Australian Government

Australian Radiation Protection and Nuclear Safety Agency

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Statement of Reasons

Decision by the CEO of ARPANSA to amend Facility Licence F0309, issued to the Australian Nuclear Science and Technology Organisation (ANSTO) to operate the ANSTO Nuclear Medicine (ANM) Facility

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R19/05763

May 2019

This Statement of Reasons does not form part of Facility Licence F0309

In the event of any inconsistency between the licence and this statement of reasons Facility Licence F0309 will prevail

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1. Decision to amend Facility Licence F0309

Under section 36(2) of the *Australian Radiation Protection and Nuclear Safety Act 1998*[1] (the Act), I decided to amend Facility Licence F0309 on 24 May 2019. The amendment enables the Australian Nuclear Science and Technology Organisation (ANSTO) to commence routine production of molybdenum-99 (Mo-99) in the ANSTO Nuclear Medicine Facility (the *ANM Facility*) for the domestic and international markets.

2. Background

On 12 April 2018 I issued Facility Licence F0309, authorising ANSTO to:

Operate a controlled facility being a nuclear installation, namely the ANSTO Nuclear Medicine Mo-99 Facility (the *ANM Facility*) located at the Lucas Heights Science and Technology Centre in New South Wales.

The licence authorised ANSTO to use irradiated uranium target plates in the *ANM Facility* for the purpose of 'hot' commissioning of the facility. A minor amendment was made to Schedule 1B of the licence on 23 August 2018.

Routine operations for supplying nuclear medicine to the Australian and international markets were not authorised. Under section 35(1)(c) of the Act I specified minimum requirements for moving to routine operations in Licence Condition 8 (LC8).

ANSTO has subsequently completed and evaluated a number of hot commissioning tests and taken other actions to address LC8. On 12 March 2019 ANSTO applied under section 63 of the Australian Radiation Protection and Nuclear Safety Regulations 2018[2] (the Regulations) for LC8 to be removed.

On 20 March 2019 while ARPANSA was in the process of reviewing and assessing the abovementioned application ANSTO submitted an urgent request in the form of an application under section 63 of the Regulations to carry out 30 production runs over a six-week period in the *ANM Facility*. The urgency was driven by the failing hydrogen convertors in the existing Mo-99 production facility in Building 54 and ANSTO's desire to mitigate risks of disruptions in Mo-99 production and delivery. This would have exposed ANSTO to the risk of having to shut down Mo-99 production altogether, which would impact on planned nuclear medicine procedures both domestically and overseas.

With regard to the urgent submission, I noted the following[3]:

> *The issue before me is whether a limited number of production runs in the ANM Facility, for the purpose of maintaining or restoring the capacity to supply nuclear medicine to the market, can be authorised while LC8 remains in force; i.e., whether I can be reasonably assured that a limited number of production runs can be carried out safely before I have formed a final view on whether or not LC8 can be removed.*

[1] https://www.legislation.gov.au/Series/C2004A00383

[2] The Regulations were remade in December 2018, superseding the 1999 Regulations. Section 63 of the new Regulations corresponds to regulation 51 in the Regulations from 1999. See https://www.legislation.gov.au/Details/F2018L01694

[3] Statement of Reasons, https://www.arpansa.gov.au/news/arpansa-authorises-limited-production-molybdenum-99-anm-facility

ARPANSA handled the request with priority and on 2 April 2019, I issued an amended Facility Licence F0309 to authorise 30 production runs in the *ANM Facility*, subject to conditions including prior notification on staffing arrangements on a weekly basis and fortnightly reports on operational experience (see section 5). I did not consider it necessary to limit the time during which the 30 production runs could be carried out. ANSTO commenced production in the *ANM Facility* on the day the licence was issued.

In my Statement of Reasons, I noted that:

> *It should be understood that authorisation of 30 production runs as per this decision does not constitute pre-approval of removal of LC8, and that production of Mo-99 in the ANM Facility beyond what is authorised in this decision will be contingent on removal of LC8 and subject to conditions issued at that time.*

ARPANSA has subsequently concluded the review of ANSTO's request to remove LC8.

2.1 Purpose and scope of this statement of reasons

This Statement of Reasons documents the reasoning underpinning my decision to amend Facility Licence F0309 with the effect that routine operations can commence.

The Statement of Reasons focuses on whether all elements of LC8 "*have been actioned to the satisfaction of the CEO of ARPANSA*" (*cf*. LC8(l)). It also documents the reasoning behind other amendments to the licence conditions.

Most importantly, this Statement of Reasons considers whether ANSTO's actions since hot commissioning was authorised in April 2018, and the submitted documentation, provide reasonable assurance that routine operations can be carried out safely.

3. Reaching the decision

The evidence and documentation underpinning my decision to amend Facility Licence F0309 include:

- the documentation submitted by ANSTO
- the assessment and verification performed by ARPANSA officers[4] as documented in the Regulatory Assessment Report
- my earlier decisions in relation to ANSTO's applications for a licence to **prepare a site** for, to **construct** and to **operate** the *ANM Facility*[5].

ARPANSA officers performed site visits, held meetings with ANSTO staff, observed hot commissioning tests and observed an emergency response exercise, as part of the regulatory review and assessment. A meeting was held between ARPANSA and ANSTO at the Chief Executive and Senior Executive levels on 8 February 2019, to seek further clarification on details of ANSTO's documentation in relation to the different elements

[4] Mr James Scott, Dr Samir Sarkar, Mr John Templeton, Mr Vaz Mottl, Mr John Ward, Mr Loch Castle and Dr Marcus Grzechnik contributed to the review and assessment. Mr Martin Reynolds, General Counsel, and Ms Gemma Larkins, Legal Officer, reviewed the Statement of Reasons and the licence.

[5] https://www.arpansa.gov.au/search/ANM%20Facility

of LC8. A meeting that among other things addressed licence applications and submissions was held on 27 February 2019 under the terms of the ANSTO – ARPANSA Liaison Forum[6].

The Nuclear Safety Committee[7] contributed significantly to discussions concerning the evidence required to underpin the decision to authorise hot commissioning. For the decision covered in this Statement of Reasons, the Committee was kept informed but was not requested to provide specific advice. However, the Committee recently[8] did discuss and provide advice in relation to safety practices at ANSTO Health, which also has relevance for the *ANM Facility*.

Section 53 of the Regulations specifies matters I must take into account in deciding whether to issue a facility licence. All of these matters were considered in the Statement of Reasons supporting the authorisations to **prepare a site** for, to **construct** and to **operate** the *ANM Facility*. However, they remain relevant for the licence amendment covered here. They are considered in section 7 of this Statement of Reasons.

I am required under section 15(2) of the Act to take all reasonable steps to avoid any conflict of interest between my regulatory functions and my other statutory functions, a responsibility that also applies to all ARPANSA officers. In reaching my decision, I have not taken into account or given any weight to any aspect of the amendment of the licence to **operate** the *ANM Facility* that could potentially benefit ARPANSA. I am satisfied that no matter which has been considered in reaching my decision conflicts – or could be perceived to conflict – with the performance of my other statutory functions. All ARPANSA officers make annual declarations of any material personal interests that could potentially conflict with their duties; ARPANSA's General Counsel makes the final determination of whether a conflict exists or may be perceived, and what risk mitigation strategies should be put in place, if any. No interest has been declared or identified that may conflict with the matters to be taken into account in reaching this decision. On this matter, see *Regulatory intersections with other functions* on ARPANSA's website[9].

4. Licence Condition 8

Sections 4.1 to 4.8 summarise my considerations in relation to whether the actions taken by ANSTO satisfy LC8 of Facility Licence F0309.

4.1 Licence condition 8(a)

> ***LC8****. Operations for the stated purpose of the facility (routine operations) must not commence until:*
>
> *(a) the structures, components, systems, material, equipment and processes have been tested using irradiated target plates in accordance with the approved program for 'hot' commissioning, and the test results have been analysed.*

The licence to **operate** the *ANM Facility* issued on 12 April 2018 authorised ANSTO to commence 'hot' commissioning. This involves extraction of Mo-99 from uranium targets that have been irradiated in the OPAL reactor, i.e. activities akin to routine operations. It also enabled testing of product quality in

[6] https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-licence-holders/ansto-arpansa-liaison-forum

[7] https://www.arpansa.gov.au/about-us/advisory-council-and-committees/nuclear-safety-committee.

[8] https://www.arpansa.gov.au/sites/default/files/nsc_minutes_15_march_2019.pdf

[9] https://www.arpansa.gov.au/regulation-and-licensing/regulation/our-regulatory-services/regulatory-intersection-other functions

preparation for seeking product approval (outside of ARPANSA's mandate; the Therapeutic Good Administration issues approvals valid for the Australian and New Zealand markets).

However, LC 8(a) specifies that routine operations may only commence after the facility is *fully* commissioned, *including* hot commissioning, and the complete set of commissioning results provide reasonable assurance of safe operations of the facility including its structures, components, systems, material, equipment and processes.

4.1.1 Overview of actions and documentation

ANSTO conducted 27 runs under the licence issued on 12 April 2018 to commission the *ANM Facility* using target plates that had been irradiated in the OPAL reactor, and to carry out product testing. The results from the hot commissioning tests are summarised in:

- *ANM Mo99 project, Hot Commissioning Report Mo-99 Production Process (Mo99_COMM-PROC-ER_8243*). This report documents the records from five runs using targets that had been subjected to different irradiation regimes, termed 'low' (two days of irradiation) and 'high' (5 or 10 days of irradiation) activity runs, for testing the safety related systems and production process. It provides detailed records of experience gained and issues identified relevant to product quality, yield, consistency, key operational parameters, radiation levels, staff training, etc. and how identified issues with the manufacturing process and the product had been resolved.

  The report records that ANSTO are satisfied with the operations, based on the test results, and are satisfied that nuclear and radiological safety has been demonstrated.

- *ANM Mo99 Facility, Hot Commissioning Report of Safety Related Systems (Mo99_COMM-SAFE_ER_8197*). The report specifically deals with nine safety related items of direct relevance for the hot commissioning stage. Outstanding issues remained, at the time of submission of the report, regarding three of these items. However, these outstanding items were appropriately addressed by the time the regulatory assessment of the application to remove LC8 was completed.

ANSTO has submitted documentation regarding radiation monitoring in Building 88 and in the Building 2 QC laboratory. Issues identified with localised radiation fields close to the windows of the hot cells have been rectified.

The documentation is detailed and comprehensive. ARPANSA's review of the documentation as well as observations made on site during commissioning, confirm ANSTO's view that the design intent, after a number of minor modifications, has been met.

At the time of this decision a total of 16 production runs have been carried out in the *ANM Facility* under the 'limited' authorisation granted on 2 April 2019. Four fortnightly reports have been received. No safety significant event has been reported in those fortnightly reports or has otherwise come to ARPANSA's attention.

ARPANSA officers have come to the conclusion, and I concur, that structures, components, systems, material, equipment and processes have, in the approved program for hot commissioning, performed as intended.

4.1.2 Conclusion

Licence condition 8(a) can be removed

4.2 Licence conditions 8(b) and 8(j)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(b) the licence holder has demonstrated operational readiness in terms of staffing numbers, competence, training, arrangements for emergency preparedness and response, and provisions for safe and secure production of Mo-99 in both Building 54 and in the ANM Facility during the initial phase of routine operations of the ANM Facility

(j) the licence holder has provided a plan for phasing out routine Mo-99 production in Building 54

The *ANM Facility* is intended to replace the current Mo-99 production facility in Building 54. However, concurrent production of Mo-99 in Building 54 and in the *ANM Facility* is foreseen during a transition phase. ANSTO refers to this phase as 'tandem operations' during which staff will be trained and gradually transitioned to the *ANM Facility*.

The Statement of Reasons supporting my decision to authorise ANSTO to **operate** the *ANM Facility* noted that during tandem operations, safety must be maintained for two production facilities by sharing experienced and trained staff and a number of other resources including services provided by other parts of ANSTO. I therefore considered it prudent to cap the combined production during tandem operations; this cap was set at the production level in Building 54 at the time of the decision. This is covered under LC9 and is further detailed in section 5 of this Statement of Reasons.

The licence issued on 12 April 2018 acknowledged that Building 54 could be maintained in an operational state after completion of transitioning. This was captured in LC10, see section 6 of this Statement of Reasons.

4.2.1 Overview of actions and documentation

The original *ANM Staffing Transition Plan P-50603* submitted with the application under section 63 of the Regulations soon became obsolete. In reality, the time available for transitioning has become considerably shorter than the 5 – 6 months originally envisaged. It is ARPANSA's understanding that ANSTO has no intention of continuing Mo-99 in Building 54 beyond 30 June 2019, which effectively limits the transitioning period and period of tandem operations to less than three months when counting also production under the terms of the 'limited' licence issued on 2 April 2019. ANSTO has informed relevant overseas customers of its inability to supply Mo-99 generated in the *ANM Facility* until product approval has been granted, and that planned cessation of production in Building 54 may lead to a temporary halt in supply of nuclear medicine to some of those customers.

As already noted, a modified transition program has been implemented through the decision to authorise limited production while LC8 is still in force. ARPANSA has confirmed that staffing at the *ANM Facility* during those production runs in all cases has included a minimum of two accredited operators, in accordance with the Operational Limits and Conditions (OLC) for the facility.

An updated transition plan (P-50603) was submitted on 15 April 2019. ARPANSA has reviewed the transition plan and other relevant documentation regarding rosters, position descriptions and training records for staff in Building 88 and the QC laboratory in Building 2. ARPANSA concludes that the number of staff with completed training satisfies the needs for production runs at the current level and could sustain an increase in production above current levels.

Documentation with regard to safe and secure operations, and for emergency preparedness and response, for the *ANM Facility* and the Building 2 QC laboratory has been reviewed and considered satisfactory. An emergency response exercise was observed under LC8(i) as described in section 4.6 of this Statement of Reasons.

I conclude that ARPANSA's review and assessment of transitioning arrangements and operational experience from the limited number of production runs authorised on 2 April 2019 provide reasonable assurance with regard to readiness to carry out safe operations and satisfy LC8(b).

Licence condition 8(j) is considered in this section as it is relevant to the transition of production from Building 54 to the *ANM Facility*. The original transition plan (P-50603, now obsolete) was predicated on complete cessation of production in Building 54 by mid-2019, which is also when the safety case for Mo-99 production in Building 54 would need to be updated. While ANSTO has stated their commitment to cease Mo-99 production in Building 54 no later than 30 June 2019, ARPANSA has also been advised that Building 54 may be repurposed in the future while maintaining capability for Mo-99 as an 'emergency' fall-back position. Such repurposing and/or 'emergency' production capability would require amendment of Facility Licence F0262 issued to ANSTO Health or potentially a new licence. ARPANSA has not received any requests for amendment or a new licence. I conclude that circumstances have changed since April 2018 to the extent that LC8(j) is no longer relevant.

4.2.2 Conclusions

Licence conditions 8(b) and 8(j) can be removed

4.3 Licence condition 8(c)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(c) the licence holder has developed plans for possess and control of the facility in case operations have to be discontinued for other than planned or short-term unplanned outages

Short to medium term outages for the purpose of maintenance, repair or upgrade can be made while maintaining all safety functions for an operating facility. For extended periods of care and maintenance before commencement of authorised operations, during extended planned or unplanned outages while maintaining the intention to resume operations, and after termination of operations; new arrangements may have to be put in place to retain and train staff, prevent degradation of safety culture, maintain integrity of systems, structures, components and equipment, and maintain controlled material in a safe state and in safe storage. A decision has to be taken on the long-term management goal; this may range from starting (or resuming) normal operations to decommissioning and dismantling.

Arrangements for care and maintenance under such circumstances, in particular if they require new or amended controls, should be covered under a **possess or control** licence. ARPANSA has developed regulatory guidance for applicants for a **possess or control** licence[10]. Note that decommissioning cannot take place under a **possess or control** licence, only under a **decommissioning** licence.

[10] See https://www.arpansa.gov.au/sites/default/files/legacy/pubs/regulatory/guides/REG-LA-SUP-240X.pdf

Subsequent to issuing ANSTO with the licence to **operate** the *ANM Facility*, ARPANSA hosted an Integrated Regulatory Review Service[11] (IRRS) coordinated by the International Atomic Energy Agency (IAEA), including a two-week review mission to Australia that took place 5 – 16 November 2018[12]. The review team suggested that:

> *ARPANSA should consider revising the regulation and guidance for licensing of research reactors to include extended shutdown and associated submission requirements.*

Although this recommendation was specifically aimed at research reactors, I note that the *ANM Facility* is a *nuclear installation* under the Act and akin to *nuclear fuel cycle facilities* as recognised by IAEA[13]. I consider LC8(c) reflects international best practice for facilities of this nature.

4.3.1 Overview of actions and documentation

In response to LC8(c), ANSTO submitted *P50634 Revision 2 – Procedure for Control of ANM Mo-99 Facility (Building 88) during long term outages.* The procedure takes effect when a determination has been made that the facility will not be operated for 12 months or longer. Other outages are envisaged to be covered by the safety arrangements that govern normal operations.

ARPANSA officers have observed that the procedure is a 'top level' document, which lacks specificity. However, it could also be argued that the circumstances that justify transitioning into possess or control status are varied and procedures should therefore remain general.

ARPANSA's review has not identified any safety issues with the approach chosen by ANSTO.

4.3.2 Conclusion

Licence condition 8(c) can be removed

4.4 Licence conditions 8(d) – (e)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(d) the licence holder has defined a dose constraint for occupational exposures to radiation in the ANM Facility and in the Building 2 QC Active Laboratory, provided an analysis of optimisation of radiation protection that outlines how different options have been evaluated in order to manage radiation risks, and provided a plan including a time-line for implementation of reasonable measures to reduce the radiation exposures, the number of exposed individuals and the likelihood of exposures

(e) the licence holder has analysed automation of the QC procedure for high activity Mo-99 liquid samples as part of the optimisation under (d)

[11] An IRRS is a peer review of an IAEA Member State's infrastructure for safety, benchmarked against the IAEA safety standards. See https://www-pub.iaea.org/MTCD/Publications/PDF/SVS-37web.pdf

[12] The IRRS Mission Report is available at https://www.arpansa.gov.au/regulation-and-licensing/regulation/independence/independent-review-of-regulatory-activities/integrated-regulatory-review-service

[13] *Safety of Nuclear Fuel Cycle Facilities.* Specific Safety Requirements No. SSR-4 (IAEA 2017); https://www-pub.iaea.org/books/iaeabooks/12216/Safety-of-Nuclear-Fuel-Cycle-Facilities

Monitoring of radiation exposures of workers involved in production of nuclear medicine at ANSTO Health (including Building 54) demonstrates generally low doses. However, some procedures, for instance quality control of high activity liquid Mo-99 samples, require some manual handling where there is potential for significant radiation exposures of the skin, hands, extremities and eyes should an event occur during the process.

Protection must be optimised taking into account exposures of individuals, the number of people exposed, and the likelihood of exposure. The Statement of Reasons supporting my decision of 12 April 2018 quoted with regard to optimisation, the International Commission on Radiological Protection (ICRP)[14]:

> *Optimisation is always aimed at achieving the best level of protection under the prevailing circumstances through an ongoing, iterative process that involves:*
>
> - *evaluation of the exposure situation, including any potential exposures (the framing of the process);*
> - *selection of an appropriate value for the constraint or reference level;*
> - *identification of the possible protection options;*
> - *selection of the best option under the prevailing circumstances; and*
> - *implementation of the selected option.*

Optimisation is guided by dose constraints that help eliminate options that lead to unacceptable exposures and focus attention on options that provide for cost-effective protection measures.

The Radiation Protection Plan submitted with the application to operate the *ANM Facility* did not consider facility-specific dose constraints for optimisation of worker protection in the *ANM Facility*. It was, however, recognised by ANSTO that specific dose constraints and a more holistic approach to optimisation was desirable. LC8(d) formalised ARPANSA's expectations on an improved approach to optimisation of protection.

An accident during a QC procedure in 2017[15] led to exposure of the skin of the hands of a QC analyst causing tissue reactions consistent with a localised skin dose of about 20 gray (Gy), or 40 times the annual dose limit[16]. This was a routine operation and no (documented) action had been taken to implement critical controls for prevention or mitigation of consequences, despite such controls being available. Although the event must be considered of low probability (several thousand of these QC procedures have been carried out without any major event having been brought to the attention of ARPANSA), the potential consequence is such that the procedure should be avoided and/or the consequences reduced through redesign of the procedure. LC8(e) required ANSTO to investigate automation of QC procedures of this nature for optimisation of protection.

4.4.1 Overview of actions and documentation

In response to LC8(d), ANSTO has updated the Radiation Protection Plan and introduced specific dose constraints for different worker categories in Building 88 and Building 2 QC laboratory. ANSTO has included

[14] Paragraph 214 of ICRP *Publication 103*, https://journals.sagepub.com/doi/pdf/10.1177/ANIB_37_2-4

[15] https://www.arpansa.gov.au/about-us/corporate-publications/reports-parliament/report-parliament-radiation-exposure-worker-ansto

[16] The annual limit for equivalent dose to the skin is 0.5 sievert (Sv), measured over any 1 cm^2 of skin exposed.

experience from the hot commissioning runs (including QC) and experience from Building 54 in the analysis. The dose constraints are in all cases below the 2 mSv annual effective dose that earlier was used as a site-wide 'ALARA objective' and are in some cases fairly close to the projected doses for the identified worker categories. ANSTO intends to review the dose constraints on a regular basis, informed by operational experience and aims for further dose reductions below the selected constraint. I consider the constraints to be appropriately set.

The Radiation Protection Plan and associated documents, e.g. the ANSTO Radiation Safety Standard, demonstrate an improved approach to optimisation. Overall, I consider the actions taken with regard to optimisation satisfy LC8(d).

ANSTO has taken action to increase safety of the QC procedure for high-activity liquid samples. A four-stage development and implementation process has commenced involving:

(i) simplification and automation of the process for opening vials containing high-activity samples which significantly reduces the likelihood of contamination events (*implemented*)

(ii) reconfiguration of fume cupboards to eliminate the need to move samples in and out of fume cupboards while they undergo testing (*in the process of implementation*)

(iii) improved automation including dispensation and dilution of samples (*in planning stage*)

(iv) designing and furnishing a purpose-built QC laboratory within Building 88 thus eliminating the need for transferring samples to Building 2 (*timing of implementation yet to be determined*)

ARPANSA officers have assessed that:

> *The documentation provided sufficient demonstration that the automation of the Mo-99 quality control process has been adequately considered, planned and implemented […] an acceptable design, which has met the risk assessment conclusions, was selected, developed and implemented.*

I consider the actions taken satisfy LC8(e).

4.4.2 Conclusion

Licence conditions 8(d)-(e) can be removed

4.5 Licence conditions 8(f) – (h)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(f) the licence holder has provided a plan, including times for completion of actions, based on the 28 recommendations of the risk assessments for the ANM Facility and the Building 2 QC Active Laboratory, and justification of alternative actions to achieve the same outcome in case such alternatives are preferred

(g) the licence holder has reassessed all scenarios that lead to 'moderate' or more severe consequences from the radiation protection perspective regardless of likelihood including "incredible" scenarios; and analysed opportunities to improve management of radiation risks through reducing the likelihood of an event leading to such consequences, or reducing the consequence should an event occur, or both

(h) the licence holder has reassessed the contribution of human factors to the likelihood of events occurring, and to the mitigation of risks, in the assessment under (g)

Licence Condition 8(f)-(h) are relevant to risk assessment and risk reduction including the need to appropriately consider human factors. The need for a revised approach to risk assessments had already been acknowledged by ANSTO following my finding ANSTO in breach of the Act in relation to the serious worker contamination event in 2017 (see section 4.4).

The risk assessment for the *ANM Facility* was the subject of significant regulatory review and was discussed among members of the Nuclear Safety Committee in the lead up to the licensing decision of 12 April 2018. An issue of concern was that a number of low probability scenarios were associated with potential exposures ranging from moderate (where statutory dose limits could be reached) to considerably more severe. Uncertainties in relation to probabilities for such scenarios should trigger actions to reduce the consequences of or - if possible - eliminate operations leading to such potential exposures.

While ARPANSA accepted ANSTO's reasoning for defining some scenarios as 'incredible', it was also concluded that the risk assessment did not sufficiently analyse the contribution of human factors to the likelihood of a safety significant event occurring.

During review of the application for authorisation to **operate** the *ANM Facility*, ARPANSA received revision 2 of the operational risk assessment for Building 88. It included 14 recommendations aimed at managing risks. ANSTO also submitted a revised risk assessment for the QC procedures carried out in Building 2; this risk assessment contained another 14 recommendations. Only one recommendation specifically addressed human factors. I considered a further analysis should take place regarding the contribution of human factors to the likelihood of events and how increased attention to such factors could contribute to lowering the overall risk.

4.5.1 Overview of actions and documentation

ANSTO has provided ARPANSA with a disposition plan for the 28 recommendations mentioned above; the actions are tracked in ANSTO's Governance and Risk Control System (GRC). It should also be noted that ANSTO has submitted revision 3 of both the *ANM Risk Assessment* and the *Risk Assessment of the B2 Quality Control Laboratory*. In a memorandum of 1 March 2019 ANSTO outlined its commitment to review and as appropriate revise the risk assessment process including increased emphasis on critical controls.

I am satisfied with the actions taken by ANSTO and I accept that a review and revision of the risk assessment process is a major undertaking that will require time. ARPANSA will monitor this work and I agree with the recommendation of ARPANSA officers that ARPANSA's expectations in this regard should be captured in a licence condition. This is further discussed in section 4.8.2. I conclude that LC8(f) has been properly addressed.

In response to LC8(g), ANSTO has revised 34 scenarios for the *ANM Facility* and four scenarios for the Building 2 QC Laboratory. These scenarios entailed moderate or more severe consequences but their likelihoods were assessed as low, resulting in a *low* overall risk. The approach used during reassessment is relevant and has considered likelihood, human error and consequences as well as critical controls. Operational experience has been considered and estimates of likelihood updated. ANSTO has also revised six scenarios with moderate or more severe consequences and with an assessed risk of *medium* or *high*. The scenarios relate to QC procedures in Building 2 resulting in potential skin exposures.

ARPANSA officers have reviewed a number of scenarios in detail. They are of the view that the estimates of risk have improved and the critical controls are appropriate. I agree and I am of the view that the actions and

documentation provided by ANSTO satisfy LC8(g) noting that the risk assessment methodology is subject to a new licence condition (section 4.8.2).

I am likewise inclined to conclude that ANSTO's updated risk assessments and ongoing work on an improved risk assessment process, which places increased attention on human factors, satisfy LC8(h). The updated risk assessment for the Building 2 QC laboratory has taken into account the contribution of human factors in relevant scenarios. A separate assessment has been carried out for Building 88. ARPANSA's review has not identified any significant weaknesses in the approach, noting that a full review and revision of the risk assessment procedure is ongoing and is captured under a new licence condition as detailed in section 4.8.2.

4.5.2 Conclusion

Licence conditions 8(f)-(h) can be removed

4.6 Licence condition 8(i)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(i) a field emergency response exercise, observed by ARPANSA, has been carried out by the licence holder based on a scenario agreed with ARPANSA that demonstrates that the emergency response arrangements are commensurate with emergency preparedness category II, and that the ANM Facility's arrangements interact in a satisfactory manner with emergency response arrangements implemented site-wide

As part of the review of ANSTO's application for authorisation to **operate** the *ANM Facility*, ANSTO's dose estimates for accident scenarios were independently verified by ARPANSA. Assumptions used in the calculations were cautious but not unrealistic.

In discussions between ANSTO and ARPANSA officers, ANSTO stated that there is a potential that protective actions may be justified under certain circumstances outside of the Lucas Heights Science and Technology Centre perimeter but not outside the 1.6 km residential buffer zone surrounding the site. ANSTO proposed that the appropriate *Emergency Preparedness Category* (EPC) for the *ANM Facility*, in accordance with the IAEA General Safety Requirements No. GSR Part 7[17], should be EPC II[18]. ARPANSA agreed with this categorisation, although it is reasonable to consider the facility being at the lower end of EPC II. ANSTO was required to plan and exercise its emergency response capabilities accordingly and demonstrate its capabilities to ARPANSA's satisfaction, before LC8(i) could be removed.

[17] *Preparedness and Response for a Nuclear or Radiological Emergency*, General Safety Requirements No. GSR Part 7, IAEA 2016. See https://www-pub.iaea.org/books/IAEABooks/10905/Preparedness-and-Response-for-a-Nuclear-or-Radiological-Emergency

[18] GSR Part 7 describe EPC II as follows: Facilities, such as some types of research reactor and nuclear reactors used to provide power for the propulsion of vessels (e.g. ships and submarines), for which on-site events are postulated that could give rise to doses to people off the site that would warrant urgent protective actions or early protective actions and other response actions to achieve the goals of emergency response in accordance with international standards, or for which such events have occurred in similar facilities. Category II (as opposed to category I) does not include facilities for which on-site events (including those not considered in the design) are postulated that could give rise to severe deterministic effects off the site, or for which such events have occurred in similar facilities.

4.6.1 Overview of actions and documentation

An emergency response exercise was planned in consultation with ARPANSA, using a scenario where a site-wide power outage had taken place resulting in total loss of power for Building 54 and the *ANM Facility*, including loss of communications within the *ANM Facility*. The exercise took place on 13 November 2018 and was observed by four ARPANSA officers. The IAEA Safety Guide No. GS-G-2.1[19] was used as reference for response actions and response times.

The ARPANSA observers commended the response to the scenario in relation to several of the criteria and identified areas where the response could be improved through further exercises. Feedback has been provided to ANSTO. Overall, ARPANSA officers considered the emergency response arrangements and capabilities to be commensurate with EPC II.

I note that ARPANSA will develop criteria or adopt internationally recognised criteria for evaluation of future licensee emergency exercises, in accordance with Recommendation 16 of the IRRS Mission Report[20]. However, I agree with the ARPANSA officers that the emergency exercise carried out on 13 November 2018 satisfies LC8(i).

4.6.2 Conclusion

Licence condition 8(i) can be removed

4.7 Licence condition 8(k)

***LC8**. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(k) the licence holder has reported any other observation or occurrence with significance for safety, not covered by (a) to (j) above

It was foreseen in my decision of 12 April 2018 that the hot commissioning tests, the analysis of compliance with LC8, or any relevant event with safety significance could reveal new issues that would require attention when considering the safety of routine operations.

4.7.1 Overview of actions and documentation

During the period since the licence to operate was issued, the following matters are worth noting:

1. A total of 26 events were recorded in the ANSTO GRC system during hot commissioning and were included in the quarterly reports to ARPANSA. The number and safety significance of these events do not give rise to concern, and their tracking and resolution demonstrate proper safety management.

[19] *Arrangements for Preparedness for a Nuclear or Radiological Emergency*, IAEA Safety Guide No. GS-G-2.1, IAEA 2007. See https://www-pub.iaea.org/MTCD/publications/PDF/Pub1265web.pdf

[20] Recommendation 16 states: ARPANSA should develop criteria for evaluation of licensee exercises, to include the exercises as part of the inspection process and ensure that licensees exercise all aspects of their emergency plan over an agreed period and in line with a graded approach.

2. My direction of 29 June 2018 to initiate an independent review of safety of processes and practices at ANSTO Health, the report of the independent review team, and ANSTO's action plan in relation to the 85 recommendations issued by the independent reviewers[21]. ARPANSA accepts that the actions identified in ANSTO's Implementation Plan will take months to a few years to complete. ANSTO's work in relation to the plan will be monitored by ARPANSA. The direction focused on ANSTO Health, in particular activities undertaken in Building 23. However, the recommendations have relevance for nuclear medicine production more broadly.
3. The storage tanks for intermediate level liquid waste in Building 54 were predicted to reach the authorised 90% of full capacity by mid-March 2019. In August 2018, ANSTO applied under what is now section 63 of the Regulations for liquid waste to be transferred to the storage tanks of the *ANM Facility*. The decision in relation to the application was put on hold awaiting the hot commissioning tests. On 13 February 2019, informed by the hot commissioning tests and having observed trial transfers using non-radioactive material, ARPANSA approved a limited transfer of intermediate level liquid waste from Building 54 to the *ANM Facility* to enable continued Mo-99 production. ANSTO's Radioactive Waste Management Plan has been updated accordingly.

Matters reviewed under points 1 and 3 do not materially challenge ARPANSA's understanding of safety of operations in the *ANM Facility.* The independent review of safety of activities in Building 23 (point 2) are discussed further in section 7. It is apparent that LC8(k) *per se* serves no further useful purpose.

4.7.2 Conclusion

Licence condition 8(k) can be removed

4.8 Licence condition 8(l)

LC8*. Operations for the stated purpose of the facility (routine operations) must not commence until:*

(l) (a) to (k) have been actioned to the satisfaction of the CEO of ARPANSA

4.8.1 Summary of conclusions regarding LC8(a)-(k)

ARPANSA's conclusions from the review and assessment of ANSTO's request to withdraw LC8 can be summarised as follows:

- LC8(a)-(e), (i) and (j) can be removed
- LC8(k) has served its purpose and can also be removed noting the need for proper attention to leadership and management for safety is further discussed in section 7
- ANSTO has addressed risk assessments in compliance with LC8(f)-(h). However, the work on risk assessments is long-term and not completed. While I am satisfied with the direction of ANSTO's work, I find it appropriate to formalise ARPANSA's expectations on this continued work in a new licence condition. The new licence condition replaces LC8(f)-(h), which can be removed.

The dot points above satisfy LC8(l) which can be removed, as can LC8 in its entirety.

[21] See https://www.arpansa.gov.au/about-us/corporate-publications/significant-regulatory-activities

4.8.2 Conclusions

Licence condition 8 can be removed

A *new* Licence Condition 8 is issued as follows:

> ***LC8.*** *The licence holder must systematically address the causes, inherent risks, critical controls, preventative and mitigating measures in the revised risk assessment of the ANM Facility. The revised risk assessment must also take into account human and organisational factors and the recommendations resulting from the previous risk assessment. The revised risk assessment of the ANM Facility must be submitted to the CEO by 30 April 2020 or at a time agreed by the CEO.*

5. Licence Condition 9

LC9*. Total Mo-99 production must be capped, and reported on, as follows:*

(a) during initial routine operations of the ANM Facility with simultaneous Mo-99 production in Building 54: the total production of Mo-99 must be capped at 2 400 six-day curie per week as a four-week average, and not increased beyond that level until production in Building 54 has ceased and operational experience of the ANM Facility provides evidence of safe operations

(b) notwithstanding the restriction on routine operations imposed by licence condition 8; the licence holder may carry out a total of no more than thirty production runs to compensate for planned outages or unplanned disruptions in the production of Mo-99 in Building 54, before removal of licence condition 8. The cap on total production remains as in 9(a)

(c) the licence holder must give ARPANSA prior notice of their intention to carry out production as specified in 9 (b) including information on weekly staffing arrangements for safe operations of the ANM Facility and, as relevant, Building 54

(d) the licence holder must for production specified under 9 (b) on a fortnightly basis, and within a week after the end of the preceding two-week period, provide ARPANSA with a report on operational experience in the ANM Facility highlighting any deviations to the process, manufacturing results, Health Physics measurements undertaken, noble gas emissions tracking, areas for improvement observed and event reporting

Licence condition 9 was amended to read as shown above on 2 April 2019 to allow no more than 30 production runs in the *ANM Facility* while LC8 remained in force (see section 2).

As LC8 has been removed, LC9(b)-(d) have become redundant.

Licence Condition 9(a) remains valid until Mo-99 production has ceased in Building 54. The amended licence condition reverts to the original wording from 12 April 2018.

Licence condition 9 is *amended* as follows:

> ***LC9****. During initial routine operations of the ANM Facility with simultaneous Mo-99 production in Building 54, the total production of Mo-99 must be capped at 2400 six-day curie per week as a four-week average, and not increased beyond that level until production in Building 54 has ceased and operational experience of the ANM Facility provides evidence of safe operations.*

6. Licence Condition 10

LC10. *For a period of 18 months after cessation of routine operations in Building 54, and contingent on ARPANSA's approval, Mo-99 production in Building 54 must only take place under special circumstances such as during short-term outages in the ANM Facility.*

The licence to operate the *ANM Facility* issued on 12 April 2018 took into account that ANSTO might wish to maintain operability of Building 54 beyond the period of tandem operations, to maintain production during temporary outages of the *ANM Facility* associated with maintenance and minor upgrades. This was captured in LC10.

This has now been overtaken by events. At the time of this decision, operations in Building 54 will continue for a limited time and ARPANSA has not received any submission in relation to future plans for Building 54. LC10 is now redundant and can be removed from Facility Licence F0309. Regulatory arrangements for Building 54 will be dealt with exclusively under Facility Licence F0262 (ANSTO Health).

Licence condition 10 can be removed

7. Matters identified in section 53 of the Regulations

Section 53 of the Regulations lists matters I must take into consideration when issuing a facility licence:

Sub-section	Matter to be taken into consideration	Comment
(a)	whether the application for the licence complies with subsection 46(1) of this instrument	Reviewed in decision of 12 April 2018. The updated Radiation Protection Plan and Radioactive Waste Management Plan are considered satisfactory for moving to routine operations.
(b)	whether the applicant for the licence has given the information asked for by the CEO	See section 7.1.
(c)	whether the application, together with the information (if any) given as described in paragraph (b), establishes that the conduct proposed to be authorised by the licence can be carried out without undue risk to the health and safety of people, and to the environment	See section 7.2.
(d)	whether the applicant has shown that there is a net benefit from carrying out the conduct proposed to be authorised by the licence	See section 7.3.
(e)	whether the applicant has shown that the magnitude of individual doses, the number of people exposed and the likelihood that exposure will happen are as low as reasonably achievable, having regard to economic and societal factors	See section 7.4.
(f)	whether the applicant has shown a capacity for complying with this instrument and the licence conditions that would be imposed under section 35 of the Act	See section 7.5.
(g)	whether the application has been signed by an office holder of the applicant, a person authorised by an office holder of the applicant or, if the licence is for a Commonwealth entity mentioned in section 45 of this instrument, someone described in paragraph (b) of that section	Signed by the CEO of ANSTO.
(h)	if the application is for a facility licence for a nuclear installation—the content of any submissions made by members of the public about the application	Reviewed in decision of 12 April 2018.

These matters were considered in my decision of 12 April 2018. However, they remain relevant in relation to authorising routine operations, in particular the matters outlined in section 53(b-f), discussed further below.

7.1 Section 53(b) *information submitted*

The ARPANSA officers are of the view that the information submitted in support of ANSTO's request to remove LC8 have enabled meaningful review and assessment. However, in some cases several iterations were necessary before the reviewers were satisfied that the documentation adequately met the intent of the conditions. This was communicated to ANSTO in the meeting between senior management of ARPANSA and ANSTO on 8 February 2019.

It was observed by ARPANSA, e.g. in relation to LC8(c) on **possess or control** licences (see section 4.2), that ANSTO's *Safety Assurance Committee* (SAC) correctly pointed out that the documentation developed by ANSTO had not properly addressed the licence condition. However, SAC subsequently accepted the documentation with no or minor changes although it still did not properly address the licence condition and no clarification was sought from ARPANSA. This points to a weakness in the operations of the SAC. This was communicated to ANSTO during the meeting on 8 February 2019. ARPANSA has received correspondence from ANSTO that a review of the SAC process is ongoing; I expect the rigour of the process to improve significantly and I encourage ANSTO to submit an application under section 63 of the Regulations regarding revised SAC operations, as soon as practicable.

The development and implementation of a new approach to safety assessments is a long-term commitment that cannot and should not be rushed. Full documentation is thus not yet available but has been requested under the newly issued LC8. I accept ANSTO's stated intentions and plans, and support recent and ongoing work aimed at improving the framework for safety assessments.

7.2 Section 53(c) *undue risk*

No new information has come to ARPANSA's attention that materially challenges the earlier conclusions regarding front-end safety (the OPAL reactor) or back-end safety (essentially waste management), noting that concerns remain around the longer term management of, in particular, intermediate level liquid waste (ILLW). The Federal Budget for the financial year 2019 – 2020 provides resources enabling ANSTO to continue construction of the *SyMo Facility* for treatment of ILLW; however, possible routine operations of the *SyMo Facility* is still several years away. Plans and commitments regarding final management of radioactive waste including disposal have been laid out in the Australian Radioactive Waste Management Framework[22], released in April 2018, but selection of a site(s) for future waste facilities, including for disposal of ILLW, are still pending. Uncertainties thus remain regarding waste management on site and regarding radioactive waste disposal. LC15 issued with the original licence on 12 April 2018 (now LC14) remains relevant:

[22] https://www.industry.gov.au/data-and-publications/australian-radioactive-waste-management-framework

***LC15**. The licence holder must by 30 June 2020 provide a report on*

(a) holdings of intermediate level liquid waste (ILLW) at the ANM Facility

(b) projected future generation of ILLW at the facility

(c) plans for treatment of the ILLW generated at the facility including projected treatment in the SyMo Facility

(d) plans for storage and disposal of the ILLW that take into account the national policy and plans for full life-cycle management of radioactive waste

(e) contingency plans should one or several components of the ILLW management system not eventuate or fail.

Regarding operations of the *ANM Facility*, hot commissioning tests have been carried out and evaluated, and have demonstrated that the design intent with respect to safety has been met (section 4.1). ARPANSA is not aware of any event with significant safety implications during the small number of production runs that have been carried out under the limited authorisation issued on 2 April 2019. The plans and arrangements for safety have in relevant parts been updated and the emergency preparedness and response arrangements and capabilities are commensurate with the hazard posed by the facility.

Transitioning of Mo-99 production from Building 54 to a modern facility and other measures including more stringent radiation protection controls, contribute to lowering the radiation risks associated with Mo-99 production.

Notwithstanding reservations regarding back-end arrangements, which remain essentially unchanged since April 2018, the information before me provides reasonable assurance that the *ANM Facility*, including the Building 2 QC laboratory, can be operated without undue risk to the health and safety of people and to the environment. Waste management remains a concern in the medium to longer term but is manageable for several years from now.

7.3 Section 53(d) *net benefit*

A very large number of nuclear medicine procedures based on Mo-99/Tc-99m technology are carried out world-wide each year that facilitate treatment of cancer and a variety of other conditions. The direct (for the patient) and indirect (for carers, family and the society more broadly) benefit is significant.

In August 2018 the OECD Nuclear Energy Agency (NEA) published its 2018 – 2023 outlook for global demand and supply of Mo-99/Tc-99m[23]. The report updates the forecast for 2017 – 2022, quoted in my Statement of Reasons of 12 April 2018. It projects a slightly increased global demand (now estimated at 9400 six-day curie per week). For the conservative 'base scenario' it indicates that the supply capacity approximately corresponds to the demand plus the desired 'outage excess capacity' (OEC). The OEC is set at 35% of the projected demand to safeguard against shortages in supply, should one or more supplier(s) be forced to reduce, or cease, production. However, NEA considers it possible that the *actual* OEC is less than the desired 35%. Overall, uncertainties remain high but data do not suggest insufficient capacity for Mo-99 production and Tc-99m generation globally over the period 2018 - 2023.

The updated projections indicate that the role of the *ANM Facility* in the global supply of Mo-99/Tc-99m is largely unchanged since my decision to authorise ANSTO to **operate** the *ANM Facility* on 12 April 2018. However, I wrote in my Statement of Reasons from 12 April 2018:

[23] See http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=NEA/SEN/HLGMR(2018)3&docLanguage=En.

> *[…] a national capability for production of Mo-99, such as offered by the ANM Facility, provides some assurance that the Australian demand for these substances can be sustained at times when the global supply may be insufficient and the national demand cannot with certainty be sustained through importation.*

I consider the risks associated with routine operations to be low and the waste management issues manageable over several years to come. It is reasonable to conclude that the benefit of the *ANM Facility* outweighs the risks, with the caveat that long-term safety is contingent on implementation of the Australian Radioactive Waste Management Framework in a timely manner. See also next section on optimisation.

7.4 Section 53(e) *optimisation*

Since April 2018, ANSTO has substantially revised its approach to optimisation, including establishing realistic and appropriate dose constraints for a number of worker categories (see section 4.4).

No new information has come to light that challenges the earlier conclusion that exposures of workers under normal circumstances would remain low. The operations in Building 88 are highly automated and require minimal physical operator interaction with active material. Quality control (QC) still requires handling of active samples with the potential for contact exposure. However, ARPANSA officers are satisfied that the equipment and processes being designed and implemented for QC work in Building 2 and ergonomic considerations will reduce radiation risks associated with QC procedures.

Exposures of members of the public, and in the environment, resulting from routine operations would be insignificant. ANSTO has also demonstrated readiness to manage emergencies at the *ANM Facility*. ARPANSA's reviewers have confirmed that ANSTO has systems and capabilities in place to deal with an emergency and keep the workforce safe. The risks to members of the public and the environment are very small.

7.5 Section 53(f) *capacity to comply*

Section 53(f) of the Regulations requires me to consider "*whether the applicant has shown a capacity for complying with this instrument and the licence conditions that would be imposed under section 35 of the Act".*

The Statement of Reasons of 12 April 2018 included a brief overview of failures to comply with licence conditions leading to breaches of section 30(2) of the Act. The overview focused on the OPAL reactor and ANSTO Health. It included the serious overexposure of a QC analyst at ANSTO Health in August 2017 which was reported as INES[24] Level 3. The event informed several sub-conditions under the umbrella of LC8.

A further three events with safety significance occurred in Building 23 subsequent to the overexposure and were considered to be breaches of section 30(2) of the Act for failing to comply with licence conditions. On 29 June 2018, informed by the series of four events that occurred since August 2017, I issued a direction to

[24] The International Nuclear and Radiological Event Scale (INES) is a tool for communicating the safety significance of nuclear and radiological events to the public. Reporting is voluntary. See https://www.iaea.org/topics/emergency-preparedness-and-response-epr/international-nuclear-radiological-event-scale-ines

ANSTO to take immediate steps to initiate an independent review of safety practices in Building 23. No further breaches have been found since mid-2018.

The independent review which outlined 85 recommendations was submitted to ARPANSA on 5 October 2018[25]. ANSTO subsequently developed an action plan listing over 160 actions to address the recommendations which ARPANSA received on 4 December 2018. On 19 December 2018 I encouraged ANSTO to commence implementation of the actions although I did not formally approve the plan as it lacked strategic intent and direction in several of the programs of work that had been established to address the recommendations of the independent review. Following several iterations, the plan is now much improved; however, at the time of this decision ANSTO staff are still consulting with ARPANSA, six months after the first plan was submitted, regarding details of the planned actions.

I understand ANSTO's desire, which also resonates with the independent review, to put forward a case for replacement of the ageing Building 23. However, in my opinion, none of the events with implications for safety that led to the direction to ANSTO of 29 June 2018 were related to the age of the facility. With appropriate resourcing and management, work practices in Building 23 could have and should have been safe.

The events recounted above specifically concern practices in Building 23 under the ANSTO Health licence (Facility Licence F0262). However, it is reasonable to expect ANSTO to take the observations and recommendations from the independent review into account across all areas of nuclear medicine production, as relevant. In my 2 April 2019 decision on 'limited' authorisation of production runs at the *ANM Facility*, I wrote:

> *At minimum, I would have expected a stated intention to consider and, as appropriate, implement learnings from the independent review report. The production imperative must never even be possible to perceive to be overtaking the safety imperative, consistent with ANSTO's own plans and arrangements for safety.*

The success of ANSTO's actions in response to the independent review will ultimately depend on the approach it takes to leadership and management for safety including *safety culture*. The issue is not new; as a matter of fact it was considered a serious issue in radiopharmaceuticals production at ANSTO ten years ago. My conclusion from ARPANSA's compliance monitoring and from the independent review is that issues remain.

In my decision of 2 April 2019 I also wrote:

> *There should in my opinion be little doubt that ANSTO has capacity to comply with the Act, the Regulations and licence conditions imposed by the CEO of ARPANSA. Recent events have, however, called into question whether this capacity has always been utilised to the best effect in relation to production of nuclear medicine.*

I have no reason to doubt the commitment of the ANSTO executives to action. The draft ANSTO Health Implementation Plan developed in response to the independent review lists actions that address such cultural traits as *effective behaviour in the workplace; identifying and strengthening safety culture in ANSTO Health*; and *modification to the safety assurance process*. I also acknowledge that ANSTO has achieved

[25] https://www.arpansa.gov.au/news/arpansa-receives-report-independent-review-team-ansto-approach-safety

certification of its Work Health & Safety Management System to the ISO 45001:2018 standard, in December 2018. The scope includes ANSTO activities *to produce and use radioisotopes, isotopic techniques and nuclear radiation for medicine, science, industry, commerce and agriculture*. The *ANM Facility* is not formally covered by the certification but is subject to the same WH&S Management System. ANSTO has stated its intent to achieve certification for the facility as soon as practicable.

The challenge, however, is to achieve real and lasting change that penetrates the whole organisation. Commissioner Hayne, in his investigation into the financial services sector[26], concluded that enforcement actions taken by the regulator had not led to the desired admissions of wrongdoing among regulated entities, which could have led to profound and lasting change. In essence, it is a question of whether the licence holder takes actions that satisfy the *letters* of the enforcement action; ***or*** achieve changes that respond to the *intent* of the enforcement action. The latter requires admissions of failure and full appreciation of the need to address systemic issues including *culture*.

As the regulatory body, ARPANSA must consider why safety culture issues persist, despite having been observed intermittently for a decade. Effective regulation requires appropriate use of enforcement and compliance monitoring that leads to genuine and durable change. ARPANSA is reviewing the approach to compliance monitoring and enforcement with the view of strengthening its effectiveness. ARPANSA's most recent report[27] under the Australian Government's Regulator Performance Framework[28] (RPF) stated the need to go beyond the RPF in monitoring regulatory outcomes in relation to safety, i.e. to monitor and strengthen the *effectiveness* in achieving the object of the Act, being *to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation*.

I have chosen to not place a specific licence condition on review(s) of safety culture at the *ANM Facility* at this point in time. ARPANSA's approach and any necessary enforcement actions in relation to safety culture of radiopharmaceutical production will be determined by ARPANSA's assessment of ANSTO's commitment and effectiveness in implementing actions in response to the independent review, and by ARPANSA's own compliance monitoring. Site-wide regulatory requirements on measures to promote safety culture are likely to be considered in the near future.

8. Conclusions and summary of amendments

As stated in section 2.2 on scope and purpose of this Statement of Reasons:

> *Most importantly, this Statement of Reasons considers whether ANSTO's actions since hot commissioning was authorised in April 2018 and the submitted documentation provide reasonable assurance that routine operations can be carried out safely.*

The main challenges to sustained safe operations of the *ANM Facility* are (directly) related to safety culture and (indirectly) to waste management. These two challenges have been given prominence in this decision as well as in the decision of 12 April 2018. In this concluding section it is sufficient to reiterate that both are

[26] The Final Report of the *Royal Commission into Misconduct in the Banking, Superannuation and Financial Services Industry,* led by Commissioner Kenneth M Hayne AC QC, was tabled in Parliament on 4 February 2019. The Report is available at https://financialservices.royalcommission.gov.au/Pages/default.aspx

[27] https://docs.jobs.gov.au/documents/regulator-performance-framework

[28] https://www.arpansa.gov.au/sites/default/files/regulatory_performance_framework_2017-2018.pdf

important, with the difference that safety culture is an issue entirely for ANSTO to urgently deal with and resolve, whereas waste management including final disposal is an undertaking, of increasing urgency, of the Australian Government.

Regarding systems, structures, components, equipment and processes of the *ANM Facility*; ARPANSA's review of actions taken to comply with LC8 has demonstrated improvements through implementation of actions in response to LC8, has not revealed new areas of concern, and has not materially challenged the conclusions from my decision of 12 April 2018. Despite the reservations stated above and in my opinion, ANSTO has provided reasonable assurance that routine operations can be carried out safely.

Routine operations are now authorised through changes made to Facility Licence F0309, as follows:

- LC8 issued on 12 April 2018 has been removed.
- A new LC8 has been issued:

  LC8. *The licence holder must systematically address the causes, inherent risks, critical controls, preventative and mitigating measures in the revised risk assessment of the ANM Facility. The revised risk assessment must also take into account human and organisational factors and the recommendations resulted from the previous risk assessment. The revised risk assessment of the ANM Facility must be submitted to the CEO by 30 April 2020 or at a time agreed by the CEO.*

- LC9, previously amended on 2 April 2019, is amended as follows:

  LC9*. During initial routine operations of the ANM Facility with simultaneous Mo-99 production in Building 54: the total production of Mo-99 must be capped at 2 400 six-day curie per week as a four-week average, and not increased beyond that level until production in Building 54 has ceased and operational experience of the ANM Facility provides evidence of safe operations.*

- LC 10 issued on 12 April 2018 has been considered redundant and hence removed.

Other conditions are retained as per the licence issued in April 2018.