Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

Statement of Reasons

Decision by the CEO of ARPANSA to amend Facility Licence F0309[1]

27 March 2020

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[1] 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, the licence will prevail.

1. Decision to amend Facility Licence F0309

On 27 March 2020, under section 36(2) of the *Australian Radiation Protection and Nuclear Safety Act 1998*[2] (the Act), I decided to remove licence condition 9 from Facility Licence F0309, issued to the Australian Nuclear Science and Technology Organisation (ANSTO). The condition restricted production of molybdenum-99 (Mo-99) in the ANSTO Nuclear Medicine Facility (the *ANM facility*). A new licence condition was imposed placing certain notification and information gathering requirements on the licence holder during the time the *ANM facility* transitions to unrestricted production.

2. Background

2.1 History of the licence to operate the *ANM facility* prior to 5 July 2019

I issued Facility Licence F0309 on 12 April 2018 authorising ANSTO to operate the *ANM facility* for the purpose of 'hot' commissioning of the facility. Routine operations for supplying nuclear medicine to the Australian and international markets would not be authorised until certain conditions had been met as specified in licence condition 8 (LC8) of F0309[3].

Nearly a year later on 20 March 2019 ANSTO submitted an urgent request under section 63 of the Australian Radiation Protection and Nuclear Safety Regulations 2018[4] (the Regulations) to carry out 30 production runs over a six-week period in the *ANM facility*. The urgency was caused by failing hydrogen convertors in the existing Mo-99 production facility in Building 54 and the imminent risk of disruptions in Mo-99 production and availability of nuclear medicine to clinics in Australia and overseas. ARPANSA handled the request with priority.

On 2 April 2019 I amended the licence authorising 30 production runs in the *ANM facility* subject to prior notification to ARPANSA on staffing arrangements on a weekly basis and fortnightly reports on operational experience. The average weekly production in the *ANM facility* and Building 54 combined was capped to allow safe transitioning of staff with experience of Mo-99 production from Building 54 to the new *ANM facility* [5]. ANSTO commenced production in the *ANM facility* on the day the licence was issued and, in fact, Building 54 has not been used for Mo-99 production since 30 June 2019.

Before the urgent request for a limited number of production runs was submitted, ANSTO had already requested removal of LC8 on 12 March 2019. Based on the review and assessment carried out by ARPANSA's regulatory officers and myself, I reached the over-arching conclusion (with explanation of my clarification in square brackets):

> *"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* [referring to safety culture and waste management; elaborated further in my Statement of Reasons on 24 May 2019] *and in my opinion, ANSTO has provided reasonable assurance that routine operations can be carried out safely."*

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

[3] https://www.arpansa.gov.au/news/arpansa-issues-licence-operate-anstos-mo-99-facility

[4] https://www.legislation.gov.au/Details/F2018L01694

[5] https://www.arpansa.gov.au/news/arpansa-authorises-limited-production-molybdenum-99-anm-facility

On 24 May 2019 I removed LC8 and thereby the limitation on the number of production runs[6]. The capping of the average weekly production remained in place to allow safe tandem operations while Building 54 remained operational, at least technically, until 30 June 2019.

2.2 Licence decision on 5 July 2019, restricting production of Mo-99 (LC9)

Despite the "*reasonable assurance that routine operations can be carried out safely*" referred to above, an event took place on 21 June 2019 when the hands of three workers were contaminated with two of the workers exposed above the annual dose limit for extremity/skin exposure. ANSTO immediately stopped production and committed to resume production only on ARPANSA's approval.

On 3 July 2019 ANSTO sought approval to resume operations on 6 July 2019. ARPANSA made observations on site and interviewed representatives of operating staff and management; reviewed ANSTO's analysis of factors contributing to the event; the revised risk assessment; revised procedures; and the plan for return to operations. Authorisation to resume operations was granted on 5 July 2019[7].

ARPANSA considered ANSTO's analysis of the immediate cause and progression of the event as credible, i.e. that ANSTO had demonstrated good understanding of **what** had happened which assisted ANSTO in implementing measures to prevent recurrence. However, in my decision of 5 July I stated, *inter alia*:

> *ANSTO's analysis of **why** the event occurred is revealing and points to sub-optimal management of organisational and human factors. While the honesty of the investigation report must be commended, the content is highly concerning. My concern stems from, inter alia, the following observations:*
>
> - *the actual content of the investigation report, in particular the human factor contribution as demonstrated, for example, in the analysis captured in the Ishikawa diagram; this correlates with preliminary findings made by ARPANSA's officers*
> - *what appears to be lack of awareness of the hazards associated with production and handling of high-activity Mo-99 products despite the serious contamination event with long-term health consequences that took place at ANSTO Health in August 2017*
>
> *ANSTO's own investigation report and the observations made by ARPANSA over the past few years demonstrate that management of safety associated with ANSTO's nuclear medicine production falls short of expectations.* ***ANSTO's Management, from the executive level down, must demonstrate leadership and lead by example in order to rectify these shortcomings.***

In the light of the findings after the accident, I considered it necessary for ANSTO to make significant efforts to further strengthen the safety of nuclear medicine production in the *ANM facility*. However, I also considered that restricted production could be carried out safely under the new arrangements implemented by ANSTO. Therefore, I capped production at a level that could satisfy the Australian market while freeing up resources, for example, for staff to be trained and knowledgeable in nuclear medicine production and for addressing and rectifying the safety issues. An amended licence was issued which imposed a new licence condition (LC9):

> ***Licence condition 9****: Production must be capped at the level necessary to satisfy the demand of the Australian market until such time ANSTO has provided, to the satisfaction of the CEO of ARPANSA:*

[6] https://www.arpansa.gov.au/news/arpansa-authorises-ansto-commence-routine-production-molybdenum-99-anm-facility

[7] https://www.arpansa.gov.au/news/ceo-arpansa-restricts-production-ansto-nuclear-medicine-facility-after-accident

- *evidence of safe operations under the authorisation granted in this decision, presented in fortnightly reports to ARPANSA that must be submitted no later than five working days after the end of the preceding two-week period, in a form agreed by the CEO of ARPANSA*
- *satisfactory training records of managers and operating staff, including in the production process, hazard awareness, safe management of events, and management of safety of time-critical operations; these records must include an evaluation of the effectiveness of training*
- *evidence of instructions and training delivered to and attended by relevant managers on the appropriate management of conflicting production and safety imperatives*
- *satisfactory staffing levels and staff roster arrangements*
- *rectification of safety significant issues that may come to light during ARPANSA's investigation into possible systemic issues contributing to the contamination event on 21 June 2019, including but not limited to organisational and human factors.*

With regard to the contamination event on 17 September 2019 ANSTO was found in breach of section 30(2) of the Act for failing to comply with sections 58 and 79 of the Regulations. The event was reported to the INES[8] database as a level 2 event ('incident').

3. Reaching the decision

On 28 November 2019 ANSTO requested the removal of LC9 to allow ANSTO '*to commence ANM routine operations in an unrestricted capacity*'.

This Statement of Reasons documents the reasoning underpinning my licence decision in regard to this request. Most importantly, it considers whether ANSTO's actions since 21 June 2019 provide reasonable assurance that production can be safely increased from the capped production level imposed on 5 July 2019 (two production runs per week).

The evidence and documentation underpinning my decision include:

- the documentation submitted by ANSTO
- the assessment performed by ARPANSA officers[9] as documented in the Regulatory Assessment Report provided to me
- 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*[10]
- matters specified in the Regulations that I must take into account in deciding whether to issue a facility licence and that remain relevant for this decision
- international best practice and other information available to me.

The Nuclear Safety Committee[11] and the Radiation Health and Safety Advisory Council[12] have taken active interest in these matters. The deliberations of these advisory bodies have informed my decision; however, neither was requested to provide formal advice.

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[8] Reported 9 July 2019, updated 6 August 2019. https://www.iaea.org/resources/databases/international-nuclear-and-radiological-event-scale

[9] Mr James Scott, Dr Samir Sarkar, Mr Robert Godfrey, Mr John Ward and Mr Andrew Wulf contributed to the review and assessment. Mr Martin Reynolds, General Counsel, and Mr John Templeton, Legal Officer, reviewed the Statement of Reasons and the licence.

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

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

[12] https://www.arpansa.gov.au/about-us/advisory-council-and-committees/radiation-health-and-safety-advisory-council

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[13].

4. Licence condition 9

Licence condition 9 required satisfactory actions to be taken in relation to five sub-conditions, as a prerequisite for removal of the cap on production. Sections 4.1 – 4.5 summarise the considerations in relation to the sub-conditions.

4.1 Safe operations

Sub-condition 1: *Evidence of safe operations under the authorisation granted in this decision presented in fortnightly reports to ARPANSA that must be submitted no later than five working days after the end of the preceding two-week period and in a form agreed by the CEO of ARPANSA*

Removal of LC9 will enable ANSTO to increase the number of production runs from two per week to about five per week using one dissolver (any further increase would require commissioning of a second dissolver cell under separate approval by ARPANSA). It should be noted that production at the *ANM facility* has until now been subject to limits imposed by ARPANSA and has so far never exceeded three runs per week.

ANSTO's intention is to step up production to, in the first instance, three then four or even more production runs per week while continually evaluating operational experience as a basis for decisions to move from one step to the next. Indeed, ongoing evaluation and implementation of improvements based on operational feedback has been standard practice since restricted Mo-99 production commenced in July 2019. This cautious approach to increasing production is in the interest of safety and is strongly endorsed. I anticipate that ANSTO continues to maintain this cautious approach including in circumstances where market demands may increase the pressure on production; ANSTO's practices in this regard will be monitored by ARPANSA as part the agency's regulatory oversight of the *ANM facility*.

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. A total of approximately 84 *production* runs for supply of nuclear medicine to the market have been carried out to date. Out of these, 59 production runs (note: 1 run was abandoned with no output) have been carried out under conditions requiring ANSTO to submit fortnightly reports (in contrast to the standard quarterly reports) of operational experience to ARPANSA.

For the purpose of this licence decision, ARPANSA has reviewed information provided in the fortnightly reports since the restricted operation commenced on 6 July 2019 (17 reports covering 59 production runs). Information provided has relevance for three of the safety performance indicators (SPI) used by ARPANSA to evaluate safety and protection: deviations occurred, gaseous discharges, and event reports. The main observations and conclusions from ARPANSA's review are summarised below:

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

- *Failure of safety systems* and *unavailability of safety systems:* On 6 September 2019 the breakdown of a gate valve in the dissolver cell prevented maintenance of the required level of negative pressure in the cell (*failure of safety systems*). The faulty gate valve was an example of a single point of failure with implications for defence-in-depth and of potential significance for worker safety. Production was halted and temporary measures were implemented with ARPANSA's approval to restore the negative pressure. This enabled staff to process the irradiated plates and remove the product and by-products including spent uranium filter cups. The modular components of the cell roof could then be dismantled and the faulty valve replaced. The works required planned and authorised bypassing of safety interlocks (*unavailability of safety systems*). The works were successfully completed and production recommenced on 6 November 2019.
- *Occupational exposures:* No abnormal or unexpected worker exposure (effective dose or extremity/skin equivalent dose) has been reported and exposures are well within the established yearly dose constraints *except* for the high skin/extremity doses incurred by three workers on 21 June 2019.
- *Event reporting:* A total of 26 events were reported and registered in ANSTO's system for event reporting. Minor deviations from procedures were observed and rectified. The number, nature and reporting of events do not give rise to concern and indicate a positive reporting culture and functioning feedback loops within the *ANM facility*.

Implementation of measures to increase defence-in-depth is limited to the changes made in direct response to the contamination event of 21 June which include reclassification of certain areas and installation of additional monitors. These are essentially 'level 2' actions[14] aimed at control and monitoring. The introduction of safety observers who take no active role in production but promote continuous improvement by feeding back their observations of production practices to operational staff and management is a measure of similar nature. In response to an *area for improvement* (AFI) raised after an 'augmented' inspection[15,16] on 19-20 August 2019, contamination clearance processes were implemented at the *ANM facility* (such processes had already been implemented elsewhere at ANSTO).

Overall, the information on operational experience provided by ANSTO, and ARPANSA's review thereof, indicates that operations in the *ANM facility* can be carried out safely and operational experience is being effectively utilised for production improvements, including safety. The operational experience since July 2019 confirm ARPANSA's earlier observations made during hot commissioning and early routine production. In agreement with the recommendation by ARPANSA's regulatory officers, I find that the information available to ARPANSA satisfies sub-condition 1 of LC9. Therefore this sub-condition can be removed.

[14] Level 2 comprises actions with the objective to 'control of abnormal operation and detection of failures' through 'control, limiting and protection systems and other surveillance features'. See INSAG-10, *Defence in Depth in Nuclear Saf*ety (IAEA 1996) https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1013e_web.pdf

[15] ARPANSA's inspection reports are, with few exceptions available at https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/inspections/inspection-reports

[16] *Augmented inspections* are, in contrast to the baseline inspection program, undertaken in response to an event or any new information of safety significance that come to ARPANSA's attention. An *area for improvement* is an identified opportunity to improve performance to achieve best practice rather than minimal compliance. See ARPANSA's Inspection Manual at https://www.arpansa.gov.au/sites/default/files/arpansa-reg-ins-man-280w.pdf

4.2 Training records

Sub-condition 2: *Satisfactory training records of managers and operating staff, including in the production process, hazard awareness, safe management of events, and management of safety of time-critical operations; these records must include an evaluation of the effectiveness of training*

ANSTO has provided information on a significant number of training activities that operating staff and managers (mainly up to middle management level) have undergone since July 2019.

ARPANSA carried out an augmented inspection focusing on training from 28 August to 6 September 2019. This involved inspection of records and interviews with staff. The inspection resulted in nine AFIs including lack of training for managers above operations manager level, unclear roles for Radiation Protection Services, deficiencies in training material (in particular around risk and consequence), and overdue training. As of February 2020 ANSTO had addressed all AFIs and ANSTO considers most of them closed. While this remains to be confirmed, ARPANSA's reviewers consider outstanding actions from the augmented inspection to be of relatively minor safety significance and not *per se* preventing an increase in production at the *ANM facility*.

Regulatory officers have questioned the effectiveness of risk information contained in risk assessments for the facility and provided in procedures and instructions. There is concern that an event with an assessed low residual risk can be perceived as not requiring the level of attention that is warranted by its consequences should such an event occur. This is an area where ANSTO has accepted that further work is needed and a revised approach to risk assessment is under development in response to a licence condition imposed on 24 May 2019[17].

Training and training records as well as other documentation have been reviewed. It is reasonable to conclude that actions taken by ANSTO since the event in July 2019 have increased the level of awareness of radiation risks and staff familiarity with the processes and systems in place to manage such risks, including the significance of radiation monitoring and proper response to alarms and contamination. The process review undertaken after each production run provides additional input to the establishment of good safety practices and their continuous improvement; this is, as previously stated, a commendable practice.

ANSTO has recruited a training officer to work exclusively with *ANM facility* and *ANSTO Health Products.* This is a good initiative that should help in improving safety practices and situational awareness in nuclear medicine production. My expectation is that ANSTO will use the new resource to address the remaining issues around training and staff hazard awareness.

Based on the review, and in agreement with the recommendation by my regulatory officers, I consider actions taken by ANSTO satisfy the sub-condition 2 of LC9. Therefore this sub-condition can be removed.

[17] *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.*

4.3 Production *vs* safety

Sub-condition 3: *Evidence of instructions and training delivered to and attended by relevant managers on the appropriate management of conflicting production and safety imperatives*

With regard to avoiding conflicts between production and safety, and managing such conflicts should they arise, the IAEA General Safety Requirements No. Part 2 *Leadership and Management for Safety* is clear[18]. Relevant requirements GSR Part 2 include the following:

> ***Requirement 2: Demonstration of leadership for safety by managers - Managers shall demonstrate leadership for safety and commitment to safety.***
>
> *3.1. The senior management of the organization shall demonstrate leadership for safety by:*
> *(a) Establishing, advocating and adhering to an organizational approach to safety that stipulates that, as an overriding priority, issues relating to protection and safety receive the attention warranted by their significance;*
>
> *[…]*
>
> ***Requirement 4: Goals, strategies, plans and objectives - Senior management shall establish goals, strategies, plans and objectives for the organization that are consistent with the organization's safety policy.***
>
> *4.3. Goals, strategies, plans and objectives for the organization shall be developed in such a manner that safety is not compromised by other priorities.*
>
> *4.4. Senior management shall ensure that measurable safety goals that are in line with these strategies, plans and objectives are established at various levels in the organization.*
>
> *4.5. Senior management shall ensure that goals, strategies and plans are periodically reviewed against the safety objectives, and that actions are taken where necessary to address any deviations.*
>
> *[…]*
>
> ***Requirement 12: Fostering a culture for safety - Individuals in the organization, from senior managers downwards, shall foster a strong safety culture. The management system and leadership for safety shall be such as to foster and sustain a strong safety culture.***
>
> *5.1. All individuals in the organization shall contribute to fostering and sustaining a strong safety culture […].*
>
> *5.2. Senior managers and all other managers shall advocate and support the following:*
>
> *(a) A common understanding of safety and of safety culture, including: awareness of radiation risks and hazards relating to work and to the working environment; an understanding of the significance of radiation risks and hazards for safety; and a collective commitment to safety by teams and individuals;*
>
> *(b) Acceptance by individuals of personal accountability for their attitudes and conduct with regard to safety;*
>
> *[…]*

The potential of a conflict between production and safety must be recognised in the planning stage as well as in any acute phase, for example when responding to an unexpected event. Regarding policies and strategies, ANSTO refers to its corporate values that include *safe*, *secure* and *sustainable* as three key principles that underpin everything that it does and every decision that is made. The WHS policy provides a number of appropriate messages including that no one should be harmed as a result of ANSTO's activities. However, the policies do not include an explicit reference to potential conflicts between production and

[18] https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1750web.pdf

safety or that safety overrides other considerations. ARPANSA's reviewers did not find explicit evidence of the management of potential conflicts although the documentation clearly spells out the managerial *responsibilities* for safety.

In consultation with ARPANSA, ANSTO rolled out a safety culture perception review involving staff across several ANSTO facilities and businesses including the *ANM facility* and *ANSTO Health.* With regard to the priority of safety, staff scored the *ANM facility* lower than other facilities. A number of factors contributing to potential bias should be considered including the recent safety event (June 2019) and that the facility is relatively new with some staff members still undergoing training and accreditation. While data should be interpreted with caution, ANSTO should analyse the reasons behind 'negative outliers' in the distribution perceptions and identify and address any systemic underlying issues.

ANSTO Managers verbally reported that they have empowered people to stop work where they feel unsafe, in line with the ANSTO-wide *stop*, *think*, *act*, *review* (STAR) approach.

On 30 January 2020 I approved ANSTO's revised safety assurance process. ARPANSA's reviewers considered the revised process to be aligned with contemporary best practice approaches to leadership and management for safety. I agree with this assessment. The new safety assurance process is based on 'individual approval based on advice' rather than 'committee approval'. The level at which decisions are taken depends on the level of risk to be managed. This is a positive step which introduces individual accountability for safety at the appropriate managerial level and promotes careful consideration of potential conflicts between safety and production.

While the totality of information available to ARPANSA indicates that the safety imperative is recognised at all levels, and that the training activities considered in section 4.2 have raised hazard and risk awareness, policies and procedures remain somewhat ambiguous. The safety culture perception review indicates that further work is necessary. Therefore, I do not find that available information fully satisfies sub-condition 3 although I am of the view that the shortfall should not prevent a well-considered and measured stepwise increase of production in the *ANM facility*.

As a result, I have decided to retain important elements of sub-condition 3 in a new licence condition 9 stated in section 6.2.

4.4 Staffing arrangements

Sub-condition 4: *Satisfactory staffing levels and staff roster arrangements*

The operational limits and conditions (OLC) define the minimum staffing level as well as the minimum level of senior accredited operators and accredited operators that must attend the facility during the production runs. The workforce plan has been revised with regard to team structure to accommodate for a progressive increase in production runs. ARPANSA's reviewers conclude that '*the current staffing level and staff roster arrangements, together with the additional staffing arrangements […], provides reasonable assurance for safe operation of the facility*.' I agree with this conclusion. Therefore this sub-condition can be removed.

4.5 Additional safety considerations

Sub-condition 5: *Rectification of safety significant issues that may come to light during ARPANSA's investigation into possible systemic issues contributing to the contamination event on 21 June 2019 including but not limited to organisational and human factors*

Three augmented inspections were carried out by ARPANSA following the June 2019 accident with a total of 12 AFIs raised and no potential non-compliance identified. The AFIs have been actioned but ARPANSA's inspectors are continuing to follow up on a number of them. No safety significant issue of concern has come to ARPANSA's attention through its regulatory oversight or been brought to ARPANSA's attention by ANSTO other than those already covered in this Statement of Reasons. Therefore this sub-condition can be removed.

5. Matters in section 53 of the Regulations

Section 53 of the Regulations lists matters I must take into account when issuing a facility licence. These matters were considered in my decision of 12 April 2018 and reviewed in the subsequent decision on 24 May 2019 to authorise routine operations. The matters I find relevant to this decision to amend Facility Licence F0309 are considered in sections 5.1 – 5.5 below.

5.1 Information submitted

Section 53(b): *Whether the applicant for the licence has given the information asked for by the CEO*

The information submitted in support of ANSTO's request to remove LC9 and move to unrestricted production, supplemented with information requested by ARPANSA or gathered by ARPANSA through its regulatory oversight has enabled meaningful review and assessment.

5.2 Undue risk

Section 53 (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

The *ANM facility* can, as concluded in section 4.1, be operated safely. As for optimisation of protection, this is considered in section 5.4. However, the risks associated with nuclear medicine production include risks associated with the front and back ends of the *ANM facility*. Previous decisions have considered the operations of the OPAL reactor which supplies the irradiated uranium plates to the *ANM facility* and the management of liquid intermediate level waste (ILW) produced in the *ANM facility*.

ARPANSA's main concerns have related to the planning and management for, and onsite storage capacity of ILW. A number of factors relevant to waste safety will require ANSTO's attention over the coming few years including the storage capacity for ILW at the *ANM facility*, storage in Building 27 and the operation of the *SyMo Facility* for treatment of the ILW. Under a licence condition for the *ANM facility*, ANSTO must by 30 June 2020 provide a report on current and future plans for management of ILW resulting from operations of the *ANM facility*[19]. These plans are intrinsically linked to the national plans for final

[19] The licence condition states: The licence holder must, by 30 June 2020, provide a report on:

management of ILW, including establishment of a facility for its disposal, as foreseen in the Australian Radioactive Waste Management Framework[20] (ARWMF).

The *SyMo Facility* is under construction but an application for a licence to operate the facility is not expected until approximately mid-2021. Should a need arise to manage liquid ILW through other means than treatment in the *SyMo Facility*, the contingency would be conventional cementation using proven technology.

While radioactive waste management is a necessary focus for ANSTO and for the Department of Industry, Science, Energy and Resources, which has government policy lead for the ARWMF, safe management of waste onsite is possible for several years.

5.3 Net benefit (justification)

Section 53 (d): *Whether the applicant has shown that there is a net benefit from carrying out the conduct proposed to be authorised by the licence*

A very large number of nuclear medicine procedures based on Mo-99/Tc-99m technology are carried out world-wide each year. These procedures 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.

The 'just-in-time' nature of Mo-99 production and subsequent manufacturing of Tc-99m generators make delivery of nuclear medicine based Mo-99/Tc-99m vulnerable to disruptions in the supply chain. The OECD Nuclear Energy Agency (NEA) has in a recent publication summarised the economic and policy environment for the global production of nuclear medicine[21]. The most recent projection of production and demand carried out by the NEA covers the period 2019 – 2024[22]. It demonstrates that production (irradiation and manufacturing of generators) capacity is well in excess of demand but vulnerable to production disruptions with several such occurrences recorded in recent years. The report acknowledges that the *ANM facility* has not reached full capacity. The over-all conclusions of the NEA in its recent projections do not vary significantly from their earlier forecasts.

The current production level at the *ANM facility* satisfies the Australian market. ANSTO has now applied for the cap to be lifted so that nuclear medicine can be delivered to the international market. This meets the intent of the facility and benefits patients undergoing procedures involving Mo-99/Tc-99m not only in Australia but elsewhere, under circumstances where global nuclear medicine supply is subject to uncertainty. I consider the issue of net benefit of the 'conduct' to have been sufficiently assessed already in

(a) holdings of intermediate level waste (ILW) at the ANM Facility;
(b) projected future generation of ILW at the facility;
(c) plans for treatment of the ILW generated at the facility including projected treatment in the *SyMo Facility*;
(d) plans for storage and disposal of the ILW that take into consideration the national policy and plans for full life-cycle management of radioactive waste; and
(e) contingency plans should one or several components of the ILW management system not eventuate or fail

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

[21] *The Supply of Medical Isotopes*. *An Economic Diagnosis and Possible Solutions.* OECD-NEA 2019. https://www.oecd-nea.org/ndd/pubs/2019/medical-radioisotope-supply.pdf

[22] *The Supply of Medical Radioisotopes. 2019 Medical Isotope Demand and Capacity Projection for the 2019-2024 Period*. OECD-NEA 2019. https://www.oecd-nea.org/med-radio/docs/sen-hlgmr2019-1.pdf

my decision on 12 April 2018 to authorise ANSTO to **operate** the *ANM facility* and confirmed in my decision on 24 May 2019 to authorise routine production.

In line with previous licence decisions on operation of the *ANM facility,* 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 ARWMF in a timely manner.

5.4 Optimisation

Section 53 (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*

Optimisation considers individual radiation exposures, the likelihood of exposures, and the number of people exposed. ANSTO has, as part of optimisation, put appropriate dose constraints in place for a number of worker categories involved in nuclear medicine production; this was recorded in the decision to authorise routine production on 24 May 2019.

The changes to routines at the back end of the packaging cell of the *ANM facility* where the contamination event took place should make a similar contamination event much less likely. The number of people exposed cannot be significantly further reduced as it is largely determined by the OLCs governing safe operations.

While ANSTO's approach to optimisation has improved, I believe there is still room for improvement. In that regard I stated in my decision of 20 January 2020 to approve ANSTO's safety assurance process:

> *Review of the ANSTO application and accompanying documentation highlights that ANSTO's approach to optimisation is focused primarily on ensuring that doses are as low as reasonably achievable (ALARA). However, ARPANSA has moved away from the 'ALARA' concept, and refers its licence holders to ICRP Publication 103* [see footnote[23]]*, paragraph 214 for the preferred approach to optimisation, including at the design stage where options are considered. There will be an opportunity for further engagement and discussion on this topic when ANSTO submits its revised risk assessment for the Molybdenum-99 Production Facility under licence condition 8 of F0309 before 30 April 2020.*

For the purpose of this decision, I am of the view that ANSTO's improved approach to optimisation is sufficient, in line with the decision to authorise routine operations on 24 May 2019. ANSTO's approach to optimisation will be further evaluated when ANSTO submits its revised risk assessment as required by licence condition 8.

5.5 Capacity to comply

Section 53 (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*

The event on 21 June 2019 was the last in a worrisome series of safety significant events during production of nuclear medicine which all constitute breaches of the Act. I acknowledge that ANSTO has invested

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

considerable time and effort in taking actions to address the safety issues. This includes the plan developed in response to the report on an independent review commissioned by ANSTO in October 2018[24]. This review was commissioned as a result of an accident that occurred at *ANSTO Health* in August 2017. While the independent review was focused on practices undertaken under Facility Licence F0262 issued to *ANSTO Health Products*, the findings are also relevant to the *ANM facility* and to ANSTO more generally. For example, the revised safety assurance process recently approved by ARPANSA can be traced back to the independent review as well as to ARPANSA's regulatory oversight.

Notwithstanding the significant events in recent years, I consider that ANSTO has both the capacity and capability to comply with the Act, the Regulations and licence conditions, and is making increased use of its capabilities in this regard.

6. Conclusions and summary of licence amendments

6.1 Conclusions

As stated in section 3, this Statement of Reasons *considers whether ANSTO's actions since 21 June 2019 provide reasonable assurance that production can be safely increased from the capped production level imposed on 5 July 2019*.

In drawing my conclusion, I have primarily considered the following:

- the design and original intent of the *ANM facility*
- ANSTO's stated intent to increase production in a staggered manner to three, then four and possibly more production runs per week while evaluating the experience gained from the preceding phase before moving to the next level
- information provided by ANSTO in support of the request under section 63 of the Regulations to remove LC9

The *ANM facility* was intended to replace the ageing Mo-99 facility in Building 54 and this has now taken effect. Production in the *ANM facility* will sustain the domestic demand for nuclear medicine based on Mo-99/Tc-99m technology and enable exportation. While the global production capacity currently exceeds demand, the supply chain is susceptible to production disturbances or failures in the relatively small number of existing (and in some cases ageing) world-wide production facilities. The *ANM facility* is likely to play a significant role in the supply of nuclear medicine in Australia and internationally for a considerable time to come.

While the disruptions that have occurred at the *ANM facility* give rise to concern, they do not materially challenge the conclusion that the *ANM facility* can be operated without undue risk to the health and safety of people, and to the environment if production is increased from the current two production runs per week. The incremental approach to production provides opportunities for production and safety improvements to be implemented in a considered manner.

The information submitted by ANSTO in relation to LC9 is satisfactory in many aspects but still leaves room for improvement in certain areas; I believe the management of conflicting safety and production

[24] *Independent safety review of the ANSTO Health approach to occupational radiation safety and operational procedures,* https://www.arpansa.gov.au/sites/default/files/independent_review_of_ansto_health.pdf?acsf_files_redirect

imperatives is of particular relevance. However, I consider the capping of production can be removed, subject to a new condition that requires prior notification to ARPANSA about increases in production above a weekly average of three productions runs and when any further increases in production occur. The practical effect of this decision is that production can be immediately increased from the current level of two runs per week to three without notification. The licence has been amended accordingly as outlined below.

6.2 Licence amendments

- Licence condition 9 of the licence issued on 5 July 2019 is removed.
- A new licence condition 9 is introduced as of 27 March 2020 which states:

The licence holder must:

(a) provide ARPANSA with at least five working days' notice of any increase in the average number of weekly production runs calculated over a four-week period commencing 27 March which exceeds 4 but not 5 runs per week, and similarly when it exceeds an average of five runs per week

(b) with any notice to increase production as described above, provide ARPANSA with information on the factors that were considered in determining that the increase could be carried out safely; the information provided should include matters which mitigate risks associated with the increased production

(c) provide evidence to ARPANSA before 30 June 2020 that appropriate and relevant instructions and training have been delivered to the senior managers for the nuclear medicine production process on how to appropriately deal with conflicting production and safety imperatives; any evidence provided should include an evaluation of the effectiveness of the training

The way the licence condition is constructed, it lapses once production step-ups have been implemented. However, it provides ARPANSA with an opportunity to assess the plans and arrangements for safety at each production increase up until full production and to intervene if necessary.