthly, review significant incidents and share learnings. ANSTO's WHS management system is currently being reviewed and rationalised in consultation with key stakeholders across ANSTO with the aim of becoming accredited to ISO 45001. ANSTO has KPI's for conventional safety and will undertake a review of KPI's used across ANSTO to incorporate as appropriate and to meet legislative and business requirements.

Reporting

Recommendation 40 relates to promoting and adhering to ANSTO whistleblowing procedures. ANSTO has an internal procedure and reporting system "Protected Disclosure (Whistle-blower) Reporting System AB-2041". ANSTO has Authorised Officers where all disclosures are handled confidentially. Alternatively employees can go externally and log their concern with 'Fair Call'. Further detailed information is provided on the ANSTO intranet for all staff. In addition, under training and development we provide an e-learn module on the 'Public Interest Disclosure Scheme'.

Review of Safety Assurance process

There are 11 recommendations that relate to safety assurance processes and a review of these processes has been underway since February 2018. The scope of these items will be incorporated in this single project which will be subject to review by ARPANSA before full implementation.

On-site availability of Health Physics support

Recommendation 80 regarding availability of Health Physics support has been addressed. Health Physics Surveyors (HPS) are now rostered on site at the Lucas Heights campus from 6am to 7pm Monday to Saturday and Sunday as required. There are also on-call arrangements which have always been in place providing 24/7 coverage of Radiation Protection Advisors (RPA) and HPS if required.