INDEPENDENT SAFETY REVIEW OF THE ANSTO HEALTH APPROACH TO OCCUPATIONAL RADIATION SAFETY AND OPERATIONAL PROCEDURES

OCTOBER 2018

Disclaimer

This report has been independently produced by the review team at the request of the Australian Nuclear Science and Technology Organisation (ANSTO). The opinions expressed in this report are based on information collected or provided to the review team and reasonable endeavours to obtain additional relevant information during August and September 2018. The review team does not express an opinion as to the accuracy or completeness of the material provided to us, the assumptions made by the parties that provided the information or any conclusions reached by them. The review team have based this report on information received or obtained, on the basis that such information is accurate and, where it is represented to us as such, complete.

Each expert reviewer has individually exercised his or her independent judgement and/or qualified opinion limited to any specific matter relevant only to their contribution. Within the limits of their qualifications and expertise, each individual reviewer has contributed their opinion to the broader review recommendations. We can confirm that no matters of significance have been withheld from the report.

Any information contained in the report is current as at the date of the report and may not reflect events or circumstances which occur after the date of the report.

The findings of this report are therefore not exhaustive but are designed to provide recommendations to support improved safety, health and organisational effectiveness.

Executive Summary

The Australian Nuclear Science and Technology Organisation (ANSTO) is Australia's national nuclear organisation and the centre of Australian nuclear expertise located at Lucas Heights in the southern outskirts of Sydney. The Lucas Heights site includes a range of research and production facilities in support of its mission, which includes a number of facilities with a potential nuclear or radiological hazard including:

- Research reactors comprising the 10MW High Flux Australian Reactor (HIFAR), which is undergoing decommissioning and the 20MW Open Pool Australian Light Water Reactor (OPAL), which has been operational since 2007.
- The ANSTO Health business which manages and operates a range of facilities that provides the Australian and international community with a range of health related products and services, including radioisotopes for therapeutic and diagnostic applications.

Among the most significant business streams for the ANSTO Health business is the production and supply of Molybdenum-99 (^{99}Mo), which has a wide range of uses worldwide in nuclear medicine for diagnostic imaging. The principal facilities involved in ^{99}Mo production are OPAL and Buildings 23 and 54. It is important to note that both Buildings 23 and 54 are relatively old 'legacy' facilities designed to the extant standards in the 1950s and 1960s and therefore may not fully meet modern standards of nuclear design, safety and operational workflows. This is acknowledged and justified, for example, in the B23 Safety Analysis Report (SAR). This is particularly significant in the context of the "Just in Time" manufacturing and supply regime applicable to short half-life radiopharmaceutical products.

The age of these facilities means that the basis for continued operation detailed within the current safety cases is likely to be based on an "as low as reasonably achievable or practicable" argument rather than compliance with modern standards and safety criteria. This is consistent with the approach set out in the B23 SAR and means that there is inevitably a greater level of reliance placed on safety measures lower down the internationally accepted hierarchy of safety measures, namely mitigating engineering systems and procedural controls. This is entirely consistent with the approach worldwide for such legacy facilities. However, it should be noted that both facilities have met the safety requirements of the applicable regulators, namely the Australian Radiological Protection and Nuclear Safety Agency (ARPANSA) and the Therapeutic Goods Administration (TGA) and have been granted licences to operate. A replacement facility for B23 has been planned for several years, but federal government budget restrictions have meant that this has not been progressed. A number of additions and modifications have been made to the facility, but these cannot possibly resolve all of the issues associated with a facility not designed for its current use.

As a result of a series of 4 reportable incidents in the Building 23 complex, including one incident classified as a Level 3 event in the International Nuclear Event Scale, the Australian nuclear regulator (ARPANSA) has become concerned that the practices in B23 pose a risk of harm to operators. It is in the interests of all ANSTO's stakeholders that there are no further similar events, as the consequences of such could be serious, particularly in terms of loss of confidence and reputation damage. As a result, there is an urgent need to identify underlying shortcomings in ANSTO's approach to safety in order to minimise that risk. This was communicated to ANSTO by ARPANSA in the form of a direction as part of the graded approach to escalation of enforcement actions. The direction to ANSTO stated that immediate steps were to be taken to initiate an independent review of the approach to

occupational radiation safety of processes and operational procedures in B23, in particular those associated with the quality control of ^{99}Mo samples. However, it is important that stakeholders do not lose sight of the importance of the work ANSTO (and ANSTO Health) does in terms of the wider positive health impacts for Australian society.

Although the scope of the review is focussed on ANSTO Health, particularly B23, the topics included within the overall scope necessitated the extension of the review into the corporate ANSTO management system, especially in the areas of safety assurance, safety assessment, organisational culture and the management baseline. As a result, there is a significant proportion of the review and resulting recommendations that are directed at ANSTO as an organisation rather than ANSTO Health as a business.

The independent review has drawn in an international team of experts in the fields of nuclear safety, safety and organisational culture, radiation protection and human factors. The results of the independent review are presented according to these technical areas.

The review has been based on information, opinion and data from the following sources:

- Documentation, survey data and other information provided by ANSTO in advance of the formal review at Lucas Heights.
- Additional documentation, data and other information requested by the review team to supplement the pre-visit review phase.
- A visit to the Lucas Heights site over the period 06 to 14 August 2018, which included discussions with the Chief Executive Officer (CEO), tours around the relevant ANSTO Health facilities and interviews with managers and staff from ANSTO Health and from other central support functions (i.e. executives, workplace health and safety, radiation protection services, safety system reliability, engineering, regulatory affairs) within ANSTO. These interviews were based on a list of requested interviewees provided by the review team in advance and staff who had expressed a desire to speak with the review team. It is important to note that all such interviews were conducted on the basis of anonymity and confidentiality. In total, 41 interviews were held comprising 18 employees from either central technical functions or ANSTO management with 23 interviews held with ANSTO Health employees (equivalent to around 20% of ANSTO Health).
- The interviews were then supplemented by data on some aspects of safety culture collected in a confidential on-line survey to staff whose functions fell broadly under ANSTO Health and ‘others’ who may have been able to provide additional insights. In total, 71 valid survey responses were received within the one-week period; the overwhelming majority of the responses were provided by ANSTO Health staff.

It is important to recognise that ANSTO is a federal government agency, operating under government controls and subject to tight budgetary and staffing constraints. ANSTO Health is a revenue generating business, which enables ANSTO to make up some of the shortfall in funds provided by the federal government.

ANSTO Health has been through a series of cultural changes since 2010. The strategy has changed to a focus on the customer, improved safety culture and performance. The intention of this is to provide a safe and reliable supply of products meeting standards of excellence, including ensuring patient safety, within a regime of reliable financial forecasting with effective demand planning. These changes were successful in changing the business. However, based on the interviews with staff within the ANSTO Health business, there is a perception amongst many that recent events have served to reverse many of these

improvements such that the culture and morale within ANSTO Health, in particular, has significantly deteriorated.

In the opinion of the review team, the interface between ANSTO and its regulators, including ARPANSA, could be improved. Although it is acknowledged that evidence was presented of the interactions between ANSTO (and ANSTO Health) and the regulator at various management and operational levels, based on practices in other countries operating nuclear programmes, there is a need for more detailed procedures and guidance by both ARPANSA and ANSTO. This is possibly due to the fact that ARPANSA is, in itself, a relatively small organisation. For example, the interfaces at different levels, from executive level down to inspector to facility level, should be formalised and a programme of such interface meetings put in place. This aids the communication and exchange process between regulators and operators and allows the appropriate fora, whereby issues at all levels may be discussed and resolved. Also, the interviews with many of the ANSTO Health staff indicated that a significant proportion did not fully understand the nuclear regulations and the associated requirements. An extension of the existing induction training modules (e.g. OPAL training) on licensing and regulation (or suitable refresher training) could resolve this issue.

One such issue, that of the status of the facility assets (in particular Building 23), should be given a much higher focus by ARPANSA as potentially having a significant effect on nuclear safety. It is acknowledged that ANSTO has recently introduced an asset management system, which defines asset owners and includes the development of asset management plans for each business (including ANSTO Health) as part of the accredited ANSTO business management system.

All nuclear facilities, irrespective of their size or function, are required to provide evidence of compliance against international codes and standards as appropriate to their facility. This must be applied in a manner that is proportionate to the harm potential of the facilities in question. This is particularly important given that the ARPANSA Act 1998 licences individual controlled facilities and not the nuclear site. The capability to safely operate these facilities is assessed by ARPANSA as part of the licence submission, including the assessment of the SAR and supporting plans and arrangements. The capability for safe operation is presented in the ‘plans and arrangements for effective control’. Ongoing compliance with the licence conditions and plans and arrangements (including ANSTO's own management systems) is assessed by frequent regulatory inspections, which specifically address a range of topics. ARPANSA have recognised that there are cross-cutting ancillary functions that are not part of the line management of the licence nominee and have undertaken separate inspections of these individual functions and their capability to provide the claimed services to the standards identified in the relevant SAR and plans and arrangements.

This requirement includes demonstrating a good safety culture and an organisational baseline, both of which are designed to provide evidence of a full suite of suitably qualified and experienced persons, together with suitable and sufficient safety documentation to provide clear and unambiguous confirmation that the facility can be operated safely. In order to demonstrate organisational capability against regulatory requirements, ANSTO are required to verify that applicable standards are fully embedded, both within their people and their management system. An integrated management system is widely accepted as the best way of demonstrating this organisational capability and it is acknowledged that ANSTO has recently significantly invested in systems that will improve this integration. ANSTO currently operates a management system that is accredited to AS/NZ 9001, AS/NZ 14001 and is subject to regular external audits. ANSTO is in the process of obtaining certification to ISO 45001 for its safety management system. The review has recommended that ANSTO

develops a nuclear baseline for its licensed facilities in line with relevant international good practice; although it is acknowledged that this is not a legal requirement under the ARPANSA legislation. This recommendation is already being advanced by ANSTO as it is viewed as a valuable addition in demonstrating organisational capability and capacity and in assessing the impact of any relevant organisational changes.

At the executive level, ANSTO does not currently have anyone with an exclusive focus on safety, especially nuclear safety. Nuclear safety advice and assurance is provided by the Chief Nuclear Officer as a Technical Authority for nuclear, who reports directly to the CEO; however, this post is not a member of the executive. The heads of ANSTO's safety functions (workplace health and safety and radiation protection services) are at a lower level and they do not exercise the degree of influence commensurate with the risks that ANSTO is managing. It is acknowledged that there is embedded resource within, for example, the B23 facility in both these technical safety areas and that ANSTO operates a rigorous assurance process at both strategic and operational levels. This includes, at tier 1: the Risk Compliance and Assurance Committee; the Reactor Assurance Committee (RAC); the Safety Assurance Committee (SAC); Workplace Health, Safety and Environment (WHSE) Committee and the Business Reliance Committee. This is supported by other committees and sub-committees. However, in the opinion of the reviewers, there needs to be someone at executive level with authority for nuclear and radiation safety, as well as conventional workplace health and safety to resolve the diluted chain of responsibility and accountability for safety. This must not dilute the line management responsibility for safety within the businesses but serves to supplement the executive's capability to demonstrate that leadership and management for safety best practice is being delivered.

Based on the interviews, several ANSTO Health employees believed that the executive are not sufficiently aware of safety related difficulties experienced by their staff. This is despite the establishment of communication fora such as the CEO's interface arrangements with the businesses, the Executive WHSE Committee and the appointment of safety coaches within the business. This may actually be a problem of communication and awareness but the expert reviewers feel that the ANSTO executive needs to improve communication within ANSTO Health, including better information gathering strategies, such as an effective walk-around and listening strategy.

ANSTO Health staff have a sense of vocation, dedication and emotional labour in terms of what they do that goes beyond that found in most workplaces. There is a level of commitment and passion for what they do that is unusual amongst nuclear organisations and provides the organisation with an enviable level of engagement and dedication. The dedication of ANSTO Health staff to patient safety is admirable; however, there is a risk that production pressures will undermine this focus, and ANSTO needs to be alert to this. This level of commitment and passion also comes with a price: it means that staff have higher expectations in terms of commitment of the organisation and the federal government to improvements. Repeated levels of expectation regarding the replacement of Building 23 have led to a level of frustration, disappointment and cynicism amongst all of the ANSTO Health staff interviewed that there is not an equivalent level of commitment at higher levels of ANSTO and the government. Despite these concerns about the current organisational and safety climate, most people were happy with the levels of emotional support from co-workers, line supervisors and some general managers. They clearly welcome the praise and recognition for their work and showed high, sometimes extraordinary, levels of personal and professional commitment to the ANSTO Health mission. They clearly wish to be "part of the solution" and not a problem.

ANSTO's incident reporting system was reviewed and the baseline statistics (i.e. number of serious incidents to number of minor incidents to number of near hits/misses) is consistent with nuclear industry norms. However, based on interviews with ANSTO Health staff, a small number reported that near misses were not necessarily all being reported; this is almost certainly a "local" issue and not a general issue within ANSTO and ANSTO Health. It needs to steer reporters so as to encourage the most useful reports. There is a level of inconsistency in the reporting on near miss/hit events and there is, in some areas, insufficient root cause and trend analysis to gain a sufficient understanding of the opportunities to resolve problems before incidents occur. It also needs to make greater use of reports to extract and implement lessons learnt. It is acknowledged 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.

However, it is perceived by the majority of the ANSTO Health staff interviewed that the organisation tends to respond punitively when things go wrong. The post-visit survey showed that approximately 50% of survey respondents did not believe that there was a 'no blame culture' operating. ANSTO should adopt a truly no-blame response to reportable incidents, and it should improve its investigations of such incidents so as to get to organisational root causes. However, it is important to recognise that a no-blame culture must not be at the expense of clear accountability based on meeting well defined performance standards. This balance is acknowledged as a difficult "tightrope to walk" and the organisation needs to take due account of both requirements. In the view of the review team, the "just culture" policy, which does envisage the possibility of disciplinary action, should be reserved for problematic behaviour that has not yet resulted in a significant incident.

In addition, based on interviews with ANSTO Health staff working in high hazard areas, the majority of staff did not understand the various health effects of radiation exposures, this being appropriate to individual duties with respect to the hazardous areas in which they work. This is believed by the reviewers to put at risk the ability to verify all persons performing high risk activities are fully competent to do so. More importantly, this puts the individual at risk. It is noted that ANSTO operates a structured training and development programme, which has been significantly developed and improved since 2017. However, many of the ANSTO Health staff interviewed perceived that there is insufficient knowledge and experience of the hazards and impacts of exposure to radioactive materials and of the nuclear licensing process and the requirements and constraints that this places on operations. It should be noted that a review of the detailed training records was not undertaken; however, given the fact that a significant proportion of ANSTO Health staff interviewed expressed this view, it suggests either a gap in the training or that refresher training is required.

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. However, this approach has not kept pace with modern standards as applied in the nuclear industry worldwide. In particular, ANSTO's focus is very much on residual risk as a probabilistic risk based approach in which safety controls are implemented in order to reduce risks to an acceptable level. The modern norm is to focus on a deterministic approach based on the inherent risk, that is to say, the 'risk' in the absence of any safety controls and in conservative, worst case conditions. This then drives the number, quality and performance requirements of safety measures needed to deliver a particular safety function. In addition, the safety assessment reviewer has expressed concerns, based on examination

of the available risk assessment documents, that the hazard identification studies are not sufficiently comprehensive to ensure that a complete fault set is identified.

The identification and selection of risk control measures, whether to meet deterministic or probabilistic targets, needs to be based on a robust evidence based process. Key to the integrity of this process is optioneering, in which all credible options are identified and assessed and the appropriate measures selected on the basis of the application of a hierarchy of control measures and a traceable and auditable decision making process. While working within limited resources and with competing priorities is accepted as challenging, it is evident from the review of ANSTO procedures that the risk reduction process does not include sufficient optioneering in line with modern nuclear standards. As a result, there is a risk that potential improvement options have been prematurely dismissed as unreasonable, partly based on the current risk assessments and risk reduction studies. However, the reviewers examined many of the risk assessments and risk reduction studies underpinning the B23 facility and concluded that they were potentially over optimistic in some of the claims, in particular, the human error probabilities and equipment reliabilities. In the risk reduction studies, for example, the use of techniques such as cost benefit analysis have not appropriately included key through life costs and benefits. It is highly advisable that future decision analysis of options ensure that elimination and prevention are the default setting and, if this is not demonstrably reasonably practicable, that meeting the minimum requirements for the specified safety class is achieved through other measures lower in the hierarchy. It is 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.

The B23 SAR was reviewed and re-issued in 2016/17, however, many of the supporting risk assessments still date from 2010/11 and have not been further reviewed and updated. Indeed, the fault sequence that occurred in the August 2017 incident had not been submitted to independent review and assurance through SAC. It is a vital element of the safety case process that the safety assessment addresses all hazards and faults in the facility with the presentation of a systematic, comprehensive and traceable series of assessments which are subject to assurance and due process.

The site visits, interviews and survey identified a range of human machine interface and factors associated with current operations in buildings B23 and B54. Nuclear medicine production inherently requires periods of high concentration, psychomotor precision and fixed timeframes and operation of machines. The psychosocial hazards of greatest concern were principally perceptions of excessive workloads, time pressure, having too much to do to complete tasks ‘adequately and safely’ and poor workplace relationships including what may be classed as ‘serious inappropriate behaviours’. Observed biomechanical hazards included tasks requiring frequent awkward postures, static postures especially at extreme joint range of motion (particularly the neck, shoulders, upper limb and hands), repetitive movements and occasional forceful movements. Around a quarter of survey respondents indicated they currently had high levels of burnout, had in the last six months experienced inappropriate behaviours from others and in the last four weeks always or frequently experienced muscular pain or discomfort. These all potentially negatively impact physical, psychological and radiological safety, job satisfaction and performance.

The discussions with staff and the documents reviewed indicated that the workload, psychosocial and biomechanical issues were not new. Indeed, actions to try to improve the design of work and management of work and work systems, facilities and plant appear to have been a recurring theme over the last decade. Some of the previous risk control

measures and worksite modifications have reduced but not eliminated residual risks. These controls and the early interventions and recovery programs such as the on-site physiotherapy and physical conditioning programmes have been welcomed by staff and are reported to have had a positive impact.

The current musculoskeletal discomfort, stress, burnout and dissatisfaction with the organisation reported by staff is of concern. For staff transferring to the new ^{99}Mo facility (Australian Nuclear Medicine [ANM]), which has been designed to modern standards (including user requirements) and will replace B54, or for those staff undertaking tasks in the improved quality control facilities within Building B2 when this is operational, some of the risks will be reduced, but will be unresolved for the remaining staff.

Much of this report discusses safety failures and likely contributors including human factors. However, work health and safety academics also recognise that most people constantly strive to adapt and maintain performance and safety despite their prevailing circumstances (such as high workloads and equipment malfunctions). There is much that can be learnt from a safety and productivity perspective by looking not only at the recent ‘failures’ but also deeply exploring with ANSTO Health staff how they are making things ‘go right’ despite the challenges. Seeking 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, will be a key part of learning from the current experiences.

Within the ANSTO safety management system, assurance provides the due process, including a proportionate level of independent challenge, to ensure that an appropriate level of assessment of any safety documentation associated with facilities or activities with a potential impact on nuclear safety is undertaken prior to implementation. The independent challenge capability needs to be independent of the operational decision-making line and forms part of the “barrier model” to ensure that safety cases are technically sound, accurate, challenging (in terms of not accepting the status quo) and produced in a timely manner. While it is evident that major modifications are being considered through this process, it is unclear in the opinion of the reviewers, based on questioning of a small number of ANSTO Health staff, as to whether all changes with a potential impact on nuclear safety, whether physical or organisational, have been subject to the full nuclear modification assurance process within the ANSTO Health business. Current best practice in the nuclear industry (through international bodies and the major nuclear national regulators) is to consider modifications in terms of “inadequate conception or execution”. This needs to be resolved as this is an area where regulators have taken severe measures against nuclear operators who fail to follow this process. It is understood that this is being taken into account in the current ANSTO safety assurance process review.

The ANSTO safety assurance process consists of a safety committee based assurance process, namely the RAC for OPAL and the SAC. It is acknowledged that the RAC has defined terms of reference and has been assessed against international standards published by the International Atomic Energy Agency and shown to be compliant. The SAC considers all high harm potential facilities and activities and, within its scope, it commissions the independent review of safety submissions. ANSTO relies upon the SAC for the independent peer review but it is unclear as to whether this includes the “nuclear safety committee” function as this term is applied internationally within the nuclear industry. This creates problems in terms of independent challenge, which therefore relies on the objectivity of the individual members of SAC to ensure they remain impartial and independent. In fact, the Chief Nuclear Officer (as the nuclear Technical Authority) provides this function and so it may be more efficient and cost effective to change the assurance arrangements to focus on

the Technical Authority as the route for independent assessment and assurance rather than a committee approach. In addition to the safety assurance process, ANSTO adopts an additional risk oversight process whereby any activities with either a high residual risk or a high mitigated consequence require additional consideration and acceptance by the executive. This risk oversight process should be consistent with and integrated with the safety assurance process as part of the overall assurance arrangements for ANSTO.

There are a number of activities at ANSTO Health which utilise beta radiation emitters; however, the ANSTO Radiation Protection Section (RPS) does not measure beta radiation. Neither the operation procedures, calibration procedures, nor the RPS training modules contain instructions for measuring beta radiation. Though beta radiation exposure may be of low occurrence, the August 2017 Level 3 incident was an example of the high potential consequences when a skin exposure occurs, even for a very short amount of time. Following this event, dose assessment was performed 'in-house' and later employed the assistance of a local radiation oncologist with varying results and low-likelihood of accuracy. This is ongoing based on the severity and longevity of the symptoms which are still being experienced so it is not possible to be accurate until the event is complete. It should be noted that there are international organisations which specialise in such accidents, such as the Radiation Emergency Assistance Center/Training Site (REAC/TS), with whom ANSTO should establish formal links, including suitable training, and amend its emergency procedures accordingly. It is understood that these links have been commenced. Even more so than skin, the lens of the eye is the most beta-sensitive external tissue in humans. Currently, ANSTO Health staff wear Perspex safety glasses as eye protection against splashes; experimental analysis to test the glasses for proper beta protection should be designed and conducted.

The RPS section, like many of the central safety support functions, is considered by the review team, based on their experience within the nuclear industry and staff interviews, to be understaffed to provide sufficient coverage for the amount of nuclear processes performed. As is often the case, demand seems to significantly outstrip supply. A significant amount of high risk/high consequence work currently occurs outside of normal work hours. A well trained, sufficiently populated RPS team is needed, along with a work schedule that would sufficiently cover any work deemed to be medium or high risk regardless of the time of day it occurs. It is understood that this flexibility of resourcing has since been implemented to ensure radiation protection coverage at all times when there is a significant hazard potential.

In conclusion, the independent safety review has raised a number of issues where ANSTO (and ANSTO Health) should review their current arrangements and safety approaches against modern international (i.e. International Atomic Energy Agency and the Western European Nuclear Regulators Association) nuclear standards. However, 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 from 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.

This review has led to the identification of 85 recommendations for improvements; these recommendations are mostly directly applicable to ANSTO or ANSTO Health, but a proportion are also relevant to the regulators including ARPANSA in order to help them to further develop as a nuclear regulatory authority. It is, however, of vital importance that ANSTO ensures an appropriate level of proportionality in the resolution of the shortfalls

identified by this review and does not forget that there needs to be an appropriate balance between the nuclear, radiological, conventional and patient safety needs. It is an all too common problem in the nuclear industry that the focus becomes nuclear and radiological safety at the expense of conventional (and in the case of ANSTO, product) safety. As such, it is vital that any actions taken to resolve issues raised by this report take due and proportionate account of all these regulatory requirements in order to ensure that the optimum solution is adopted.

Contents

Preface

This report was authored by a team of independent experts, appointed by the Australian Nuclear Science and Technology Organisation (ANSTO). The team comprises:

David Jones	Lead Reviewer and Expert – Safety Assessment and Safety Assurance
Prof. Andrew Hopkins	Expert – Human and Organisational Factors
Dr. Lynn Williams	Expert – Safety Culture and Organisational Baseline
Dr. Peta Miller	Expert - Human Factors
Brent Rogers	Expert – Radiological Protection

The information, statements, statistics and commentary in this report has been derived from the review of documents, site visit observations, opinions and information provided by key informants including interviewees and a survey of ANSTO Health staff. This material was collected during August and September 2018. The review team does not express an opinion, nor can we necessarily know the accuracy or completeness of all the information which was provided to us. We have based this report on the assumption that the information given to us was accurate and, where relevant, complete. Where no other source is implied or stated, our information comes from interviewees. The findings of this report are therefore not exhaustive, but are designed to provide recommendations to support improved safety, health and organisational effectiveness. We encourage ANSTO, where required, to undertake their own investigation of the many important issues raised in this report and use our comments and recommendations to guide future improvements.

The expert review team can confirm that each has read, understood and noted the code of conduct contained within the Uniform Civil Procedure Rules 2005. Whilst this document is not for use in a court of law, in its spirit the review team has ensured our opinions are well considered and based on sound information.

Each expert has individually exercised his or her independent judgment and/or opinion in relation to any matters relevant to their review contribution and within the limits of their qualifications and expertise and, where relevant, to the broader review recommendations. We can confirm that no matters of significance have been withheld from the report.

As lead reviewer, I would like to acknowledge the expertise and contribution of the experts within the review team and the dedication and professionalism shown by them at all times. In addition, I would like to thank the management and staff at ANSTO, on behalf of the review team, for their commitment and willingness to share information, experiences and opinions in a transparent and open manner. Without their input, this review would not have been able to identify as comprehensively both the positive aspects of the business and the issues and problems which require resolution.

David Jones

1 Introduction

1.1 Background

The Australian Nuclear Science and Technology Organisation (ANSTO) is a statutory body of the Australian government, formed in 1987 to replace the Australian Atomic Energy Commission. It is Australia's national nuclear organisation and the centre of Australian nuclear expertise and is widely recognised as an international player in the field of nuclear science and technology. ANSTO's head office and main facilities are located at Lucas Heights in the southern outskirts of Sydney.

The Lucas Heights site includes a range of research and production facilities in support of ANSTO's mission, which includes:

- The High Flux Australian Reactor (HIFAR), which was a 10 MW research reactor based on the United Kingdom Atomic Energy (UKAEA) DIDO reactor at Harwell, UK and was Australia's first nuclear reactor, operating between 1958 and 2007; it is now permanently shutdown awaiting decommissioning.
- The Open Pool Australian Light Water Reactor (OPAL), which is a 20 MW pool type nuclear research reactor and was officially opened in April 2007.
- The Australian Centre for Neutron Scattering, which is the home of neutron science in Australia and a leading facility in the region comprising 15 neutron beam instruments, which are classified as diffractometers, small-angle spectrometers imaging and reflectometry instruments and inelastic spectrometers.
- The ANSTO Health business, which manages and operates a range of facilities that provide the Australian and international community with a range of health related products and services including radioisotopes for therapeutic and diagnostic applications.

In addition, ANSTO operates facilities on other sites including:

- The Australian Synchrotron, which is located at Clayton near Melbourne to examine the molecular and atomic details of a wide range of materials.
- The National Research Cyclotron at Camperdown, which forms part of a network of cyclotrons around Australia that produce radioisotopes used in combination with nuclear diagnostic imaging.

The nuclear and radiological facilities at ANSTO's Lucas Heights site are subject to several different regulators, depending on the context. For the purposes of this report, the key regulators are:

- The Australian Radiological Protection and Nuclear Safety Agency (ARPANSA) is the Australian Government's primary authority on radiation protection and nuclear safety and, as part of this role, regulates nuclear and radiological facilities through the granting of licences to operate facilities and the monitoring and inspection of nuclear and radiological facilities for compliance against the terms of the licence.
- Comcare, the Australian Government body with responsibilities for the Work Health and Safety Act 2011 (WHS Act), the Safety, Rehabilitation and Compensation Act 1988 (SRC Act) and the Comcare scheme.

- The Therapeutic Goods Administration (TGA) which regulates the supply, import, export, manufacturing and advertising of therapeutic goods by conducting assessment and monitoring activities to ensure that therapeutic goods available in Australia are of an acceptable standard and do not pose a risk to patient safety.

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

- Molybdenum-99 (^{99}Mo) and its decay product, Technitium-99m (^{99m}Tc), which are used worldwide in nuclear medicine for diagnostic imaging.
- Chromium-51 (^{51}Cr), 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.
- Iodine-123 (^{123}I) 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.
- Iodine-125 (^{125}I), 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.
- Iodine-131 (^{131}I), which is a nuclear medicine treatment for an overactive thyroid and also may be used to treat thyroid cancer.
- Samarium-153 (^{153}Sm), which is used to help relieve the bone pain that may occur with certain kinds of cancer (e.g. prostate cancer).
- Lutitium-177 (^{177}Lu), 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.
- Gold-198 (^{198}Au), which is used in some cancer treatments and for treating other diseases and is being investigated as an injectable treatment for prostate cancer.
- Iridium-192 (^{192}Ir), which is used as a source of gamma radiation for treating cancer with the application of brachytherapy.
- Yttrium-90 (^{90}Y), which is used to treat liver cancer.
- Gallium-67 (^{67}Ga), which is used through a scan to locate and examine different tumours and specific inflammations, especially of the lung.
- Thallium-201 (^{201}Tl), 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.

The principal radioisotope product produced by ANSTO Health is the ^{99}Mo product. It should be noted that many of these radioisotopes have relatively short half-lives, meaning that the operation of a “Just-in-Time” process for manufacture and supply is vital to their effectiveness. This constraint, by its very nature, introduces pressures into the production process, which ANSTO Health has to carefully manage.

One of the principal facilities involved in the production of radioisotopes is the Building 23 and 23A complex, which is operated under a single nuclear licence (Facility Licence F0262) issued by ARPANSA. The primary operations within the facility are:

- To act as a receiving point, from the OPAL reactor or elsewhere, for all radioactive material to be processed by ANSTO Health in the facility (excluding ^{99}Mo).
- Manufacture of radiopharmaceuticals and radiochemicals.
- Conduct testing of radiopharmaceutical and radiochemical products in compliance with quality systems and established product specifications.
- Pack all radioactive products for transport from the facility to customers.

B23 was constructed in the late 1950s, comprising hot cells for the receipt of irradiated targets from OPAL and radiochemical hot cells for the manufacture of radioisotopes. For the ^{99}Mo production process, B54 acts as the receipt and chemical processing facility with B23 acting as the quality control and generator packaging facility. The recently constructed Australian Nuclear Medicine (ANM) facility which is a purpose built modern standards facility for ^{99}Mo processing will replace B54 and has the capacity to triple ^{99}Mo production relative to the existing facilities.

It is important to note that both B23 and B54 are relatively old 'legacy' facilities designed to the extant standards in the 1950s and 1960s (i.e. the early days of the civil nuclear programme) and therefore may not fully meet modern standards of nuclear design, safety and operational workflows. This is consistent with the findings of the recently completed B23 safety case which states that:

> "*The original construction and the various extensions and modifications to the facility conformed to the codes and standards applicable at the time. As a result of the lack of codes in existence at the times of construction and progression in code and standards development over the last 40 years, there are areas where the facility does not strictly conform to the present requirements of some of these codes and standards. A number of risk assessments have been carried out on ANSTO Health's operations, and none of these risk assessments have identified risks that can be attributed to the current situation of compliance with the codes and standards. Work towards compliance with the current codes and standards is ongoing and any changes and modifications carried out are in line with the current codes and standards."*

The age of these facilities means that the basis for continued operation detailed within the current safety case is likely to be based on an "as low as reasonably achievable/practicable" argument rather than compliance with modern standards and safety criteria. This means that there is inevitably a greater level of reliance placed on safety measures lower down the internationally accepted hierarchy of safety measures, namely mitigating engineering systems and procedural controls. This is entirely consistent with the approach worldwide for such legacy facilities.

1.2 Safety Incidents

Over a 10 month period from August 2017 to June 2018, a total of 4 safety related incidents on the B23 facility were reported to ARPANSA. These incidents are summarised below.

1.2.1 Skin exposure exceeding statutory limit, August 2017

An event occurred in the B23 facility during a routine quality control procedure that resulted in contamination of the hands of a quality control (QC) analyst [1]. The event involved the manual handling of a vial containing a high activity solution of ^{99}Mo (approximately 4.5GBq) in a volume of less than 0.6ml. The analyst, according to routine procedures, attempted to de-cap a crimped seal of the vial containing 4.5GBq and the vial was accidently dropped within the fume cupboard and splashed onto the gloves of the analyst. The analyst was wearing two pairs of gloves and found both pairs to be contaminated. In addition, the analyst then self-monitored their hands and discovered that both also had radioactive contamination.

Upon removal of the analyst's gloves, skin contamination was detected which was reduced through successive washing and decontamination treatments.

The preliminary dose reconstruction indicated that the analyst received an extremity dose of 850 mSv. This dose is in excess of the statutory annual extremity dose limit of 500 mSv. ANSTO's initial dose assessment was explicit in stating that the estimate was sensitive to a number of different factors and the staff member involved would have daily reviews to determine whether evidence of tissue reactions presented, which would invalidate the initial estimate. In the subsequent days, the tissue reactions (i.e. deterministic effects) in the form of erythema and blistering that developed were inconsistent with either the location or the level of contamination reported. The radiation oncologist treating the analyst subsequently estimated an exposure of 20Gy or more to parts of the skin which has subsequently been corroborated by ANSTO's modelling.

This event was rated by both ANSTO and ARPANSA as a Level 3 incident according to the International Atomic Energy Agency (IAEA) International Nuclear and Radiological Event Scale (INES) [2]; Level 3 is equivalent to an exposure causing non-lethal radiation effects (tissue reactions) on a single worker. This event is the only Level 3 (and above) rated incident reported worldwide in 2017. It should be noted that Level 3 events are regarded as serious events in the nuclear industry and any additional events at this level may result in loss of confidence in the organisation. It is in the interests of all stakeholders that there is not another such event.

1.2.2 High activity concentration event for quality control samples, March 2018

This event relates to a potential non-compliance with ANSTO Health procedures during the ^{99}Mo quality control process in B23. This resulted in a high activity concentration of 25 GBq/ml being prepared rather than the expected concentration of 2.7 GBq/ml. This is a considerably higher concentration than that specified in the relevant procedures, which had been amended following the contamination event reported in section 1.2.1 above. No significant additional exposure was incurred by any operator as a result of the deviation; however, the event constitutes a loss of control and a degradation of the defence-in-depth provisions.

1.2.3 Implementation of a relevant change with significant safety implications without prior approval, May 2018

A potential non-compliance with Regulation 51 of the ARPANSA regulations was identified relating to a proposed modification to the ^{123}I MIBG process in B23. The regulations require that the holder of the licence (ANSTO) must seek the approval of the ARPANSA Chief Executive Officer (CEO) for any modification that potentially has a significant impact on safety that changes the details in the application for the licence or modifies the source or the facility mentioned in the licence. The modification submission was under assessment by ARPANSA, but the modification was implemented prior to approval being obtained.

1.2.4 Event involving a spillage of a ^{99}Mo solution, June 2018

This event involved an operator moving a trolley between two rooms in B23 as part of the quality control operations. The trolley was being used for the movement of ^{99}Mo solution contained in a vial within a shielded lead pot. During the transfer, one of the trolley wheels fell off and the shielded pot fell to the floor, failed and the lid came off, resulting in contamination of the floor. The solution comprised approximately 900 MBq of ^{99}Mo in 0.9 ml of solution. The operator's gloves were lightly contaminated but no skin contamination was

detected by health physics surveyors. More significant contamination was detected on overshoes and one safety boot; however, the resulting radiation exposure to the operator was minor.

1.2.5 Outcome of these events

As a result of the first event, ARPANSA concluded that ANSTO were in breach of Section 30(2) of the ARPANSA Act 1998 (the Act) as a result of failing to take all reasonably practicable steps to prevent accidents involving controlled materials and significantly exceeding a statutory dose limit. However, despite the issue of the breach notice, the three subsequent events have resulted in ARPANSA concluding that the practices in B23 pose a risk of harm to operators and that there is an urgent need to identify underlying shortcomings in ANSTO's approach to safety in order to minimise that risk. This was then communicated to ANSTO in the form of a direction under the Act [3] as part of the graded approach to escalation of enforcement actions. The direction to ANSTO stated the following:

- Take immediate steps to initiate an independent review of the approach to occupational radiation safety of processes and operational procedures in B23, in particular those associated with the quality control of ^{99}Mo samples.
- 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:
    - The external reviewer and supporting experts must be considered suitable for the task by ARPANSA before being appointed by ANSTO;
    - The terms of reference for the review must be approved by ARPANSA.
- 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.
- Provide ARPANSA with a progress report 30 days after commencement of the review.
- Within 60 days after the commencement of the review, provide ARPANSA with the final report, including the recommendations by the reviewer and ANSTO's response to those recommendations.
- At the same time, provide a plan and associated timescales for the implementation of actions responding to the report's recommendations for ARPANSA's approval.

This document is the independent reviewer's report referred to above.

2 Scope of the Independent Review

The overall engagement terms of reference are to review the following areas:

- The current safety culture within ANSTO Health (B23), 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 processes for safety assurance to ensure:
    - Responsibility and authority is delegated to appropriate persons; and
    - Correct enterprise oversight is in place, with independent processes for escalation.
- The current processes 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.

The review is to be conducted by an independent and competent review team based on the principles of trust, learning and accountability, consistent with a learning or 'Just Culture'. Observations and recommendations will be based on ARPANSA and/or IAEA Standards and relevant good international practice.

The independent review has been broken down into the following activities in order to meet the objectives:

2.1 Safety Culture

The current safety culture within ANSTO Health has been assessed in order to measure all major dimensions of safety and quality specific to the broader ANSTO environment.

The approach will be able to be applied with appropriate utility and granularity to identify any differences in safety culture within different sections of ANSTO Health operating in B23 and will also be appropriate for future application across the ANSTO group.

2.2 Human Factors

The review has assessed the person-machine interface within nuclear medicine production, particularly related to B23 ^{99}Mo production and the associated quality control activities. Factors that can affect human performance, both positively and negatively, have also been reviewed.

2.3 Safety Assurance and Incident Reporting

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

2.4 Hazard Identification and Risk/Consequence Assessment

The review has assessed the current processes for conducting hazard identification and consequence and risk assessments across ANSTO Health. This included an assessment of the robustness (process owner identified, inputs and outputs identified, key stakeholders identified etc.) of these processes and their suitability for the ANSTO Health environment. Samples of current B23 risk assessments have been reviewed against modern standards and relevant good practice. The review has also assessed the escalation process for 'high risks' within the organisation and compared the current processes against international best practice, particularly with reference to deterministic assessment and identification of required levels of control.

2.5 Organisational Capability and Nuclear Baseline

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

2.6 Optimisation

The optimisation of control measures within ANSTO Health B23 operations have been reviewed, recognising the age of the facility. The effectiveness of measures introduced by ANSTO Health subsequent to the August 2017 event to date, in terms of reducing potential consequences of incidents and thereby risks, have also been assessed.

It should be noted that certain of these activities are specific to B23 and the ANSTO Health business, while others can only be reviewed and examined on the basis of the ANSTO organisation with the practical application of the company level procedures within ANSTO Health and B23 providing the business level review. This approach has been agreed with the ANSTO senior management.

3 The Review Team

The review team appointed by ANSTO and approved by ARPANSA are as follows:

External Reviewer: David Jones

David has worked in the nuclear industry for 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 nuclear safety and risk management consultancy. 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 and safety assurance processes.

He has 10 years' experience in the operation of high hazard potential facilities in support of the UK and European fast breeder reactor programmes. In addition, he was heavily involved in the management of the production of safety cases developed in support of licensing of major UK 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 30 years including the sites at Dounreay, Windscale, Harwell, Winfrith, Devonport, Amersham (GE Healthcare) 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, British Energy (now EdF), EdF (new build), Horizon (new build) and NDA Radioactive Waste Management.

He was a member of the team managing and producing the GE Healthcare Drytec ^{99}Mo 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, safety assessment techniques, safety cases, nuclear regulations and site/facility licensing.

Expert: Andrew Hopkins

Andrew is Emeritus Professor of Sociology at the Australian National University in Canberra. He was an expert witness at the Royal Commission into the 1998 Exxon gas plant explosion near Melbourne. He was a consultant to the US Chemical Safety Board in its investigation of the BP Texas City Refinery disaster of 2005, and also for its investigation into the BP Gulf of Mexico oil spill of 2010. He has written books about all these accidents. More than 90,000 copies of his books have been sold.

He has been involved in various government workplace health and safety reviews and has performed consultancy work for major companies in the mining, petroleum, chemical and electrical industries, as well as for defence. He speaks regularly to audiences around the world about the human and organisational causes of major accidents.

He has a BSc and a MA from the Australian National University, a PhD from the University of Connecticut and is a Fellow of the Safety Institute of Australia. He was the winner of the 2008 European Process Safety Centre safety award, the first time it was awarded to someone outside Europe. He is an honorary fellow of the Institution of Chemical Engineers in recognition of his "outstanding contributions to process safety and to the analysis of process safety related incidents".

Books by Professor Hopkins include:

- Making Safety Work (Allen & Unwin, 1995).
- Managing Major Hazards: The Moura Mine Disaster, (Allen & Unwin, 1999) Lessons from Longford: The Esso Gas Plant Explosion (CCH, 2000).
- Lessons from Longford: The Trial (CCH, 2002).
- Safety, Culture and Risk (CCH, 2005).
- Lessons from Gretley: Mindful Leadership and the Law, (CCH, 2007).
- Learning from High Reliability Organisations (CCH, 2009). Edited.
- Failure to Learn: the BP Texas City Refinery Disaster (CCH, 2008).
- Disastrous Decisions: The Human and Organisational Causes of the Gulf of Mexico Blowout (CCH, 2012).
- Nightmare Pipeline Failures: Fantasy Planning, Black Swans and Integrity Management. (CCH 2014) with Jan Hayes.
- Risky Rewards: The Effect of Company Bonuses on Safety (Ashgate, London, 2015), with Sarah Maslen.
- Quiet Outrage: The Way of a Sociologist (CCH: Sydney, 2016).

Expert - Lynn Williams

Lynn has over 21 years' experience of nuclear safety and quality systems within the nuclear industry including the implementation of nuclear safety management systems. She has a detailed knowledge of regulatory and nuclear industry codes and standards including the safety and security requirements of the UK nuclear regulator, the Office for Nuclear Regulation (ONR), the American Society of Mechanical Engineers (ASME), the IAEA GS-R documents, the French RCCM code for the design and construction of mechanical equipment for pressurised water reactors, IAEA quality requirements NQA-1 and design and construction management regulations. She is an expert in ISO 19443 assessment and implementation.

Lynn has been involved in the UK generic design assessment process for UK nuclear new build and was an appointed assessor for the French European Pressurised Water Reactor (EPR) and the Westinghouse AP1000 reactors. She is a third party certification auditor and is qualified to nuclear industry EAC11 for ISO9001/14001/OHSAS18001 & NQA-1. She also undertakes supply chain management assessments.

She has authored nuclear organisational baselines and documentation to support management and control of organisational change.

Expert – Peta Miller

Peta is a highly qualified and experienced human factors and ergonomics professional with over 35 years' experience within the private and public sector, in national research, policy and practice. She has detailed knowledge of the Australian work health and safety legislative requirements. She has led and managed teams and provided expert technical content advice on workplace health and safety legislation including aspects of the model law, regulations, codes of practice and guidance and information material. This included for example: good work design, psychological health and safety, hazardous manual tasks, health and safety representatives, notifiable incidents, working at height, diving, agriculture,

construction and other selected priority industries. Her PhD investigated the effects of high workloads on health, safety, performance and job satisfaction.

Peta is also a senior researcher at the University of New South Wales School of Business leading work health and safety projects.

Expert – Brent Rogers

Brent is a highly experienced health physicist and radiation protection specialist. He specialises in radiation safety in hospital, university and industrial platforms. Currently, he provides advice and technical support in ionising and non-ionising radiation and laser safety at hospitals including Prince of Wales, Royal Hospital for Women, Sydney Children's Hospital and the Sydney Eye hospitals. In addition, he has spent 10 years as a regulator of the radiation safety industry as a licensing officer, inspector, trainer and policy writer, advising the Regulatory Agency and the Minister on matters relating to ionising and non-ionising radiation in New South Wales. He is accredited in ionising radiation safety by the Australasian Radiation Protection Accreditation Board and is certified as a Medical Laser Safety Officer by the Bureau of Laser Safety. He is a full voting Board Member of the Australasian Radiation Protection Society (ARPS).

4 Overview of the Review

4.1 Review Stages

The independent review has been undertaken in the following stages:

Stage 1 – Documentation Review

The first step in the review process was to obtain relevant documentation in order to carry out a desk based review. An initial group of documents was provided by ANSTO at the commencement of the project, and this was supplemented by additional material requested by the team over the course of the review. The full list is presented as Appendix A. The desk based reviews then informed both the question set for the site visit interviews and provided much of the baseline information on arrangements, processes and procedures which underpin the review and this report.

Stage 2 – Site Inspection Visit

A site inspection visit was held on the Lucas Heights site over the period 6 to 14 August 2018 involving the full review team with additional visits following this period for individual experts to confirm information and to further probe in key areas. During the week at Lucas Heights, interviews were conducted with personnel from ANSTO, in particular, from ANSTO Health and the central technical support functions. These interviews provided a good deal of the evidence on which this report is based.

These interviews were based on a list of requested interviewees, provided by the review team in advance, and staff who had expressed a desire to speak with the review team. It is important to note that all such interviews were conducted on the basis of anonymity and confidentiality. In total, 41 interviews were held comprising 18 employees from either central technical functions or ANSTO management with 23 interviews held with ANSTO Health employees.

Stage 3 – Report Preparation

The Lead Reviewer has drawn together the study report. Each of the substantive sections has been led by a single expert with support from other members of the team, where appropriate. This means there is some repetition, but it was thought desirable that each section be able to be read as a self-contained document. The recommendations contained in these sections have been integrated into a coherent set of recommendations at the end of the report.

The full work plan is attached as Appendix B.

It should be noted that the scope of the independent review is limited to the documents provided and the information and staff available at the time of the review.

4.2 Structure of the Review Findings

The review findings have been structured on the following basis:

- Section 5 presents the general findings of the review related to topics that were considered to be applicable across all the specialist subject areas.
- Section 6 presents the results of the human and organisational factors review led by Andrew Hopkins.

- Section 7 presents the results of the safety culture and organisational baseline review led by Lynn Williams.
- Section 8 presents the results of the human factors review led by Peta Miller.
- Section 9 presents the results of the safety assurance review led by David Jones.
- Section 10 presents the results of the safety assessment process review led by David Jones.
- Section 11 presents the results of the optimisation and effectiveness of control measures review led by Brent Rogers.

Individual recommendations raised by the authors are contained within the body of the relevant sections in order to ensure clarity and traceability from the issues to the recommendations. Where equivalent recommendations have been raised in different sections, the first use of the recommendation has been retained and the text in the other sections cross reference the retained recommendation and refer to the relevant section of the report. The recommendations have subsequently been collated, individually numbered and minor rewording performed in order to ensure a consistent style.

In addition, the recommendations have been prioritised on the following basis:

- '**High**' priority represents a recommendation that the review team believe is essential for ANSTO to commit to an implementation plan for close-out in order to address a deficiency which has the potential for a major impact on nuclear or radiological safety.
- '**Medium**' priority represents a recommendation that the review team believes is necessary for ANSTO to commit to an implementation plan for close out to address a deficiency with the potential for a significant impact on nuclear or radiological safety.
- '**Low**' priority represents a recommendation that the review team believes is necessary for ANSTO to commit to an implementation plan for close out to address a deficiency with the potential for a minor impact on nuclear or radiological safety.
- '**Areas for Improvement'** represents those recommendations that are considered to provide ANSTO with an opportunity to improve nuclear or radiological safety.

5 General Review Findings

ANSTO is a federal government agency, operating under government controls. It has many functions, including providing radiation and radiation protection services to governments, conducting its own research and facilitating the research of scientists based in other institutions who seek to use its facilities. Its nuclear reactor at Lucas Heights is also used as the basis of several subsidiary nuclear businesses. One of these is ANSTO Health, which is a revenue generating business enabling ANSTO to make up some of the shortfall in funds provided by the federal government. Like most governmental bodies, ANSTO (and its businesses including ANSTO Health) operates under tight budgetary and staffing constraints. This is a major contributing factor to the problems observed during the review.

ANSTO has been through a series of cultural changes since 2010. Since that date, the strategy has been changed to a focus on the customer, providing a safe and reliable supply of products meeting standards of excellence, including ensuring patient safety, within a regime of reliable financial forecasting with effective demand planning.

The output from ANSTO Health is often described simply as “product”, for sale on a market. This does not capture the reality. The “product” consists of potentially life-saving doses (or dose generators). These are manufactured to order and dispatched to hospitals around Australia and even overseas. The generators ANSTO Health dispatches result in about 10,000 diagnostic or therapeutic doses a week. The radioisotopes that form the basis of these treatments decay radioactively and become unusable within a matter of days, so timing is critical, and manufacture must be aligned to aircraft flight schedules to ensure that the radioisotopes get to patients in time. This is an excellent example of a “Just in Time” manufacturing and delivery process.

Based on the staff interviews, it is clear that ANSTO Health staff feel a close connection with the patients to whom these radioisotope doses are delivered. They have a strong sense that they are saving lives, including the lives of children, and they are sometimes even aware of the identity of these children. Several of the staff (including senior managers) became quite emotional while talking with the review team about this and even more so when operational factors resulted in the organisation not being able to meet their commitments. One manager described being contacted by a mother expressing her thanks for the life-saving doses ANSTO Health had provided for her child, while another became distraught over a fortnight delay in providing a therapeutic dose of iodine to a child. Many staff in ANSTO Health therefore have a sense of vocation about what they do that goes beyond that found in most workplaces. There is a level of commitment and passion for what they do that is highly unusual amongst nuclear organisations, and this provides an enviable level of engagement and dedication. As a result, they are prepared to work extended hours in order to maintain the flow of life-saving doses. However, there are potentially significant health and safety consequences from working in this way.

In addition, this level of commitment and passion also comes with a price. It means that staff have higher expectations in terms of commitment of the organisation and the federal government to improvements (see discussion below with regard to B23 replacement).

The conditions under which these radioisotopic doses are manufactured are also an important part of the overall context. Doses must be sterile when delivered; if contaminated with biological organisms, they can be detrimental to the patient. However, in some cases, they cannot be sterilised by the usual means and so must be produced in an aseptic environment. There are rigorous manufacturing conditions imposed by Australia’s TGA to ensure that ANSTO Health is indeed producing “sterile injectables”. The need for these strict

controls is not always understood by outsiders. For example, after a recent shut down of generator production caused by mechanical failure, the production site had to be thoroughly cleaned and then had to be left undisturbed for 14 days before being tested. This 14-day period is the time it takes for any remaining contaminating organisms to multiply to the point where they can be detected. 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. Despite the production pressures, the management decision was taken to delay the return to production to address emerging safety issues in conjunction with production staff. This conservative decision has cost ANSTO a significant proportion of its revenue due to the need for the importation of generators from abroad to ensure supply to Australian hospitals. This decision has affected the organisation's reputation, but was considered the right thing to do in nuclear and radiological safety terms. It is a good and positive example of the right decisions being made in terms of the IAEA leadership and management for safety model.

The generator issue is an example of the demonstration that ANSTO Health fully understands the requirements related to the sterility of the products based on many years of experience in this area. In balancing the respective priorities, particularly those related to nuclear/radiological safety and product safety, ANSTO Health (and the ANSTO organisation) has to challenge regulatory requirements to ensure that it is operating appropriately but not over conservatively. This is the balance between availability of life-saving medicines, product safety and worker safety that is the key aspect of operations within ANSTO Health. It is only through appropriate challenge and evidence based assessment that this balance can be optimised.

There is another set of requirements that must be observed rigorously to protect the workers themselves from the radiation hazards with which they work. The requirements for both patient and worker safety therefore provide a tight set of constraints within which the work must be carried out. However, in the context of nuclear and radiological safety, it is important to note that ANSTO is not operating facilities with a major hazard potential (i.e. the potential for significant off-site impacts in the event of an accident). ANSTO does not operate nuclear power plants, fuel manufacture, reprocessing or weapons production facilities, and so any safety and environmental requirements must be considered against the need for “proportionality”. This is consistent with the approach set out by IAEA [4] which calls for a graded approach to the safety assessment and the implementation of the requirements, to provide flexibility. In addition, it is recognised that the level of effort to be applied in carrying out the necessary safety assessment needs to be commensurate with the possible radiation risks and their uncertainties associated with the facility or activity. The application of the graded approach or proportionality needs to be agreed with the regulator in terms of how the requirements of the Act can be applied to facilities in which the hazard is restricted to within the working area.

We recommend that 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 (High Priority).

As stated in Section 1, many of the facilities, in particular B54 and B23, are relatively old facilities (in nuclear industry terms) designed to standards applicable in the 1950s and 1960s. As such, they do not meet modern standards both in terms of nuclear safety and in operational workflows, as detailed in the recently updated B23 safety case. A number of additions and improvements have been made over the years that 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. This issue will be resolved for ^{99}Mo production by the replacement of B54 with the new ANM facility, but there remains the issue of B23 as a facility that is reaching the stage where it will become no longer fit for purpose. Many times during the site visit interviews, staff referred to B23 as a facility at the extremes of its capability with a culture of "make do and mend". This has led to a general view amongst ANSTO Health staff in B23 that the facility is continuing to operate through a series of "sticking plaster" changes and upgrades that cannot possibly resolve all of the issues of a facility not designed for its current use. Whilst ANSTO continues to discuss the need for funding to replace the facility with the federal government, a capital budget exists for improvements to the facility. The CEO has made it clear to staff that money will always be made available for safety improvements. In addition, the CEO has stated that decisions on the best options for safety improvements should not be influenced by cost, rather what will provide the greatest benefit in the shortest period of time to implement. However, amongst a proportion of the ANSTO Health staff interviewed, there is perceived to be a culture of seeking lower cost solutions to safety and operational issues, which may not present the optimal solution, whilst a similar number of ANSTO Health staff made statements consistent with the CEO's position. This, in common with other areas, may be more of an issue of communication and reinforcement of the message rather than an underlying issue. This type of issue is, however, not uncommon in the nuclear industry worldwide, where there are several older plants continuing in operation with the same problems. However, these older facilities are rarely used in a production capacity and certainly not within a "Just in Time" approach as their availability and reliability becomes a significant production and business risk.

Regarding ANSTO Health, amongst many of the staff interviewed, there appears to be a lack of awareness of the existence of a strategic plan as to where the business is going in terms of future direction, how to get there etc.. This, combined with the increased level of scrutiny within the business over the past 12 months, has led to considerable uncertainty. In addition, the view is that this has led to staff within the business becoming more defensive particularly within B23.

A replacement facility for B23 has been planned for several years by ANSTO, and the need for this has been the subject of informal discussions between ANSTO and Canberra for some time now. It has also been included as a priority in ANSTO's Corporate Plan for the past three years. In September 2017, the need for a replacement facility was included in ANSTO's input into the Agency Resourcing Review currently being undertaken by the Department of Finance. However, no formal capital requests to refurbish or replace B23 have yet been formally submitted to the Australian Federal Government. Repeated heightened expectations and then subsequent failure to secure backing for replacing this ageing facility has led to frustration, disappointment and cynicism amongst the staff that their commitment to the Australian community is not matched by senior ANSTO managers or successive governments. Despite this perception by staff, the review found that ANSTO management have been working extremely hard to flag the need for appropriate funding and share a strong commitment to replace B23, but their efforts have not been adequately communicated to the staff. Federal government budget restrictions have meant that the level of expenditure required would be unlikely to be forthcoming. However, given the age of the facility and the likelihood that operational and safety problems will continue due to ageing factors, a new facility is considered necessary in order to secure the capability within ANSTO and Australia more generally to manufacture radioisotopes for healthcare needs, both in Australia and for potential export markets. This may need a different financial strategy to deal with this issue including, for example, partial funding from the capital market.

We recommend to the federal government that it commits 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 (High Priority).

Not only will this facilitate ANSTO's business, but, as the review team has suggested, it will able it to deal more effectively with its process risks.

We recommend that ANSTO senior management commits to regular engagement, dialogue and communication with ANSTO Health staff regarding future projects (Area for Improvement).

It is also important to recognise that, in addition to the nuclear/radiological hazards inherent within the ANSTO Health activities, ANSTO has successfully operated the OPAL research reactor since 2007. The OPAL safety management system is a well-established system commensurate with the operation of a nuclear facility that includes sufficient technical staff to support on-going operations, changes and safety issues. OPAL has been the subject of a number of inspections including a random interim inspection by the IAEA in 2013 plus a periodic safety review and a security review in 2014, as well as regular ARPANSA inspections. Therefore, it is possible that some of the answers to ANSTO Health's safety management problems are already available within OPAL. It would be considered more appropriate to apply relevant good or best practice in terms of "Learning from Experience" from OPAL as a first choice before engaging with potential external support. It is understood that this relevant good practice from OPAL is planned to be used to improve training within ANSTO Health and the review team fully supports this.

We recommend that 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 are relevant (High Priority).

Nuclear regulators worldwide are now increasing their focus on "Learning from Experience" (LfE) or "Retour d'Expérience" (REX) as part of the demonstration of both organisational competence and being a learning organisation. IAEA are also embarking on a programme of encouraging the industry to adopt LfE within their processes using an old proverb which says "a fool learns from his own experience, but a wise man learns from the experiences of others." The IAEA is adamant that a key contributor to enhancing nuclear safety is the ability to learn from experience [5]. As well as addressing the causes of more significant events occurring nationally or internationally, this should also include learning from the causes of low level events, to be certain that more significant events are prevented. The review team understands from discussions with ANSTO managers that, for example, there are examples of areas within the business where such analysis of low level events including LfE identification and dissemination is well-practised and operating effectively but this is not consistently applied.

We recommend that ANSTO, in conjunction with ARPANSA, institute a process of "Learning from Experience" within their management processes, including extending the network to include overseas experience (Medium Priority).

6 Organisational Factors Review

Lead Author – Andrew Hopkins

6.1 Introduction

This section deals with a number of organisational factors. The particular issues were not determined beforehand but were identified in the review of documents and the interviews held. Some of these organisational issues apply to the ANSTO Health business while others are more generic and are therefore more applicable to ANSTO itself. This is made clear in the text.

6.2 An Executive Manager for Safety

In the current ANSTO organisation structure, there are three separate safety functions:

- Conventional workplace health and safety (WHS).
- Radiation safety/health physics (Radiation Protection Services).
- Nuclear safety (including the safety assurance process, see Section 9).

Each of the WHS and Radiation Protection Services (RPS) groups is headed by a “manager” while the nuclear Technical Authority function is provided by the Chief Nuclear Officer (CNO), who is part of the CEO’s team reporting directly to him. “Managers” in the ANSTO context are relatively lowly positions with less authority and status than a general manager who, in turn, has less authority and status than an executive manager. These two safety managers therefore wield relatively little power in the ANSTO hierarchy. Currently both managers answer to an executive manager, although a general manager position between them and the executive manager has been created and may shortly be filled.

If the new post is filled, it may give the managers a champion at a higher level, but a champion who sits one level down from the executive committee. That person will answer to an executive general manager whose span of control includes other demanding responsibilities such as human resources, industrial relations and security. This leaves safety in a one-down position, figuratively, as well as literally.

High hazard organisations that are truly safety conscious usually have a safety director (or some equivalent post) at the executive level; certainly, most nuclear organisations do. This role typically provides the executive with advice and is able to provide a veto where necessary if he/she feels that safety will be compromised. In addition, the role provides the executive level interface with the regulators. Often, this person manages the independent assurance and due process arrangements in order to ensure independence from the operations but as this is provided through the CNO, this may not be a necessary change.

We recommend that ANSTO appoint an executive manager for safety who has nuclear competence and experience (High Priority).

There are good reasons for appointing the safety champion at the executive level. If they are to do their job well, they must be in a position to challenge members of the executive, which is difficult to do from a one-down position. One such challenge would be whether or not business unit leaders are authorising sufficient resources to be able to significantly reduce or indeed eliminate hazards. In many organisations, this executive role also includes environment and quality within the terms of reference.

[redacted]

[redacted] It seems there may be an impediment to communication at this point in the organisational structure. (This will be further discussed below). The appointment of an executive safety manager would provide a direct route by which safety matters can reach the executive.

The appointment of a safety manager with nuclear expertise at the executive level is particularly important in ANSTO's case. In the view of our nuclear safety expert, there is currently insufficient nuclear expertise at the executive level. It is acknowledged that ANSTO has had an equivalent role to the CNO since 2008. This position sits in a number of ANSTO tier 1 committees that focus on safety and nuclear safety and is responsible for providing advice to the CEO and executives on nuclear and radiation safety. However, in the opinion of the review team, this operates at a level down from the executive and should be an executive position.

Part of the problem for a safety manager is that many decisions are decisions about levels of risk and involve balancing safety against competing priorities. These decisions are not always clear cut and may involve a level of judgement as well as assessment. The higher the manager is in the hierarchy, the more likely it is that their view will prevail. This point is not always well understood, so the following example is provided to demonstrate it [6].

A metalliferous (hard rock) mine suffered a major underground rock fall. No one was killed or injured, but mining was interrupted for months. The mine was owned by a multinational mining company. It was the jewel in the company's crown and the interruption cost the company dearly. Accordingly, it set up an incident investigation team to understand what had gone wrong. The team was chaired by a senior company manager, who wrote the report. The author was invited onto the team to give an organisational perspective.

The mining method was to break up the ore body using explosives and transport it to the surface, leaving large underground caverns, which would later be filled in. Provided the rock surrounding a cavern was solid, the roof formed a natural arch which prevented cave-ins. But if the caverns were too close together, the ability of the surrounding rock to support the roof was reduced, leading to a greater risk of collapse. This was the most significant risk the mine faced. It was therefore vital that the size of the blocks to be extracted and the sequence of extraction, be carefully risk assessed. This was the job of the geotechnical specialists. If they failed to do their job properly, or if their advice was not heeded, people might die. As someone told the inquiry, the job of the geotechs was to keep the managers out of jail.

Unfortunately, though, the head geotech did not have sufficient organisational clout. He reported to the mine's head of planning, who sat on the mine's senior management team. The head of planning was responsible for designing the production sequence so as to maximise production, while also managing the risk of cave-in. He was thus the "point of aggregation" between the geotechs, who naturally erred on the side of caution, and the production planners, whose aim was to maximise production. The head planner's job was to balance these competing pressures.

As mining progressed, the mine was slowly running out of blocks that could be easily mined. But the economic pressures were relentless and the planners chose a mining sequence which led ultimately to failure. The geotech specialist had felt uneasy about the mining plan. “If I’d had my way”, he told the inquiry, “I would have changed the mining sequence”. He had had a “gut feeling”, he said, that the proposed sequence was not sound. His concern was based on geotechnical experience, but not hard referenceable data - professional judgments about risk seldom are. This meant that he was easily over-ridden. The inquiry asked his boss why he had not paid greater attention to the geotech’s concerns. His response was that he “could not talk to the business on the basis of a gut feeling”.

What is clear from this account is that if the head geotech specialist had been higher in the organisational structure, his concern would have been more difficult to ignore. Indeed, given the right organisational structure he would have been in a position to veto the proposed mining sequence. This author’s advice was that the head of the geotech group should be one step up in the organisational hierarchy, to ensure that his “voice” carried greater authority. That seemed to be a modest proposal in the circumstances. However, the chair of the inquiry panel was uneasy about making a recommendation that might be unacceptable to the top leadership of the company. Instead, the words he used in the report were as follows.

“The influence of the geotechnical function needs to be strengthened: the investigation team identified through numerous interviews that the geotechnical team’s voice is not strong enough and that their concerns are diluted under the production pressures and priorities”.

(italics and underlining in the original).

This certainly captured the inquiry team’s concern, but it fell short of the particular recommendation this author had urged that the team make. Notice that the above recommendation echoed the author’s use of the word “voice”, which was intended to be somewhat metaphoric. However, the vagueness of the above wording allowed the mine to adopt a more literal interpretation. It chose to strengthen the voice of the head geotech by providing him with assertiveness training. In so doing, it provided a very individualised solution to what was essentially an issue of organisational structure.

There are other reasons for making a safety appointment at the executive level. Elsewhere in this report (see section 7), the review has recommended that ANSTO adopt a “nuclear baseline” approach to ensure that its organisational structure is properly designed to deal with safety. This will involve considerable effort and needs to be driven from the top of the organisation. An executive safety manager would be the best person to drive this process.

A well-resourced safety function headed by an executive manager will be able to ensure that the organisation is continually monitoring and measuring the safety controls that have been identified as critical to ensure that they remain in good order. This means more than occasional auditing. Monitoring needs to be built into organisational practice and processes.

The situation at ANSTO is complicated by the existence of a CNO position as the Technical Authority (TA). This position answers directly to the CEO and is intended to provide him with direct advice on nuclear matters. The CNO has no staff. The role is evolving and the CNO has acquired considerable de facto authority in the organisation. He currently has something

of a mentor role for staff in the radiation protection function. If ANSTO were to appoint an executive manager for safety, the relationship between the two roles would need to be clarified. They could perhaps be collapsed into one, or some other division might be worked out (e.g. the executive safety role provides the “policing” function for safety, health, environment (and quality) while the CNO provides the TA function for nuclear safety to all areas of the business as well as the CEO).

There is also a senior manager for governance, risk, compliance and assurance, who answers to the Group Chief Financial Officer (CFO). This position should also have a dotted reporting line to the proposed safety executive.

This last proposal raises another possibility. There are currently managers for quality, compliance and validation located within ANSTO Health. They have a comparable role to the technical authorities in some high hazard organisations. Their location in a business unit can place them in a conflict with more senior business unit managers at times (this will be further discussed below). In high hazard organisations, such people sometimes answer up a functional line to avoid this problem. At ANSTO Health, these managers could be provided with a dotted line to the senior manager for governance, risk, compliance and assurance, with an expectation that this person would provide them with additional technical and moral support.

There are two contrasting ways in which the executive safety role can be viewed. One is as the conscience of the organisation; the other is as a policeman. This dichotomy is not particularly helpful since in reality the role involves both. In particular, the safety function must be able to ensure that procedures are complied with and that decisions about risk are made objectively and conscientiously. To do this will require a significant apparatus, with staff embedded in the various business units. (The concept of embeddedness is discussed later).

6.3 Building 23

The focus of the review team’s attention was ANSTO Health’s Building 23. This is where the manufacture of various radioactive isotopes occurs and where quality control and assurance takes place.

As stated earlier in this report, B23 is a relatively old building, built as a research facility, now operating as a manufacturing facility. This means that process flow in the building is not smooth, which creates problems. Furthermore, ANSTO Health is continually seeking new markets and has increased production to a point that is challenging the capacity of the building. For instance, during the interviews, more than one person stated that the ventilation system is barely coping with the demand. Several ANSTO Health staff stated that the philosophy is to “sweat the asset”, meaning, operate it as intensively as can reasonably (i.e. safely) be done. However, the majority of interviewees did not feel that the ANSTO Health management would compromise safety for production. Many of the interviewees told the review team that the intensity is actually beyond what is reasonable and that a new building is desperately needed. Until such time as the Australian government commits to a replacement facility, it is uncertain as to how long ANSTO will have to continue operations in this building.

One of the suggestions made to the review team was that ANSTO Health needed to take a “vintage car” approach to maintenance and capital works in B23. The analogy is appealing, but problematic. Vintage cars are maintained by their owners without regard to whether this makes sense economically. Expenditure on B23 on the other hand must be justified on economic grounds within the capital budget that exists for improvements to the facility. It is

acknowledged that the CEO has made it clear to staff that money will always be made available for safety improvements in B23. This capital budget is included within the ANSTO Health asset management plan. This is likely to be difficult to continue to do while the future of the building remains in doubt. This is also addressed in the recommendation concerning funding in Section 5 of this report.

The review team examined closely the work station at which a worker suffered a radiation exposure and burn in August 2017 and has yet to return to work [1], which has been the subject of a report to parliament [7].

What was seen at the work station surprised the review team. The worker was required to reach forward and around a transparent shield barrier to perform an operation with both hands. The best way to visualise this is to think of reaching around a tree trunk, with both hands, to perform a critical procedure behind the tree, except that the tree trunk is transparent so that you can see what you are doing. The operator must use tongs to grasp a small bottle round the neck and carry out a difficult manoeuvre to lever a cap from the bottle. To do this effectively and reliably takes formal training and three months of supervised practice with decreasing supervision as the operator becomes more competent. The operator in question had been doing the procedure for 6 weeks at the time of the accident. The operator grasped the bottle with the tongs. It slipped and splashed some of its contents onto the operator's glove, resulting in a dose of radiation to the hand. Based on the review team's experience and opinions, what is surprising is that this accident had not happened earlier.

What is of particular concern is that the procedure had not been subjected to a dedicated risk assessment that had been submitted through the safety assurance and risk governance processes before being submitted to ARPANSA. This, in retrospect, raises concerns regarding ANSTO Health's risk management and assessment process. This is further discussed in Section 10 of this report with comments on the risk assessments themselves in Appendix C. Regardless of this, in the opinion of the reviewers, the procedure is ergonomically unsound, increasing the risk of musculoskeletal injury, as well the risk of radiation exposure. This ergonomic issue is highlighted in Section 8 of this report.

One risk control measure introduced subsequently was to dilute the material being analysed by a factor of 10. It is hard to see how the current procedure can be further de-risked and the work practice continues. A possible option would be to introduce shielded glove boxes, used in other parts of the facility. No doubt there are others, such as automation of the process to remove the human from direct contact with the radiation source, which could be identified and assessed through appropriate optioneering. For example, a shielded glove box solution would require a significant modification of the current equipment, at significant cost. In addition, it would require an element of remote handling to eliminate the potential for hand exposures through the gloves. An automation process would need to consider system reliability and what to do in the event of a breakdown. It is likely that man entry to retrieve the situation is unlikely to be acceptable from a safety point of view and the only solution would be to allow the sample to radioactively decay. This would probably necessitate a redundant automation system in another fume cupboard to prevent production issues from a lack of QC sampling capability. It is acknowledged that a modification is currently being progressed whereby the QC activities are relocated to B2 which will include a level of automation to significantly reduce the risks to the operators. However, the lack of a permanent replacement solution to B23 is undermining the possibility of truly effective risk control in this matter (see recommendation regarding funding in Section 5).

6.4 The Culture of Executive Management

The review team was asked to consider the safety culture at ANSTO. The culture of any organisation is determined by its top leadership and it is, therefore, appropriate to reflect on the culture of executive management. There are a number of observations that can be made about this.

6.4.1 Incentive schemes

Some of the drivers of the behaviour of executive managers can be inferred from the goals specified in their performance agreements. In particular, looking at the weightings for these various goals gives a sense of priorities. Not surprisingly, in nearly all cases, financial and business goals are the most heavily weighted. Safety or risk reduction, when explicitly mentioned, may count for only 15%. There is a single notable exception, for whom safety and risk reduction counts for 25%. Of course, safety is implicitly present in some other goals, but the pattern of emphasis on business goals is clear.

[redacted] This is not intended as a personal comment about this manager; responsibility for the content of performance agreements of the executive lies ultimately with the CEO and the Board. As such, this is a matter of organisational practice, not individuals. The result is that, looking at the executive as a group, nowhere is there any counterbalance to the business goals that generally receive the greatest weighting. The review team was not provided with the performance agreement for the CEO and so we are unable to comment on his weightings.

There is a threshold safety requirement which, if not met, may result in the loss of all bonuses for the year. The threshold is a requirement that there be no fatalities, serious injuries or incidents of dangerous exposure to radiation. The Level 3 incident of August 2017 meant that this threshold was not reached and, as a result, no bonus was paid that year. However, because these events are rare and unpredictable, it is hard to see how such a hurdle can have much effect on the day to day behaviour of senior managers.

This provides a further reason why it is highly desirable to have someone on the executive committee primarily focused on safety - nuclear, radiological and conventional - and willing to challenge other executives on safety within their particular function, as discussed above. The performance agreement of this executive role must emphasise safety above all else.

6.4.2 Communication

Amongst a significant proportion of the ANSTO Health staff interviewed, there is a perceived invisible barrier to communication between the executive and lower levels of the organisation. Whether this is more pronounced than at other levels is not clear. There is a perceived tendency for “bad news” to remain stuck at lower levels of all organisations and ANSTO is not immune from this. A senior executive spoke of the fact that information about risk seems to get stuck at lower levels and remains “under the radar” of the executive. This is despite the fact that the CEO and the executive have established a range of communication means by which this “upwards” communication of issues can be facilitated.

A widely recognised strategy for dealing with this is the management walk-around. This is not just a matter of showing the flag and saying how important safety is. There is quite an art to doing this effectively. The key to getting people on the shop floor to open up about

problems they are having is to approach them with humility, professing one's ignorance and desire to learn [8].

We recommend that ANSTO should introduce a carefully thought out walk-around policy and train its managers in how to do this effectively (High Priority)

Interestingly, communication downwards from the CEO and executive could also be improved. According to several interviewees, there is a widespread perception that the top group either does not know or does not care about the hardship created by financial stringency. They would be surprised to hear how much effort that members of the executive have put into trying to secure a permanent solution. This is perhaps a story worth communicating. This is also addressed in the recommendation concerning funding in Section 5 of this report.

6.4.3 Going in to bat?

Executive managers differ in the extent to which they support their direct reports at executive level. The review team came across two styles: In one case, an executive manager coached his subordinate in how to make the case for capital funds and then went in to bat for it at the executive level. The other style was to block requests from subordinates for extra posts or funds on the grounds that none were available. The review team think this should be a matter for discussion at the committee.

6.4.4 Placating the CEO

A small number of staff (not on the executive) told the review team that the executive aimed to placate the CEO rather than challenge. The review team cannot, of course, vouch for this but, if so, this is an aspect of the culture of the executive that should be tackled.

It is acknowledged that the CEO holds a fortnightly meeting with senior subject matter experts in the absence of the executive team. The meeting is focused on all aspects of governance, risk and compliance and is conducted directly with the CEO to allow the communication of first-hand data and expert opinion in a full and open manner.

This may actually be a problem of communication and awareness but the expert reviewers feel that the ANSTO executive needs to improve communication within ANSTO Health and to reinforce the fact that these interfaces with the CEO should be open and honest. This includes the passing on of problems, difficulties and issues.

6.4.5 Management style

Big differences were reported in the way that members of the executive handled their subordinate staff. Some executives were reported to be approachable and helpful while others were perceived to be intimidating. This discourages the reporting of bad news (see above). Some executives would benefit from coaching in this respect.

We recommend that ANSTO should consider introducing 360-degree appraisals for its senior staff to ensure that the voice of subordinates is heard (Low Priority)

6.5 Management Issues

For convenience, this section groups together several issues from the review findings under one heading. They are

- Respectful challenge or undue pressure?
- Conflict resolution.

- Centralisation and embeddedness.

6.5.1 Respectful challenge or undue pressure?

Collective decision making requires diverse inputs and the ability of people to challenge each other, respectfully. This is one way to avoid “groupthink”. Respectful challenge is likely to be most effective where the people involved are of roughly equal status, that is, where the power imbalances are not too great. However, some of the challenges the review team encountered involved senior managers challenging people at more junior levels who nevertheless had ultimate decision-making authority because they were TGA license holders or “authorised” persons, noting that the TGA operates a licencing regime for the protection of patient safety. These authorised decision makers were making decisions to stop production, or delay re-start, on grounds of patient safety, which of course meant ANSTO Health would be unable to supply pharmaceuticals. The challenge from senior managers in these circumstances was perceived to be particularly insistent in certain cases. The problem is that, while senior managers assumed their challenges were respectful, that is not the way they were perceived by the decision makers who were being challenged. Their perception was that their technical competence was being challenged by senior people who did not understand the technicalities. They felt disrespected and untrusted.

Interestingly, these lower level decision makers stood firm, which is testimony to their strength of character and sense of responsibility. But the damage done to morale was considerable. The situation might perhaps have been diffused it they had had a dotted line to the senior manager for governance, risk, compliance and assurance. One of the celebrated characteristics of high reliability organisations is that they defer to expertise, wherever it may be in the organisation.

Despite the production pressures and following the challenge reported above, the management decision was taken, based on the advice of the lower level decision makers, to delay the return to production to address emerging safety issues. This conservative decision has cost ANSTO a significant proportion of its revenue due to the need for the importation of generators from abroad to ensure supply to Australian hospitals. This decision has affected the organisation's reputation, but was considered the right thing to do in nuclear and radiological safety terms.

We recommend that ANSTO reflects further on how it deals with its licence holders and other authorised persons in terms of technical challenge (Area for Improvement).

6.5.2 Conflict resolution

Another matter the review team became aware of in ANSTO Health was ongoing conflict between various managers. In particular, they had criticisms of each other that were not voiced effectively and not resolved. There is clearly a role for the human resources element of PCSS here. The PCSS function has several performance coaches, one of whom is stationed for some period every day in B23. They have the capacity to help resolve these problems, perhaps conveying complaints to people who can do something about them. A PCSS representative was insistent that they are available to perform this function, but at least one interviewee stated that PCSS was not assisting with conflict resolution among managers. It is desirable that PCSS find a way to deploy its resources more effectively into this arena to help defuse these tensions.

We recommend that the PCSS function find a way to more effectively deploy their resources in the arena of conflict resolution (Area for Improvement).

6.5.3 Centralisation and embeddedness

The organisation is moving towards a greater degree of centralisation, meaning that support staff will be employed in central functions and deployed as needed on a temporary basis into the businesses. The reasoning is that this will enable central function staff to be deployed and re-deployed more easily to places of greatest need. It also provides a better support base for them.

There is some opposition to this in ANSTO Health. For example, health physics staff are currently deployed to ANSTO Health but ANSTO Health say they are not always able to fit in with the expectations of the host organisation. For example, ANSTO Health may start work at 0700H and carry out a number of safety critical tasks before the health physics staff arrive, possibly as late as 0900H. This particular issue has now been resolved (see Section 11), but ANSTO Health staff remain concerned about this model. The point is a valid one, but there are organisational solutions to this problem.

Deployed staff need to have two reporting lines. First a “solid” line back to their function, where solid means, amongst other things, that this is where they are primarily evaluated. Second, there should be a dotted line into the host organisation, meaning that there is someone in the host organisation responsible for allocating their tasks and ensuring that they conform to any host organisation requirements and standards. Details of such arrangements always need to be defined and agreed, as they are in an existing service level agreement.

The other objection heard from some ANSTO Health staff to the new model is that functional staff deployed only temporarily do not necessarily understand the specificities of the business. In particular, engineers deployed into the business may not necessarily fully understand the principles of Good Manufacturing Practice (GMP) that are so important for the delivery of sterile injectables for patients unless they have received the appropriate training and have the necessary experience. They must therefore be trained. If engineers rotate rapidly through the business they will all need to be trained, which would require extra resources. ANSTO has resolved this problem by deploying staff long term in the host organisation. To symbolise this longer-term deployment, it would be useful to change the term to “embedded”, a term which is used in some other organisations that function in this way.

We recommended that relevant functional staff be described as “embedded” in the host business. **They should have a dotted reporting line to someone in the host business (Medium Priority).**

6.6 Just Culture

The review team’s terms of reference specify that the review should take account of the principles of “just culture”.

The source of the just culture model is Jim Reason’s book, *Managing the Risk of Organisational Accidents* [9]. In it, he provides a simplified test for whether or not it is appropriate to blame an employee who violates rules. He calls it the substitution test (p208). Mentally substitute the individual concerned with someone else who has the same training and experience and ask: “in the light of how events unfolded and were perceived by those involved, is it likely that this new individual would have behaved any differently?” If the answer is no, there are clearly systemic factors that generated the behaviour concerned and it is better to change those factors than to blame the individual rule violator. This principle applies to managers as much as it does to frontline workers. Most rule violations would pass

the substitution test, meaning that other, similarly-situated individuals would probably have done likewise.

Even in the case of deliberate rule violations, the appropriate response is to seek to understand why, rather than to resort to discipline. The only cases in which discipline is unquestionably warranted in Reason's just culture model is where there has been sabotage, malicious damage or "substance abuse without mitigation".

One can also go beyond Reason's model to ask whether individuals who engaged in malicious behavior were driven to it by work-induced frustrations or stress. The point is that as soon as we attribute blame, the quest for causes comes to an end. But we need to ask why the individual chose to behave badly. Once we ask this question, further explanatory factors come into view. This issue is addressed in Section 8 of this report. Suffice it to say that, under a just culture model, resorting to disciplinary action after an incident has occurred is seldom likely to be justified.

In the opinion of the reviewers, ANSTO is too readily resorting to disciplinary processes after incidents. This is the view of many of the ANSTO Health interviewees the review team spoke with. The review team were made aware of cases in which allegations of "serious misconduct" were made, followed by an external investigation, which found that none of the allegations was substantiated. At least in hindsight, it seems that ANSTO resorted too quickly to a disciplinary process.

[redacted] We conclude that ANSTO's initial allegation of serious misconduct in this matter was unjustifiably hasty and in violation of the just culture model it endorses.

PCSS advised us that, more recently, it has created a "restorative justice" approach to better manage these types of people-related challenges. Time will tell how effective this will be. It was not the approach taken in the past.

This is not to say that disciplinary action is never appropriate as it forms part of the responsibility and accountability matrix. The problem with the disciplinary processes mentioned above is that they were taken following specific, high profile incidents, reportable to the regulator. The resort to disciplinary procedures following incidents is fraught with problems. This is because there are always many factors contributing to the incident, and even many factors contributing to the behavior that has been singled out for a disciplinary response following the incident. Disciplinary action in these circumstances looks very much like scapegoating. It is best to operate a no-blame policy in these circumstances, rather than a just culture policy [10].

As a general rule, it is better to reserve disciplinary procedures for behavior that has been identified as problematic but has not led to any specific incident or accidents (for example bullying). This should be in the context of the normal performance management process. In this context, actions can be measured and proportionate. Many employees support accountability and responsibility principles being applied in this way. We were told by a small proportion of interviewees that PCSS is not giving enough support to managers who want to

performance-manage their subordinates in this way. It is acknowledged, though, that many ANSTO managers have received training in managing conflict and managing disciplinary meetings with staff, which has received positive feedback across the organisation.

Several ANSTO Health employees stated that one of the consequences of ANSTO's disciplinary processes after an incident is that staff are made to feel anxious. Part of the problem is that matters are shrouded in secrecy; although it is difficult to see how this can be resolved given the need to maintain a level of confidentiality to protect the people involved. People do not know why action has been taken and they do not know the result. The question in many minds is: "who's next?" This is not good for morale. It is also potentially dangerous, because people may fear that reporting an incident could result in disciplinary action against themselves or their colleagues. In fact, in some of the interviews, a small proportion of staff admitted that events, in particular, near misses were not being reported because of this fear.

In the event of significant disciplinary actions, members of the ANSTO executive apply a management of change process to identify, amongst other effects, whether any action such as suspension might cause anxiety amongst staff. This leads to the establishment of certain mitigation measures. However, in a recent case, they were unsuccessful and many of the staff felt that an injustice had been done.

We recommend that ANSTO adopt a no-blame policy in responding to serious incidents and reserve the disciplinary process for behavior that has been identified as problematic but has not led to any specific incident or accident (High Priority).

6.7 Incident Investigation

ANSTO's event investigation guidance (AG-2375) invokes two methods to identify root causes: Ishikawa event analysis and "5-whys".

The "5-whys" method was developed by Toyota (Figure 1):

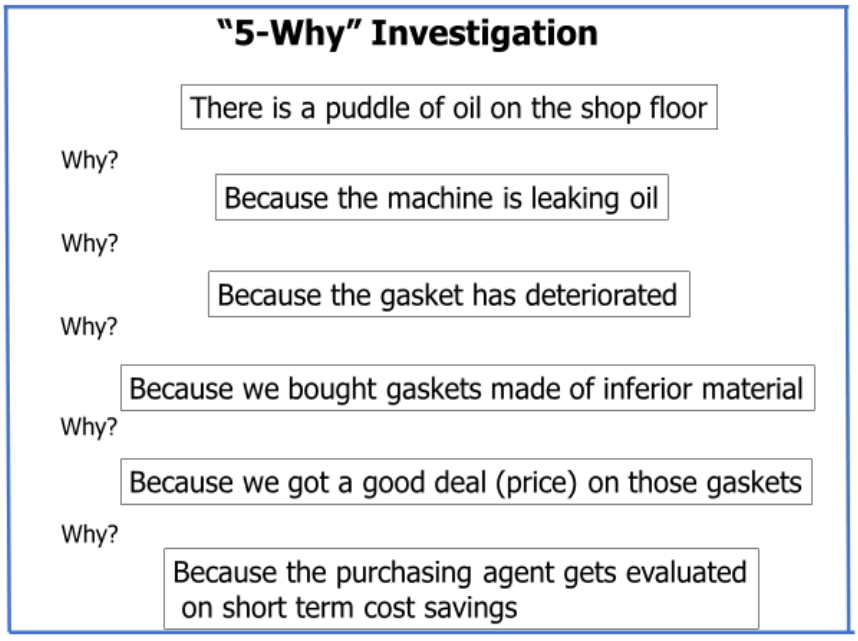


Figure 1: Toyota Investigation Method

As can be seen, this takes a trivial incident and traces it back to an organisational root cause - the remuneration system.

ANSTO's event investigation guidance provides the following example of a "5-whys" inquiry (Figure 2):

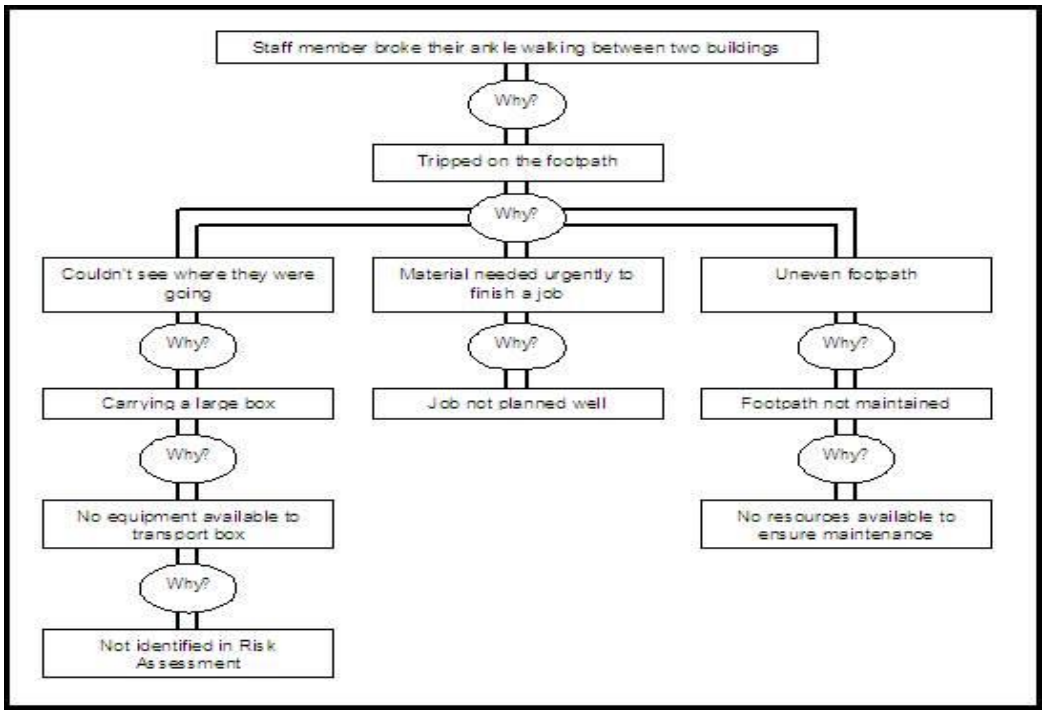


Figure 2: ANSTO Example of "5-Whys"Approach

This example correctly recognises that there may be more than one line of causal reasoning to be followed (3 in this case). But in each case, the questioning stops short of getting to the organisational causes. If the questioners had focused on the right side of this diagram and asked: "why were no resources available to ensure maintenance?" this would have taken them immediately to organisational causes which have far more claim to the label - root cause.

Consider now a recent investigation in which a sample of radioactive material was being transferred in a pot on a trolley to a quality control testing laboratory. The trolley wheel came off, the pot fell to the floor and the radioactive material was released onto the floor [11]. The incident investigation identified the following two "root causes":

- A workbench with wheels, insufficient railings, not on a maintenance plan and never intended to be used as a transport trolley, was utilised as a transport trolley.
- Lack of rigour and specificity in the procedures available at the time.

Elsewhere in the document, the authors specifically answer the fifth "why" question as follows:

- Because trolleys in the facility are difficult to source.
- Because the trolley did not say it was not meant to be used in this manner.
- Personnel are too busy or do not put enough importance on event reporting/putting in maintenance requests.

However, none of this gets to organisational root causes. Investigators need to get beyond the circumstances of the particular incident. They must continue to ask "why" until they get to truly organisational causes.

The second aspect of the investigation process is the Ishikawa event analysis, see Figure 3 below.

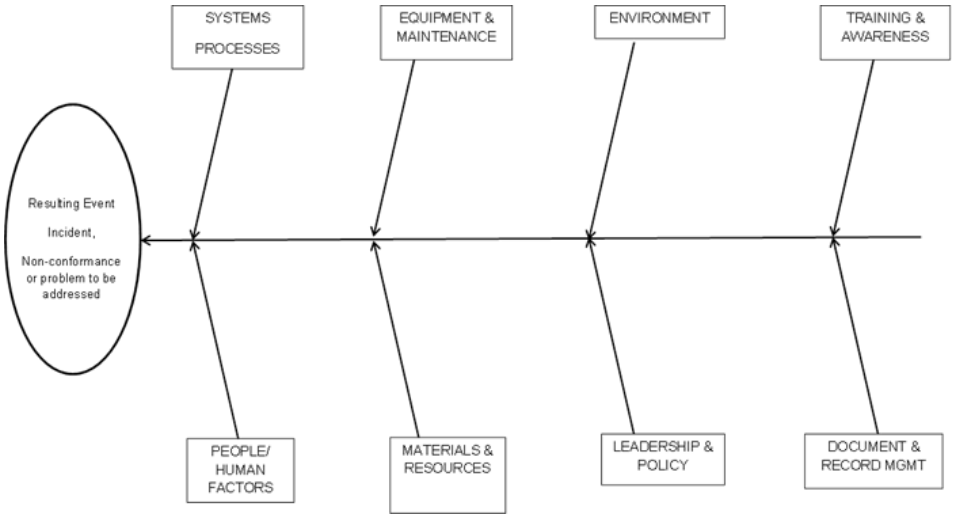


Figure 3: Ishikawa Event Analysis

Leadership and policy is a vitally important element of this analysis which can certainly take the analyst back to organisational root causes. This is what the investigators in this case wrote:

"Leadership & Policy:

Management unaware of the previous failures related to the trolleys.

Throughout the investigation, it was determined that the trolley that had failed had had previous issues with the wheels becoming loose, and in once instance, approximately one week prior, falling off. If these 'near hit' events had been reported, the issue with a workbench being used as a trolley may have been determined and rectified, potentially preventing this incident from occurring."

These are very important observations and invite numerous "why" questions concerning leadership and policy. But these questions were not asked. In short, ANSTO is not making best use of its incident investigation process.

Why has ANSTO's incident investigation failed to get at organisational root causes?

It was suggested to the review team that one of ANSTO's problems might be that engineering thinking is "convergent" rather than "divergent". Since it was engineers that carried out this root cause analysis, this hypothesis is directly relevant here. However, the engineering function has subsequently had time to think about the issue and has designed an entirely new and much safer trolley for the job. So, the problem is not really with the engineering way of thinking. It is really about resourcing and about trying to solve problems within the context of a system currently in operation.

If incident analysis is to fulfil its potential, it needs to take the category "Leadership & Policy**"** as seriously as possible and identify causes at this level as the root causes.

We recommend that ANSTO ensure its incident investigations get to true root causes in the area of leadership and policy (High Priority).

6.8 Reporting

One of the themes identified in various interviews with ANSTO Health personnel is that there are incidents not being reported into the event reporting system that should be. In certain limited cases, incident investigations show that the precursor events leading to the incident had occurred before but had not been reported. For example, there had been several unreported cases of wheels falling off trolleys, before the one which precipitated the reportable spill of radioactive material. The problem is that this observation is made with hindsight - people did not recognise their significance until after the event. ANSTO needs to steer its reporting in the right direction. One way to do this is to identify the most 'helpful' report for recent time period, say a month and celebrate it with an award. The process of deciding upon which is the most 'helpful' report will focus all minds on the purpose of the reporting system and encourage reporting of precursor events. Those judging the helpfulness of reports will need to be forward looking and, in so doing, they will encourage all staff to be more forward looking, precautionary and risk-aware. Winners each month should be announced by the CEO and there should be some significant reward attached [12].

Here is an example of a report, submitted on 18 June 2018, after the trolley incident in which the pot fell off a trolley whose wheel had come off:

"A trolley was observed to be labelled within the production facility that it was safe to use for 6mm lead pots. I observed that the trolley is not safe to use for 6mm pots as the bunding is not large enough to stop the pots from falling off the trolley if they are too close to the edge or if the pot falls over and rolls off."

This was evaluated in the reporting system to be of "major" potential consequence, which is clearly based on hindsight. But suppose this had been reported prior to the trolley incident. Judges required to identify the most helpful report might well have recognised the significance of this report and awarded this reporter the accolade. In so doing, they would have increased everyone's awareness of the potential for an incident such as eventually happened.

It is important to include some level of balance into the review. ANSTO's incident reporting system was reviewed and the baseline statistics (i.e. number of serious incidents to number of minor incidents to number of near hits/misses) is consistent with nuclear industry norms, including within ANSTO Health. This suggests that, in the main, incident and near miss reporting is being implemented correctly but that there are limited examples where this is less than optimal. It is understood that measures have been put in place to resolve these differences.

We recommend that ANSTO steer its reporting system in the right direction by identifying, celebrating and rewarding the most useful reports (Medium Priority).

Another issue is that there is not enough real LfE from incidents occurring. There is inconsistent evidence of issues such as minor events or near miss/hits being evaluated at the ANSTO level to see if there are themes that are common or can be helpful for other areas. It is understood that all incidents reported through the incident management system are analysed monthly, irrespective of the severity rating or the type of safety incident (including near misses). The breakdown agencies (i.e. what is causing the incidents) are analysed and the top 4 to 7 agencies with a potential rating of moderate or above are identified. The data are also analysed annually and reported to the CEO and the Executive

WHSE Committee. The WHS team uses the annual analysis to assist in identifying targeted safety focus topics for implementation. However, the perception amongst many of the ANSTO Health staff interviewed is that the some of these types of issues do not seem to be being communicated beyond general manager level and tend to stay within the businesses rather than being communicated across the organisation. The ANSTO incident reporting system (GRC) contains a lessons learnt entry, but several interviewees stated that this is rarely used or acted on. In fact, a report from GRC for safety incidents and investigations have been completed from mid-2017 until the present date shows that 65% had the lessons learnt section completed. This should be improved but demonstrates that the situation is not as negative as some people perceive.

We recommend that ANSTO should place greater emphasis on routinely identifying the lessons contained in its incident data base 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 (High Priority).

This process should be led by the CEO (or the CNO as the nuclear TA) with formal terms of reference which include core members (or nominated suitably qualified and experienced representatives) from each function. The involvement of a representative of ARPANSA would be beneficial in order to demonstrate the content, performance and outcome of Safety Performance Indicators (SPI), Operational Excellence (OPEX) and LfE are in accordance with nuclear regulatory due process.

7 Safety Culture and Organisational Baseline Review

Lead Author – Lynn Williams, supported by Sarah Wilson and Julie Marshall (human factors experts, Marshall Wilson Ltd.)

7.1 Introduction

This section of the report is divided into 2 elements, that of the ANSTO Health Safety culture, and the ability of ANSTO as the corporate body (and ANSTO Health as the business unit) to demonstrate that adequate organisational baseline arrangements are embedded to verify compliance against the applicable regulatory requirements. It is important to distinguish these against the scope of the review, as detailed in Section 2, whereby the safety culture is reviewed at a divisional level as a result of the Safety Climate Survey while the organisational (nuclear) baseline can only be assessed at the corporate level.

It is not the intention to assess ANSTO's organisational capability against the expectations of a fully commissioned nuclear power plant or similar facility but to proportionately review against the nuclear, radiological and conventional safety risks as required under the auspices of regulatory compliance applicable to ANSTO. However, due note and best practice will be taken from the IAEA and the Western European Nuclear Regulators Association (WENRA) reference documents in order to provide guidance to ANSTO under recommendations made by this report.

A desktop review of documentation presented by ANSTO was conducted prior to the site visit, the intention of which was to gain an initial understanding of ANSTO's ability to demonstrate compliance and best industry practice. This review was conducted in preparation for interviews and assessments at the Lucas Heights site.

During the review, due cognisance of ARPANSA, TGA, Comcare and IAEA guidance was taken, which included but was not limited to:

- IAEA GSR Part 2 – Leadership and Management for Safety [13].
- TGA – Australian Regulatory Guidelines for Medical Devices (ARGMD) [14].
- Nuclear Industry Code of Practice (NICoP) - Nuclear Baseline and the Management of Organisational Change [15].
- IAEA documents:
    - Key Practical Issues in Strengthening Safety Culture [16].
    - Managing Change in the Nuclear Industry [17].
    - Application of the Management System for Facilities and Activities [18].
    - The Operating Organisation for Nuclear Power Plants [19].
    - Feedback of Operating Experience from Events in Nuclear Installations [5].

7.2 Safety Climate Survey Review

A review of the ANSTO Health Safety Climate Survey (dated May 2018) prior to the site visit was undertaken and the following noted.

7.2.1 Adequacy of the culture review

7.2.1.1 Quantitative vs qualitative measures

The survey has been focused around gaining a quantitative measure of how good safety culture is perceived to be, rather than trying to gain a description of the culture and what aspects of culture are perceived to be positive or negative.

The survey tool is considered adequate for a 'health check' of culture. However, as both the workshops and questionnaire surveys indicate a need to improve in a range of areas that directly impact delivery of safe operations, then a greater search for a qualitative basis of the ratings would be needed for effective and efficient improvements. A greater understanding of the overall culture dimensions need to be ascertained, for example:

- What is considered acceptable behaviour?
- What is considered to be important?
- What is the working atmosphere and style?
- What are the management and leadership styles?
- How do the company structures and systems impact on the delivery of safe operations?
- How do the working practices meet relevant good practice (RGP)?
- How do the working practices meet stakeholder, regulator expectations?

Currently the qualitative information (comments) from the survey is only being provided in the negative case. Qualitative information can however be ascertained from more than surveys (see suggestion 1 below).

7.2.1.2 Data collection method

The workshop and survey is wholly opinion based and therefore may not have had adequate measures to take account of conscious and unconscious biases people introduce when reporting in this way.

Psychological theory tells us that people's unconscious biases come from the way attention, perception and memory work:

- We only perceive a small amount of information from the environment.
- People do not consciously choose what information they attend to from their environment, attention is focused based on experience or task or feelings at the time.
- Anything we have not paid attention to or noticed at the time can never be recalled from memory – it's gone.
- Our memories are not exactly what happened and recalling events in a workshop setting could be influenced by social biases, e.g. conformity and obedience.

Any additional work would benefit from trying to gain some more objective data (see suggestion 2 below).

The data set of 72 participants represents approximately 60% of the total ANSTO Health staff complement. If the participation rate is considered too low, ANSTO Health should consider whether a paper based alternative could be made available, in line with some of the comments raised.

7.2.1.3 Participation of managers and leaders

The workshop was framed as a report to the ANSTO Health managers and the survey does not readily identify what level of managers were involved. This implies a bias to the solution as being things that need to be done to make staff perform better, which will limit and detriment any effective improvement (see suggestions 3 to 5 below).

Overall, whilst the survey tool and workshops have made a start to data collection, they are not stand-alone tools, but a means to start a discussion, explore the dimension of culture qualitatively and make gradual improvements in safety. It is stressed that improvements in this type of measure will not be achieved quickly; resurveying of this nature should not be undertaken for approximately 2 years after implementation of any improvement programmes.

7.2.2 Suggestions for an improved understanding of safety culture

1. Seek opportunities to identify what the culture is rather than how good or bad it is; this may include:
    a. Structured interviews with a selection of staff across the business/facility, hear their perceptions and determine whether or not the views were supported i.e. by documented evidence or others sharing the same view.
    b. Observations of work at different times of the day.
    c. Review and benchmarking of procedures and processes.
    d. Investigation trending/analysis tools and findings.
2. Where people's opinions are sought, request evidence and events to explore their opinions, rather than asking for subjective opinion. If the participant is requested to examine actual occurrences rather than opinion of what is done, this will reduce some of the bias based on our cognitive limitations and biases, e.g. instead of the question "do people work outside the rules":
    a. Are you ever required to work outside of limits and conditions?
    b. How many times in the last 3 months did you need to work outside of limits and conditions?
    c. Discuss an occasion where you were required to work outside limits and conditions.
3. The difference between ratings and experiences of people with different seniority within the organisation needs to be understood, so that improvements can be led and implemented by the leaders and managers in the business. It appears that managers have not participated in the survey and their inputs are essential. A possible question set is provided:
    - Do we have a clear prioritised programme for the enhancement of safety which my staff have been involved in developing?
    - Have we published an agreed clear statement of our expectations for safety?
    - When I ask my staff what our expectations for safety are, can they tell me?
    - How do I know that my managers are really committed to the view that a 'safety first' plant is also a well-run plant?

- Does safety feature in all management meetings as a topic or as part of the discussions of the project?
- When did I last make my commitment to safety apparent through my actions and my expectations clear to all personnel working on my project?
- How do I support a questioning attitude in my team and those contractors who work within the project?
- Do I consistently praise good practices and challenge poor ones?
- The last time that we were behind schedule, did I question whether shortcuts could be taken due to time pressure?
- Do my staff understand what could happen to the project or to people if an agreed procedure is not followed?
- Am I aware of how 'work-arounds' would be revealed to me — and am I actively looking for them?
- Was our last decision on project plan, maintenance or plant operation a conservative one?
- Following an unexpected event, did I ask first about the safety implications, or did I ask first when the plant would be back online?
- Am I sure that our system to implement findings from event reports and peer reviews is working?
- Do I deal promptly with unsafe acts and/or conditions when I see them or when they are pointed out to me?
- Do I have a good independent view of the safety performance of my plant and/or project?
- Do all my staff fully understand the potential safety consequences of mistakes which they may make?
- Do we systematically look at other organisations and other parts of our own organisation to see what we can learn from them?
- Do I encourage my staff, working in teams, to think about how we can enhance safety?
- How do I know that we are not becoming complacent?
- How do I know whether our procedures and management processes are working properly?
- What evidence do I have that we really are a 'learning organisation'?

4. Change will need to be designed and led from the top of the organisation and according to a committed (in accordance with common practice within the nuclear industry), visible and coherently prioritised programme that can be delivered alongside everyday improvements and deliveries. Comments in the survey indicate a division between 'doers' and 'managers' so this needs to be overcome, not least to achieve a no blame culture instead of the implied blame culture highlighted in Section 6. Human factors theory tells us that errors and violations that lead to unsafe working practices are largely predictable or well-intended deviations from defined operating methods due to problems with task design, operational regimes (e.g. task scheduling, shift times), equipment or

usability problems, lack of clarity or inappropriate training and procedures or inappropriate task support (supervision, technical support, workload, communication). A holistic approach to the issues is required, rather than a focus on getting people to perform better.

5. Managers and supervisors should seek to understand and visibly commit to the fact that improvements will come from improvements to systems and processes that allow staff to deliver production roles in normal/off-normal/fault and emergency scenarios, not from solutions focused on changing people's behaviours or attitudes. A manager/leader driven programme is required to establish a safety culture review process to analyse the safety climate and identify where improvement should be targeted and where safety climate strengths can be used to achieve the improvements (Figure 4). The programme will require all core safety management system elements including policy, organisation, planning and implementation, measuring performance, audit and review.
6. Interpretation of results would benefit from exploring differences within and between teams (sub-cultures), e.g. between shift teams, between different roles (operations, quality, other, production, etc.).

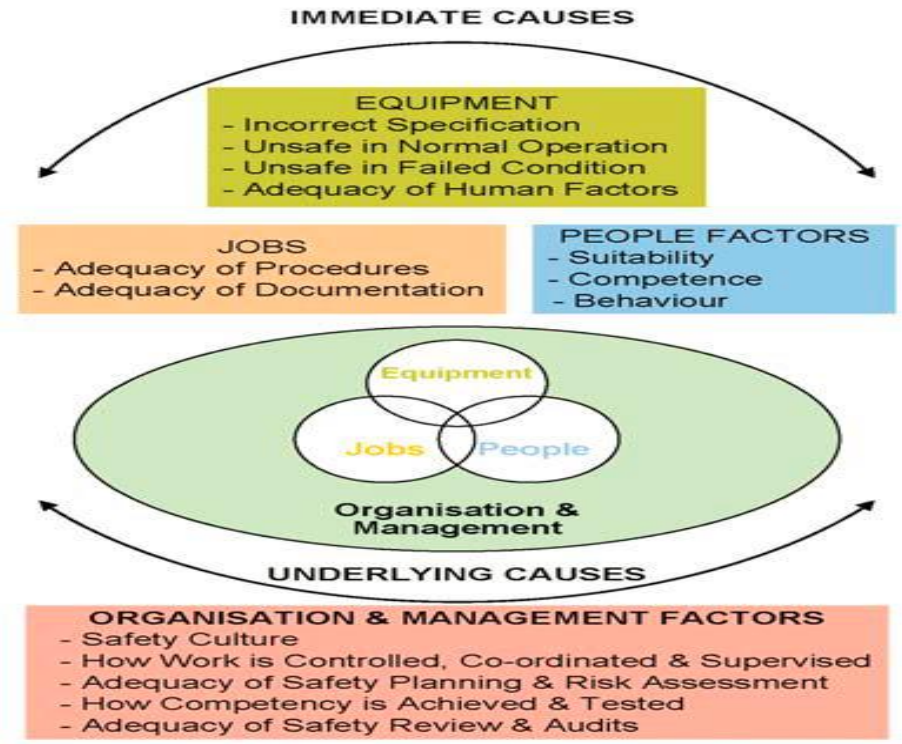


Figure 4: Immediate and Underlying Causes of Accidents

7. Measures of safety culture need to reflected coherently and consistency in overall everyday measures of performance [20]:
    i. The success of safety initiatives.
    ii. The reporting of near-miss occurrences, incidents and accidents.
    iii. Employees working safely.

iv. Employees taking work related risks.

v. Influencing production pressures.

vi. Implementing safety behaviour interventions and health interventions.

vii. Effectiveness and credibility of safety officers.

viii. Effectiveness and credibility of safety committees.

Alternatively, the UK Health and Safety Executive (HSE) Safety Culture Briefing Note 7 lists the main factors, indicates what would show that you had a good safety culture and what would support the safety culture.

8. Subjective opinion of workplace comfort and operability provides a useful baseline to compare against the outputs of the ergonomic review. Where opinion of workplace comfort and operability is incongruent with the findings of the ergonomic survey, this would indicate levels of dissatisfaction that staff may have been less willing to self-report. It is relatively commonplace for the perception of operability issues to be rooted in or at least contributed to by wider person, task and organisational factors.

A secondary benefit is that the subjective opinion of workplace comfort and operability could be used to inform the scope of the ergonomic review in identifying any areas of particular focus.

We recommend that ANSTO 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 (High Priority).

7.3 Safety Culture – Site Assessment

Evidence and dialogue presented during the visits to locations where high radioactive hazard work is conducted gave the review team cause for concern on the wellbeing and treatment of some of those interviewed. There was anecdotal evidence from the interviews amongst a proportion of ANSTO Health staff (see Sections 6 and 8) of pressure to rush jobs, high levels of stress, harassment and even bullying together with a fear factor of raising issues either verbally or via the GRC system. This view was not held by all staff but was a common theme amongst many of the interviewees.

Significant gaps are clear between the executive and the workforce and there is a view amongst a significant proportion of ANSTO Health staff that the mentality to just ‘get the job done’ is wrongly enforced.

Examples of bullying and intimidating dialogue presented during discussions include:

‘if you raise this as an issue be prepared to face the consequences’

‘blame despatch for production issue’

‘why are you raising this? Just sign it off’

‘challenge me and I will shorten your career’

Clearly, in the pursuit of appropriate balance, these statements need to be separately tested. This has not formed part of this review and will need to be part of the follow-up process. Despite the alleged statements above, personnel interviewed displayed a remarkable

resilience to do the right thing and to ensure that safety remains of paramount importance. First and foremost was the clear understanding demonstrated of the 'end product' and the reliance on ANSTO Health to meet deadlines for the wellbeing of those requiring treatment. Calls had been made, and thanks offered to individuals, by parents of children who had received lifesaving treatment, as detailed in other sections of the report.

An extraordinary amount of emotion was displayed during interviews (none that any of the review team had ever previously witnessed) from people at all levels, so much so that, in some cases, interviewees were asked if they wished to take a break or to cease the interview. None did, such was their wish to contribute to the assessment in an attempt to improve the existing culture and to operate in a more positive climate.

The ANSTO CEO and executive should take due note of the level of commitment displayed by persons interviewed and should take all measures to ensure this is recognised and not compromised by the issues found during this assessment.

Issues surrounding resources and the urgency to meet deadlines, coupled with the pressures of frequent position/post changes in recent years, or having to report to senior management/executive level, have served to create a difficult atmosphere in the view of a significant proportion of ANSTO Health staff, based on the interviews. During the interviews, some staff claimed to have witnessed a change in behaviours; in some cases, a withdrawal and blame culture ensued due to internal pressures and an increase in stress.

Whilst employee assistance programmes are available to ANSTO Health staff, not all persons interviewed were aware what this service offered, and very few were able to articulate how this service works. Not many of the ANSTO Health staff interviewed displayed confidence that support or guidance was openly available or encouraged.

We recommend that 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 (Area for Improvement).

This should include ensuring that their actions discourage complacency, encourage an open reporting culture as well as a questioning and learning attitude with a readiness to challenge acts or conditions considered to be adverse to safety.

We recommend that 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 (High Priority).

NOTE: During the site assessment, a more detailed analysis of safety culture was conducted, the results of which are captured under Section 8, which articulates more clearly the issues surrounding ergonomics, workload, stress, musculoskeletal skeletal issues and personnel behaviours. Recommendations to ANSTO regarding human factors and ergonomics are further captured within Section 8.

7.4 Organisational Baseline – Nuclear Baseline

Under the auspices of the global nuclear industry, it is common practice to introduce an organisational baseline structure, more commonly known as a nuclear baseline (NB), for those organisations operating a nuclear facility.

Indeed under the requirements of IAEA Safety Guidance documents, all IAEA members are advised to have an adequate system for demonstrating organisational capability for the management and compliance of a nuclear operating licence as documented under, but not limited to:

- Leadership and management for safety [13].
- Managing change [17].
- Application of the management system for facilities and activities [18].
- The operating organisation for nuclear power plants [19].

The principal purpose of a nuclear baseline is to verify that suitable and sufficient organisational structures, staffing and competences are in place to effectively and reliably carry out those activities which could impact on both nuclear and conventional safety. The second, important purpose is to provide a clear description of the currently intended staffing levels as a reference point or 'baseline', against which the nuclear operator can assess the potential impact upon nuclear safety of proposed organisational changes.

We recommend that the development of 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 (High Priority).

In preparing its baseline, ANSTO should therefore consider all activities which have the potential to impact upon nuclear, radiological and conventional safety. This includes those activities with a positive impact and those which, if inadequately conceived or executed, could lead to an immediate or latent (direct but not immediate) detriment to safety.

Within the nuclear baseline, ANSTO should be able to demonstrate that it understands the nuclear safety roles that need to be delivered and that these roles will be carried out by suitable and adequately competent resource. This includes, for example, the governance of nuclear safety, the 'Intelligent Customer' capability, drafting and quality assuring of safety related documents, as well as frontline work. It should also include roles that have a positive contribution and a decision to make with regard to nuclear safety. Decision making is a vital part of a nuclear baseline, where an organisation should ensure all persons holding this responsibility are suitably qualified, experienced and competent to do so. These decisions include those of a technical, design, engineering, safety and quality nature, where both independence and stakeholder integration is vital. It is not sufficient just to show that all roles are 'covered', but that those individuals in post can realistically carry these roles out to the required standard and capacity.

As a minimum, ANSTO should be able to demonstrate how site safety is identified, implemented, monitored and governed within not only ANSTO Health, but those stakeholders and suppliers who have an impact on safety in whatever guise or function.

Further, the nuclear baseline should demonstrate that ANSTO (and, in particular, ANSTO Health) has adequate suitably qualified and experienced personnel and competencies to discharge its responsibilities for delivery and oversight of nuclear safety. It should be noted that ANSTO considers that a nuclear baseline for its licensed facilities in line with relevant international good practice would be beneficial to the organisation; although it is acknowledged that this is not a legal requirement under the ARPANSA legislation. Discussions with ARPANSA held as part of this current review confirmed that the regulator believes that a nuclear baseline review would be beneficial.

At the present time, ANSTO (and ANSTO Health) has not undergone a nuclear baseline review; although this is not because there is not the willingness or commitment to undertake it. In fact, such a study has been planned for some time but the frequent management changes in recent times has meant that there has not been a period of stability sufficient to undertake a nuclear baseline review. The recommendation regarding the nuclear baseline review is already being advanced by ANSTO as it is viewed as a valuable addition in demonstrating organisational capability and capacity and in assessing the impact of any relevant organisational changes.

This is not to say that ANSTO (and ANSTO Health) cannot meet the requirements of demonstrating that they are a competent organisation but that the baseline review and associated evidence cannot presently be presented in a coherent document.

An integrated management system is widely accepted as the best way of demonstrating this organisational capability although it does not necessarily fully cover the requirements of a nuclear baseline. Evidence presented during the site visit verified compliance against international management standards and it is acknowledged that ANSTO has recently invested significantly in systems that will improve this integration. ANSTO currently operates a management system that is accredited to AS/NZ 9001, AS/NZ 14001 and is subject to regular external audits and is in the process of obtaining certification to ISO 45001 for its safety management system. In addition, it is acknowledged that both IAEA and ARPANSA have carried out inspections and audits on the Lucas Heights site.

It should also be noted that ISO audits are a ‘snapshot in time’ and refer to processes rather than people and do not interrogate or verify whether any further specific codes and standards are adequate. Improvement opportunities exist under this recommendation that would further enhance the ability of ANSTO to demonstrate robust management arrangements exist which would satisfy these requirements under the auspices of a nuclear baseline.

7.4.1 Nuclear baseline shortfalls

Shortfalls identified during the assessment and following prior review of documents are broken down as follows:

7.4.1.1 Organisation structure by discipline

Whilst a selection of extant ‘organisation charts’ were presented, during the interviews several people stated that many changes to the organisation had been made over the past months and years (some ongoing), without stakeholder involvement or the effect of these changes being formally captured. Clarity on ownership, accountability and responsibility is viewed by many staff participating in the interviews as ambiguous. Both of these factors caused significant frustration as experienced during dialogue with interviewees, which exacerbated the ability of the organisation to demonstrate organisational capability in accordance with regulatory requirements. This includes the very basic ISO 9001 standard, Clause 5.3. For example, based on the interviews, some staff stated that requests for additional staff have been declined or not actioned based on head count and/or budgetary constraints. This may be because of federal government restrictions, but this message had not been communicated sufficiently. At times staff are perceived to have been assigned to other positions without the full impact on the resourcing being considered.

Several members of ANSTO Health staff stated during the interviews that people had been having to work extended hours, with little or no opportunity to recoup extra hours worked due to the workload. This was, according to several of the ANSTO Health interviewees, coupled with statements that a management decision had been taken to prevent time off being taken

once the benchmark for accrued hours had been exceeded. This could not be confirmed with ANSTO Health management and so remains a subject requiring resolution or testing post-review.

We recommend that ANSTO 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 of urgency (Area for Improvement).

Further concern exists where a significant proportion of ANSTO Health staff stated that they did not fully understand the corporate safety requirements. During some interviews, it became clear that for many, little was known of the detail contained in regulatory requirements (ARPANSA, TGA, Comcare) other than they existed. This may, as has been expressed elsewhere in this report, be a question of additional training or refresher training. It is noted that there are existing training modules on these topics used within the OPAL facility and these may be useable as the basis for improved knowledge transfer into ANSTO Health. Also:

- Accountabilities and responsibilities:
    - Some interviewees were unclear on their individual roles, this was emphasised during questions asked on changes to the organisation structure and the impact on their position descriptions, which were judged by the reviewer to be ambiguous and not reflective of current work practices. Persons interviewed, in some cases, stated that they were unsure who their direct reports are due to perceived dual reporting structures and any future “embedding” of staff from central technical services departments into the operating areas will need to take this into account.
- Performance standards:
    - Again, unclear on performance measures and against what criteria other than production deadlines, as discussed in Section 6.
- Roles and responsibilities:
    - Co-ordination and collaboration within each discipline and stakeholder involvement not defined, very much a silo mentality.
    - There is no clear understanding of the roles of the technical, design and independent nuclear safety authorities, or how these functions interface during changes to safety systems and equipment or personnel.
    - Significant risks exist due to the lack of understanding and interface between people and systems.
    - Problems/issues in some areas were not flowed through to other work areas which created further pressures. This can exacerbate an increasingly difficult working atmosphere from both a horizontal and vertical perspective.
- Position Descriptions (PD) are slightly ambiguous, for example:
    - ‘Asset & Process Engineer’ and ‘Asset Engineer’ – what is the difference?
    - Are responsibilities for those PDs which contain the words ‘Area Supervisor’ to work under the auspices of AP-2952 – Role of Area Supervisor?

- Delegations of authority are documented in line with AS-1682 Delegation Manual, yet delegation of authority is not clear on the PD.
- Validation Manager PD has the post classification documented as 'Band ?'
- PDs do not appear to require competency levels to be demonstrated which begs the question on how the requirements of a nuclear baseline can be verified.

Based on the expertise of the reviewer in this area, the examples above, together with documents provided by ANSTO and reviewed prior to the investigation team site visit, will require to be improved if ANSTO is to demonstrate they have the organisational capability to meet the IAEA standards, or indeed those of ARPANSA, through a nuclear baseline.

We recommend that senior management and/or responsible person(s) conduct an assessment of their individual department/section and identify posts required to perform each activity (Medium Priority).

This should include (as much as reasonably possible) a timeline percentage of activities conducted (man hours) to determine where resource shortfalls exist.

We recommend that each post should have a Role and Competency Profile (RCP) that 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 (Area for Improvement).

We recommend that 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 (see under change management paragraph) (High Priority).

7.4.1.2 Change management

The arrangements for change control are set out in the 'ANSTO Health Change Control Procedure'. A general comment regarding the procedures reviewed is that an author, approver and custodian is (generally) used but not in all cases. The term 'custodian' is often used but tends to refer to a department/discipline/section, rather than an individual. This has the potential to cause confusion on who is ultimately responsible, who are the stakeholders and how are the processes are rolled out to the organisation to ensure they are understood and able to be followed. There was no indication of the owner of this document. The document reviewed has no review date (although it is acknowledged that this is contained in the electronic document management system) or reference number; it contains many further references to a variety of other ANSTO documents making it almost impossible to read as a "stand-alone" procedure. It contains an overload of words with no clear indication of what the document is intended to do.

With regard to change management in the context of resource, examples of resource 'reallocation' were given during interviews; one example of this was persons being removed (at the request of a member of the executive) from one area to another, which was perceived to have been initiated without due cognisance of their responsibilities and workload. These were considered to be major and significant to safety. This should not be allowed without undertaking a review of the effect on safety and communicating the results to the staff involved. Whilst it is recognised resource is currently at a premium, safety and quality should not be compromised during any potential organisational changes.

Change management is not confined to personnel, but also includes safety systems and their associated systems, structures and components (SSC) as well as resource. Changes that may have an impact on nuclear safety are modifications requiring specific consideration and should be actioned as such.

Stakeholders should be actively engaged at the earliest opportunity and through all parts of the transitional change and the content of change management should include, as a minimum:

- Risk Assessment – Risk Register – Resources – Accountability – Structure – Safety Management – People Factors – Categorisation – Implementation - Communication Plan – Monitoring and Review – Ownership and Co-Ordination.

Vulnerabilities within any organisation are required to be unambiguous and include existing structure and resource and future demands on:

- Demographics.
- Overloading.
- Singleton positions.
- Competencies.
- Governance.

The investigation report related to the localised spillage of a sample from the trolley in B23 is a clear demonstration of the impact on ANSTO Health when changes to SSC and resource are not adequately considered and assessed in accordance with the safety significance that the activities, the SSC or resource performs. The residual risk had been calculated within the B23 QC laboratory risk assessment as being potentially high but, had a deterministic safety approach been adopted, it is likely that the conclusion of the assessment would have been that this method of moving samples with this type of trolley could not meet the appropriate deterministic safety criteria. Clearly the decision to use a trolley which was not designed to be used as a means of transporting radiological goods or items, should not have been made and the incident could have been avoided.

During the assessment, questions on the change management procedure were asked of several interviewees, with most of those verifying they knew of, or had heard of, the procedure, but were not sufficiently familiar with how changes are identified, captured or implemented. All change management arrangements should be captured and applied to all activities that have the potential to impact on nuclear and radiological safety in order to demonstrate the nuclear baseline is extant. As with other areas, it is important to take benefit from LfE in other areas such as the OPAL change management and control processes, which may be directly relevant to ANSTO Health.

We recommend that 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 (Area for Improvement).

This process should include change management terms of reference (TORs), change proposals, transition plans (including human factors) and stakeholder involvement through to completion. In addition, changes should be classified in terms of their safety significance,

based on relevant good international practice, with the basis for the classification being based on the most conservative assumptions and impacts, i.e. deterministic safety methods (see Section 10).

The review team acknowledges that ANSTO has been recognised by Comcare on their recently developed 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. This toolkit will be a critical element in the implementation of the recommendations highlighted by the review.

We recommend that the classification for change management of any physical change that 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 (Area for Improvement).

Furthermore, SSC and personnel changes shall be categorised based on importance to safety (i.e. harm potential if inadequately conceived or executed) and the requirements of appropriate codes and standards and applicable quality standards (see Section 10).

7.4.1.3 Measurement, assessment and improvement

Interviews with personnel confirmed a high degree of understanding regarding safety and quality. However, several ANSTO Health staff during the interviews stated that they felt there was limitation on their ability to implement improvement initiatives due to resource difficulties, lack of engagement with senior management and executives, lack of direction and the content of meetings considered as ‘instructions’ rather than stakeholder engagement.

Improvements and enhancement of safety performance was difficult to quantify, where examples of personnel formally raising safety issues not of a positive nature was discussed by interviewees. Interviewees suggested this is due to lack of engagement between senior management and the executive and the negative reporting culture within a limited number of areas in ANSTO Health, as discussed in Section 6. However, it is clear from the walkdown of the ANSTO Health facilities and a review of a sample of incident reports that 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 changes to additional people resources, upgrades to equipment, process and documentation improvements.

Issues surrounding the raising of incidents in certain areas on site (via GRC) are a major concern, as is the ‘resistance’ to report incidents due to the perception of repercussions for those raising concerns or for those implicated (see Section 6). Clearly, given that the incident reporting statistics within ANSTO Health are similar to nuclear industry norms, this is considered by the reviewers to be a local issue rather than a general issue. Despite the well communicated ANSTO (and ANSTO Health) management commitment to encouraging people to report incidents, unsafe acts, improvements, etc., a significant percentage of ANSTO Health staff interviewed referred to “*repercussions from senior management and executives*”. Examples were given to members of the assessment team during dialogue, however, these are not referenced to maintain confidentiality.

As a result, in certain areas within the business, incidents are sometimes not recorded. Had this not been the case, prior incidents (6 in total) regarding trolley use would have been

identified and preventive measures instigated had due process been followed. Clearly this would have been a major factor in the prevention of the trolley incident [11].

We recommend that 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 (Medium Priority).

Reporting of incidents should be encouraged by senior leadership and all members of the executive, evidence of which should be formally presented to the CEO. It is acknowledged that the CEO receives the monthly incident data and individual radiation safety reports daily and there is major commitment and encouragement from the CEO for a positive incident reporting culture. This needs to be part of a continuous improvement cycle of further reinforcement, communication, review and refreshment such that all reporting is presented as a positive influence and is part of a proactive approach to demonstrate ANSTO as a 'Learning Organisation'.

7.5 Measurement, Assessment and Improvement of Leadership for Safety and of Safety Culture

Senior management are required to regularly commission assessments of leadership for safety and of safety culture within its own organisation (qualitative not quantitative) including:

- Safety decisions:
    - The competency of persons within ANSTO Health making a decision with regard to nuclear safety should demonstrate they have the competence to do so. There is a clear assurance process within ANSTO for the provision of advice to support decisions with safety implications and this forms an essential part of demonstrating that ANSTO is a competent organisation. Anecdotal evidence presented by some ANSTO Health staff during interviews suggested that they believed that some safety decisions are being taken in order to meet production deadlines and attempts at decisions being taken out of the hands of competent people without consultation or recognition of the consequence. This could not be verified. It is, however, important that ANSTO Health ensures that the safety related decision process is robust with the necessary "checks and balances".
- Safety Performance Indicators (SPI):
    - SPIs are a useful means of focussing attention on particular safety parameters and progress on improvement programmes. It is understood that ANSTO has a series of SPIs as part of its general Key Performance Indicators (KPIs) monitoring system with trend analysis, improvement initiatives and verification of lessons learned (both internal and external). During the interviews, several ANSTO Health staff referred to the KPIs which are collated and reported by ANSTO Health, but the view was that much of the data and reporting was not used to drive change. Further, it was not clear as to who is responsible and accountable for SPIs, nor could many interviewees verify how SPIs are communicated.
    - It is important that there is clarity over how or where SPIs are identified, what they are, that they are specific enough to facilitate change, how they would

originate and that they are understood and documented, particularly those specific to ANSTO Health (Figure 5).

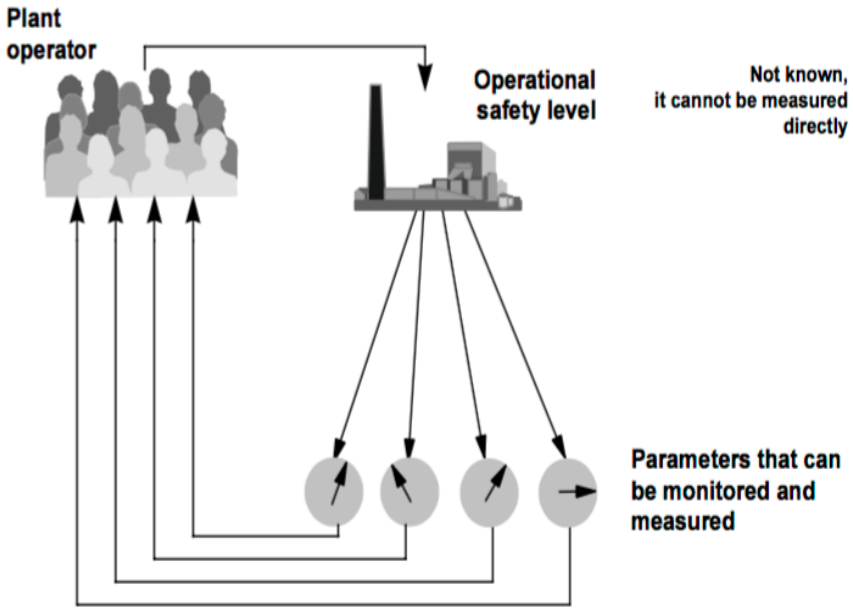


Figure 5: Inferring Safety Performance from the Information Provided by Safety Indicators

The IAEA has published its guidance for the development of operational safety performance indicators for nuclear facilities [21] based on the following key attributes:

- Plants operate safely.
- Plants operate with low risk.
- Plants operate with a positive safety attitude.

This framework can be used as the basis for a set of relevant indicators for ANSTO Health (see Figure 5 and Figure 6). It is understood that other areas of ANSTO operate a SPI reporting and monitoring process based on the IAEA guidance and this should be used as a reference point. It is important that ANSTO Health develops business specific and relevant SPIs to help manage the change and performance improvement in the organisation rather than select a set of generic measures that actually do not contribute to organisational improvement.

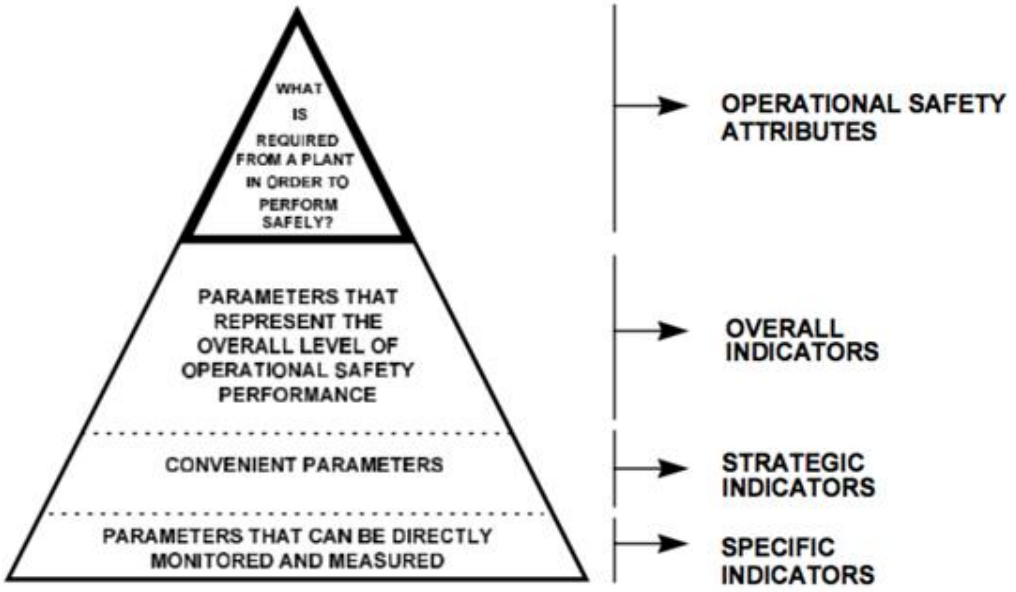


Figure 6: An Approach to Monitoring Operational Safety Performance

We recommend that a series of specific Safety Performance Indicators for ANSTO Health 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 (Low Priority).

Within the Nuclear Institute [22], the IAEA has developed the following strategic principles:

Principle 1 - The responsibilities, standards and supporting arrangements for the development, use and oversight of SPIs should be defined as part of the management system.

Principle 2 - SPIs should be developed and used as an integral part of the organisation's wider management review and performance improvement arrangements. They should be used to support decision making in conjunction with other appropriate performance information.

Principle 3 - SPIs should be developed and used in a way which maximises ownership and engagement and is aligned appropriately with responsibilities.

Principle 4 - The need for performance monitoring should be established objectively based on the wider business need including the hazard profile of the organisation.

Principle 5 - The SPI framework should include a combination of short and long term, leading and lagging indicators with established causal links between them.

Principle 6 - SPIs should be owned by the individual who has the accountability for managing the performance described by the SPI.

Principle 7 - SPIs should be measured, monitored, and reported on a routine basis.

Principle 8 - Individual SPIs should be clearly defined and recorded within the management system.

Principle 9 - Communication of SPI performance should be clear, concise and consistently reported.

Principle 10 - SPIs should be used in conjunction with other information to inform management review and decision making.

Principle 11 - SPIs should be subject to regular review so that the SPIs individually and collectively evolve based on the needs and strategic direction of the organisation. The review should include removing obsolete measures, improving existing measures and developing new measures.

7.6 Review of Processes and Position Descriptions

Under the requirements of a nuclear baseline, management processes and activities should be developed, owned, assessed and reviewed and effectively managed to achieve the organisation's goals without compromising safety.

From the sample of documents reviewed, it was difficult to verify that processes, procedures and work instructions have a defined document owner. Personnel interviewed were aware of some of the procedures, but not all; of those that did, it was clear during discussions that a significant percentage of management procedures did not meet regulatory requirements (this was verified during document reviews prior to and during the site visit) or described the intended activities performed by personnel.

This begs the question, who reviews the documents for compliance, where are reference and regulatory requirements identified, and by whom. It is understood that the change control procedure sets out the process for approval and who reviews (there is a wide range) for compliance. There was little evidence of stakeholder involvement, or interface arrangements within disciplines, during the production or implementation of internal procedures. Where such procedures relate to nuclear safety, they should be subject to quality assurance commensurate with their safety importance in accordance with IAEA guidance.

Further, many of the ANSTO Health staff interviewed stated that they had little detailed understanding of the requirements of ANSTO's regulatory bodies. Whilst awareness of the nuclear licence is evident, the content and the methodology of the compliance requirements of ARPANSA, TGA, Comcare and ISO could not be demonstrated to be well understood in the sample of staff interviewed on this topic.

If, based on the assumption from the interviews that the regulatory requirements are not fully understood (and in some cases only an awareness may be expected), it begs the question on how processes and procedures are able to verify compliance. Without this understanding, ANSTO Health is not able to confirm safety is not compromised or to verify that suitably qualified, experienced and competent persons are performing these activities.

There is a myriad of documents which includes: Position Descriptions, Procedures, Health Plans, Plans and Arrangements for Safety, Safety Delegations, WHS Accountabilities, Delegations Manual, Organisational Structures, Management Reviews, *et al*. However, none of these clearly and unambiguously identify and document what these adequate

competencies for those activities being conducted are and how these are determined. As a result, the overall structure of the safety management system (from policy to arrangements to procedures to guidance) appears to the reviewers to be over complicated and requires review and possible future update.

We recommend that ANSTO undertakes a 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 (Area for Improvement).

The main function of a process within the nuclear industry is to demonstrate organisational capability by the following:

- Ownership.
- Accountability.
- Responsibility.
- What do you do?
- How do you do it?
- Who does it?

Processes reviewed contain some of this information, but none are able to describe unambiguously how activities are performed. Nor is there evidence at this stage that persons performing each activity are still in that position, or if that position still exists.

Examples of risk assessments presented show several dated 2010 (with no reviews subsequent to the 2010 issue) and another that was reviewed and authorised by the same person, all of which are a clear shortfall with regard to stakeholder engagement and compliance with ANSTO's own procedures.

In accordance with best practice and due process and to demonstrate organisational capability, nuclear regulators would expect a nuclear baseline to demonstrate clearly defined roles and responsibilities, unambiguous interface arrangements with relevant stakeholders and both resource and infrastructure clearly determined.

Safety Assurance Committee (SAC) examples viewed:

- AG 5856 – Safety Committee Flow Chart, where the flow refers to steps such as 'Define Scope of Project', 'RAC Review and Approval', 'Assessors confirm responses are satisfactory, SAC Manager issues document package to Safety Assurance Committee' – with no further information on who does what, or how these activities are conducted.

- AG 2426 – Submissions to the Safety Assurance Committee, the first paragraph … *'This practice is recommended to General Managers and Institute Heads to facilitate implementation of their legislated risk management responsibilities. This practice should be read in conjunction with AG1094 ANSTO Guide: Operation of the Safety Assurance Committee …'* AG 2426 was approved by SAC chair on 29/11/2013, with the custodian being Leader, Systems. The document is almost 5 years old. In addition, AG1094 was approved by the SAC Chair on 11/6/2014, custodian again given as Leader, Systems. This document is over 4 years old, and there is no evidence to verify who the responsible person within 'Leader, Systems' is. Neither of these guidance documents is easy to follow without reviewing a myriad of further

referenced documents, nor can the question of, If the guidance isn't followed (given that it's only 'guidance') then what …?

7.7 Implementation of Nuclear Baseline and Interface with ARPANSA

There are many positives to be taken from implementing a nuclear baseline, both for ANSTO (including ANSTO Health) and ARPANSA as the regulatory body, not least of which is to give clarity and openness to both parties, which is currently difficult to demonstrate. Based on the experience of the expert reviewer, general areas of concern with regard to the existing baseline include:

Procedures are:

- Fragmented, standalone sub-systems, maintained independently.
- Unclear in showing a clear link from hazard, risk and the procedural controls.
- Difficult to understand.
- Lacking in ownership by the workforce.
- Costly to develop documents.
- Lack visibility of individual accountabilities.
- Disguise valuable information within volumes of text.

Figure 7: Best Practice Representation of Alignment of Corporate Governance to Workforce

For the successful implementation of a nuclear baseline approach, the basic fundamentals need to be unambiguous:

- Strategy and objectives.
- Meet regulatory requirements.
- Clarification of each person's role.
- Implementation, management and monitoring compliance.
- Removal of 'Functional Fortresses' - (visible inputs and outputs).
- Horizontal processes rather than vertical - (across multiple departments and business units).
- Consistent format to procedures and instructions.
- Streamlining of operations – removes redundancy/waste.
- Integration of risk and compliance into processes.
- Capture best practice across organisation.
- Provide clarity and understanding.
- Provide process ownership and create discussion improvements between stakeholders.
- Determine responsibilities.
- Create awareness and ownership.
- Definition of inputs and outputs.

However, it is insufficient to implement a baseline without fully understanding what the content is based upon.

The review team were able to identify shortfalls between ANSTO and ARPANSA with regard to the lack of understanding that a proportion of ANSTO Health personnel interviewed have of regulatory assessments and the ability of ARPANSA to assess the organisational capability of ANSTO in a more structured manner. This may be, in some part, due to ARPANSA being a relatively 'new' regulatory body and the current structure of inspections being based on a more high level review rather than getting 'into the weeds' of the organisation.

It is considered that a number of improvement initiatives with regard to implementing a more open and transparent regulatory inspection structure are applied. In addition, these improvements could increase the ability of ANSTO in providing sufficient information via a set of safety management arrangements and competency frameworks.

We recommend that both ARPANSA and ANSTO develop documentation that offers guidance on the interpretation and implementation of ARPANSA licence conditions and that takes 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. (Medium Priority).

This recommendation is, of course, intended to compliment the Licence Condition requirements of ARPANSA, not to replace them. This will form the basis of a more clearly defined reporting and inspection structure and provide a more cohesive interface and improvement strategy going forward. Further information and recommendations related to the regulatory interfaces between ANSTO and ARPANSA are contained in Section 9.

We recommend that 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 (Medium Priority).

In conclusion, the review team believes that a nuclear baseline will provide greater awareness of individual responsibilities, access to key information and provide the highest level of operational transparency (see Figure 8).

In order to demonstrate compliance under the auspices of: ARPANSA, TGA, Comcare, et al., ANSTO should take due cognisance of the Nuclear Baseline and the Management of Organisational Change: Nuclear Industry Code of Practice (NICoP).

Figure 8: Overview of Nuclear Baseline Principles

8 Human Factors Review

Lead Author – Peta Miller

8.1 Introduction

This section considers the human factors[1] including job and task factors and people characteristics that may have implications for workplace health and safety and performance at ANSTO Health. In preparing this section, particular attention was focused on the person-machine, person-task and person-job factors associated with B23 ^{99}Mo operations and the associated QC activities. Given the high interaction between the factors, they are discussed where possible under relevant topic headings but there are necessarily some overlaps and duplications. This section also builds on the human factors including the organisational context and safety culture referred to in other sections of the report.

A desktop review of relevant documents provided to the review team by ANSTO, ARPANSA and Comcare, together with correspondence and material supplied by staff within ANSTO Health, was undertaken. Semi-structured interviews were held with senior executives, managers, supervisors and workers from across ANSTO Health, ANM QC, WHS, RPS, Engineering, Maintenance and relevant supporting areas.

Brief observations of high-risk and other work areas, processes, workstation layout and processes were also undertaken. This information was supplemented by analysis of written policies and procedures. Potential biomechanical hazards and risks were referenced against standard ergonomics instruments and WHS regulations and Codes of Practice [23]. The psychosocial hazards, risks[2] and outcomes (musculoskeletal discomfort, bullying, burnout, job satisfaction) were benchmarked against Australian standards derived from the People at Work tool [24]. Supplementary data on some aspects of safety culture was also collected in a confidential on-line survey about current job roles.

All staff whose functions fell broadly under ANSTO Health and 'others' who may have been able to provide additional insights were invited to respond.[3] In total, 71 valid survey responses were received within the one-week period. Overwhelming the majority of responses were from ANSTO Health staff. This achieved a good response rate for an on-line survey [25]. Comments in this chapter derived from the survey therefore pertain only to ANSTO Health.

Overwhelmingly staff interviewed reported feeling highly committed to their work and the delivery of high-quality products and expressed a desire to be 'part of the solution not the problem.'

However, many staff during the review interviews and those who completed the survey in the open comments section reported feeling distressed, anxious, angry, frustrated and disillusioned. While this can be attributed to different causes, which are discussed in this and other chapters, issues identified by the review through the interviews and the survey (especially in the free text comments) included perceptions of:

- High workloads and production pressures.

[1] Human factors refer to environmental, organisational and job factors, and human and individual characteristics, which influence behaviours at work in a way which can affect health and safety.
[2] Psychosocial risks included those associated with the nature and content of the work and the social relations and conditions under which the work is performed.
[3] Review scope was for ANSTO Health so the 'others' invited to participate were limited to support areas. Others identified as from 'Safety System & Reliability, Radiation Protection Services, Health Physics, Technical and Development'

- ‘Inappropriate’ workplace behaviours.
- ‘Lack of management support’.
- ‘Scapegoating’.
- A ‘failing safety culture’.

These are discussed in more detail in the following sections.

8.2 Review Findings

Peoples’ judgements about their task and job load, and so, overall workload and its tolerability, are derived from factors shown in Figure 9. These broadly include:

- Work demands - the task and job content and context - factors people must cope with including total working hours and shift arrangements, task specific cognitive[4], physical[5], emotional and temporal demands and the team and organisational culture in which the work is done.
- Job factors affecting work demands and motivation include perceived task and job control, variety, skill utilisation and task ‘purpose’ (delivery of life saving technology).
- Coping capacity - factors that affect peoples’ individual coping capacity including perceived support and their own personal circumstances and attributes.[6]

These factors all operate within a broader organisational context and climate. All factors ultimately interact with and impact on ‘performance adequacy’, that is, the peoples’ perception of their own capacity to meet the required performance standards and their satisfaction with this.

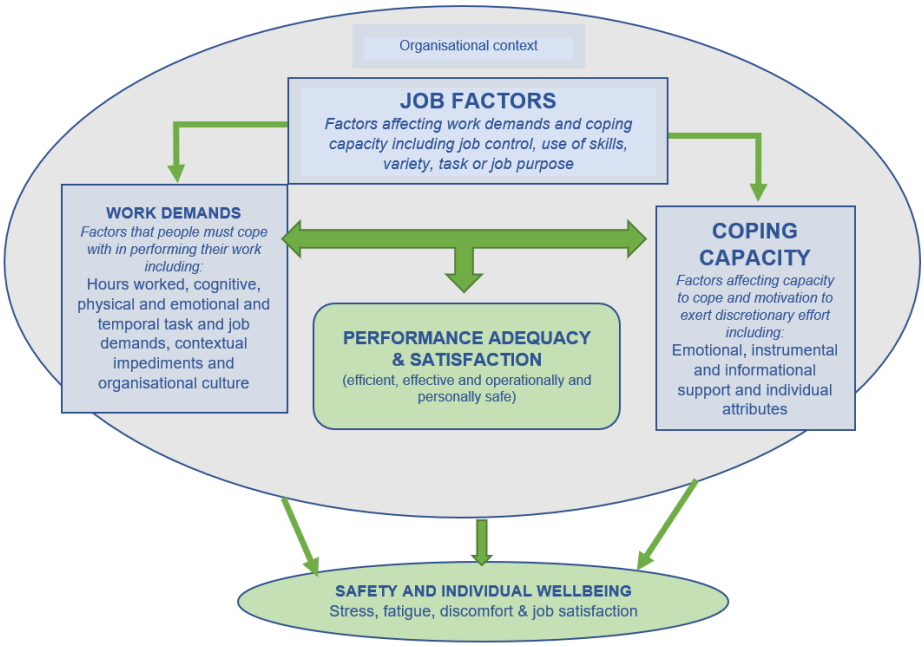


Figure 9: Interaction Between Work and Job Factors, Coping, Performance and Wellbeing (adapted Miller, 2004)

[4] Cognitive workloads will include perceptual and information processing demands
[5] Biomechanical demanding, working around hazardous chemicals and energies, and in challenging working environments (vibration, noisy, extreme temperatures, poor lighting etc.)
[6] Conceptual models concerned with primarily concerned with preventing or managing psychological harm group some of these factors as ‘psychosocial hazards and risks’.

In turn, these directly or indirectly impact on individual work-related wellbeing including levels of stress, fatigue, body part discomfort and satisfaction with their job and, more broadly, the organisation. All these interdependent factors impact directly or indirectly on safety.

While workload is subjective, it is strongly influenced by quantifiable work, task demands and observable organisational factors. It is undisputable that the risk of safety related slips, lapses and mistakes will increase during periods of excessively high workload and when staff are stressed and/or fatigued. Of note is that job and work demands are generally considered 'psychosocial' risks and are known to contribute to work-related psychological injuries. Guidance on the management of these is outlined on the Safe Work Australia and the Commonwealth WHS regulator Comcare's websites [26].

The focus of the review is on factors within the control and the responsibility of ANSTO Health, discussion of individual workers and their attributes are not presented.

8.2.1 Working hours and general time pressure

Building 23 shifts operate between 06:00-16:00 weekdays and 22:00-14:00 on Saturday and Sunday. In Building 54, there is a 24-hour, 7 day a week production schedule.

The total numbers of hours people work each day, over a week and even over several months will directly and indirectly affect their performance and health and safety. A recent systematic review showed that regularly working over 8 hours in a day carries an increased risk of accidents that is cumulative, so the risk of accidents at around 12 hours per day is twice the risk of that at 8 hours [27]. Shift work, including working at night, carries a substantially increased risk of accidents.

During the interviews conducted by the review team, some staff reported the need to frequently work long hours, but most expressed concerns were not about the actual hours worked, but around the perceived time pressure whilst they were at work (see later discussion) and the need to defer asking for or taking leave due to perceived staff shortages.

The review team was told of instances where workers on recreation or serious sick leave were repeatedly asked by managers (or line supervisors were directed to ask them) to return to work to resolve issues. Given when people are unwell or fatigued, their decision making may be compromised (an error creating situation), this action increases the risk of potentially serious slips, lapses and mistakes. This reflects many issues but not least the apparent lack of adequately skilled staff to deal with peak workloads and crises.

In the survey, responses to the question 'what impacts your decision to take leave': 36% reported negative work pressure, understaffing, burnout; 30% (need for) family workload balance and 25% family or personal reasons.

> *'I just can't take leave… when our team is under so much extra pressure'*
>
> *'I am unable to take my leave when I know tasks will then be done by co-workers who may not be familiar with how to do them'*
>
> *'I feel I need to work unreasonably hard to just prepare to take time off, just to make sure everything is covered, even if it is just one day or an afternoon.'*

It is noted that ANSTO does have a range of policies to allow staff 'flexible work arrangements' and to take different leave types which if approved and used will help to reduce fatigue, stress and burnout. The issue is we heard some staff felt without appropriate numbers of qualified experienced staff this would just mean the workloads would just increase for others or the work would just be there when they returned.

The timeframes for nuclear medicines production are fixed to accommodate, for example, ^{99}Mo, ^{99m}Tc half-lives through the "Just in Time" manufacturing and supply process.

Concerns about 'poor' task scheduling, delays in getting materials or undertaking maintenance were common.

Staff clearly understood the time and resource pressures on many of the areas providing materials and support to them, but this did not appear to reduce their frustration and stress and concerns about the flow-on impacts for their own work outputs and quality.

A common complaint from ANSTO Health staff responding to the survey and in the interviews was the general pressures to meet production deadlines and a 'lack of senior management understanding', even when in their view, there were insufficient staff to do the processes safely and in compliance with TGA standards. The potential for errors and reduced product safety was clearly expressed.

This was illustrated during the review team's visit by the release of an external communication, without consultation with all relevant staff, that production would resume by a specified date, when staff had clearly indicated this was not possible.

Working hours and time pressure: those reporting 'Often' or 'Always':
36% I have to neglect some tasks because I have too much to do
18% I have unrealistic time pressures
15% I have unachievable deadlines
11% I am pressured to work long hours
[ANSTO Health Survey August 2018]

There was a level of resentment expressed to the review team by several ANSTO Health interviewees that the unique time pressures that ANSTO Health staff face are not well understood by the broader ANSTO community. Staff making these complaints indicated felt they were the 'cash cow for everyone else to get funding from'. These sentiments were also reflected in the survey open comments.

There was a general commentary from respondents that their frustration and stress associated with understaffing was not sufficiently recognised or dealt with by management, despite the known production and quality pressures.

Whilst recruitment processes are more complicated at ANSTO due to security clearance requirements and the specialised nature of their work, long delays in recruitment will increase workloads and are generally reflective of inadequate change management processes. This sentiment was consistent with findings from the survey.

Given the clear research evidence that the risks of slips, lapses and errors increases with fatigue, ANSTO Health staff need to be encouraged to use their leave as required. They are more likely to take leave when it is needed do so if they believe there are adequate measures in place to ensure this will not result in unreasonable pressure on themselves or others in the team.

Clearly there is an urgent need to monitor workloads especially around safety critical tasks, adjust staffing levels to ensure these are appropriate during both normal operations and during emergency situations.

We recommend that staffing levels are reviewed and addressed to ensure all staff can take leave, without placing undue pressure on other employees (Medium Priority).

We recommend that 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 (Medium Priority).

We recommend that workloads should be reviewed and monitored and effectively managed during organisational change and controls to manage workloads documented in the change management plan (Medium Priority).

8.2.2 Cognitive demands

Staff reported their work required high levels of sustained concentration, vigilance and manual dexterity. Over 80% of survey respondents reported their work needed their undivided attention and that they needed to keep track of more than one process at the same time, some of these critical. This was also a source of satisfaction noted by some people during our interviews. However, generally, the cognitive demands reported in the survey were equivalent to Australian benchmarks.

Staff were acutely aware of the negative consequences on product quality and production timelines if they were to make errors.

Despite the ageing facilities, no staff complained during the walk rounds by the review team about the machine-person interfaces including information displays and controls causing them particular confusion or stress. It is the review team's opinion that this was due to their high levels of familiarity with the equipment.

Staff reported that, with greater training and experience, the cognitive demands of their work reduced. There is a high reliance on training and the need to precisely follow task procedures at ANSTO Health. To moderate cognitive demands during critical tasks, reminders (for example, note on the on/off switch in the hot cell lines) or safety observers were used (see Section 8.2.7). There was awareness of the need to build in, for example, more explicit cues and hazard warnings in the text to alert operators to potential safety or quality issues in the new QC processes.

Staff responsible for training and developing procedures discussed strategies they used to make documents more user friendly, acknowledging more work was required to ensure that these, in fact, do translate to improved competency.

However, reliance on training and procedures especially during high workloads without additional controls is risky. Two issues were noted by the review team regarding the effectiveness of this control:

- It is highly dependent on the adequacy of training (including if it suits the learner).
- It is highly dependent on the fact that the task demands do not exceed the person's capacity to cope.

It will be important that the implications of inadequate staffing levels, especially during safety critical processes, are explicitly included as part of the management of change processes.

8.2.3 Physical demands

This section of the report does not discuss issues associated with handling hazardous substances including radiological materials, except noting people's awareness of the material toxicity (especially during open source handling) influences their decisions, for example, to slow down their movement to increase movement accuracy. The latter is influenced consciously or unconsciously by the prevailing perceived time pressures.

The main physical demands observed during the review were the biomechanical demands, for example, those associated with:

- Interfaces with specialised plant such as the hot cells.
- Working with radiological and chemical materials.

- Working in and around laboratory equipment such as fume cabinets, trolleys and mobile waste bins.
- Using small tools and equipment such as forceps, pots and decappers.

The review team noted the scope of the 2009 ergonomic report on 'Body Stressing Risks in ARI' which included some production[7], generator distribution and laboratory assistant tasks. While this report's focus was principally on the body stressing (biomechanical) risks, the author briefly noted psychosocial risks arising from 'change management', 'excessive cognitive' and 'perceptual work demands' and 'relationships and conflict'. The focus of that report's recommendations was on minimising the biomechanical risks for those tasks sampled. It did not comprehensively examine nor recommend controls for the psychosocial risks noted.

The biomechanical risk controls introduced shortly after the 2009 ergonomic report and the subsequent and ongoing modifications introduced by ANSTO Health such as task rotation of high-risk activities are likely to have reduced exposures to some biomechanical hazards. An on-site physiotherapist and exercise physiologist now run strength programmes which have been well received by staff.

The review team was told that these collective efforts have led, as an example, to reduction but not elimination of incidents associated with manipulator use.

While these interventions have been greatly appreciated by staff, they are principally lower order controls. Control options appeared to put a priority on radiation safety (for example, physical barriers to reduce the shine path) and have not eliminated hazards especially for small stature workers. Nor have they addressed the underlying psychosocial hazards and risk factors. When the review team asked about this, staff said '*it is just so much better than it was'* and *'we did what we could with the available budget'.*

During the visit, a range of unacceptable musculoskeletal hazards were observed associated with some ANSTO with some ANSTO Health tasks. This included frequent awkward postures, tasks requiring extreme joint range of extreme joint range of motion (especially in the neck, upper limb, hands and back) with repetitive movements repetitive movements requiring great precision and occasional forceful movements (e.g. moving lead waste bins). moving lead waste bins). The risk of injury for people with short stature, large abdominal or chest dimensions and chest dimensions and pre-existing musculoskeletal issues would be significantly higher. Some of biomechanical Some of biomechanical demands are clearly illustrated in

Figure 10 below.

[7] Working at the cell face, working in yttrium glove and tong boxes, working in thallium & gallium glove and tong boxes and assembling Gentech generators

Operation of the Hot Cell Controllers due to their Fixed Equipment Layout is Highly Dependent on Training and Skill to Ensure Wrist and Arm Postures are Acceptable.

Fixed Height Workstations Limit Sitting Comfort.

Small Stature Workers Cannot Easily Manipulate Pots Behind Radiation Screen or Reach into Storage Containers Without Adopting Awkward Postures

Steam Cleaning, Repetitive Motions with Extreme Range of Movements.

Figure 10: Examples of Biomechanical Demands

The biomechanical hazards and risk controls in B23 and B54 are in stark contrast with those in the new ANM facility where most hazards have been eliminated or prevented through automation or the risks minimised through significant improvements, for example, improved hot cell design.

Biomechanical risks to operators undertaking production work in hot cell lines should be largely eliminated or minimised where these processes are being relocated to the new ANM facility. The ongoing process to refurbish the QC room layout and equipment in B2 using a user centred design approach is noted and commended. It should reduce the work-related musculoskeletal disorders (WMSD) risks but only for staff operating in those locations.

Despite the proposed inclusion of a safety observer (see Section 8.2.7), the safe materials flow through B23 appears likely to remain an issue due to constrained access in rooms, through corridors and human traffic.

Muscular demands even at sub maximal force eventually lead to short term fatigue in motor units, reducing grip strength and dexterity [28]. Small muscles like those in the hand fatigue relatively quickly, especially during ‘static’ hold postures (isometric contractions), thereby increasing the risk of handling errors. In the longer-term, fatigue leads to musculoskeletal discomfort, increasing the risk of Work-related Musculoskeletal Disorders (WMSDs). Importantly, these clearly increase the likelihood of errors.

WMSDs are the most common cause of workers’ compensation claims in ANSTO Health. The presence of psychosocial hazards has already been discussed. The link between biomechanical hazards and injury risk, specifically high workload and other psychosocial risks is well established. A model for this association is noted in Figure 11.

It is noteworthy that at the time of the review in the ANSTO Health survey, 22% of staff reported they 'always' or 'often' and 34% sometimes[8] experienced muscular discomfort over the last four weeks.[9] This was generally worse for the shoulders and neck.

The International Congress on Occupational Health recognises the importance of identifying musculoskeletal discomfort which is 'at risk of worsening with work activities', that is to say, where risk factors have not been addressed [29]. Body part discomfort is strongly linked to the subsequent risk of developing musculoskeletal injuries and disorders.

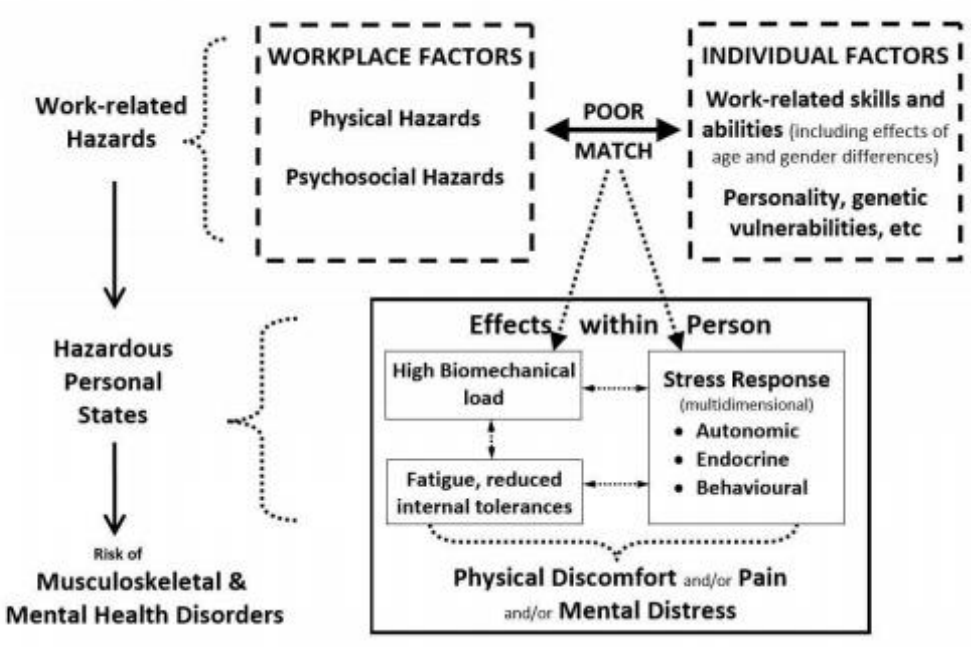


Figure 11: Model for Association Between Physical and Psychosocial Hazards [30]

It is clear that the biomechanical hazards and risks for staff remaining in ANSTO Health need to be addressed as a matter of urgency. Any future examination of WMSD risks must include all high-risk tasks undertaken by ANSTO Health staff and address the relevant psychosocial risks. Further, these should achieve ALARP risk reduction.

We recommend that the WMSD risks for staff remaining in ANSTO Health should be controlled as a matter of urgency to ensure risk controls are ALARP (High Priority).

To help achieve this, ANSTO should ensure all architects, engineers and others creating or procuring designs to modify the ANSTO Health facility or equipment understand and accommodate an appropriate anthropometric range. They should also apply a user centred design approach in accordance with ISO 9241-210. This standard requires designers to consider the following 6 key principles:

- The design is based upon an explicit understanding of users, tasks and environments.
- Users are involved throughout design and development.
- The design is driven and refined by user-centred evaluation.
- The process is iterative.

[8] Fairly often, sometimes
[9] Discomfort, ache or pain

- The design addresses the whole user experience.
- The design team includes multidisciplinary skills and perspectives.

Example of user-centred design/using lower order controls

Following the 2017 incident, ANSTO Health operational staff and engineers (multi- disciplinary team) are collaboratively developing and testing prototype trolleys, mobile lifting equipment, fume cabinet, decappers and procedures including 'safety observers' for safer sample transportation and processing (see examples below). The collaborative user centred design approach is applauded and represents good practice.

Prototype Trolley, Lifting Equipment and Fume Cupboard B2

Nevertheless, there is clearly scope for further designs of equipment to reduce the biomechanical risks associated with awkward postures. For example, with the solution shown safe and comfortable use of the fume cabinet will still not be possible for all staff, especially those of small stature. This demonstrates a concern the review team had that optioneering may not be considering the full range of viable long-term control options such as automation.

It should be noted that, while typically designers should allow from the 5th percentile female to 95th percentile male, given serious implications of body part discomfort on safety, we suggest where possible that range be extended.

ANSTO should also strive to understand (perhaps through an anthropometric survey) the physical characteristics of all staff undertaking high-risk work at ANSTO Health. This information would be useful for future designers or procurers of plant and equipment.

We recommend that architects, engineers and others designing or procuring modifications to ANSTO facilities and equipment should accommodate relevant human factors including normal anthropometric ranges (Area for Improvement).

8.2.4 Emotional demands

The main emotional demands associated with performing tasks at ANSTO Health appear to be associated with working with others within their facility and the broader ANSTO environment and the responsibility staff feel to deliver quality products to patients. Emotional demands reported by staff were equivalent to Australian benchmarks but the relationship to job satisfaction and bullying is pertinent. 53% of those reporting low job satisfaction reported their work frequently[10] put them in emotionally disturbing situations (an example from the

[10] Fairly often, often or always

survey, production delays impacting patients), compared to only 36% of the time for those with high job satisfaction.

8.2.5 Bullying

Bullying and harassment are known psychosocial hazards which can lead to serious work-related psychological injuries. If it is found to have occurred, it may be considered by regulators as a failure of the duty of care under WHS legislation. Allegations of 'unacceptable behaviours' ranging from what appeared to be at least in contravention with ANSTO's own values, to likely harassment or bullying deserve highlighting.

About 1 in 5 ANSTO Health survey respondents reported that they believed they had in the past 6 months 'experienced bullying' by a supervisor (20%), by a manager (14%) or co-worker (14%). Very few reported they had 'experienced bullying' from a subordinate (3%).

It should be noted that this does not necessarily mean that, if these instances had been or are fully investigated, the allegations would have been upheld and found to meet the strict legal test. Nevertheless, staff perceptions that they have, in their view, been bullied or harassed are serious. Outstanding and future bullying and harassment allegations need to be promptly investigated and fairly resolved.

It is worth considering what might drive otherwise reasonable people to at times behave poorly. Even though bullying behaviour plays out during interactions between people, there is clear empirical research evidence that shows that there is increased prevalence of workplace conflict and poor behaviour where there is a perception of:

- Excessive workloads, unreasonable time pressure, deadlines and inadequate numbers of skilled or experienced staff.
- Significant power imbalances between individuals.
- Inconsistent and unfair application of rules and procedures and protocols.
- Previous poor behaviours had not been effectively managed [31].

How people emotionally react and behaviourally respond to high workload periods and to others 'poor workplace behaviours' is strongly shaped by their own experiences and perceptions of events. If staff have had previous negative experiences at work, as some clearly reported to us, they are to some extent primed and can be understandably very sensitive to what others may perceive as relatively benign situations even from people who had not 'bullied' them. This can be exacerbated if people are not making allowances for the natural differences in communication styles, especially when people are under stress.

> *'telling us we need to improve our people skills without addressing the underlying issues is not much help'*
>
> *'Employee Assistance Programs are not the solution, it just allows us to avoid looking into the causes of what is causing poor mental health around here'*

Conversely those staff who are regarded by others as the ones behaving poorly may see their behaviour as reasonable in the absence of clear feedback and in the face of their own workload and other pressures.

It would be useful to run some programmes to help staff identity their own and others' communication styles and coping strategies and how these might change when people are experiencing high workloads. Further, inclusion of alleged serious unacceptable behaviours (such as breeching ANSTO or APS codes of conduct) should be included in the ANSTO incident register, with appropriate confidentiality. This should help trigger investigation and appropriate and fair investigation and resolution responses.

Active promotion of the ANSTO's "whistle-blowing" procedures and protections, including confidentiality and anonymity, should occur. This will allow the organisation to promptly address issues. Contraventions of ANSTO behaviours, codes and procedures should continue to be treated very seriously.

However, it is the reviewer's opinion that it is not usually helpful to adopt a 'perpetrator victim model' when investigating and resolving poor workplace behaviours as this tends to polarise positions and inhibit issue resolution. Instead, the review team strongly suggests that ANSTO uses a causal analysis approach to identify underlying contributing factors to alleged poor behaviours. We emphasise policies and training are part of the control mix and are alongside elimination or minimisation of workload and cultural issues. To re-establish trust in some limited circumstances, a voluntary restorative justice process may be helpful [32].

On a positive note, overall levels of perceived procedural justice reported in the survey were comparable to other Australian workplaces. Complaints around perceived procedural injustice were limited to specific instances about which ANSTO management are, or should be, aware. However, these instances and alleged bullying appear to have been destabilising, and considerable effort will be needed to de-escalate emotions and to restore trust and goodwill amongst affected individuals and/or groups.

We recommend that unacceptable behaviours including allegations of bullying and harassment should be included in the incident register with the appropriate anonymity protections (High Priority).

We recommend active promotion of and adherence with the ANSTO whistleblowing procedures (Area for Improvement).

We recommend that a causal analysis approach be used when investigating and responding to alleged poor workplace behaviour including bullying (High Priority).

We recommend that staff who have experienced harm arising from recent events should be offered easy access to appropriate support to assist their recovery (Area for Improvement).

8.2.6 Job control

Job control captures a range of factors relevant to staff in ANSTO Health which importantly are known to moderate high workloads, reduce stress and fatigue and increase job satisfaction. Job control includes peoples' decision authority and latitude - such as over how and when the work can be done. Clearly this is, and should be, strictly controlled at ANSTO Health and so the slightly lower levels of job control in the survey, compared to Australian benchmarks, is unsurprising.

However, control also includes the opportunity for people to express their views and believe their opinions and skills are valued. Indeed, consultation with those involved in doing the work is a requirement under section 274 of the WHS Act 2011 and clearly articulated in the IAEA requirements noted in Section 7. Further ANSTO values explicitly include those of 'working together' with 'trust and respect'.

There was mixed evidence around the job control and, in particular, worker consultation and involvement. There were positive examples such as the inclusion of staff in the design of ^{99}Mo QC processes in B2 (where teams are collaboratively developing and testing options). However, other circumstances where staff who were critical to understanding processes believed they were

'all the changes to the org structure are exhausting especially when we need to get them to understand our work'

'they are not just sweating the assets they are sweating the goodwill of staff'

'we are tired of reactive solutions to known issues'

not appropriately consulted or their views unreasonably discounted.

Although change management is discussed elsewhere, relevant to this section are examples where staff told us they had requested organisational or operational changes be 'risk assessed'. They reported that, where their ideas did not align with the managers and supervisors' views, they were labelled 'blockers' and communication with them was shut down.

This perception of lack of authentic change consultation by some is likely to be contributing to the concerns we heard from some ANSTO Health staff that '*our safety culture is failing*', as discussed earlier.

Closely associated with the experience of time pressure, job control and support (discussed next) is that of role overload. People typically enjoy having a reasonable 'span and level of responsibility', so long as it is associated with appropriate demands and support. The review team heard repeatedly from managers and supervisors who felt 'too stretched' trying to manage all aspects of their role, especially during peak workloads and when 'dealing with the current emotional fallout of recent decisions'. It was clear that the cost of advocating for their areas (and sometimes feeling they were not being heard) and supporting distressed staff so they stayed at work to finish the tasks was exhausting and impacting their own health and wellbeing.

One strategy to recover from stress and fatigue discussed earlier is to take leave. Yet staff told us of instances where they did not feel they could use their flexi-time or take leave because the area was chronically short staffed. Some, allegedly, were told they would lose their high flex time balances if they did not take leave, putting them in a no-win situation. This could not be verified by the reviewers.

The staff shortages and production pressures also limit people's control over their working time arrangements including family friendly hours. For some, this was a source of significant distress.

> *'in my experience this is not a family friendly workplace at least for some ANSTO Health staff… no matter what the say.'*

The review team acknowledges that the highly specialised nature of the tasks with specific security clearance requirements means staff are sometimes difficult to recruit in a timely manner. As a result, retaining experienced staff is critical to the ongoing efficiency of operations. During the interviews, some staff who had previously indicated they had never before seriously contemplated leaving the organisation reported they now felt this way. This is consistent with the findings from the ANSTO Health survey, in which 14.3% of staff reported they were likely to resign from the organisation because of a stress-related problem.[11]

8.2.7 Support

There are broadly three types of job support:

- Instrumental support i.e. having the correct working tools, equipment and materials to do your job well and safely (for example, efficient user-friendly IT systems, well designed functioning decappers, sufficient spare parts).
- Informational support i.e. having all the information you need about your job and tasks when you need it and provided in a user-friendly format. For example, what is needed to be done, by whom and when to meet expected quality, performance and safety standards. Examples of informational support provided to the review team

[11] Grouping likely, very likely, or extremely likely

include the work procedures, safety alerts, toolbox talks and team briefings about decisions which impact their work.

- Emotional support from peers, supervisors, managers including executives and, where required, WHS, occupational health nursing or PCSS. Emotional support should be appropriate, timely and delivered in a style that suits the individual and is then a powerful moderator of perceived workload and so stress and fatigue.

8.2.7.1 Instrumental and informational support and training

Lack of instrumental and informational support are some of the most powerful predictors of stress, fatigue, body part discomfort, poor self-rated performance and job dissatisfaction [33]. The safety implications of these outcomes are obvious.

Frustration and stress associated with working with ageing facilities, '*putting bandages over the problems'* has already been discussed. However, individual and team coping in the face of these performance impediments also generated pride, comments in the ANSTO Health survey included: '*people in this group work really hard and to get the results we do with the equipment and processes, we are quite remarkable*'. This pride does not outweigh the negative effects of frustration and stress.

Clear comments emerged on the need for staff to have 'cross training' to understand other teams' roles, pressures and responsibilities and how all their work in ANSTO Health intersects, especially 'on the big safety issues'.

The review team repeatedly heard from staff who were interviewed and in the survey about the importance of being kept informed about the short and long-term facilities planning, so '*we know what we are really dealing with and for how long'*. The sense of uncertainty was clearly a source of frustration and stress for some.

Those interviewed also consistently raised concerns about the lack of 'adequate' support from ancillary service areas whilst explicitly recognising these teams had their own resource pressures to manage. However, for example, one manager of a technical support services function indicated their service model is to encourage line areas to build safety into their normal business risk management and take control of risk identification and, where possible, control. This recognises those who do the work know the real issues and are usually best placed to recognise appropriate solutions, then be supported only where required by outside experts. This is also consistent with the planned changes in the safety assurance model detailed in Section 9 which is focussed on ensuring that operational line management are responsible for safety not the central support functions. However, this model relies on ANSTO Health staff understanding this philosophy and having appropriate skills and time to do their own assessments to the required quality.

There are WHS, ARPANSA and TGA expectations around training and competency, especially when performing high-risk tasks or those associated with product quality. There is clear evidence that considerable care is being taken at ANSTO Health to provide comprehensive training including on-line learning modules, with a competency-based assessment for some around high-risk tasks. These actions are supported by on-the-job training and procedures. Staff indicated that, since the recent safety incidents, more training had been delivered.

Revisions of the written procedures around high-risk tasks are underway to improve clarity, insert specific safety warnings and information and learnings from recent events. Those interviewed recognised the need for pre-task and sub-task safety and quality checks when performing hazardous activities, but this was reported to sometimes be more cursory in periods of high time pressure. The provision a safety observer to counter this is discussed elsewhere.

Given the necessarily large numbers of procedures at ANSTO Health, it appears challenging with current staffing levels to ensure these are always up-to-date, let alone modified to suit individual learning styles and capabilities especially around safety critical processes. Given the importance of training, this is important. The need for further training on radiation exposure consequences and risk assessments is dealt with in Section 10.

Several supervisors and managers noted how useful the general leadership and management training they had received was to feeling more competent when dealing with personnel issues. We heard appeals from some respondents for '*more consistent contact from HR, especially when there are performance or mental health problems'*

In Section 7, reference was made to the need for high levels of clarity around role ownership, accountability and responsibility supported by appropriate documentation to meet nuclear baseline standards. It was noteworthy, therefore, that the majority of people (73%) completing the survey reported good levels of 'role clarity' and understanding how their work fitted into the overall organisational goals. While it was beyond the scope of the review to confirm, it is plausible that this reflects that a range of informal and formal effective actions. These might include, for example, branch and team discussions, task training and information provided by management around strategic and operational expectations.

We recommend that training documents should be user-friendly and include explicit hazard warnings and cues in the text to alert operators around safety or quality issues (Medium Priority).

Safety Observer

Safety observers have been introduced to provide additional support during high-risk tasks such as ^{99}Mo transportation. There is currently a proposal to introduce safety observers for all ^{99}Mo related tasks. The review team heard during the review interviews that this suggestion has received mixed responses. While there was appreciation for this assistance from some respondents, if this helps relieve some administrative tasks, there were also complaints that this was not addressing the '*causal factors, our failure to automate our most hazardous tasks and reduce time pressures'*. The limited impact of this improvement on the safety assessment is discussed in Section 10. Other comments included '*it is not fair if they are only watching us but are on a higher pay level*'.

8.2.7.2 Emotional support

Emotional support from team members and others outside the team is a powerful workload and stress moderator. It was clear most staff valued and, in the survey, rated as very good the support they got from their supervisors (72%) and co-worker (79%). Any critical comments about the lack of support and adherence with ANSTO values was limited to a small number of managers.

One method leaders can use to better understand what is going on and to show support is to undertake regular walk arounds (without other executives in tow), taking time to talk with individual workers about production and safety issues. Many people named the managers who had regularly done this and continued to do so after a crisis was resolved. They indicated this deeply appreciated and noted by staff.

> *'some managers listen but don't understand, others just aren't even listening'*
>
> *'why should I keep caring and trying when in a crisis the senior execs don't come in or talk with us about the problems, they just give directions'*

Reward and recognition are a powerful source of satisfaction and can (at least temporarily) moderate perceived excessive workloads, so it is noteworthy staff reported very high ratings (72%) for praise and recognition of their work.

Emotional support from senior executives and managers, supervisors, colleagues and family is helpful, at least in the short term and does help contribute towards a positive organisational culture, but is not by itself an effective long-term risk control. The review team noted the pride and sense of purpose that staff reported and recognition they receive about their work is clearly a strong motivator for them to keep spending discretionary effort, even when the demands were high.

8.2.8 Organisational change and culture

In Section 7, the reported inadequate documentation of a change management process compliant with the nuclear baseline was noted. Recent changes did not appear to be consistent with ANSTO's own document - Health Change Control Procedures.

The lack of organisational stability and a perception amongst some staff, based on the interviews and survey results, that there is ongoing 'reactive organisational change' risks eroding motivation (discretionary effort) and, as one respondent noted, '*creates a perception of chaos in staffs' minds.'* The review team heard concerns from some ANSTO Health staff about lack of clarity around reporting lines, for example, leave approval delegations were not allocated to the daily operations supervisors, with clear implications for effective shift planning.

Staff recognised that it takes time for organisational change to embed, for new managers and staff to understand the operational challenges (if they have not previously worked in these roles) and to build mutual trust and respect.

Satisfaction with the change consultation processes were at Australian benchmark standards. However, 59% of staff responding to the survey were not satisfied with the way organisational change is currently being implemented.

Disturbingly, 50% disagreed with the statement '*we have a no blame culture for safety issues.'* A third of those who completed the survey reported that despite the ANSTO values, the '*root causes for safety issues*' were not being appropriately investigated.

8.2.9 Communication and trust

High performing functional teams with effective communication strategies will 'push' not 'pull' information to other team members to assist the group's performance [34]. This includes providing news that might not be welcome, so it was disappointing when we heard comments like '*now I will just keep my head down and follow orders and not offer suggestions until I am asked*.'

In an organisational climate where trust is low, or at least between some of the parties, where information is frequently rejected or not listened to or where sharing is viewed as risky, people will hold back. This is likely to be part of the issue around inconsistent or slow notification of some incidents.

Information provided in this organisational climate can be interpreted or misinterpreted as malicious, sabotaging or naive. As one respondent commented '*I was accused of playing the safety card whenever I brought up real problems that needed to be solved'.* Ineffective communication leads to loss of meaning or misunderstandings and is an error producing situation with potentially catastrophic consequences [35].

During the interviews, there were some indications of conflict between teams around allocation of limited resources, especially where this was perceived as undermining their own capacity to deliver. However, positively, the survey indicated that within teams themselves there were very low levels of conflict reported about how to do the tasks (16%) and between team members themselves (18%), perhaps reflecting the sentiment shared with the review team that, in ANSTO Health, they felt they were '*all in it together'*.

8.3 Consequences for Safety and Workplace Behaviours

People's innate and learnt neurophysiological and behavioural responses to high workloads and stress are well documented. They are noteworthy here for the performance and safety implications for ANSTO Health's high-risk tasks.

There is an inverted curvilinear relationship between arousal and performance. People generally enjoy and perform better when there is some (enjoyable) task challenge and more poorly when there is either too little (boring or monotonous tasks) or just too much to cope with. The relationship between stress and performance is a more linear relationship and, with increasing stress performance, rapidly degrades. With regard to arousal, few staff reported their work was boring or monotonous, indeed the interest, challenge, passion and commitment to their work was palpable. This is an asset which must not be wasted.

Whenever task loads (temporal, cognitive, biomechanical and/or emotional demands) are too high, to conserve effort, people will tend naturally to restrict or narrow attention and information gathering, are more distractible, have reduced working memory, have slower reaction times and decreased vigilance, especially for what they consider to be non-critical aspects of the task or job.

People also tend to be much more susceptible to decision making biases, including for example:

- Fixating on initial or threat-related information.
- Predominately seeking and using facts to confirm our pre-existing view.
- Basing our judgements only on readily available information.
- Failing to fully adjust for subsequent information.
- More negative interpretations of ambiguous information.
- Believing our performance is typically better than it is.

People will also delay activities they perceive as less critical. The effects on risk-taking are mixed, with the tendency to be more or less risk averse influenced by our personality, training and experience [36]. These all impact on our safety related decisions, including risk assessments, as discussed in Section 10.

It is worthwhile to remember how high demands and stress affect workplace behaviour. With increased workloads and stress, people's coping capacity is eroded and their willingness to spend 'discretionary effort' is severely reduced. This may mean, for example, people who normally are willing to take on extra duties refuse or, if they agree, feel resentful. They may be less willing or able to patiently coach and explain tasks to others. They are more likely to display inappropriate (sometimes uncharacteristic) behaviours such as yelling, derogatory comments or just 'not listening'. In addition, as noted earlier, they are far more prone to poor decision making. This may, in part, explain some of the poor workplace behaviour reported or displayed by staff, including managers, alleged by some ANSTO Health staff interviewed.

Much of this report discusses safety failures and, in this chapter, likely human factors contributors. However, work health and safety academics [37] also recognise that most people constantly strive to adapt and maintain performance and safety despite their prevailing circumstances (like high workloads and equipment malfunctions). There is much that can be learnt from a safety and productivity perspective by looking not only at the recent 'failures' but also deeply exploring with staff how they are usually are making things 'go right'. This includes seeking insights from what is happening on a regular day to day basis and how this affects patterns of safety, performance and satisfaction.

ANSTO Health should learn by exploring when things go right in 'safety successes' despite unexpected and challenging circumstances (Area for Improvement).

8.4 Burnout, Job Satisfaction, Sick Leave and Staff Retention

There is a legal duty to control risks from fatigue, irrespective of any individual's willingness to work extra hours or the need to meet production targets. It is well known that long working hours and shift work disrupts circadian rhythms (hormone-sleep relationships) and there is clear evidence that feeling tired and being fatigued impairs cognitive functioning, dexterity, strength and thus safety [26].

Constantly battling to advocate for safety or quality is stressful and tiring and will contribute to increased risk of burnout, absenteeism and staff turnover. Around 1 in 5 survey respondents were experiencing high levels of job burnout, and a third were experiencing moderate levels. Nearly 30% reported they 'seriously believed in the near future that 'they would take sick leave for a stress-related problem'.

> *'I just wish I could take more leave, but there is no back up person, I always feel exhausted.'*

In an open response question asking survey respondents what factors influence their decision to take leave or to consider resigning, 36% reported 'understaffing, burnout, poor mental health and high workloads'. Of those with low job satisfaction scores, 57% reported 'excessive time pressure, understaffing and feeling burnout' was influencing their decision to take leave compared to 6.3% for those with high job satisfaction.

The risks to ANSTO Health's business and its people of high staff absenteeism and turnover on workload are serious and foreseeable.

Within ANSTO Health, a range of risks associated with current operations impacting on human safety and performance were confirmed during the human factors review. There will be significant reductions in biomechanical risk for those staff moving to the new ANM facility and some reduction for those who will now be undertaking ^{99}Mo QC activities in the refurbished B2 area, when this becomes operational. However, for staff remaining in B23 and B54, unless there are significant changes to the way work and work tasks are designed and managed, unacceptable musculoskeletal risks to people and potentially their performance will remain.

Given the current levels of distress for some ANSTO Health staff, prompt action (including those noted in our recommendations) are required to eliminate or minimise the risk of psychological harm.

Monitoring whether these changes have been effective, using safety climate surveys supplemented by psychosocial risk assessment, is highly advisable. The review team suggest a baseline assessment be undertaken within the next three months and repeated every six months for two years or until the measurements indicate the level of risk has reduced to an acceptable level. Data collected by the review team is confidential so cannot be used as a baseline; however, use of a tool such as the People at Work supplemented by organisational and specific safety and culture items as recommended in Section 7 should be considered.

Like many organisations, ANSTO, based on the interviews, surveys and observations, appears to have struggled to appropriately and comprehensively consider all the relevant organisational, job, task and people risk factors associated with safety critical tasks. This is reflected in the incidents and outcomes considered by this review.

To be truly effective, risk management processes (especially for safety critical issues) must be holistic and human centred. This means they should systematically consider the combined hazards and risks for each safety critical task and all the viable control options.

They should then consider all safety critical tasks for a whole job and, where required, groups of jobs. This should be applied to the risks associated with a complete production life cycle. This is necessarily time consuming and complex and ensuring appropriate resourcing of this activity and others recommended by this review should itself be included in future workload planning.

A number of ANSTO Health staff expressed concerns to the review team about periods of inappropriately high workloads for groups of staff. This presents serious threats to people's safety and performance. Workloads must be adjusted either by increasing the numbers of skilled and experienced people undertaking critical tasks or reducing the job and task demands. While providing additional emotional support is always welcome, this by itself will not make excessively high workloads safe or sustainable.

The review team recognises that organisational change is required for ANSTO Health and the broader organisation to remain innovative and efficient. Whenever planning, implementing and monitoring organisational change, appropriate consideration of workloads must be a priority.

Clearly organisational action is required quickly to improve the design of work and management of work and work systems, facilities, plant and equipment within the higher risk areas of ANSTO Health. It is acknowledged that working within limited resources and with competing priorities is challenging. However, under the Cth WHS Act (section 18), for a control option including, for example, automation or those recommended by this review to be dismissed as unreasonable, it needs to be 'grossly disproportionate to the risk' [38].

We recommend that 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 (Medium Priority).

While it is usual as part of the cost benefit analysis (CBA) of control options to account for WHS costs, they frequently do not always appropriately include long-term benefits such as reductions in errors, improvements in product quality and timeliness, costs of after-market safety modifications, personal protective equipment, supervision and training, absenteeism and attrition and true costs of reputational harm. The assessment of proportionality will be inaccurate if these factors are not appropriately considered [39].

During future risk reduction studies involving CBA or multi criteria decision analysis tools, the full range of higher order controls with elimination as the default should be considered and must meet the minimum requirements for control for the specified safety class. This is discussed further in Section 10. In addition, in order to ensure senior decisions makers engagement in these discussions, risk reduction and procurement decisions which relate to high risk tasks should be formally approved or rejected by the executive.

We recommend that 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 (High Priority).

While this will be normal practice for significant purchases, relatively low-cost orders can also significantly impact work demands in ways not always immediate to those making the decisions. Therefore, it would be highly advisable to ensure those areas responsible for procurement decisions to be supported to fully understand the potential implications of decisions on safety. This might include, for example, by visiting and talking with supervisors in ANSTO Health as part of their induction and ensuring learnings from the recent events are included in their procurement processes and procedures and staff training.

We note that other nuclear operators have included, for example, specific procedures within their management system aligning the safety importance of systems (i.e. the safety class) to specific codes and standards, quality provisions and accreditation needs for suppliers.

We recommend that ANSTO develops suitable controls related to the procurement of systems performing a safety function which reflects their safety classification (Medium Priority).

The human factors review also highlighted many areas where ANSTO Health is doing well, these should be celebrated. Despite the highly technical nature of the work and the age of some of the equipment, staff did not report excessive cognitive task demands. Overall most people were happy with the levels of job control and very pleased with the levels of emotional support from co-workers, line supervisors and some general managers. They clearly welcome the praise and recognition for their work and showed high sometimes extraordinary levels of personal and professional commitment to the ANSTO Health mission. This human capital must not be wasted.

9 Safety Assurance Review

Lead Author – David Jones

9.1 Introduction

This section of the report deals with the safety assurance approaches adopted at ANSTO, as detailed in the arrangements, procedures and guidance and how this is implemented through the line management and the company level due process. The review has considered ANSTO practices against relevant good practice from other nuclear organisations. In addition, the review has recognised that ANSTO has commenced a programme of work to change both the safety assurance and risk management and oversight approaches and functions and these proposed changes have also been reviewed.

9.2 Scope of Review

The current ANSTO safety assurance process has been reviewed on the basis of the documentation contained within the ANSTO management system. The review has concentrated on the current process as the extant model within ANSTO. However, 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. The modified processes have been included within the independent review.

9.3 Regulatory Expectations

International best practice in the management, delivery and assurance of safety cases supporting nuclear facilities are set out in IAEA Safety Guides, in particular, GSR-Part 4 [4]. This document sets out the relevant good practice in terms of the requirements for independent verification of safety submissions such that:

“The operating organisation shall carry out an independent verification of the safety assessment before it is used by the operating organisation or submitted to the regulatory body.”

Nuclear regulators expect to see the following as part of the assurance and due process cycle in order to ensure compliance with this principle:

- A challenge culture whereby receiving advice and challenge are an expected and accepted part of routine business.
- An independent challenge capability that is independent of the operational decision-making line, has oversight of nuclear safety leadership, management and decision making at all levels of the organisation.
- The establishment of an independent internal regulation function or suitable alternative; note that this can be separated from the internal challenge function.
- Proportionate peer review of all new safety cases, modifications, changes and reviews to existing cases which may have an impact on nuclear safety.
- Provision of adequate nuclear safety advice which supports effective, proportionate nuclear safety leadership, management and decision making at all levels of the organisation including suitable representation at the executive level of the organisation.

- Adequate organisational capability for nuclear safety advice and independent challenge.
- Appropriate organisation, staffing and management of the nuclear safety advice and independent challenge capabilities.

The aim is to provide sufficient diversity, redundancy, checks and balances to ensure that suitable and proportionate barriers are provided to protect against erroneous decision making and action within the organisation by ensuring that challenge and advice is built into the ways of working.

For independent challenge to be effective, true independence is required and defined as the freedom from conditions that threaten the ability of an individual to carry out their responsibilities in an unbiased manner. This is often demonstrated by the provision of advice or challenge from a person who has no direct line management responsibility for, or vested interest in, an activity and who has not previously been involved in developing the ideas or decisions, such as the CNO. In addition, boards, the executive and senior management should have access to independent sources of information on nuclear safety performance and the success or otherwise of policies and strategies.

In order to meet these expectations, ANSTO operates its safety assurance process in accordance with AG-1094.

9.4 The ANSTO Safety Assurance Process

The ANSTO safety assurance process consists of a safety committee based assurance process, namely the Reactor Assurance Committee for OPAL and the Safety Assurance Committee (SAC). The safety committees play an important role in monitoring and review and the independent verification/peer review of safety case submissions. The role of the SAC is determined by the hazard category of the plant, modification, experiment or change to operational activities. Facilities are categorised on the basis of harm potential (i.e. worst case radiological consequences) as F1, F2 or F3 and the category determines the safety approval route. Specific activities (i.e. changes or modifications, organisational changes etc.) are categorised as A or B depending on the harm potential based on the risk matrix (AG-2395) from inherent risk on the following basis:

- Category A for activities with an inherent risk of ‘Very High’, ‘High’ or ‘Medium’. It is implied that this is equivalent to unmitigated worst case radiological consequences and initiating event frequency in the absence of control measures but this needs to be made clear.
- Category B for other activities.

The SAC control and approval process is based on safety submissions which reflect the harm potential. It is stated that the residual risks (i.e. post inclusion of preventative, protective and mitigative safety systems) should be ‘Low’ or ‘Very Low’ otherwise SAC will consider the acceptability of the justification to proceed. The safety assurance process should consider all submissions based on inherent risk regardless of residual risk and should provide the challenge to ensure that submissions and their associated safety assessments are technically correct and reflect ANSTO arrangements. In addition, one of the roles of SAC and the “peer review” function is to examine the safety assessments to ensure that the safety measures/systems adopted by the design are fit for purpose, appropriate to the safety function and demonstrated to be able to deliver the safety function.

Within AG-2426, the arrangements for operating the SAC and its sub-committee are set out. The SAC is effectively a multi-disciplinary committee of subject matter experts. Whilst most SAC submissions relate to a range of hazards, SAC has recognised that, in the case where only 1 or 2 hazards were applicable, approval could be deferred to a smaller sub-group of relevant experts. This smaller group comprises the sub-committee. It is noted that Category B submissions do not require SAC approval, with attendant risks and optimisation of controls being achieved through advice from WHS, RPS and SSR as necessary. The reviewer has a concern that, under the present arrangements, there may be submissions that are under categorised and therefore not subject to the appropriate level of scrutiny. It is unclear as to what checks and balances are in place to make sure that accidents that have been assigned lower fault classes have not been under-assigned.

We recommend that the arrangements for the assurance and due process associated with Category B proposals are more clearly set out and implemented, including the terms of reference for the sub-committee to the SAC and that SAC has at least a retrospective (perhaps quarterly) review of all Category B proposals as part of the auditing function (Area for Improvement).

For Category B proposals, the flowchart in AG-5856 states that the justification is recorded and signed off by the Responsible Officer through form AF-2322. This does not appear to include any independent review of the categorisation to confirm that it has been correctly categorised and leaves the process open to under-categorisation in order to expedite implementation.

It is understood that the role of SAC is as the independent assessment and approval function for high hazard modifications/tasks. However, during the development/concept phase of a project, SAC can be approached to give advice on whether a particular approach is likely to be appropriate. SAC does this in the role of independent experts and at a high level advice, rather than detailed advice, which is the domain of the specific subject matter experts.

We recommend that all changes that 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 (Medium Priority).

The SAC process focusses on the hazards and controls to ensure that the inherent risk has been appropriately addressed and that the control measures have been optimised and that the inherent risk is ALARP. This process focus will be formally addressed in the revised safety assurance process. Within Step 1 & 2 of AG-2426, the implication is that SAC are only looking at the residual risk but in the absence of a deterministic safety assessment, how do they judge the adequacy and sufficiency of safety systems? This is more important than the numerical risk values. This is particularly important given the fact that risk assessments are assigned event frequencies based on a qualitative allocation which does not seem to be backed up by suitable analysis such as fault and event tree analysis. Plus the determination of risk reduction measures to ensure that the risk is ALARP is an essential part of the safety submission and needs to set out how you go about determining the ALARP solution e.g. optioneering, risk reduction review studies, application of the hierarchy of risk control measures, substantiation of safety measure performance. It should be the role of the SAC to advise on their sufficiency and suitability.

We recommend that the safety assurance process is 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 (Area for Improvement).

There are other committees which SAC interfaces with as part of the assurance and governance process. Any submissions for which the residual risk is medium or above, or where consequences of individual fault sequences reach a set threshold, will be submitted to the Executive WHS Committee and the Risk Oversight Committee. The WHS Committee will assess whether the net benefit is sufficient to tolerate the risk level and for how long. The Committee, through the executive representation will also have the mandate to cease the activity and to allocate financial and human resources to implement additional controls to reduce the consequences/risks to a broadly acceptable/ALARP levels.

The Risk Oversight Committee is not mentioned within the safety assurance process and its role in providing advice or consent needs to be made clear within the arrangements. Part of the role of the SAC is to peer review the assessments to confirm that the residual risks are correct and have not been over or under estimated. This provides a level of assurance that the residual risks have been assigned correctly and appropriately and that the activities passed forward to the risk oversight process are genuinely the high risk activities. In this way both processes are shown to work together in advising the CEO on safety important matters.

It is important that the assurance and due process arrangements are understood by all staff to be a mandatory requirement (i.e. they are part of the legal arrangements and not guidance) otherwise there is a risk that modification submissions and high risk activities are not notified prior to their implementation. It is a vital part of being a competent organisation in the nuclear industry that the assurance and due process arrangements work correctly and efficiently and that there is no opportunity to by-pass or otherwise introduce lack of clarity. This will need a fast track process where urgent submissions are required to be considered but that is not atypical.

We recommend that the safety assurance (both nuclear/radiological and conventional) and risk management/acceptance processes are 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 (Area for Improvement).

The approvals of submissions in AG-2525 seem inconsistent. Elsewhere in the document, it states that the SAC advises the CEO whereas it also states that the approval of activities is by the relevant General Manager or Institute Head for Category A and the appropriate manager/supervisor for Category B.

Clarity of accountability and responsibility for safety is vital here; it is our understanding that the role of the SAC or its sub-committee is to provide safety assurance and approval, not to provide advice and the advisory function is that of the CNO. Related to this is the regulatory (i.e. IAEA) expectation that, as part of the independent challenge culture, there is independent representation for nuclear safety at board or executive level, ideally by means of a dedicated nuclear safety director who is effective in challenging the board about improving standards of nuclear safety performance. This is addressed further in Section 6.

We recommend that the SAC arrangements 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 (Area for Improvement).

Within AG-1094, it seems that the independent assurance (i.e. peer review/independent nuclear safety assessment role) is managed by the SAC through the appointment of several assessors by members of the SAC. The fact that a register of competent assessors is maintained is good evidence of control and the use of suitably qualified and experienced persons for roles which impact on nuclear safety. However, there is a need to demonstrate independence within the assurance process to ensure that there is sufficient challenge and expertise external to the management line. This is an important part of the assurance process and is difficult to demonstrate by the creation of "Chinese walls" within an individual department. Given the size of ANSTO and its resource teams, it is unlikely that anything more formal can be established but consideration needs to be given as to how independence will be assured, especially where the safety case author and reviewer are in the same line management chain. It is acknowledged that demonstration of independence has not, in practice, been a major problem due to the professionalism of the SAC assessors and committee members.

We recommend that ANSTO examines how to ensure that true independence between authors and reviewers can be maintained for the "goodness" of the independent challenge function (Medium Priority).

Where it is stated that certain submissions do not need specialist assessment, the criteria for this must be made very clear otherwise there is a risk that this can be used to short cut the assurance process to meet programme constraints. If there is a need a fast track process, this should be clearly set out within appropriate constraints and the appropriate assurance support specified. Also the means by which disagreements/conflicts between assessors managed – it is understood that the role of the SAC to decide on such conflicts and recommend a solution.

Within the ToRs, the SAC membership is detailed; where mandatory members cannot attend, the nominated replacements should also be formally appointed as part of the SQEP named list whereas the document suggests that this can be anyone within the department rather than a nominated deputy.

We recommend that the arrangements for deputising for named members of the SAC are more formally recorded including demonstration that the nominated deputies are suitably qualified and experienced (Area for Improvement).

From this review, it has been concluded that the safety assurance process within ANSTO relies upon the SAC for both the independent peer review and the "nuclear safety committee" function. This creates problems in terms of independent challenge which therefore relies on the objectivity of the individual members of SAC to ensure they remain impartial and independent. While this is clearly the case with the present membership, this arrangement relies on the individuals themselves rather than the process and is hence vulnerable in terms of demonstrating totally objective and independent review and challenge. In fact, the CNO as TA for nuclear provides this function and so it may be more efficient and cost effective to change the assurance arrangements to focus on the TA as the route for independent assessment and assurance rather than a committee approach.

Safety committees are a useful part of the assurance process where there is a large site with multiple high hazard facilities. However, as the OPAL reactor already has a dedicated safety committee (which is considered wholly appropriate given the fact that it is an operating reactor with a potential off-site hazard based on fully unmitigated consequences), the other

facilities comprising the ANSTO Health business fall into a lower hazard category group. It is unlikely that any of the facilities within ANSTO Health have the potential for a significant off-site impact based on unmitigated consequence and hence it may be more efficient and effective to streamline (and concentrate) the assurance process. Given the issues which have arisen within ANSTO Health, giving the line management full (and clear) responsibility for safety would be positive for all parties. In this way, the Responsible Officer within the business is responsible for obtaining the necessary technical support (including subject matter experts from RPS, Safety System Reliability, WHS etc.) and for ensuring that there is independent verification and validation of any proposal. The role of the assurance and due process then becomes one of independent review of the proposal (and its supporting documents) and advising the CEO (and executive and line management) of its acceptability.

We recommend that ANSTO takes 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 (High Priority).

The safety assurance process also includes the role of ARPANSA. It is not clear from the available procedures how interactions with the regulator are managed and implemented. Our experience is that a clear and concise arrangements level procedure (not guidance) is essential in controlling regulatory interactions and contact.

We recommend that regulatory interactions are included within the assurance and due process arrangements level documents (Medium Priority).

It is understood from the discussions with the CNO that there is a current project to review and revise the ANSTO safety assurance process based on increasing the level of responsibility and accountability for safety to the line management chain. This means that the SAC may cease to exist in its present form and that the independent challenge and review function will form part of the compliance phase of a project or modification. This will place an increased level of workload on supervisors and managers in the operational and project teams which will need to be recognised. Under the present categorisations, for nuclear/radiological hazards, all inherent risk activities at ‘Medium’ or above (i.e. design basis accidents as defined in Appendix D) or require submission to the regulators (e.g. Regulation 51 submissions) will require independent review by the CNO. This implies that only those faults in this class pass to the CNO but surely the decision to involve the CNO is based on the hazard category of the proposal? As stated earlier, it is important if the categorisation process is to continue to be used that the CNO approves any categorisation assessment on AF-2322 to provide assurance that the categorisation process is working effectively.

Our experience with other nuclear operators/licensees and regulatory bodies is that if the regulator loses confidence in the organisation’s ability to categorise changes/modifications correctly, it tends to resort to a zero tolerance policy for a period of time. Under such a regime, all changes/modifications, regardless of harm potential, may be called in for assessment by the regulator which effectively adds months to any implementation programme even for relatively minor changes. The business implications of this approach would be enormous. Hence, it is vital that the ANSTO senior management has confidence that all changes are being categorised and processed in line with ANSTO procedures (see earlier recommendation regarding role of CNO in approving all change categorisation assessments).

We recommend that the CNO (or SAC) initiates 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 (Low Priority).

ANSTO does not have an appetite for any risk with a residual risk rating of 'High' or 'Very High' or with a mitigated consequence or impact level of 'Major' or above. However, these risks may be accepted under certain conditions with the approval or endorsement of the ANSTO executive. It is noted that it is the responsibility of the Risk Owner to notify the Responsible Executive of the existence of a 'High' risk or 'Major' consequence safety or radiological fault scenario. The Responsible Executive has an obligation to obtain and record inputs from suitably qualified and experienced subject matter experts to confirm the risk rating. Where this risk rating relates to a nuclear/radiological hazard, the CNO (and the nuclear safety assurance process) should also be part of this process. In line with industry best practice, no 'High' risk or 'Major' consequence nuclear/radiological scenarios should be accepted until such time as the CNO (as the TA) or the safety assurance process has completed its review and concluded that, in their opinion, there is nothing reasonably practicable that can be done (or is willing to be done) in order to further reduce the residual risk. An equivalent process should be in place for non-radiological hazards using the Workplace Health, Safety and Environment (WHSE) Committee. At this point, the Responsible Executive makes the decision based on the input of subject matter experts, including the CNO, as to whether they will accept this risk or demand further risk reduction measures. The CEO's endorsement is sought following the risk acceptance decision by the Responsible Executive. This is where the integration of the safety assurance and risk management processes will be very important in ensuring that due process is always followed and that no short cuts can be followed to expedite decisions.

It is important that the safety assurance and risk management processes are coherent in their approach. The safety assurance process should be examining proposals based on inherent risk and making a judgement as to whether the safety functions are satisfactorily delivered by safety systems of the required quality and with the required level of defence-in-depth in order to provide assurance that nuclear safety standards are met. It is only when this process has failed to deliver a suitable solution and there remains a high residual level of risk that the risk management framework process becomes involved.

The proposed modified approach to safety assurance is considered to be a workable solution to the issues raised by this review as it ensures that the independence of the peer review and challenge is provided by the CNO who reports directly to the CEO (and the Board if necessary). This eliminates the earlier problem of maintaining "Chinese walls" in the technical departments and the proposed change would strengthen the ability to deliver true independence. This will require the following:

- The CNO needs some assurance that the categorisation process based on inherent risk is being undertaken correctly so he will need to be involved the approval of all categorisations or some retrospective audit/check function of lower category changes.
- The CNO will need to have access to independent support (e.g. OPAL staff, external contractors, ANSTO specialists) in order to help with the potential workload should a number of submissions require independent review at the same time.
- The change will require consideration as an organisational change with due consideration and review including engagement with ARPANSA.

- The communication of the revised processes within the business is vital to its successful implementation and the engagement and commitment of senior and middle management to implementing it will be invaluable.

9.5 Change/Modification Management

Guidance for the ARPANSA Reg.51 determination is set out in AG-2434. One question that arises is “how does the ARPANSA Reg. 51 determination fit with the change categorisation process?” There seems to be significant overlap so perhaps they could be combined into a single process? For example, any change that requires a Reg. 51 submission could be automatically Category A (as long as the definition of Category A is based on either inherent risk or Reg. 51) and has to go through full independent assurance review and then ARPANSA approval before it can be implemented on the approval of the CEO. It is acknowledged that Category A submissions may not be based on nuclear or radiological hazards and so this group of hazards, although still requiring SAC consideration, do not require approval by ARPANSA.

We recommend that ANSTO investigate further the possibility of including Reg. 51 submissions within the definition of Category A for inherent risk (Area for Improvement).

One question that is not made clear in the ANSTO procedures is whether ARPANSA automatically call in any Category A submissions based on the inherent risk for approval. Normally the safety due process arrangements would specify that certain categories of facility or change have to be submitted to the regulator and cannot proceed until the regulator grants formal approval. It is understood that the ANSTO arrangements require that any modifications with “significant implications for safety” must be submitted to ARPANSA for approval.

It is noted that the definition of change includes management and organisational changes; however, AG-2525 is more appropriate to physical changes where the inherent risk can be readily determined based on failure rates/probabilities and consequences. Organisational changes are more difficult to categorise as it is very difficult (or even impossible) to assign an inherent or residual risk. Typically, management and organisational changes are categorised differently on the basis of the magnitude of the change e.g.:

- Category A for major organisational or management change with a significant potential impact on safety including changes related to the licence or other authorisations, which is equivalent to a Reg. 51 submission.
- Category B for organisational and management change with a limited potential impact on safety and with no impact on the licence or other authorisations.

As with physical changes, the basis for the category must be if the change is inadequately conceived or executed. This prevents perceived organisational improvements from being implemented without adequate due process. An example would be the recent change to replace the on-site emergency response capability to an outsourced organisation. On the face of it, the change appears to be an improvement with a low change category but if one applies the premise of “inadequately conceived or executed”, there are a number of potentially serious outcomes. For example, the tender specification could have been inadequate, the selected company may not have been suitably qualified or resourced to deliver the capability or the handover arrangements could have been poorly planned. All of these have the potential to make the change potentially serious in terms of impact based on the inherent risk. The measures listed as possible initiating events then drive the

preventative and mitigative measures that make the residual risk low but the change must be assessed on the basis of its inherent risk i.e. Category A.

Also, what is the process for consideration and approval of management or organisational changes, is it the same as physical changes (i.e. SAC, Risk Oversight Committee etc.) or not?

We recommend that ANSTO examines 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 (Area for Improvement).

9.6 Regulatory (ARPANSA) Interfaces

The corporate guide to meeting ARPANSA's requirements (including formal reporting) are set out in AG-5455, which includes the key roles and responsibilities within ANSTO for interacting with ARPANSA, including the Regulatory Affairs Manager.

Interactions and interfaces with the regulator (in the case of nuclear safety, ARPANSA) should be taking place at several different levels from:

- Formal interactions at CEO/Executive level to discuss policy and arrangements level issues including organisational issues and compliance with arrangements, to liaise on relevant matters including future developments, to resolve any outstanding issues, discussions on enforcement notices and close-out progress, to undertake regulatory liaison and reviews of site safety performance including annual/periodic performance reviews.
- Formal interactions at licence holder (facility) level, for which ANSTO has appointed licensing officers for each nuclear facility holding a licence to operate, which deal with facility specific issues e.g. safety cases, incident reports, compliance inspections etc.
- Informal interactions between the site/facility inspectors and licensee staff in which the regulator can offer informal advice and assistance to licensees on specific topic areas.

Interactions with ARPANSA are managed through the Regulatory Affairs Manager who reports to the CEO as part of his organisational governance. The ANSTO guidance requires that all formal communications with ARPANSA are directed through the Regulatory Affairs Manager as the CEO's representative, but these procedures are not currently in the "mandatory" part of the ANSTO management system. In addition, there is no formal framework for regulatory interface meetings at the different levels; it is our view that a more formal, regular interface at the various levels will aid communication and continuous improvement for both ARPANSA and ANSTO.

We recommend that a more formal structure and programme of interface meetings and other interactions is put in place between ARPANSA and ANSTO as part of both organisations' arrangements (High Priority).

This will enable, in the interim, a more open structure whereby ARPANSA and ANSTO can have dialogue 'at the coal face' and freely discuss any concerns prior to potential issues being raised.

10 Safety Assessment Process Review

Lead Author – David Jones with support from Adam Kilborn (3TSC).

10.1 Introduction

This chapter deals with the safety and risk assessment approaches adopted at ANSTO, as detailed in the arrangements, procedures and guidance and how this is implemented at a facility level through safety cases, risk assessments and the close-out of the safety assessment process. The review has considered ANSTO practices against relevant good practice from other nuclear organisations, taking due account, however, of the need to adopt proportionality and a graded approach which recognises the relatively reduced harm potential of ANSTO's operations in comparison with other international nuclear operators.

10.2 Scope of Review

The current ANSTO safety assessment process has been reviewed on the basis of the following documents:

Part A – Arrangements and Guidance

These are the ANSTO documents that set out the safety assessment methodologies and the safety case requirements for all facilities and activities with a potential nuclear/radiological hazard.

Part B – Application in B23 SAR and Supporting Documents

In addition to the arrangements level documents, a high level review of their application has been performed in the B23 Safety Analysis Report which was reissued in 2016/17 and a number of risk assessment reports produced in support of B23 and B54 operations.

A high level review of the risk assessments reported in these documents is contained in Appendix C. In addition, the desk based review has also been underpinned by a site visit and a series of interviews with safety assessment practitioners and with staff responsible for the interfaces with the Safety Systems and Reliability (SSR) group and with the implementation of recommendations and improvements.

10.3 Review of Arrangements and Guidance

10.3.1 Safety cases and reports

Safety cases are produced for nuclear and radiological facilities in accordance with AG-2428 using the format and content set out in AG-2429. It is noted that there is a requirement to periodically review and update the safety cases but no timescale is specified. It is noted that the facility licence requires a periodic review every 10 years; hence it would be sensible to either reflect the regulatory expectations for review in the guidance or, if appropriate, to introduce a more frequent periodic review e.g. every 5 years or following implementation of major Cat A modifications.

We recommend that the arrangements for the review and update of safety assessments and safety cases are 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 (Area for Improvement).

The format and content of the SARs is comprehensive and appropriate, one question is that, given the age of some of the facilities, how are ageing and obsolescence issues managed through the safety assessment and safety case?

We recommend that the safety case formats 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 (Area for Improvement).

While the SAR format covers new and existing facilities, it is unclear as to whether this is the format that should be applied for modifications. This would clearly not be appropriate as the SAR covers issues which are reported on a facility basis and are not relevant to a modification but formats for modifications submissions are needed. This will also instil a level of formality in change control within the facilities with the requirement to formally submit safety documentation.

We recommend that the safety case format documents includes a format for change/modification submissions (Area for Improvement).

10.3.2 Hazard identification

With respect to the hazard identification process in AG-2390, the principal requirement is that the HAZID process should be systematic, comprehensive, auditable but proportionate to the hazard. Quite rightly, the guidance does not push the assessor automatically towards HAZOP as this may not always be the most appropriate approach.

Hazard identification studies using the HAZOP methodology have been performed and the review has examined the reports associated with a number of these studies. As an example, the HAZOP study report for the Mo-99 external liquid waste interim storage tanks system (ANSTO/S/TN/2007-22) has a total of 14 nodes with 14 fluid based guidewords and a similar number of overview guidewords for the overall facility. The HAZOP has been completed in 1 day and the records look very light including:

- The hazard consequences are mostly missing.
- There are virtually no recorded safeguards which would be consistent with a concept design not a fully detailed design.
- It seems that the study has only recorded information where there is a recommendation.
- Where is the evidence that the recommendations have been adopted and, where they have not, what has been done?
- There should be a finalised HAZOP record showing the finalised design and its safety measures to allow a realistic fault analysis to be performed.
- In the experience of the reviewer, a HAZOP of this type would normally take 2 to 3 days.

These conclusions also apply to the increased ^{99}Mo capacity modification (ANSTO/T/TN/2015-21), where a total of 18 process guidewords and a similar number of overview guidewords have been completed in 2 hours. While it may be correct that no new hazards were identified, it is unlikely that the complete set of guidewords could be adequately discussed in this time. Similarly, the carbonate formation HAZOP for the B54 external waste tanks (ANSTO/T/TN/2008-24) was completed in a single day; this may be reasonable but the report suggests that several potential scenarios have been dismissed as incredible as they require either multiple engineering system failures or a gross human error. Based on dependencies, this may not be appropriate.

By contrast, the HAZOP study for the Mo-99 dispensing and packing process in B23 hot cells (ANSTO/T/TN/2011-23) was programmed over 5 days and the records look relatively extensive. Similarly, discussions with staff involved in the ANM design, in which there was a strongly integrated design and safety process, confirm that the HAZID studies were conducted in stages, as relevant to the design element's maturity and that these studies were programmed into the overall design programme. As a result, the output from the HAZOP studies was comprehensive and extensive. In addition, the SSR members were embedded within the project team which aided the development of the design and safety analysis.

The review of the HAZOP studies suggests that, in several cases, insufficient time is being allocated to the studies to allow a systematic and comprehensive process and that the output records are insufficiently detailed to give confidence that all credible failures and resulting faults have been identified. This is based on the experience of the safety assessment expert within the review team. This may be due to pressures on the availability of operations staff to participate in HAZOP studies. This is an important issue as the quality of the safety assessment is dependent on the quality, sufficiency and extent of the hazard identification studies and they, in turn, are totally dependent on the relevance of the people involved in the study.

We recommend that any future projects, in particular changes or modifications within existing facilities, have sufficient time and resources allocated to the hazard identification studies and that this step acts as a gate to prevent any further progress on the change if this requirement is not met (High Priority).

In addition, there is a concern that changes which may be assessed in terms of the impact on GMP are not then being fully subjected to a nuclear modification process which would require a formal HAZID and safety assessment. For example, there was no evidence presented that the decision to use transfer trolleys in B23 had been formally assessed as a modification in nuclear terms with the appropriate considerations of hazards etc. If this change had been subject to a HAZOP, it is almost certain that its suitability would have been questioned and the incident could have been prevented. Similarly, according to a limited number of ANSTO Health interviewees, changes are believed to have been implemented on the basis of TGA requirements without considering sufficiently the nuclear change control requirements.

We recommend that the change management process within the nuclear facilities takes 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 (Medium Priority).

10.3.3 Safety analysis

The risk assessment process adopted in the arrangements and implemented in the B23 SAR is a semi-quantified probabilistic assessment based on the risk analysis matrix in AG-2395. The key stages of the process are detailed and comments are provided below.

The risk assessment consists of 2 distinct stages, the assignment of inherent risk and the residual risk (post implementation of controls). It is unclear in both AG-2390 and AG-2395 that the matrix is used for both applications and would be aided by a flowchart showing the risk assessment process from inherent risk to residual risk allocations. For example, it is not clearly stated as to the basis for the inherent risk. Typically this should be based on:

- The initiating event frequency (IEF) of the event (i.e. the frequency of the event which initiates the fault in the absence of any preventative safety systems) using best estimate assumptions (except for natural external events which should be on the basis of conservative assumptions).
- Unmitigated radiological consequences based on conservative “worst-case” assumptions (suitably balanced to avoid over-excessive conservatisms in the calculations) with no account taken of protective or mitigating safety systems unless they are demonstrably unaffected by the fault e.g. bulk massive shielding.

The fault frequency (i.e. the frequency based on some combination of initiating event frequency and safety system failure probabilities with which the accident leading to the undesired radiological consequence is realized) then forms the basis of the residual risk. This is combined with the appropriate radiological consequences (unmitigated, partially mitigated or fully mitigated) depending on the safety system failure modes. Within AG-2395 the calculation of IEF for inherent risk can readily be based on the table but for the residual risk, somehow account needs to be taken of the probability of failure on demand i.e. pfds (reliability) of safety systems, the operators etc. which drives the assessor towards a quantitative calculation rather than assignment to a class.

We recommend that the definitions, inputs and requirements associated with calculating inherent risk and residual risk are made clear (Area for Improvement).

A key comment on these arrangements is that the current basis is probabilistic (i.e. residual risk based) and there is no deterministic, design basis analysis. As such, this means that numerical probabilistic analysis is being used to justify the acceptability of operations, the safety systems therein and the availability of these safety systems to act in the prescribed manner. There is no structured assessment as to their suitability, sufficiency and robustness to challenges to performance of the safety function although there is a hierarchy of safety controls which is applied. In older facilities such as B23, there is usually an increased level of dependency on procedural safety measures but these should be subjected to the same level of rigour in terms of demonstration and substantiation than engineered systems.

The deterministic safety assessment forms the most important element of the safety analysis in modern standards safety approaches worldwide, including as advised by regulators and the IAEA. Within the nuclear industry, the premise is that conservative design, good operational practice and adequate maintenance and testing should minimise the likelihood of faults. The deterministic assessment assumes that faults may still occur and so a facility must be capable of tolerating them without unacceptable consequences by virtue of the facility’s inherent characteristics or safety systems. This is achieved by the deterministic analysis of the most serious faults i.e. those above pre-determined “harm potential” criteria such as the inherent fault classes in the AG-2395 matrix or a suitable radiological consequence threshold. The inference is that, should the relatively serious faults be adequately protected against by the inherent safety of the design and/or the safety systems afforded, then faults of lesser significance will also be adequately protected against. This is normally then demonstrated, in terms of the acceptability of the risk across the full range of faults, through the residual risk and the probabilistic safety assessment.

The deterministic assessment will specify the requirements for the number, quality and mutual independence of safety systems to be implemented in order to ensure that there are always sufficient and operable engineered safety systems in place to provide the necessary defence in depth. In addition, it permits the role of procedural safety systems to be assigned, their relative importance designated and then substantiated as suitable and sufficient

(usually through robust human factors assessment and task analysis). The deterministic assessment demonstrates that the safety systems within the engineering design provide sufficient defence in depth that the pre-defined design basis targets for frequency and mitigated (i.e. with correct functioning of the claimed safety systems) radiological consequence are met. As such, it is reasonable to assume that, if the deterministic targets are met, the probabilistic targets will also be met.

We recommend that ANSTO modifies 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 (High Priority).

A discussion on the deterministic approach and how it could be applied for ANSTO facilities is attached as Appendix D.

One of the difficulties that many safety case owners and facility operators have found in many countries is the traceability issue where each fault assessed can be traced back through any fault grouping or bounding, sentencing for assessment and the HAZID process and in the other direction to safety functions, claimed safety systems, specific performance requirements of safety systems and documentation that provides the demonstration, justification or substantiation. This is often referred to as the “golden thread” based on claims, arguments and demonstrable evidence. This is often documented in a fault schedule, engineering schedule, fault and protection schedule.

We recommend that ANSTO 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 (Area for Improvement).

Within the QRA guidance (AG-2398), the PSA is stated as being used to analyse the effects of propagation of the initiating event; this is correct but it does more than that. The PSA quantifies the risk from individual facilities (and from the site as a whole) based on best estimate assumptions and to demonstrate that these risks are balanced (i.e. no particular fault or fault sequences dominate the risk profile and/or a disproportionate level of reliance is placed on a small number of safety systems). The calculated risks are then compared with pre-defined criteria and targets in order to make a judgement as to whether the residual risk from the facility can be accepted and has been reduced to a level which is ALARA/ALARP. As such, the PSA provides an estimation of the risk remaining even where the deterministic criteria are fully met. The PSA also considers the performance of safety systems in delivering their safety function on a probabilistic basis in order to identify even very unlikely plant failure modes resulting from multiple safety system failures which might nevertheless contribute significantly to risk due to their high potential consequences. In addition, the PSA examines potential interdependencies and the resulting vulnerabilities to dependent failure of safety systems and permits the required reliabilities for both engineering systems and operators in delivering the safety functions to be assessed.

We recommend that the role of PSA is clarified especially if the deterministic approach proposed earlier is adopted (High Priority).

It is noted that the B23 Safety Analysis Report was reviewed and re-issued in 2016/17; however, many of the supporting risk assessments still date from 2010/11 and have not been further reviewed and updated. Indeed, the fault sequence which occurred in the August 2017 incident had not been modelled and assessed in the risk assessments and had therefore not been subject to independent review and assurance. It is a vital element of the safety case process that the safety assessment addresses all hazards and faults in the

facility with the presentation of a systematic, comprehensive and traceable series of assessments.

10.3.4 Risk control measures

The hierarchy of risk control measures is set out in AG-2407 and follows the “Eliminate, Substitute, Isolate, Engineering Controls, Procedural Controls, PPE” structure which is a well-recognised approach. The deterministic approach will also push the assessors and designers towards the additional sub-hierarchy of preventative measures then detection/protection and finally mitigating measures as the priority. This is often represented in a “Bow Tie Diagram” (Figure 12) as below:

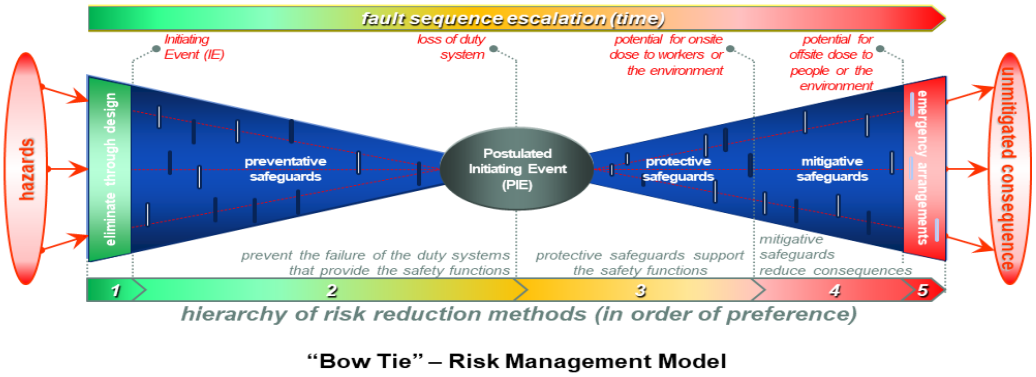


Figure 12: Bow Tie Risk Management Model and the Hierarchy of Safety Measures

We recommend that the hierarchy of risk control also include the “prevent, protect, mitigate” priorities as well as the preference for passive over active and engineering over procedural (High Priority).

Within older facilities such as B23, this is often difficult to achieve but it drives the operators and engineers towards having to make special justifications for any higher risk hazards where procedural controls are the principal means of assuring safety.

It is noted that ALARP is referred to under “implementation of risk controls” – the guidance (or arrangements) need to make clear if it is ALARA for normal operations exposures and ALARP for accidents and given that they are both legal terms, are they both enshrined in the law? It should be noted that this review has assumed the international nuclear industry assumption that ALARA and ALARP (together with so far as is reasonably achievable or practicable) are equivalent and that neither places any additional constraints or requirements relative to the other.

We recommend that the relative roles of ALARA and ALARP are made clear in the procedures and guidance (Area for Improvement).

The SSC categorisation process set out in AG-2494 looks good. ANSTO should consider the criteria for radiological consequences appropriate to the SSC class; for example, the mini cyclotron worked example states that a 30 second evacuation period can be assumed. This is more appropriate to a PSA type approach, whereas SSC classification should be based

on conservative deterministic assumptions including exposure times even for revealed exposures. For example, the functioning of radiation monitors should not be automatically assumed as they also need to be classified on the basis of their safety importance. That would suggest the interlock is Class 2 as the primary means of delivering the safety function and the radiation detectors are Class 3 as they support the higher class interlock.

We recommend that the SSC categorisation is driven by deterministic safety demands rather than probabilistic (High Priority).

In terms of implementation of safety measures, there is no clear evidence that the claimed safety measures are recorded on a formal maintenance, inspection and test schedule linked to the safety case and, when unavailable due to maintenance, what are the substitution arrangements? In order to ensure that maintenance related activities are properly planned, there should be a maintenance strategy supporting the SAR which sets out the maintenance, inspection and test arrangements in terms of time-based periodic and preventative maintenance activities in order to optimise safety measure performance.

We recommend that the maintenance, inspection and test requirements for each facility be formally documented from the safety analysis claims and supported by a suitable strategy (Medium Priority).

For operating limits and conditions (OLCs), current industry guidance is focussed on the importance of an “onion model” approach to safety limits such that there is sufficient safety margin that provides a level of defence in depth similar to the model in Figure 13 below:

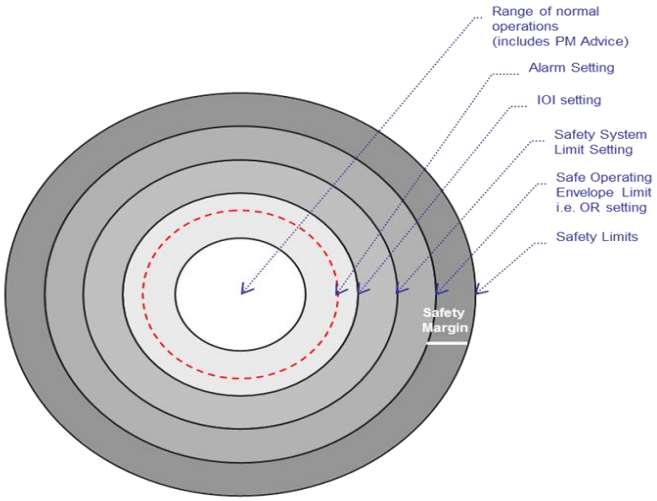


Figure 13: Onion Model for Operating Limits and Conditions and Procedural Safety Systems

The highest level of procedural safety measures are often referred to as “Operating Rules” and they are the conditions or limits in the interests of safety as identified by the safety assessment. This means that operations must be compliant with these rules at all times and a breach of a rule means that the facility is potentially outside the bounds of its safety case and hence is a reportable incident. Adherence to Operating Rules is assured through

operating procedures which are prepared, reviewed and approved through a quality assurance system appropriate to their importance and harm potential, often based on the deterministic design basis thresholds.

We recommend that ANSTO examines 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 (Medium Priority).

10.3.5 Risk reduction

The application of a robust risk reduction process, from concept through to design and into the operational phase of a facility up to and including decommissioning, is a fundamental requirement for achieving and demonstrating nuclear safety. Risk reduction requires a critical review of proposed or existing provisions to determine whether more can practicably be done to reduce risks. Demonstration is required that risks are not just low but as low as reasonably practicable (ALARP). The demonstration of ALARP must also consider compliance with modern standards and conformance with relevant good practice. This style of thinking has been given an authoritative stamp by the health and safety regulator in the UK, the Health and Safety Executive (HSE), which has produced an influential document [40]. These principles have been enshrined within the nuclear safety regulations within the UK.

In order to demonstrate that risks are reduced to a level that is ALARP, it must be shown that nothing further could practicably be done to reduce the risks. That is, it must be clearly shown that the 'costs' of any further safety improvement would be grossly disproportionate to the safety benefits achieved by implementing it. Therefore, any safety improvements that are practicable to implement must be included in the list of credible options for assessment. In the context of ALARP, 'cost' refers to all negative impacts of implementing an improvement and is not simply a measure of the financial element. The ALARP assessment must be a holistic demonstration considering all phases, from construction through to closure, and all risks to people and the environment, both radiological and conventional.

Where risks or radiological consequences are high then the demonstration of ALARP must be more rigorous than if they are low. This increased rigour includes the need for greater detail in the assessment to ensure that any assumptions or uncertainties are adequately accounted for in the conclusions and the assessment is appropriately conservative.

An ALARP assessment must consider all the various options that could improve safety and then implementation of the option or combination of options that achieves the lowest level of residual risk, provided this is reasonably practicable. It is neither adequate to start with the cheapest option first, nor to use options that involve excessive cost to argue that there are no reasonably practicable improvements. A suitable level of optioneering is a vital element of the risk reduction process. For example, a robust risk reduction process with suitable optioneering should have ruled out the acceptability of the use of the B23 QC laboratory for ^{99}Mo sample work on ALARP grounds, both in terms of the normal operational hazard of optimisation through time, distance and shielding, the manual handling risks and the radiological risk. Activities with a high level of risk such as this should not be passed up to the Executive for risk acceptance until every credible option to eliminate or reduce the risk has been explored and justified as not being reasonably practicable. In addition, option selection should be based on a documented auditable decision making process including

tools such as cost benefit analysis, multi-criteria decision analysis for larger, more complex projects.

We recommend that the ANSTO risk reduction process is made more robust and that the requirement for formal option studies and decision processes are included within the process as a specific requirement (High Priority).

The tolerability of risks is built into the model in Figure 14 below.

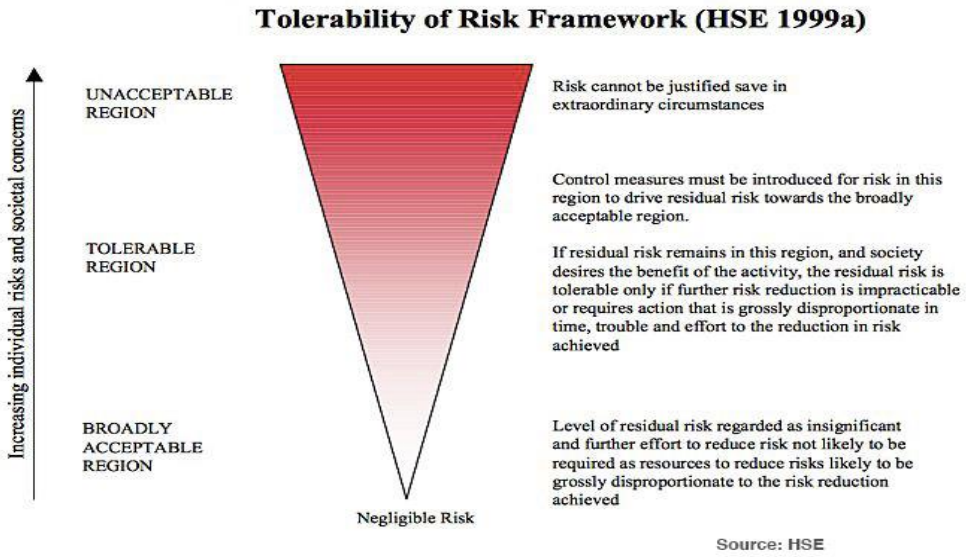


Figure 14: Tolerability of Risk

At the highest level, if a risk is deemed unacceptable (or intolerable), the activity is ruled out, unless a way can be found to reduce it to the point that it falls into one of the lower levels.

Within the “tolerable” region, risks must be assessed and controlled, so far as reasonably practicable, which is to say, efforts must be made to reduce them as long as the cost of those efforts is not grossly disproportionate to the benefits.

It should be noted that UK law does not recognise an “acceptable” region; at the bottom of the scale is the “broadly acceptable” region. According to the HSE, “risks falling into this region are generally regarded as insignificant and adequately controlled…. The levels of risk characterising this region are comparable to those that people regard as insignificant or trivial in their daily lives”. Further action to reduce (such) risks may not be necessary “unless reasonably practicable measures are available”.

Within the nuclear industry, which has a very well established risk assessment approach, the tolerable and broadly acceptable levels of risk can be numerically derived. For example, in the UK these are set at:

- Tolerable level (Basic Safety Limit): 1E-04 per year (worker and member of public).
- Broadly Acceptable Level (Basic Safety Objective): 1E-06 per year (worker and member of public).

This creates a slight ambiguity in that it is uncertain as to the point at which further risk reduction is not necessary. The ANSTO risk reduction effectively sets that at a residual risk level of LOW or VERY LOW; however, given the uncertainties and interpretation of numerical values associated with quantified risk assessment, there is a risk that faults that should be further examined are dismissed from further risk reduction.

We recommend that ANSTO removes the criterion that LOW/VERY LOW risk is acceptable and transitions to a broadly acceptable criterion requiring further risk reduction unless it is grossly disproportionate in terms of reduced risk and cost (Area for Improvement).

Another example of how the philosophy of continuous improvement has undermined the idea of ALARP is the use of the trolley in B23. The trolley was introduced as a way of reducing the risk of manual transport of the pots and the associated dropped load hazard. There was no suitable optioneering or consideration of whether the "improvement" actually reduced risk or merely introduced a new means of initiating the hazard. The concept was based on the assumption that it improved safety but unless the change is passed through a formal modification assessment with optioneering, design and safety assessment, it is impossible to be certain that the chosen solution is the right one. In addition, there was no attempt to demonstrate that the chosen solution was fit for purpose or could be substantiated as meeting the safety function. Hence, in reality, all that happened was that the initiating event changed from a human error to the failure of equipment that was not specifically designed for the task. It could be argued that the change actually increased the risk as the operators were trained, competent and well aware of the consequences of dropping the pot, whereas the equipment had no safety features to speak of.

Likewise, changes had been made in the B23 QC laboratory to install a physical barrier to reduce the "shine path" of the sample being tested by the QC analyst. This was aiming to optimise the dose received as an incremental improvement, but it took no account of the ergonomic issues, which impacted both on manual handling hazards and the musculoskeletal impacts, and the likelihood that a QC analyst could make a mistake and drop the vial. In fact, the "improvement" almost certainly increased the likelihood of human error such that the frequency (and hence the risk) of a dropped vial breaking and spilling its contents had actually increased. It is clear that the principles of a user centred design and the ALARP risk reduction approach were not followed, otherwise this option would have been highly unlikely to proceed.

It is noted from Section 8 that a proposal has been made to include a safety observer for ^{99}Mo QC operations and other high risk operations. While this may be a sensible idea in terms of providing assurance and support to operators, its impact in terms of risk reduction should not be over-estimated. The comments raised in Appendix C regarding over optimistic human error probabilities for faults means that probabilities probably need to be significantly increased. In addition, the impact of a safety observer is very limited in terms of reduction in the event probability and frequency unless it can be demonstrated that the observer is completely independent, otherwise there is a level of human dependency between the operators and the observer. For example, relevant good practice suggests two different 'human performance limiting values (HPLVs)' for human errors, one for a single operator and a lower value for teams to allow for interactions and dependencies:

- Human performance limit: single operator, HPLV =1E-04.
- Human performance limit: team of operators performing a well-designed task, very good performance shaping factors etc., HPLV =1E-05.

We recommend that the risk assessments involving operator errors are re-examined to take into account human performance limiting values and dependencies (Area for Improvement).

On the positive side, the risk reduction reviews undertaken on B23 during summer 2018 looks like a good example of applying a robust approach but it did not examine organisational and human factors issues which would need to be included within the process.

10.3.6 Management of safety case forward actions (recommendations)

The B23 SAR and the associated risk assessments have identified a number of recommendations for changes and risk reduction measures. It is noted that finalised residual risk is based on these recommendations being implemented. There is no evidence that the recommendations have been adopted and closed-out in full, otherwise the residual risk values may be open to question. For example, some of the risk review notes provided state that certain recommendations have not been implemented – this means that the SAR does not accurately reflect the current state of the facility.

Many countries adopt a more formal process for managing actions and recommendations arising from the safety case process. These “forward actions” are usually reviewed and categorised in terms of importance with the designers/operators to agree a form of wording which is more appropriate (e.g. specific, measurable, achievable, relevant and time-bound - SMART) while not precluding any options for resolution that are then transferred to the designer/operator to own. In other words, these forward actions are owned by the designer or operator and their close-out is part of the safety case close-out. As a result, a schedule of these forward actions is passed via the safety assurance process for monitoring and review and to the nuclear regulator for their consideration. Hence the safety case is not considered to be complete until the forward actions are closed out, implemented or, if rejected, a sound justification is presented and accepted by the safety assurance process. Often the regulator will require progress reports on forward action implementation as part of the regular review with the nuclear operator.

We recommend that the forward actions arising from the safety assessment and safety case process are formalised within the risk reduction process and that a formal process for their implementation and close-out is included within the ANSTO procedures (High Priority).

10.4 Safety Case Manuals

Many nuclear operators have produced safety case manuals which address the processes, procedures and methodologies for all aspects of the nuclear safety case and safety assessment process. The manual is a useful tool both to demonstrate to the regulator that there is a robust process for safety cases and the associated assessments and for ensuring consistency of approach, especially where external contractors are being used in the process. Many aspects of the safety case manual are already contained within the current ANSTO guidance but it is accepted that it is incomplete and is not maintained up to date.

We recommend that ANSTO considers the production of a safety case manual/safety assessment handbook (Low Priority).

10.5 Training

During the course of the site based interviews, the review team observed that, although ANSTO staff were provided with basic radiation safety, very few understood the health effects of exposures and hence the importance of not risking additional exposures by intervening to remediate incidents before health physics staff has assessed the situation.

We recommend that ANSTO include basic information about the health effects of radiation exposures within their radiation safety training modules (Area for Improvement).

11 Effectiveness of Control Measures Review

Lead Author – Brent Rogers

11.1 Introduction

This section relates to control measure optimisation, with a concentration on the ANSTO radiation protection procedures, practices within the ANSTO Health business and the provision of radiation protection services.

11.2 Scope of Review

The documents reviewed for this section included the radiation survey procedures, instrument calibration procedures for dose rate measurement, radiation and contamination surveys of the Building 23 and Building 54 areas used for production of ^{99}Mo (hereafter referred to in this section as 'moly'), the flask clearance survey document, including completed ones, the process map outlining the 'moly' process, the report of the skin contamination incident which occurred in August 2017, the dose reconstruction for that incident, along with the reports of the other incidents germane to this review.

A tour of the applicable areas on the ANSTO campus included Buildings B2, B23 and B54.

In addition, interviews were held with a range of staff providing radiation protection services (RPS) across the site, but in particular, to ANSTO Health and B23. The radiation controls associated with RPS responsibilities to the whole of ANSTO, the 'moly' process, along with the particulars of the skin contamination and trolley spill events were discussed in these interviews.

11.3 Review Findings

During the interviews, the interviewees recognised that there are gaps in their radiation protection systems. Gap analysis has been difficult, as the workload is such that meeting the organisational demands requires all of their time and thinking. The situation has caused the radiation safety staff to feel vulnerable in that events beyond their control could occur, including ones with deleterious effects, such as the accident of August 2017.

A significant finding from the interviews, which has led to a feeling of vulnerability within the RPS function, is the point that nearly all of the radiation protection staff have had the totality of their health physics training at ANSTO, and it is the only place they have ever worked. This situation has led to what might be considered 'local procedure myopia' or 'The ANSTO Way', where the staff consider that the entirety of the science is contained within the ANSTO procedures. It is acknowledged that the CNO, the RPS Manager and Lead Radiation Protection Adviser (RPA) all have overseas (UK) nuclear experience which amounts to over 90 person-years. However, the dearth of health physicists with training and experience from elsewhere has led to an inability to take advantage of and improve ANSTO's methodologies through cross pollination and incorporation of relevant good practice that were gained elsewhere. This latter point is a key part of the optimisation process.

It is acknowledged that this is a balance between the development of internal staff and the availability of external staff to enter the ANSTO organisation. The RPS group have adopted an external accreditation course for health physics surveyors, which is actually used in the UK for accreditation at the RPA level. Staff members have also been sent overseas for

training and visits to overseas nuclear facilities in order to counter-balance this lack of international best practice experience.

11.3.1 Beta dose rates [41]

One gap found in this review goes directly to ANSTO meeting its duty of care to employees who work in the 'moly' process. As ^{99}Mo has a reasonably high beta energy (Q-value 1.36 MeV), the dose rate due to this beta should be measured and recorded on the radiation survey maps that are drawn up for the areas and spaces being surveyed. A review of the ANSTO radiation survey procedures, instrument calibration procedures along with the skin contamination report with its corresponding dose reconstruction alarmingly do not include any information about the beta dose rate. One would not expect to be able to determine the level of risk to the workers in these areas without knowing the level of hazard therein and, likewise, a meaningful dose reconstruction from beta radiation could not be performed without knowing the beta dose rates.

Further, during the interviews with the radiation protection staff, there was some acknowledgement of the existence of the concept of a 'beta factor'. However, the review team members were not comfortable that the staff knew what it was or how it is used to obtain beta dose rates. This is not surprising, since the beta factor is not determined in the instrument calibration process and it is not evident that determination of beta dose rates is covered in the radiation protection training that all RPS staff receive.

During the building tours, the review team had the opportunity to see the radiation detection instruments that are staged in the area for use. None of the instruments viewed were ion chambers with windows, which is the necessary type of instrument to measure beta radiation. In addition, had the ion chamber instrument been available and properly used with respect to the accident of August 2017, the health physics group would not have been restricted to the 2000 counts per second limitation of the contamination instrument used in the controlled areas.

In conclusion, ANSTO has the ability to detect beta radiation and measure beta contamination ($Bq \cdot cm^{-2}$) using a contamination monitor. However, the best a contamination monitor can provide with respect to radiation levels ($Gy \cdot hr^{-1}$) is a qualitative estimate. The method for measuring beta radiation in mixed beta-gamma fields using an ion chamber instrument is provided in [41]. Further, as evidenced by the incident of August 2017, beta radiation is a hazard that employees are exposed to. As a result, "duty of care" would stipulate that such a hazard would be measured and not '...used for indicative purposes only...'

We recommend that ANSTO implement a training scheme to include proper measurement of beta radiation for all RPS personnel (Medium Priority).

11.3.2 Eye protection

Even more than skin, the primary part of the body that is most sensitive to beta radiation is the lens of the eye. At present, all personnel entering into the moly process areas are provided with and are required to wear Perspex glasses as splash protection. The review team feel this is probably sufficient for shielding the lens from the beta sources that may be encountered. However, the review team suggest that ANSTO RPS devise an experiment to ensure that the Perspex glasses do indeed provide such levels of protection.

We recommend that ANSTO RPS set up an experiment to ensure the Perspex glasses used as splash protection for the eyes also provides sufficient protection from beta radiation (Medium Priority).

11.3.3 Job coverage

Another finding of the review team, which is mentioned elsewhere in the report but will also be covered here for completeness, is that RPS should be providing job coverage during phases in the work day when radiological work is occurring. Whilst it is recognised that this may not be plausible for every item of work, there certainly should be coverage available when all high risk work activities are taking place. As discovered in the August 2017 accident, there was no health physics coverage at the time of the accident and a surveyor (not the on-call emergency surveyor) who happened to start his day at 0730H arrived 30 minutes post-accident. It is unlikely that the QC personnel who attended the accident prior to health physics arrival would have the detailed training necessary to quickly and efficiently apply the decontamination techniques required. This accident is evidence that ANSTO is not meeting its duty of care with respect to the workers by not having health physics support when such high risk work is occurring.

We recommend that ANSTO RPS roster staff to ensure health physics coverage when high risk activities are taking place (High Priority).

It is understood that plans are underway within RPS to provide health physics coverage on a 0700H to 1900H basis.

Similarly, the review team has discovered that some items are cleared from radiologically controlled areas by non-radiation protection staff during quiet hours. This practice has a low risk if the items cleared are of similar low risk. From the interviews, the review team learned that a pilot project was started in which operational personnel were allowed to clear low risk items such as laundry carts, followed by an assessment of how well it worked then increasing to higher risk items. What in fact happened, as reported, is that they went straight from laundry carts to flasks, which are the higher risk items in the daily process. It is unclear how many flasks are cleared by operational staff over a particular timeline, but there was an uneasiness among the surveyors interviewed that the practice is radiologically sound.

We recommend that ANSTO undertake an assessment and validation of the clearance procedure of high risk items, such as flasks by non-health physics persons (Area for Improvement).

This discussion also identified that the workers at ANSTO as a whole routinely use terminology, such as ‘release’, ‘cleared’, and ‘free-released’ improperly. The interviewed staff assured the review team that any item that was ‘cleared’ for unlimited use in non-controlled areas would be done so by health physics staff. The team noted there is a caveat in Section 2 of ANSTO document I-4155 Clearance from Active Areas that ‘other accredited persons’ may perform clearances. RPS management identified the practice of operations personnel being able to clear flasks from radiologically controlled areas to be a ‘win’; however, the review team would suggest that an assessment of how well this functions is in order.

11.3.4 The dose reconstruction

One of the downsides of not having RPS coverage when the accident occurred is the difficulty in being able to re-enact the accident under controlled conditions so that a proper reconstruction could occur. While the review team has few issues with how the reconstruction was conducted, the possibilities of what dose the worker received are wide ranging. It was expressed during the interviews that RPS chose not to retrieve the contaminated gloves and other wipes from the waste bag, as they deemed the risk was too

high for the RPS staff. The review team's position is that RPS staff should be trained well enough to protect themselves, so that the level of contamination they were dealing with could be ascertained. That said, without using an ion chamber in the manner described in the 'beta dose rates' section above, that value would not have been able to be ascertained.

As a second step, ANSTO chose to have the employee's medical condition reviewed by a radiation oncologist who would have experience with radiation skin burns. This was unlikely to yield much useful data, as the types of burns radiation oncologists deal with are due to skin entrance air kerma (dose) from a gamma source (linear accelerator) which affects skin differently than contamination from a liquid beta source.

The use of these two methods has resulted in wildly ranging final skin dose estimates of 0.85 Gray (Gy) on the low end, up to 20 Gy on the high end. All this while, the extremity thermoluminescent dosimeter (TLD) measured a comparatively minuscule 1.83 mGy. The likelihood is that the dose reconstruction has underestimated the dose, while the bio-dosimetric method has overestimated it and the extremity TLD has proved all but useless for measuring beta radiation. Despite this, RPS has assured the review team that these dosimeters contain the necessary chips and filters to properly measure beta radiation.

There have been two reports provided determining what effective dose would be assigned to the worker due to the skin contamination. One report was based on the 850 mSv per 1 cm^2 reconstruction and the second relied on the 20 Gy over 200 cm^2 bio-dosimetric estimate. At the time of the review, both reports remained in draft. As a final accepted effective dose is assigned, this should be added to the effective dose that is in the workers dosimetry record for the year 2017.

If ANSTO considers a plausible dose reconstruction to be of importance, it may consider conferring with the Radiation Emergency Assistance Center/Training Site (REACT/TS) which resides at Oak Ridge National Laboratory in the USA. This group has the experience and renown for investigating such accidents and performing dose reconstructions.

We recommend that 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 (High Priority).

It is acknowledged that these links have been commenced.

11.3.5 Proper use of units

In the skin contamination accident report, there are many uses of the unit "cps/cm^2", which should be listed in their SI equivalents. The review team recognises that many of these uses are to show the decreasing level of contamination over time due to decontamination effort. However, it does not deliver to the reader the quantity of radioactivity per unit area which exists at any time, nor does it convey the exposure rate (see paragraph above regarding beta dose rates). The team recognizes that in the appendix dose reconstruction, CPS are eventually converted to Bequerels (Bq), but one would have consumed the entire accident report prior to reaching the appendix to realise this.

Also, in the accident report, the beta dose is listed first in Gy then converted to Sieverts (Sv). There are two reasons why this is unnecessary and incorrect. Grays are actual physical

units of absorbed energy per unit mass whereas Sv is a measure of probability or more accurately, risk. Probability and risk are given consideration when one is measuring stochastic (probabilistic) effects such as cancer, but not useful when measuring deterministic effects which have thresholds for this effect, such as skin burns, cataracts, etc. Secondly, whilst it is recognised that the quality factor for beta radiation, is one (1), all measurements involving beta radiation should be recorded in units of Gy. The reason for this is because with beta radiation, the deterministic effects will always outweigh the stochastic ones.

There are many occasions throughout the documents provided (e.g. skin contamination dose report, high activity QC #1 and #2 and the change in procedure to reduce exposure to hands during operations) where the term 'specific activity' is used, when what is most likely meant is 'activity concentration'. ^{99}Mo only has one specific activity (17,780 TBqg^{-1}), however, the activity per unit volume of a solution containing ^{99}Mo (i.e. activity *concentration*) can be varied by dilution, which is what is occurring during decontamination and lowering the amount of activity in QC samples. The term 'specific' generically means 'per unit mass', and the term 'concentration' means per unit volume. For instance the Gy, which is a measured unit in Jkg^{-1}, is a unit of *specific* energy.

We recommend that ANSTO review their procedures to ensure proper uses of physical units and amend them based on the review (Area for Improvement).

Getting these wrong probably has little or no impact on safety, however, as ANSTO is recognised as the premier scientific organisation in Australia with respect to nuclear safety, it would do well to ensure the use of proper units on documents it publishes. The reviewer understands the reasoning for the use of Sv, as it allows comparison with legal dose limits for communication with the general public; however, the fact that the legal dose limit has been exceeded is well established and so the correct units should be used.

11.4 Staffing

The RPS group sits under the PCSS portfolio and has positions for 27 personnel, made up of

- 1 Manager who is trained and qualified as an RPA.
- 6 RPAs (including their leader).
- Health Physics Surveyors (including their team leader).
- 1 external dosimetrist with 1 technical assistant.
- 1 internal dosimetrist with 1 technical assistant.
- Project health physicists.
- 1 administrative staff.

This section currently provides health physics and dosimetry support to all sections of ANSTO from approximately 0730 – 1630H on weekdays. Outside of these hours, pre-arranged support is provided when necessary work is planned. The section also provides an on-call service for emergent work that may happen on a 24/7/365 basis.

At the time of the review, there were 10 Health Physics Surveyors employed in RPS, with 3 vacancies. At present, the typical time it takes for a surveyor to complete their class room and on the job training is 3 to 6 months, with the additional time for security clearance to be completed.

An additional 4 qualified health physicists reside in the Customer Advocacy and Value Chain. This group provides commercial services for ANSTO, including radiation safety training.

The review team considers this to be a lean level of staffing for the amount of work and responsibility of the RPS group as it stands now and increases the risk of further accidents due to lack of sufficient health physics coverage. This consideration doesn't account for the increased workload that will occur should ANSTO accept the recommendations of this Review. Any increase in workload would need to be off-set by a reduction elsewhere for ANSTO to meet its duty of care to its workers, from the standpoint of radiation protection.

We recommend that ANSTO reviews 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 (Medium Priority).

An issue brought to the attention of the review team by several interviewees is the insufficiently low number of operators who are qualified to perform aseptic pharmaceutical procedures. This is the method required to synthesize the therapeutic cancer drug ^{123}I-MIBG. As of the time of the review, only three ANSTO Health staff were certified to perform this procedure and, on at least one occasion, all were absent on some sort of leave. On one occasion, this situation left ANSTO unable to synthesize this drug while a paediatric cancer patient from Brisbane was admitted in a local children's hospital with treatment scheduled. The procedure was postponed for at least a week due to the amount of time the synthesizing process takes. The interviewees who spoke of this incident were very emotional about this situation ranging from anger to sobs.

We recommend that ANSTO increases 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 (Medium Priority).

12 Recommendations

The recommendations raised throughout this report have been collated, individually numbered and minor rewording performed in order to ensure a consistent style. The full collated set of recommendation are presented in Appendix E.

13 Conclusions

As a result of a series of 4 reportable incidents in the Building 23 complex, including one incident classified as a Level 3 event in the International Nuclear Event Scale, the Australian nuclear regulator (ARPANSA) has become concerned that the practices in B23 pose a risk of harm to operators. As a result, ARPANSA issued a direction to ANSTO stating that ANSTO were to take immediate steps to initiate an independent review of the approach to occupational radiation safety of processes and operational procedures in B23, in particular those associated with the quality control activities.

An independent review undertaken drawn from an international team of experts in the fields of nuclear safety, safety and organisational culture, radiation protection and human factors.

In conclusion, the independent safety review has raised a number of concerns where it is considered that ANSTO may not be meeting modern standards approaches with regard to safety, including nuclear, radiological and conventional. This has led to the identification of 85 recommendations for improvements; these recommendations are mostly directly applicable to ANSTO or the ANSTO Health business, but a significant proportion of these recommendations are also relevant to the regulators, including ARPANSA, in order to help them to further develop as a nuclear regulatory authority. It is, however, of vital importance that ANSTO ensures an appropriate level of proportionality in the resolution of the shortfalls identified by this review and does not forget that there needs to be an appropriate balance between the nuclear, radiological, conventional and patient safety needs. It is an all too common problem in the nuclear industry that the focus becomes nuclear and radiological safety at the expense of conventional (and in the case of ANSTO, product) safety and it is vital that any actions taken to resolve issues raised by this report take due and proportionate account of all these regulatory requirements in order to ensure that the optimum solution is adopted.

Appendix A: Schedule of Documents for Review

Reference	Title	Notes
	May 2018 Safety Climate Survey Results	
	May 2018 Safety Climate Survey Individual Responses	
	2018 High Reliability Workshops Agenda and Minutes	
R18/04720	Facility Licence F0262 – Assessment of ANSTO's Review of High Risk/Hazard Tasks in B23	Letter
	ARPANSA Report to Parliament on August 2017 Incident	Report
R18/07432	ARPANSA Direction to ANSTO	Letter
R17/13159	ARPANSA Inspection Report Nov 2017	Report
C2016C00977	ARPANSA Act 1998, Compilation 12	Legislation document
F2017C00573	ARPANSA Regulations 1999, Compilation 18	Legislation document
R-2014-33-TR	ANSTO Health Plans and Arrangements for Safety	Report
F0262	B23 & B23A Facility Licence	Licence
R-2010-17-TR	B23 Safety Analysis Report	Safety Case
R-2014-33-TR v02	B23 Plan and Arrangements	Report
	B23 Radioactive Material Movement Safety Assurance and Corrective Actions, June 2018	Note
	Review of High Risk / Hazard Tasks in ANSTO Health Building 23 Production Facility, June 2018	Report
	ARPANSA Response to B23 High Risk Review	Letter
GRC 4864	Incident Report, June 2018	Report
	Group Executives KPI Schedule, 2017/18	Excel Spreadsheet
	Position Descriptions	PD039, PD069, PD103, PD108, PD129, PD463, PD550, PD734, PD847, PD937, PD1261, PD1362, PD1442, PD1518,

Reference	Title	Notes
		PD1533, PD1607, PD1612, PD1644, PD1815
ANSTO-T-TN-2006-2 rev 5	Accident Analysis and Risk Assessment of the Mo-99 Production Process in B54	Report
ANSTO-T-TN-2009-18 rev 0	Risk Assessment of the External Liquid Waste Interim Storage (ELWIS) Facility	Report
ANSTO/T/TN/2008-24 rev 0	Carbonate Formation Risk Assessment	Report
ANSTO/S/TN/2007-22 rev0	HAZOP of Mo99 External Liquid Waste Interim Storage Tanks, B54	Report
ANSTO-T-TN-2010-08 rev 0	B23 Cr-51 Risk Assessment.	Report
ANSTO-T-TN-2010-11 rev 0	B23 I-123 MIBG Risk Assessment.	Report
ANSTO-T-TN-2010-13 rev 0	B23 Samarium-153 Risk Assessment	Report
ANSTO-T-TN-2010-14 rev 0	B23 QC Risk Assessment.	Report
ANSTO-T-TN-2010-15 rev 0	B23 IHB Risk Assessment.	Report
ANSTO-T-TN-2010-27 rev 0	B23 I-125 Risk Assessment.	Report
ANSTO-T-TN-2010-29 rev 0	B23 Mo-99 Risk Assessment.	Report
ANSTO-T-TN-2011-04 rev 0	B23 Tl-Ga Risk Assessment.	Report
ANSTO-T-TN-2011-05 rev 1	B23 I-131 Risk Assessment.	Report
ANSTO-T-TN-2011-07 rev 0	B23 Bulk Chemical Handling Risk Assessment.	Report
ANSTO-T-TN-2011-09 rev 1	Risk Study of the B23A Waste & GenTech Washing Facility.	Report

Reference	Title	Notes
ANSTO-T-TN-2011-23 rev 2	Risk Assessment of Mo-99 Dispensing and Packing Process in B23 Hot Cells.	Report
ANSTO-T-TN-2013-09 rev 1	B23 Lu-177 Risk Assessment	Report
ANSTO-T-TN-2015-11 rev 0	Y-90 Risk Assessment.	Report
ANSTO-T-TN-2015-21 rev 0	HAZOP and Risk Assessment for Mo-99 Capacity Increase.	Report
ANSTO-T-TN-2016-02 rev 2	B2 QC Laboratory Risk Assessment.	Report
	Periodic Risk Review Working Notes	I-123, I-131, IHB, Lu-177, Mo-99 Gentech, QC, Y-90
AG-2525	Work Health and Safety Categorisation of Activities	Guidance Note
AG-5856	Safety Assurance Committee Process Flowchart	Guidance Note
AF-2321	Safety Assurance Committee Application Form	Form
AF-2322	Safety Assurance Committee Determination Form	Form
AF-2327	Results of Safety Assurance Committee Assessment Form	Form
AG-2426	Submissions to Safety Assurance Committee	Guidance Note
AG-1094	Operation of the Safety Assurance Committee	Guidance Note
AF-1095	SAC Sub-committee Form	Form
AG-2434	Guidance for Reg. 51 Determination	Guidance Note
AE-2301	Work Health & Safety Risk Management Standard	Standard
AG-2395	Risk Analysis Matrix	Guidance Note
AG-2390	Hazard Identification and Risk Assessment Guide	Guidance Note
AG-2392	Health and Safety Issues to Consider During Purchasing	Guidance Note
AG-2398	QRA	Guidance Note

Reference	Title	Notes
AG-2399	SSR Support in Risk Assessment	Guidance Note
AG-2428	Safety Analysis Reports (SAR) for Facilities	Guidance Note
AG-2429	Completing SARs for Facilities	Guidance Note
AG-2505	ALARA Assessment	Guidance Note
AG-2494	Guidance on SSC Categorisation	Guidance Note
AG-2407	Hierarchy of Risk Control	Guidance Note
AG-2430	Lucas Heights Site Description	Guidance Note
AG-5445	Guidance on ARPANSA Requirements	Guidance Note
AG-2454	Role of Contract Supervisor	Guidance Note
AP-2952	Role of Area Supervisor	Guidance Note
AG-3212	Role of Building Manager	Guidance Note
AG-2367	Role of Health and Safety Committee	Guidance Note
AG-2368	Role of Health and Safety Representatives	Guidance Note
AG-1666	Nuclear Installations, Prescribed Facilities and Source Licences	Guidance Note
AG-2362	WHS Accountabilities, Responsibilities and Actions	Guidance Note
AP-2300	WHS Management System Overview	Procedure
AG-2372	Incident Response	Guidance Note
AG-2508	Radiation Safety Data	Guidance Note
AG-2509	Area Classifications	Guidance Note
AG-2375	Event Investigations	Guidance Note
	ANSTO Health Data	Powerpoint Presentation
	ANSTO Health Overview	Powerpoint Presentation
	QC Roster ANSTO Health 2018	Powerpoint Presentation
	ANSTO Health 2017 Roster	Excel Spreadsheet
AG-1682	Delegations Manual	Guidance Note
AG-2436	Conduct of SAC Audits	Guidance Note
AG-6119	Asset Management Roles & Responsibilities	Guidance Note

Reference	Title	Notes
GRC 3273	Investigation Report , QC Hand Exposure	Report
18/154	Investigation Report, High QC Sample	Report
GRC 4598	Investigation Report, MIBG Change	Report
GRC 4864	Investigation Report, Trolley Spill	Report
AG-5801	CEO Direct Reports	Guidance Note
G-2165	Office of the CO	Organisation Chart
G-1908	PCSS	Organisation Chart
	ANSTO Corporate Plan 2017/18	Report
	ANSTO Operational Framework	Report
	B23 Incidents During 2016, 2017, 2018	Excel Spreadsheet
	ANSTO Health Management Meetings Agendas & Minutes FY 2016	Reports
	ANSTO Health Management Meetings Agendas & Minutes FY 2017	Reports
	ANSTO Health Management Meetings Agendas & Minutes FY 2018	Reports
	Schedule of Operational Health Physics Procedures & Instructions in BMS	Report
I-4155	Clearance of Items from Active Areas	Work Instruction
I-550	Radiological Surveys for Radiation & Contamination	Work Instruction
I-6176	RPS Incident Response	Work Instruction
	Summary of Comcare Engagement with ANSTO and ANSTO Health (de-identified)	Excel Spreadsheet
	Personal correspondence provided to the review team by staff (emails, letters and documents pertinent to the review)	Documents

Appendix B: Detailed Work Plan

The detailed work plan including the individual activities is summarised below.

Task 1 & 5 – Safety Culture and Organisational Baseline Review

Reviewers: Lynn Williams, Andrew Hopkins and Peta Miller

Work Breakdown:

Task	Title	Detailed Activities

Task	Title	Detailed Activities

Task 1a and 5a	Review Prior to Site Inspection Visit	• Health survey and safety culture analysis results
		• Risk assessments appropriate to safety
		• Prepare assessment criteria based on the following methodology:
		  ○ NIAC/NUPIC
		  ○ IAEA SG suite
		  ○ ARPANSA legislation, codes and standards
		  ○ Nuclear Industry Code of Practise (NICOP) – Management of Organisational Change

Task 1b	Review Prior to Site Inspection Visit	• Methodology will include but not be limited to:
		  ○ Forensic examination of the previous incidents, reviews, reports and actions
		  ○ Review organisational structure
		  ○ Review of existing safety culture tool survey
		  ○ Recommend supplementary question themes and trigger events [Cognitive testing and reliability assessment of survey items is not possible within the current project timeframes]

Task 1c and 5b	Site Inspection Visit	• Conduct assessment of existing nuclear baseline in accordance with ARPANSA (and/or other) regulatory requirements
		• Business Management System processes, procedures and supporting documentation
		• Management of change process
		• Conduct interviews with selected personnel from each discipline to assess the nuclear safety culture in accordance with IAEA requirements
		• Assess the capability of ANSTO to meet the requirements of IAEA & ARPANSA including but not limited to:
		  ○ Business model & process/procedure overviews
		  ○ Organisational baseline
		  ○ Management of organisational change
		  ○ Core and supporting process maps – including interface arrangements
		  ○ Review of compliance capability against nuclear

Task	Title	Detailed Activities
		standards ○ Assessing and verifying SQEP & competence • Review performance agreements of senior executives and renumeration system and relationship to production for relevant staff • Forensic review of reported incidents including: ○ Additional examination of the previous incidents, reviews, reports and actions ○ Semi-structured interviews with report authors and those with responsibility for implementation ○ Interviews with ARPANSA representatives ○ Additional reviews of organisational structure
Task 1d and 5c	Draft Report Inputs	• Production of draft chapters for each topic area for incorporation into draft report

Task 2 – Human Factors Review

Reviewers: Peta Miller and Andrew Hopkins

Work Breakdown: Noting this component will also draw heavily on insights from other review tasks (Tasks 1, 4 & 5).

Task	Title	Detailed Activities
Task 2a	Review Prior to Site Inspection Visit	• Incident and workers' compensation data and historical records • Event investigations reports • Risk assessments in ANSTO Health for key tasks • Health survey and safety culture analysis results (past and current) • Position descriptions • Safety assurance processes and delegations • Task/job assessment methodology • Reference ARPANSA legislation, codes and standards and other relevant Australian national material

Task	Title	Detailed Activities

Task 2b	Site Inspection Visits	• Apply task/job assessment methodology:
		  ○ Semi structured interviews with workers, supervisors and managers
		  ○ Operator centred observations of high risk tasks
		  ○ Workload surveys and analysis as required (short survey or semi-structured interview (to be done in conjunction with Tasks 1&4) to probe how task and job factors are perceived by workers and supervisors to influence fatigue, musculoskeletal and psychological status and short and long-term decision making/performance, satisfaction and production
		  ○ Conduct assessments across all shifts of human-machine interface for high-risk tasks with particular regard to cognitive, psychological and biomechanical demands
		• Conduct assessments across all shifts of broader work design and system issues pertinent to the high-risk task execution that may impact health, safety and/or performance including: fatigue, stress, body part discomfort and job satisfaction
		• Review Business Management System processes, procedures and supporting documentation with regard to above
		• Review management of change process with regard to above
		• Review risk assessment and incident reporting processes with regard to above
		• Consider intersection between production pressures versus health and safety during task execution
		• Undertake a survey with staff on psychosocial hazards and risks in the workplace within ANSTO Health.
		• Assess the capability of ANSTO to meet ARPANSA and Comcare requirements including but not limited to human factors issues associated with the design and management of work and of the high-risk tasks.

Task 2c	Draft Report Inputs	• Production of draft chapter for each topic area for incorporation into draft report

Task 3 - Safety Assurance Review

Reviewer: David Jones

Work Breakdown:-

Task	Title	Detailed Activities
Task 3a	Review Prior Site Inspection Visit	• Review of ANSTO supplied processes and procedures covering the safety assurance/due process for plant, modifications, experiments and changes to operations and incident reporting and investigation against relevant good international practice including: o Categorisation of activities including the basis for categorisation o Safety case/assessment requirements associated with category of activity o The level of scrutiny to be applied to safety submissions associated with categorised activities including internal verification, independent review and safety committee consideration o The role of management and the Executive and the safety committees in the approval of activities including how disputes and disagreements within safety assurance are resolved. o How urgent requirements requiring fast track processes are managed. • Review whether the correct enterprise oversight is in place, with independent processes for escalation within the organisation e.g. reporting of events and near misses, application of learning from experience particularly near misses and related events, high risk activities etc.
Task 3b	Site Inspection Visit	• Visit to ANSTO site to review any additional documentation and to interview representative ANSTO staff regarding their experience of the safety assurance process and the extent to which it is rigidly applied and complied with in accordance with the approved procedures
Task 3c	Draft Report Inputs	Production of draft chapter for each topic area for incorporation into draft report

Task 4 – Review of Hazard ID and Risk/Consequence Processes

Reviewer: David Jones

Work Breakdown:-

Task	Title	Detailed Activities

Task	Title	Detailed Activities
Task 4a	Review of B23 Safety Report and Supporting Data	• Undertake a high level review of the current B23 Safety Analysis Report and supporting risk assessments against modern standards and relevant good practice.
Task 4b	Review of Safety Assessment Methodologies and Approaches	• Review the current processes and procedures for conducting hazard identification and its effectiveness in terms of a comprehensive and systematic process; this will include reviewing the appropriate application of the HAZID process (i.e. taking enough time, applying enough rigour, having appropriate skills) as part of the site visit. • Review the current processes and procedures for conducting safety analysis (i.e. consequence and risk assessments) across ANSTO Health including any deterministic/probabilistic approaches and acceptability criteria/targets. • Review how the safety analysis information is used to identify, classify and demonstrate as suitable and sufficient any safety measures (engineered and procedural) and how these are implemented and demonstrated as meeting safety functions on the facility. • Review how the risk reduction process is applied including the application of best practice in terms of safety measure hierarchy. • Assess the robustness (process owner identified, inputs and outputs identified, key stakeholders identified etc.) of these processes and their suitability for the ANSTO Health environment. • Assess the current escalation process for ‘high risks’ within the organisation and its application within ANSTO Health. • Issue of initial findings prior to site visit. An important part of this review is to compare the current processes against relevant international good practice, particularly with reference to deterministic assessment and identification of required levels of control. As a result, advice will be provided to ANSTO as to how a deterministic safety assessment approach could be incorporated within the ANSTO processes.
Task 4c	Site Inspection Visit	• Visit to ANSTO site to review any additional documentation and to interview representative ANSTO staff regarding their experience of the safety assessment process and the extent to which it is rigidly applied and complied with in accordance with the approved procedures.

Task	Title	Detailed Activities
Task 4d	Draft Report Inputs	• Production of draft chapter for each topic area for incorporation into draft report

Task 5 – incorporated within Task 1 work plan.

Task 6 – Optimisation and Effectiveness of Risk Control Measures

Reviewer: Brent Rogers

Work Breakdown:-

Task	Title	Detailed Activities
Task 6a	Review of Control Measure Optimisation	• Review the current processes and procedures for radiological protection services/health physics • Review risk reduction studies and reviews undertaken to date for their appropriateness and the implementation of recommendations • Review survey data (radiation and contamination) and incident reports • Review current processes for hierarchy of risk controls against best practice • Review ANSTO training and qualification/certification policies/procedures for RPA and Surveyors • Review instrumentation selection and calibration procedures & practices to evaluate fitness for purpose
Task 6b	Site Inspection Visit	• Visit to ANSTO site to review any additional documentation and to interview representative ANSTO staff regarding their experience of the RPA/health physics and optimisation processes and the extent to which it is applied and complied with in accordance with the approved procedures
Task 6c	Draft Report Inputs	• Production of draft chapter for each topic area for incorporation into draft report

Appendix C: Application of Safety Assessment Approach in B23 SAR and Supporting Documents

The application of the risk assessment approach has been reviewed at a high level for the sample of risk assessments provided.

Risk Assessment Reports

It is noted that many of the risk assessments date from 2009/10 and use a different risk matrix to that specified in AG-2095; the assumption is that the current matrix is a revision of the one in place in 2010.It is also noted that many of them appear not to have been reviewed and updated since that date which does not comply with ANSTO's management system procedures which state there should be a 3 yearly review.

For the assignment of event frequency, it is noted that some faults have been quantified to calculate the frequency while others have been assigned a qualitative value. There should be some evidence that the qualitative assignments can be defended by referenceable and demonstrable calculations. For example, there are no clear references for the human error probabilities or equipment probability of failure values used in some assessments. For traceability, it is important that the source assumptions and data are fully transparent. For example, the B23 QC laboratory assessment includes full visibility of the frequency calculations while other risk assessments do not.

More detailed comments are provided below.

B54 External Waste Tanks Hazard Identification

The carbonate formation HAZOP for the B54 external waste tanks (ANSTO/T/TN/2008-24) was completed in a single day; this may be reasonable but the report suggests that several potential scenarios have been dismissed as incredible as they require either multiple engineering system failures or a gross human error. While the multiple valves etc. represent strong safeguards, if they are the same type of valve or operated by the same people, there is a dependency which means that common mode failure is possible and the incredibility of failure argument may not apply. For the human error, if it was assumed that the HEP for failing to close the valve is 1E-02 (maybe 5E-03 if it is very clear, supervised and in clear operating procedures) and then failure by the same operator to detect it next time is 1E-01 (even if they are different operators it might be difficult to claim better than that), the overall HEP is 1E-03 to 5E-04. Depending on how many times per year this operation is done, the IEF could be 1E-02 pa if it is 10 times per year which is a credible event (and the most likely to occur).

B54 Mo-99 Production Risk Assessment

The dropped load frequencies assigned appear optimistic. Based on US power plant data in NUREG1774 over the period 1968-2002, the study concluded typical failure probabilities for nuclear cranes of 5.6E-05 per lift for heavy loads with over 56% of the events reported due to human error for very heavy loads while the human error contribution is around 70% for less heavy loads. Even given more modern single failure proof cranes with higher reliability levels, the human errors associated with maintenance, rigging, failure to follow procedures, load path restriction violations, inadequate surveillance tests etc. are unlikely to reduce the failure probability by more than an order of magnitude. Hence a realistic figure of 5E-05 (or 1E-06 for a modern standards single failure proof crane) per lift is realistic; for an example case of 2 lifts per week (100 per year), this makes the dropped load frequency around 5E-03 per year which makes the likelihood class and the residual risk class change. This kind of

question arises from the lack of use of referenceable data and analysis to build up the event frequency.

Another question regarding the flask which would be resolved by moving away from the probabilistic based approach to the deterministic approach is the drop withstand of the flask (or package for other faults in risk assessments). In the deterministic approach, if it can be demonstrated that the package can withstand the worst case drop without damage then the fault is terminated by a protective measure within the design in terms of the radiological hazard (but not the industrial hazard) and would not be considered further. It is only if this substantiation cannot be provided then the search for additional safety systems and a probabilistic analysis would be undertaken.

For the fault of lifting transport flasks with the flask door open, the likelihood should be justified with referenceable reliability values. This applies to many of the faults involving lifting active materials in and out of flasks and hot cells etc. where interlocks and radiation detectors are claimed but no reliability values are quoted to justify the frequency claimed.

For the external events assessment, surely the building and the hot cells etc. have been designed against a particular building code to withstand a certain magnitude earthquake, typically either a 1E-03 pa or 1E-04 pa event? The probabilistic assessment should look at beyond design basis events and examine whether there is a cliff edge beyond which there would be major damage and the potential for a radiological event.

The assessment of in-facility fires has assumed that such fires resulting in a radiological event are very low frequency. While there may be low flammable inventories etc., experience is that there is a tendency for such materials to build up over time such that very low probabilities and frequencies are unlikely to be justifiable. In particular, reliance on the fire detection systems in the safety analysis should be kept to a minimum level as such systems are commercial off the shelf standard items and therefore high reliabilities cannot be claimed.

Cr-51 Risk Assessment

These risk assessments generally look good. For example, for fault A3 (dropping lead pot and glass vial breaks), the likelihood could be derived as:

Trained operator makes a mistake (error of commission)	1E-02
Failure of glass vial (assume this happens as nothing else can be demonstrated)	1
Failure of lead pot	1E-01
No of operations	12 per year

Event frequency = 1E-02*1*1E-01*12 = 1.2E-02 per year (Unlikely) so this is agreed.

I-123 MIBG Risk Assessment

For the needle stick injury (A4), given the fact that working in a glove box with thick neoprene gloves, the HEP for making a mistake during the syringing needs to take into account enhancement factors such as EPCs so a HEP of 1E-05 seems optimistic. Is there any data that demonstrates that a finite probability of the needle penetrating the glove can be claimed, if not, you probably have to assume 50% chance? The HEP would probably be of the order of 1E-03 so that leaves an event frequency of 1E-03*0.5*112 (i.e. 5.6E-02 pa i.e. Unlikely). Given the risk value is “High” anyway, it is probably OK. Has an engineered control been put in place (R4) and what is the revised residual risk?

For faults A6 and A8, the HEP for dropping the liquid of 1E-03 needs some justification and can a claim of 0.1 for breakage of the glass vial be justified? It's more likely that 0.1 applies to the combined event of vial breaking and contents escaping.

For fault A7, given that several events have occurred, is the allocation of "Unlikely" justifiable on the basis of the improvements implemented; this needs demonstration.

B23 QC Risk Assessment

The likelihood calculations in Appendix C look optimistic. For example, a standard value for HEP of 3E-03 has been assumed then a factor has been included for either a low speed adjustment factor for controlled conditions (1E-02) or an adjustment factor for good practices (1E-02). Plus another 1E-02 has been included in several assessments that covers the human error of contacting the vial. Given that it is all the same operator and the initial HEP value is based on a well-practiced, low stress activity under good procedures there is some double-counting. Hence, the overall HEP of an operator error leading to contamination is well below the best claimable human performance limiting values. The reviewer suspects that all of the human error based likelihoods are somewhere between 1E-02 and 1E-03 too optimistic.

B23 IHB Risk Assessment

The likelihood calculations are purely qualitative with no numerical demonstration. The crane lifting faults have the same comments as for B54 Mo-99 production.

B23 Mo-99 Risk Assessment

Not surprisingly given the nature of operations carried out, there are several risks assigned as Medium with recommendations to reduce the risk. This is a good case in point of either the recommendations have been adopted and the risk is reduced or the facility is continuing to operate with risks which are not necessarily demonstrated to be ALARP/ALARA without SAC/CEO approval.

The crane failure fault in the IHB (A1) assumes the dropped load is extremely unlikely; given the earlier comments regarding nuclear crane failure rates this suggests the likelihood will be higher (e.g. 1E-05 for crane failure times the no of operations per year). Is the transport package substantiated and demonstrated to survive the expected drop, if so then the additional failure mode of operator error in lifting above the drop height withstand could be relevant? What is the basis for the dose calculation, assuming that the operator can tell straight away that the crane has dropped the package, it can be assumed that evacuation is rapid (less than 1 minute,) so the dose should be based on an average location in the room during this process over the period of exposure – is this the basis?

For faults A3 and A4, is the dose based on actual experience on the facility?

For faults A6, A15 and A22, given that the event has happened several times, is the likelihood of unlikely credible? The likelihood needs to be demonstrated through referenceable data and calculations.

For fault A8, can the HEP of 1E-03 be justified or referenced to a specific HEART/THERP data source?

For fault A17, the HEP for dropping a Tc-99m generator of 1E-04 is normally applied as a human performance limiting value where there is supervision etc. Given that this is a manual operation and given that it is happened once before, a value of 1E-04 per transfer seems

very optimistic. Also see earlier comment about vial failure plus sample escaping being assigned 1E-02 which also seems optimistic given it is a glass vial.

For fault A20, the HEP of 1E-04 and the vial breaking and releasing the contents (a further 1E-04) seems very optimistic unless you can substantiate it through real tests.

For fault A21, the HEP for a needle stick injury has been assumed as 1E-05 which seems very low and is equivalent to the lowest HPLV claimable under extremely controlled conditions and a high level of independent supervision. Is this credible?

B23 Ga-67 and Tl-207 Risk Assessment

The likelihoods should be justified.

B23 I-131 Risk Assessment

The frequencies for dropping a sample pot/ion chamber pot appear very low given that it is an operator error induced event. In the table 27 (and 32 and 37 and 42 and 47 and 54 and 59), the HEP has been assumed as 1E-03 and an additional 1E-02 has been included for controlled conditions; normally the HEP value takes this into account and a HPLV would be applied of 1E-04 at best for the combined activity. Also if recovery is performed by the same people/team involved in the event, there is a dependency so a further reduction of 1E-02 is difficult to justify unless it is performed by a completely different team.

Appendix D: Deterministic Safety Assessment Approach

Introduction

Following an initial review of the safety assessment processes adopted within the ANSTO safety, health and environment arrangements, it is clear that the approach applied to all nuclear facilities is based on a quantified or semi-quantified risk assessment and a comparison of the risk against pre-determined criteria from the risk matrix approach set out in AG-2395. This approach provides a risk quantification for comparison against acceptability criteria but does not facilitate a safety analysis which examines the fault tolerance of the plant in order to identify the important safety functions and systems and the demands that are placed on them. Modern best practice for the safety analysis of nuclear facilities in most countries, including IAEA advice, is that the most serious hazards in terms of operator and public radiological consequences from fault conditions should be assessed primarily through a deterministic safety approach with the quantified (probabilistic) assessment supporting the deterministic analysis. In this way the design and the safety analysis can be developed iteratively and in an integrated manner.

The application of this approach requires the following:

1. Identify fault conditions via a robust and systematic hazard identification process (e.g. HAZOP).
2. Group identified fault conditions for ease of subsequent assessment (e.g. same or similar consequences, location, safety systems, etc.).
3. Ensure that there is full traceability from each fault assessed through the screening/sentencing/HAZID process; this is often recorded in a fault schedule/fault protection schedule.

Deterministic Safety Approach

The deterministic approach (often referred to as design basis analysis) is a robust demonstration of the fault tolerance of the facility by virtue of the effectiveness of its safety systems, in particular, the engineered systems. Faults which should be subjected to deterministic safety assessment should be those for which the harm potential (i.e. worst case radiological consequence in the absence of safety controls) have the potential to exceed defined thresholds, often legal dose limits.

This approach is used to:

- Generate the limits and conditions on the safe operation of the facility.
- Permit the identification and categorisation, on the basis of their safety significance, of safety systems, defined as a system, or a combination of procedures, operator actions and safety systems that prevent or mitigate a radiological consequence, or a specific feature of plant designed to prevent or mitigate a radiological consequence by passive means.
- Specify the performance requirements of safety systems e.g. reliability, withstand to certain events, safe state during fault conditions etc.
- Dictates the degree of substantiation required for both engineered and procedural safety systems.

The thresholds for the application of the deterministic approach vary across individual nuclear operators. It is important that such a threshold in terms of sentencing faults to the type of analysis appropriate to the harm potential is not overly complex. The most important requirement for the sentencing is that the thresholds for frequency and consequence should be based on harm potential in the absence of safety controls in order to identify the worst case event. This means that for the "inherent hazard/risk" for fault sentencing, the frequency should be that of the initiating event based on best-estimate assumptions (except for external events which should be conservative). The measure of safety significance employed for radiological consequence is usually the "unmitigated dose" as the worst that could be delivered under those circumstances. That is the effective dose which would be delivered should the fault occur in the absence of any safety measures other than purely deterministic measures (i.e. passive safety measures) which deliver the safety function in a purely passive manner e.g. massive bulk shielding.

From the review of ANSTO processes, there are 2 relatively straightforward options for the deterministic thresholds:

Option 1: The basic thresholds are for faults with unmitigated consequences in excess of:

On-site: 20mSv

Off-site: 1mSv

and that the initiating faults should be 'reasonably foreseeable' (i.e. initiating event frequency (IEF) in excess of 1E-05 pa for internal faults or 1E-04 pa for natural external hazards).

Option 2 – use the existing risk matrix in AG-2395 for inherent risk (based on unmitigated dose and best estimate IEF) with any fault which falls into the Very High, High or Medium risk classification being designated as design basis faults and therefore subject to a deterministic safety analysis. This has the advantage of using existing ANSTO processes rather than introducing a new threshold within the safety assessment process.

Designation of Safety Functions and Systems (Engineered and Administrative)

The basic aim of the deterministic safety assessment process must be to demonstrate that there are suitable and sufficient safety systems in place within the design to ensure that safety is maintained through all design basis faults. This involves providing demonstration that there is adequate defence in depth provided by these safety systems. Therefore, demonstration must be provided that there are a sufficient number of safety systems and they are of the required quality and capable of delivering their required safety functions.

Safety functions are the principal functions to be implemented to protect against the main hazards on site (i.e. confinement of radioactive material, shielding from effects of external radiation, reactivity control, heat removal). These are sometimes referred to as 'critical safety functions'. The safety functional requirement (SFR) is the specific function required to maintain the facility within the safe operating limits and conditions determined both for normal operations and the fault analysis (in particular by the deterministic safety analysis). Safety functional requirements provide a statement of the function (i.e. the need) that the safety systems, as the design solution, protecting against a particular fault must deliver. The safety functional requirement must be implemented to prevent and/or mitigate the consequences of a fault or mitigate the exposure due to the presence of a hazard under normal operating conditions. It is possible that the safety functional requirement will be delivered by engineered or procedural safety systems or a combination of the two.

Safety systems (including structures, systems and components (SSC) for engineered systems and operating rules/limits and instructions for procedural controls) must then be identified that meet these requirements. These claimed safety systems are classified in accordance with their safety importance. The safety systems (engineered or procedural) must then be substantiated to demonstrate they are truly capable of meeting their safety functions and maintaining the facility within its safe operating envelope (i.e. limits and conditions). This is often presented via a tiered system of safety functional requirements comprising:

- Level 1 SFRs which are based on:
    - The prevention or mitigation of the consequences;
    - The main hazard;
    - The challenge (i.e. initiating event or routine hazard) associated with realising the consequence.

e.g. *Prevent/mitigate* [global consequence] *due to* [main hazard] *resulting from* [challenge].

- Level 2 SFRs which define the specific performance requirements that safety systems and their SSCs must deliver
    - The unique description of the SSC;
    - The requirement that the SSC must meet;
    - The criterion against which compliance with the requirement is assessed.

Safety functional requirements are classified in terms of their importance in delivering nuclear/radiological safety. Possible examples based on either inherent risk or harm potential (i.e. unmitigated consequences) are shown below:

ANSTO Inherent Risk/Fault Class	**Potential Worst-Case Consequence in the Event of Failure to Meet SFR**	**SFR Class**
Very High	≥ 250 mSv to most exposed worker ≥ 10 mSv to most exposed member of public	1
High/Medium	≥ 20 mSv and < 250 mSv to most exposed worker ≥ 1 mSv and < 10 mSv to most exposed member of public	2
Low	≥ 2 mSv and < 20 mSv to most exposed worker ≥ 0.1 mSv and < 1 mSv to most exposed member of public	3
Very Low	≥ 0.1 mSv and < 2 mSv to most exposed worker ≥ 0.01 mSv and < 0.1 mSv to most exposed member of public	4

Notes:

1. The classification is applied to the SFR (not to the entire system) to ensure that substantiation is focused on the key parts of the engineered or administrative system only.
2. Below 0.1 mSv to a worker or 0.01 mSv to the public, the doses are within the range of normal operational doses and can be managed in accordance with normal dose management arrangements. No designated safety systems need to be identified.

Process for Deterministic Demonstration of Safety for Identified Fault Conditions

Once the faults and associated SFRs have been classified, the identification of suitable and sufficient safety systems forms the next step. The engineered safety systems and the associated SSCs identified to keep with the safe working envelope must be demonstrated to be capable of doing so and their importance to safety must be clear and unambiguous. The requirements in terms of number, quality and reliability of safety systems apply to initiating faults and their fault sequences or groups. The fault/SFR class is then used to specify the basis of the minimum number and quality of the set of safety systems that would be required to achieve the target level of reliability. In addition, the safety functions are developed to ensure safety measures of the correct type, number and quality are specified, the systems that are proposed are substantiated against their functional specifications and claimed reliability to demonstrate that they are capable of operating as required. This forms part of the defence in depth approach.

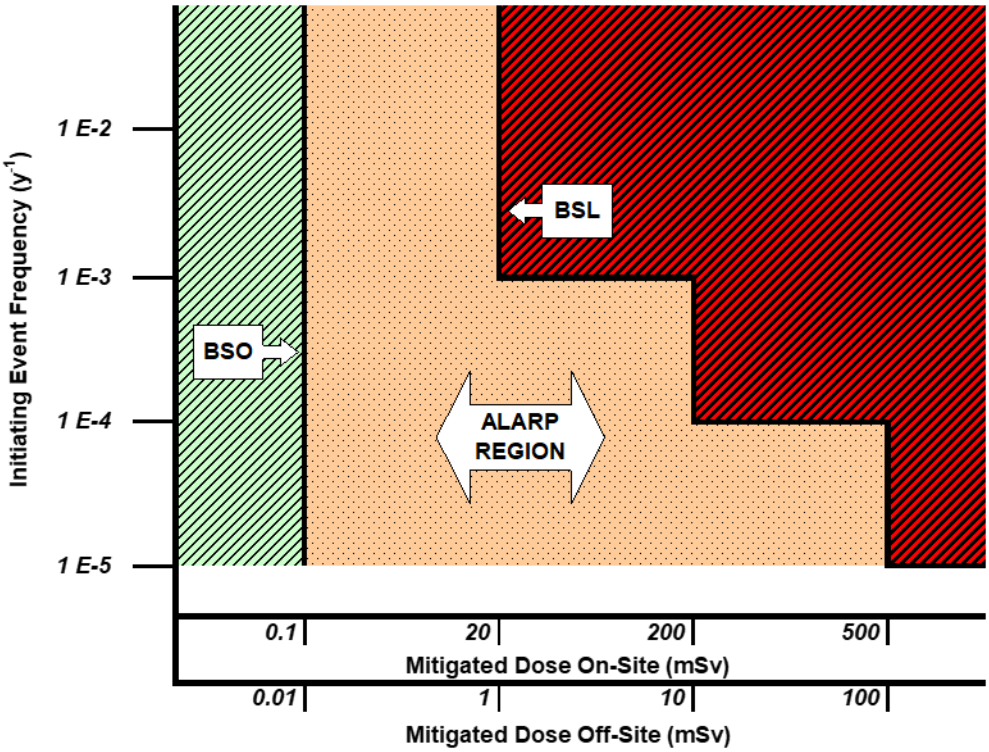
The qualitative criteria for the deterministic analysis that the safety measures should achieve, so far as is reasonably practicable, are as follows:

- None of the physical barriers to prevent the escape or relocation of a significant quantity of radioactivity is breached or, if any are, then at least one barrier remains intact and without a threat to its integrity.
- There is no release of radioactivity.
- No person receives a significant dose of radiation.

The quantitative acceptance criteria for safety systems claimed as protection against a design basis fault are defined in terms of a sufficiently low event frequency or a mitigated effective dose on or off the site received by any person arising from a design basis fault sequence where the combination of safety systems operate as intended. The deterministic assessment criteria which provide the basis for the safety demonstration can take many forms; an example is in the figure below where:

- The Basic Safety Limit (BSL) represents the tolerability limit, above which it is not considered acceptable to operate unless a specific case can be made; as a minimum, each safety system, on its own, must be capable of reducing the dose from a design basis fault sequence below the BSLs.
- The Basic Safety Objective (BSO) represents the objective for a new facility designed to modern standards and best practice; the very low mitigated dose values for the BSOs shall be taken to emphasise a fundamental preference for safety systems which terminate design basis faults rather than mitigate their consequences.
- The ALARP/ALARA region (which for existing and legacy facilities often is representative of where the faults within the deterministic assessment reside) requires suitable and sufficient risk reduction studies and analysis to be conducted in

order to demonstrate that everything reasonably practicable/achievable has been implemented.



Safety System Requirements

In order to meet the deterministic qualitative and quantitative criteria, safety systems need to be identified and substantiated as able to deliver the relevant SFRs. Engineered safety systems/SSC are classified on the basis of their safety significance (e.g. Class 1, 2, 3 or 4, as appropriate). Safety significance must be judged on the basis of the ultimate harm potential of the fault sequence(s) that the safety system is intended to protect against, as determined by the fault analysis. This gives rise to two groups of engineered safety measures/SSC as follows:

- Engineered safety systems/SSC classified as Class 3 or Class 4 which are necessary to ensure risks to workers and others are as low as reasonably practicable and/or below the relevant BSO.
- Engineered safety systems/SSC classified as Class 1 or Class 2 which protect against faults with the potential to deliver significant radiological consequences and to keep risks below the relevant BSL, with Class 1 reserved for protection against potentially severe accidents.

An example scheme is outlined below:-

Inherent Hazard Class	Unmitigated Consequences	Minimum Safety System Requirement
Very High	≥ 250 mSv to most exposed worker	At least 3 redundant safety systems, at least 2 diverse safety systems, suitable segregation and the set of systems must meet Single Failure Criterion against

Inherent Hazard Class	Unmitigated Consequences	Minimum Safety System Requirement
	≥ 10 mSv to most exposed member of public	common cause failures (CCF). Procedural safety systems not acceptable for new plant or modifications. Use of software-based systems alone unlikely to be justifiable. Robust management arrangements for substitution or to suspend relevant operations in the event of safety systems being unavailable (e.g. due to maintenance). Safety systems substantiated as Class 1 or 2. Target probability of failure on demand (pfd) < 1E-06 to ≥ 1E-07.
High/Medium	≥ 20 mSv to most exposed worker ≥ 1 mSv to most exposed member of public	At least 2 diverse safety systems with appropriate redundancy supported by detailed CCF analysis to demonstrate negligible pfd compared to independent failure probability and set of systems must meet Single Failure Criterion. Procedural safety systems not acceptable for new plant or modifications. Use of software-based systems alone unlikely to be justifiable. Robust management arrangements for substitution or to suspend relevant operations in the event of safety systems being unavailable (e.g. due to maintenance). Safety systems substantiated as Class 2. Target pfd < 1E-04 to ≥ 1E-06.
Low	≥ 2 mSv and < 20 mSv to most exposed worker ≥ 0.1 mSv and < 1 mSv to most exposed member of public	At least 2 safety systems with appropriate redundancy with CCF potential demonstrably low (including dependencies due to operators). Safety systems substantiated as Class 3. Target pfd <1E-02 to ≥ 1E-04.
Very Low	≥ 0.1 mSv and < 2 mSv to most exposed worker ≥ 0.01 mSv and < 0.1 mSv to most exposed member of public	One Class 4 safety system (if this class is used). Target pfd <1 to ≥1E-02.

The specification of safety systems must be in accordance, as far as is reasonably practicable, with the following hierarchy:

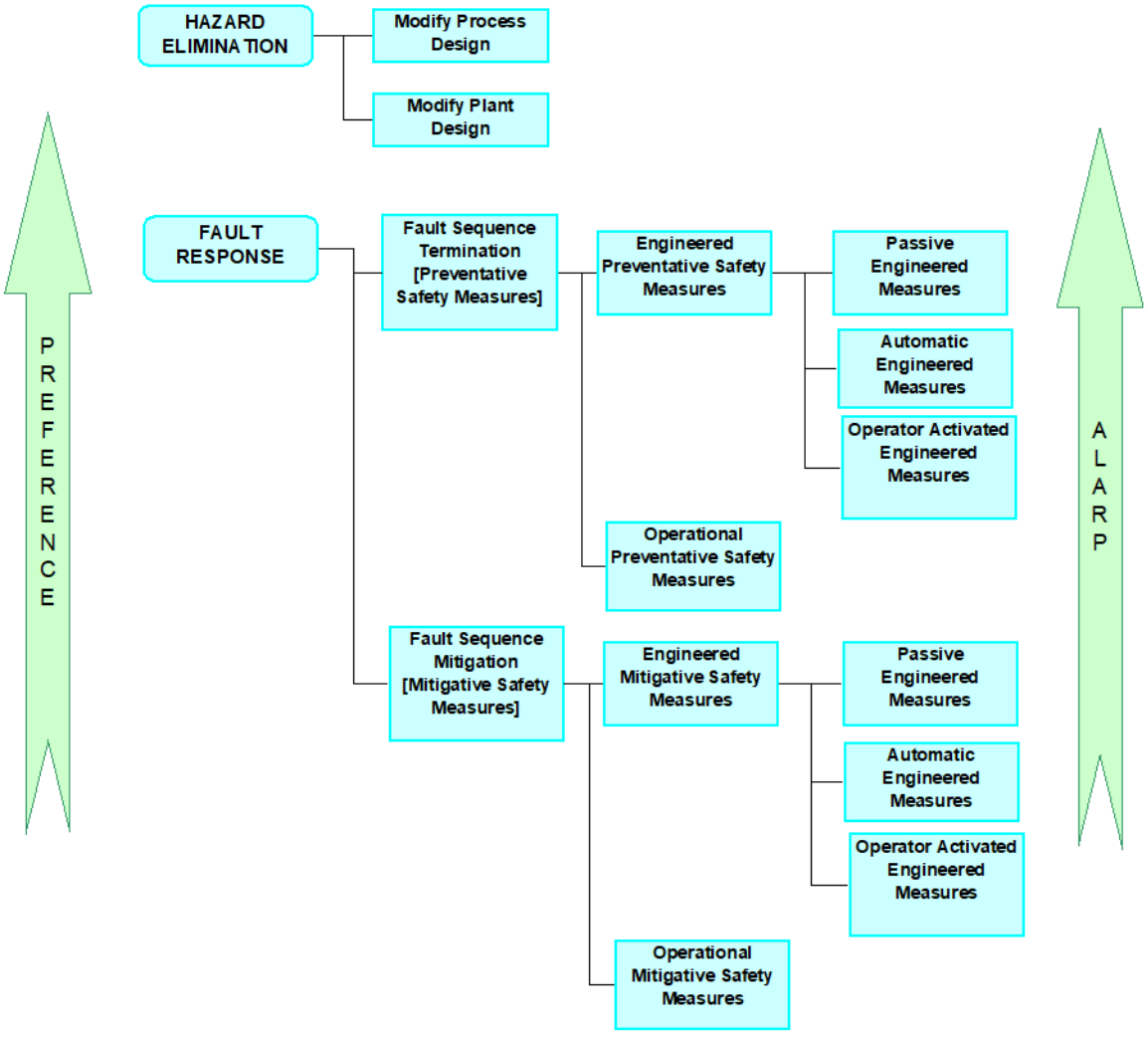
- Priority is given to eliminating potential fault conditions within the engineering design or the process itself rather than by providing safety systems to cope with the fault condition.
- Where elimination does not prove possible, the safety systems provided may be engineered or operational/procedural, preventative or mitigative and active or passive in their delivery of the safety function. In this context, preventative safety

measures are those that respond to the initiating fault to terminate the fault sequence before the hazard is realised. Mitigative safety measures are then those that respond only after the hazard is realised to reduce the consequences to the exposed groups (i.e. facility workers, other on-site workers or members of the public). The priority to be applied is:

- Engineered rather than administrative;
- Able to prevent the fault rather than mitigate its consequences;
- If engineered, passive rather than active (i.e. operating by actuation);
- If engineered and active, automatically acting rather than requiring operator response or intervention.

- The safety systems within the engineering design must provide sufficient defence in depth that the pre-defined design basis targets for frequency and mitigated (i.e. with correct functioning of the claimed safety systems) radiological consequence are met.

This is shown diagrammatically below:



Substantiation of Identified Safety Functional Requirements

All safety systems claimed within the safety analysis (normal operations and faults) must have demonstrable and auditable evidence to show that any design complies with the design expectation and can deliver, with adequate margins of safety, its safety functions and related performance requirements. This is referred to as substantiation and may be applied to both engineered safety systems and procedural safety systems (through appropriate human factors analysis). An example structure is outlined below.

SFR Class	Engineered	Procedural/Administrative
1	• Class 1 Engineering Substantiation Report (ESR) for existing plant or Design Substantiation Report (DSR) for new plant[1] • Walkdown proforma (existing plant only). • Inclusion on Safety Commissioning Schedule (SCS) (new plant only).	• Not appropriate for Class 1 SFRs.
2	• Class 2 ESR (existing plant) or DSR (new plant)[2] • Walkdown proforma (existing plant only). • Inclusion on SCS (new plant only).	• Specific task based human factors assessment of the specified SFR. • Generic human factors assessment of the plant level management system. • Description of the plant level management system.
3	• Class 3 substantiation proforma. • Walkdown proforma (existing plant only). • Inclusion on SCS (new plant only).	• Generic human factors assessment of the plant level management system. • Description of the plant level management system.
4	• Walkdown proforma (existing plant only). • Inclusion on SCS (new plant only).	• Description of the plant level management system.

Notes:

1. Class 1 ESR/DSR will include detailed engineering investigation, analysis and modelling, verification of calculations using best practice models and codes, Failure Modes and Effects Analysis (FMEA), transient analysis and calculation of margins.
2. Class 2 ESR/DSR includes the same basic considerations as Class 1 but engineering investigation, analysis and modelling will be more limited with the report essentially limited to transient analysis, FMEA and verification using best practice models and codes.

Conclusion

One of the recommendations arising from the independent safety review is that ANSTO develops and implements a deterministic safety assessment approach to its nuclear and radiological facilities as the primary safety analysis. In this way, the semi quantified risk assessment and PSA approaches can be used to support the deterministic approach in line with international best practice, including the demonstration of defence in depth. This note sets out possible options for the implementation of a deterministic approach including how this approach can be applied using the current ANSTO safety assessment methodologies.

Appendix E: Schedule of Recommendations

Recommendation No	Recommendation	Priority
R1.	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.	High
R2.	ANSTO senior management commits to regular engagement, dialogue and communication with ANSTO Health staff regarding future projects.	Area for Improvement
R3.	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.	High
R4.	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 are relevant.	High
R5.	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.	Medium
R6.	ANSTO should appoint an executive manager for safety who has nuclear competence and experience.	High
R7.	ANSTO needs to reflect further on how it deals with its licence holders and other authorized persons in terms of technical challenge.	Area for Improvement
R8.	The ANSTO PCSS function should find a way to more effectively deploy their resources in the arena of conflict resolution.	Area for Improvement
R9.	ANSTO should introduce a carefully considered walk-around policy and train its managers in how to do this effectively.	High
R10.	ANSTO should consider introducing 360 degree appraisals for its senior staff to ensure that the voice of subordinates is heard.	Low
R11.	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.	Medium
R12.	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	High

Recommendation No	Recommendation	Priority
	any specific incident or accident.	
R13.	ANSTO should ensure its incident investigations get to true root causes in the area of leadership and policy.	High
R14.	ANSTO needs to steer its reporting system in the right direction by identifying, celebrating and rewarding the most useful reports.	Medium
R15.	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.	High
R16.	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.	High
R17.	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.	Area for Improvement
R18.	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.	High
R19.	The development of 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.	High
R20.	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 of urgency.	Area for Improvement
R21.	Senior management and/or responsible person(s) should conduct an assessment of their individual department/section and identify posts required to perform each activity.	Medium
R22.	Each post should have a Role and Competency Profile (RCP) which includes clearly defined behavioural competencies, accountabilities, ownership and responsibilities. Senior	Area for Improvement

Recommendation No	Recommendation	Priority
	management should determine the competencies and resource necessary to carry out the activities of the organisation safely and shall provide them.	
R23.	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.	High
R24.	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.	Area for Improvement
R25.	The classification for change management of any physical change that 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.	Area for Improvement
R26.	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.	Medium
R27.	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.	Area for Improvement
R28.	A series of specific Safety Performance Indicators for ANSTO Health 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.	Low
R29.	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.	Medium
R30.	Nuclear safety management arrangements, as demonstrated within IAEA Safety Fundamentals, are implemented which should document the interface arrangements between ANSTO and ARPANSA.	Medium
R31.	WMSD risks for staff remaining in ANSTO Health should be controlled as a matter of urgency in order to ensure they are ALARP.	High

Recommendation No	Recommendation	Priority
R32.	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.	Medium
R33.	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.	High
R34.	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.	Medium
R35.	Staffing issues should be addressed to ensure all staff can take leave accordingly, without placing undue pressure on other employees.	Medium
R36.	Workloads should be reviewed and monitored and effectively managed during organisational change and controls to manage workload documented in the change management plan.	Medium
R37.	Architects, engineers and others designing or procuring modifications to ANSTO facilities and equipment should accommodate relevant human factors including anthropometric ranges.	Area for Improvement
R38.	A causal analysis approach should be used when investigating and responding to alleged poor workplace behaviour including bullying.	High
R39.	Unacceptable behaviours including allegations of bullying and harassment should be included in the incident register with the appropriate anonymity protections.	High
R40.	ANSTO should initiate a programme of active promotion of and adherence with the ANSTO whistleblowing procedures.	Area for Improvement
R41.	ANSTO Health should learn by exploring when things go right in ‘safety successes’ despite unexpected and challenging circumstances.	Area for Improvement
R42.	Training documents should be user-friendly and include explicit hazard warnings and cues in the text to alert operators around safety or quality issues.	Medium
R43.	Staff who have experienced harm arising from recent events should be offered easy access to appropriate support to assist their recovery.	Area for Improvement
R44.	ANSTO should develop suitable controls related to the procurement of systems performing a safety function which reflects their safety classification.	Medium
R45.	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	Area for Improvement

Recommendation No	Recommendation	Priority
	of all Category B proposals as part of the auditing function.	
R46.	All changes that 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.	Medium
R47.	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.	Area for improvement
R48.	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.	Area for Improvement
R49.	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.	Area for Improvement
R50.	ANSTO should examine how to ensure that true independence between authors and reviewers can be maintained for the “goodness” of the independent challenge function.	Medium
R51.	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.	Area for improvement
R52.	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.	High
R53.	Regulatory interactions should be included within the assurance and due process arrangements level documents.	Medium
R54.	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.	Low
R55.	ANSTO should investigate further the possibility of including Reg. 51 submissions within the definition of Category A for inherent risk.	Area for Improvement
R56.	ANSTO should examine the possibility of a differentiated categorisation system to define management and organisational changes and that the safety assurance and due process	Area for improvement

Recommendation No	Recommendation	Priority
	arrangements for organisational changes are set out and fully documented.	
R57.	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.	High
R58.	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.	Area for Improvement
R59.	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.	Area for Improvement
R60.	The safety case format documents should include a format for change/modification submissions.	Area for Improvement
R61.	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.	High
R62.	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.	Medium
R63.	The definitions, inputs and requirements associated with calculating inherent risk and residual risk should be made clear.	Area for improvement
R64.	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.	High
R65.	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.	Area for Improvement
R66.	The role of PSA should be clarified especially if the deterministic approach proposed earlier is adopted.	High
R67.	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.	High
R68.	The relative roles of ALARA and ALARP should be made clear in the procedures and guidance.	Area for Improvement
R69.	The SSC categorisation should be driven by deterministic safety demands rather than	High

Recommendation No	Recommendation	Priority
	probabilistic.	
R70.	The maintenance, inspection and test requirements for each facility should be formally documented from the safety analysis claims and supported by a suitable strategy.	Medium
R71.	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.	Medium
R72.	ANSTO risk reduction process should be made more robust and that the requirement for formal option studies included within the process as a specific requirement.	High
R73.	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.	Area for Improvement
R74.	The risk assessments involving operator errors should be re-examined to take into account human performance limiting values and dependencies.	Area for Improvement
R75.	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.	High
R76.	ANSTO should consider the production of a safety case manual/safety assessment handbook.	Low
R77.	ANSTO should include basic information about the health effects of radiation exposures within their radiation safety training modules.	Area for Improvement
R78.	ANSTO should implement a training scheme to include proper measurement of beta radiation for all RPS personnel.	Medium
R79.	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.	Medium
R80.	The ANSTO RPS roster staff to ensure health physics coverage when high risk activities are taking place.	High
R81.	ANSTO undertake an assessment and validation of the clearance procedure of high risk items, such as flasks, by non-health physics persons.	Area for Improvement
R82.	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	High

Recommendation No	Recommendation	Priority
	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.	
R83.	ANSTO review their procedures to ensure proper uses of physical units and amend them based on the review.	Area for Improvement
R84.	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.	Medium
R85.	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.	Medium

Appendix F: References

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