Australian Government

Australian Radiation Protection and Nuclear Safety Agency

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Statement of Reasons

Decision by the CEO of ARPANSA on Facility Licence Application A0309 from the Australian Nuclear Science and Technology Organisation (ANSTO) to operate the ANSTO Nuclear Medicine Mo-99 Facility

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Decision by the CEO of ARPANSA on Facility Licence Application A0309 from the Australian Nuclear Science and Technology Organisation (ANSTO) to operate the ANSTO Nuclear Medicine Mo-99 Facility

R18/04183

April 2018

This statement of reason 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. Introduction

On 12 April 2018 I decided to issue Facility Licence F0309 under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998*[1] (the Act), authorising the Australian Nuclear Science and Technology Organisation (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 purpose of the facility is to extract and purify molybdenum-99 (Mo-99) from uranium target plates irradiated in ANSTO's OPAL reactor, for the domestic and international market; and will involve activities incidental to extraction and purification of Mo-99 such as quality control and waste management, as outlined in the application. No other purpose has been stated or is authorised under the licence.

The licence authorises ANSTO to commence commissioning of the *ANM Facility* using active material including irradiated target plates ('hot' commissioning). Routine operations for the stated purpose *must not* commence until authorised by the CEO of ARPANSA. Authorisation of routine operations requires that certain conditions, specified in the licence, have been fulfilled.

Under section 35(1)(c) of the Act, I have issued a number of licence conditions specific to the *ANM Facility*. The licence conditions are detailed and explained in section 5 of this statement of reasons.

2. Background

This is the third in a series of decisions regarding facility licences for the *ANM Facility*, located at the Lucas Heights Science and Technology Centre (LHSTC) in New South Wales:

- On 4 October 2013, I issued a licence to ANSTO under section 32 of the Act to **prepare a site** for the *ANM Facility* (Facility Licence F0270).
- On 27 June 2014, I issued a licence to ANSTO under section 32 of the Act to **construct** the *ANM Facility* (Facility Licence F0285).

The Statements of Reasons and the supporting Regulatory Assessment Reports (RAR) prepared by ARPANSA officers are available at the ARPANSA website[2, 3].

- On 7 April 2017, I received an application for a licence to **operate** the *ANM Facility* (Facility Licence Application A0309).

This statement of reasons documents the reasoning underpinning my decision[4] in relation to Facility Licence Application A0309.

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

[2] Prepare a site: https://www.arpansa.gov.au/news/ceo-decision-ansto-nuclear-medicine-molybdenum-99-facility

[3] Construct: https://www.arpansa.gov.au/news/decision-ceo-ansto-anm-facility

[4] 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 functions, a responsibility that also applies to all ARPANSA officers that have a role in the decision making process, such as contributing to the Regulatory Assessment Report. I have not given any consideration to any aspect of the licensing decisions regarding the *ANM Facility* that could potentially benefit ARPANSA or conflict – or be perceived to conflict - with my other

2.2 Purpose and scope of this statement of reasons

The statement of reasons focuses on the safety of the **operations** of the *ANM Facility* and partly draws on considerations made in relation to the decisions to authorise ANSTO to **prepare a site** for, and to **construct** the facility. The main focus is on whether:

- the facility has been built as approved
- commissioning activities using irradiated target plates ('hot' commission) can be authorised
- the facility can be brought to a safe controlled state in case of events with safety significance during commissioning
- the purpose, risk analysis, safety analysis, safety features, safety arrangements and end-of-life arrangements provide for net benefit, no undue risks, and for protection of people and the environment from the harmful effects of radiation.

For the purpose of this statement of reasons and unless otherwise stated, *health* and *safety* refers to all factors that contribute to *protection of people and the environment from harmful effects of ionising radiation* (i.e. the object of the Act). This includes radiation safety[5], nuclear safety, waste safety, transport safety, physical protection and security, and emergency preparedness and response. Safety as it relates to other matters, e.g. as covered in the work health and safety legislation or as regards the safety of the product being manufactured in the facility and its use in medical applications, is outside of my mandate.

3. Reaching the decision

3.1 Evidence and documentation

The evidence and documentation underpinning my decision include:

- the application and supporting documentation[6]
- considerations in relation to the decisions to authorise ANSTO to **prepare a site** for, and to **construct**, the facility
- applications and approvals under regulation 54, to construct items important for safety
- supplementary documentation provided by ANSTO at ARPANSA's request

functions. All ARPANSA officers make annual declarations of interests that could potentially conflict with their duties; ARPANSA's General Counsel makes the determination of whether a conflict exists or may be perceived that must be managed. No interest has been declared that may conflict with 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

[5] Radiation safety has the same meaning as radiation (radiological) protection in this statement of reasons.

[6] The application and supporting documentation are available on ARPANSA's website, https://www.arpansa.gov.au/have-your-say/anm-mo99-facility-operating-licence-application

- the review and assessment of the application and supporting and supplementary information, carried out by ARPANSA's regulatory and science officers and documented in the Regulatory Assessment Report[7,8]
- inspections, verifications, observations and document reviews carried out by ARPANSA's regulatory officers on site
- submissions received in response to the invitation under sub-regulation 40(3) to people and bodies to make submissions in relation to the application.

ARPANSA's assessment is based on the Act and the Australian Radiation Protection and Nuclear Safety Regulations 1999[9] (the Regulations), as well as on subsidiary regulatory guidance[10] developed by ARPANSA for licence applicants and licence holders. It is also based on national codes and guides that are predominantly published in the Radiation Protection Series (RPS)[11], some of which form part of the licence conditions specified in the Regulations (regulation 48).

The assessment and decision is further informed by advice from the Nuclear Safety Committee, and by international best practice, both of which I have taken into account in my decision.

3.2 The Nuclear Safety Committee

The *Nuclear Safety Committee*[12] (NSC) advises the CEO of ARPANSA on matters relating to nuclear safety and the safety of controlled facilities, including developing and assessing the effectiveness of standards, codes, practices and procedures. The NSC normally meets three times a year and performs work inter session. The NSC is one of three bodies established by the Act that provide advice on matters relating to safety, national implementation of policies and standards, and matters of concern in society, to the CEO of ARPANSA; the others being the *Radiation Health and Safety Advisory Council* and the *Radiation Health Committee*[13]. Functions and procedural arrangements are outlined in the Act and Regulations, and further elaborated in *Roles and Expectations of the Advisory Bodies*, available on ARPANSA's website[14].

- The NSC met on 10 March 2017. Members were given an orientation on the *ANM Facility* on site, sighted the facility (which at the time was in its main phase of construction) and met with key ANSTO staff with responsibility for the establishment of the facility.
- The NSC met on 30 June 2017. Members had previously received a copy of ANSTO's Operational Risk Assessment, with a request to review the document ahead of the meeting. Members provided ARPANSA with a list of questions regarding the risk assessment out of session, which ARPANSA took into account when requesting ANSTO to provide further information on the risk assessment.

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[7] Lead reviewer was Dr Samir Sarkar, Section Head, National Codes and Standards Section, Regulatory Services Branch. Contributors to the review were from the Regulatory Services Branch: Mr Jim Scott, Mr Loch Castle, Ms Diane Harrison, Mr Andrew McCormick, Mr Vaz Mottl, Ms Julie Murray, Mr Chris Nickel, Mr Garth Sheehy, Mr John Templeton, Mr John Ward, Ms Francesca Wigney and Mr Andrew Wulf. Contributors from the Radiation Health Services Branch were: Dr Gillian Hirth, Dr Marcus Grzechnik, Mr Scott Muston and Mr Blake Orr. Mr Martin Reynolds, General Counsel, reviewed the statement of reasons and the licence.

[8] www.arpansa.gov.au/news/arpansa-issues-licence-operate-anstos-mo-99-facility#rar

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

[10] See https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides

[11] See https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications

[12] Membership, minutes and other documentation is available at ARPANSA's website; https://www.arpansa.gov.au/about-us/advisory-council-and-committees/nuclear-safety-committee. The Committee is chaired by Dr Tamie Weaver (VIC).

[13] Further information on all advisory bodies is at https://www.arpansa.gov.au/about-us/advisory-council-and-committees

[14] See https://www.arpansa.gov.au/about-us/advisory-council-and-committees/roles-and-expectations-advisory-committees

- The NSC met on 20 October 2017. Members had received a first and early draft of the RAR for discussion. The minutes state:

  > *The Committee discussed a number of the aspects considered in the assessment including the risk assessments, waste, commissioning processes, quality assurance and ongoing monitoring. The Committee concluded that some changes and additional information would be desirable to verify that the facility had been built as planned and approved.*

  ARPANSA has subsequently continued its assessment of these matters and performed verification of conformance with approved specifications of structures, components, systems and equipment; as reviewed in the RAR and summarised in this statement of reasons.

- On 15 March 2018, Members visited ANSTO and sighted the *ANM Facility*, including areas that will be forbidden for routine access should operations using irradiated targets commence. The facility had at the time reached its final stages of completion and commissioning using non-radioactive material and un-irradiated target plates ('cold' commissioning).

- On the next day, 16 March 2018, the Committee met to discuss, among other items on the agenda, the licensing and associated licence conditions for the *ANM Facility*. Committee members had received a preliminary version of this statement of reasons, and draft licence conditions. A number of issues that are further dealt with in this statement of reasons were discussed in detail. Members deliberated on whether a licence to authorise operations was appropriate and if so, what form is should take. The Committee supported my preliminary intention to authorise only commissioning tests using irradiated target plates (i.e. *not* routine operations). The minutes from the NSC meeting record the view of the NSC as follows:

  > *The Committee reviewed and discussed the information supplied with the application including the assessment of risk and benefit, resourcing, and waste. The Committee supported the CEO's preliminary intention to authorise only hot commissioning of the facility and left it with the CEO to decide on an appropriate way to implement this constraint. A range of licensing options, and conditions, were discussed which could efficiently and effectively achieve this outcome.*

Licence Condition 1 (see section 5[15]) constrains the operation of the *ANM Facility* to only hot commissioning. As detailed in this statement of reasons, a number of conditions collectively captured under Licence Condition 1 will have to be fulfilled before transition to routine operations can be considered.

3.3 International best practice

Sub-section 32(3) of the Act requires the CEO of ARPANSA to consider *international best practice* in relation to radiation protection and nuclear safety when deciding whether to issue a licence. In my view, and for the purpose of this decision, consideration of international best practice involves the following:

- the radiation protection, and nuclear safety and security objectives as a part of siting, design, operation, and decommissioning; compared to those laid out in the international framework for safety, security and radiation protection documented in international standards
- technical standards for construction, materials and other features relevant to safety

[15] Note that the numbering of the licence conditions in this statement of reasons differs from that in the licence. This is because a number of standard conditions are included in the licence that are not dealt with in this statement of reasons, which only deals with conditions that are specific to the *ANM Facility*.

- experience from siting, construction, operation, and decommissioning of similar facilities in countries with an advanced infrastructure for safety.

The elements of the international framework for safety, which I consider international best practice, are laid out in, *inter alia*, the Safety Fundamentals and Safety Requirements published by the *International Atomic Energy Agency* (IAEA)[16]; in the IAEA Fundamentals and Recommendations on Nuclear Security[17], and in the Recommendations of the *International Commission on Radiological Protection* (ICRP)[18]. The framework is supported by assessments of health and environmental risks such as the scientific evaluations carried out by the *United Nations Scientific Committee on the Effects of Atomic Radiation*[19] (UNSCEAR). ARPANSA, and Australia, play very active roles in the international fora that continually develop and improve the international risk assessments and the framework for safety (including security).

ARPANSA's approach to international best practice aligns with the Australian Government's policy on international standards and risk assessments[20], noting that the relevance of such standards and risk assessments in the Australian context has to be evaluated on a case-by-case basis. ARPANSA maintains information on a selection of relevant standards and risk assessments on its website[21]. ARPANSA's regulatory guides prepared for applicants and licence holders, as well as the RPS suite of publications developed in collaboration with state and territory regulators across Australia, reflect international best practice as applicable in the Australian context.

3.4 Matters specified in the Regulations that must be taken into account when issuing a facility licence

Sub-regulation 41(3) specifies matters that I must take into account in deciding whether to issue a facility licence. The matters are the following:

1) whether the application includes the information requested
2) whether the information establishes that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment
3) whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility
4) whether the applicant has shown 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 social factors
5) whether the applicant has shown a capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act
6) whether the application has been signed by an office holder of the applicant, or a person authorised by the office holder of the applicant

[16] See http://www-ns.iaea.org/standards/

[17] See http://www-ns.iaea.org/security/nuclear_security_series.asp?s=5&l=35

[18] See http://www.icrp.org/publications.asp

[19] See http://www.unscear.org/unscear/en/publications.html

[20] See https://www.education.gov.au/news/international-standards-and-risk-assessments

[21] See https://www.arpansa.gov.au/regulation-and-licensing/regulation/international-best-practice

7) for a nuclear installation, the content of any submissions made by members of the public about the application.

Sections 4.1 to 4.7 of this statement of reasons deal with these matters.

4. Reasons for the decision

4.1 Does the application include the requested information?

Sub-regulation 41(3) specifies that, in deciding whether to issue a facility licence, I must take into account whether the application includes the information requested.

4.1.1 Stepwise process for application and regulatory review

It is implicit in the Regulations (see Schedule 3, Part 1) and established good practice that the licensing of a complex facility for which no design certification has been issued, will be staged with each stage subject to separate application, regulatory review and assessment, and decision. This applies to the *ANM Facility*, which is a *nuclear installation* under regulation 11. While not strictly a *nuclear fuel cycle facility* as defined by the IAEA[22], the IAEA Specific Safety Requirements SSR-4[23] includes facilities for "*separation of radionuclides from irradiated thorium and uranium*" under the safety requirements for nuclear fuel cycle facilities, based on:

> *[…] the processes and hazards at facilities that produce isotopes by chemical separation from nuclear material can be similar to the processes and hazards at facilities for the processing and reprocessing of nuclear fuel. The requirements of this publication* [i.e. SSR-4, explanation added] *relating to criticality safety and confinement can also be applied to these processes, in accordance with a graded approach*.

A staged process is appropriate for the *ANM Facility*, considering its complexity and the nature of the activities. It mitigates problems arising from important issues that potentially had been overlooked at the onset of the project, and acknowledges that plans may have to be significantly altered or projects even terminated, should any significant issue come to light at any stage of the licensing process. A determination should be made with regard to whether new issues, identified during the stepwise licensing process, materially challenge the decisions reached in *preceding* licensing stages, and on what course of action that in such case should be taken. Importantly, the regulator needs to be prepared to use its authority to pause projects or reverse decisions, should this be deemed justified.

The applicant should also submit information about *subsequent* licensing stages that provides the decision maker with sufficient information on the feasibility and full life-cycle safety of the facility and activity in question.

I briefly summarise considerations made in the preceding decisions in section 4.1.2. With respect to future licensing stages, decommissioning and management of radioactive waste are dealt with in other places in this statement of reasons.

[22] *IAEA Safety Glossary*, IAEA 2016; https://www.iaea.org/sites/default/files/17/11/iaea-safety-glossary-rev2016.pdf

[23] *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

Specifically for a facility of this nature, *commissioning* may require a step-wise process of its own. While the applicant should provide results from commissioning tests with an application to **operate** a facility, it is reasonable to separate between 'cold' commissioning without radioactive material or irradiated target material, and 'hot' commissioning with irradiated target material. In the case of the *ANM Facility*, hot commissioning involves tests using irradiated uranium target plates. Processing of irradiated targets is akin to routine operations and is, for the purpose of this decision, considered part of the application to **operate** the *ANM Facility* and the regulatory decision on that application.

An analysis of results from hot commissioning and further regulatory authorisation is required before routine operations for the stated purpose (production of Mo-99 for the domestic and international markets) may commence. Licence condition 1(a) has been issued to that effect (see section 5 of this statement of reasons).

4.1.2 Items identified in previous decision

Reponses to issues raised in relation to the licence to prepare a site for the ANM facility

In the statement of reasons underpinning my decision to grant ANSTO a licence to **prepare a site** for the *ANM Facility*, I requested ANSTO to consider:

> *Operational waste and contingencies. This applies in particular to the continued production of intermediate level waste in the case that the SyMo Facility does not go ahead or becomes - for whatever reason - inoperable; and, in the case that there are further delays in the establishment of the National Radioactive Waste Management Facility.*
>
> *Decommissioning and management of decommissioning waste […]. I consider it IBP* [international best practice; clarification added] *to consider the end-of-life aspects of a facility already at the planning stage, i.e. to consider the management of waste before the waste arises. Whilst the proposed facility may only be a small part of the decommissioning activities at the LHSTC, consideration of these aspects at the planning stage is important to avoid the creation of legacy situations.*
>
> *Accident analysis. As the plans for the construction of the facility progress, further analysis of accident scenarios will be expected, involving a range of potential scenarios and mitigation. I expect these analyses to be performed in consultation with ARPANSA staff.*

ANSTO's response to the above requests were dealt with in the RAR and statement of reasons underpinning the licence to **construct** the *ANM Facility*. No matter was identified in the review and assessment of the licence application that materially challenged the validity of the earlier decision to authorise ANSTO to **prepare a site** for the facility.

In the time between the two licensing decisions, a licence to **prepare a site** for, and **construct**, the *SyMo Facility* was issued[24]. ANSTO's intention is to treat liquid intermediate level waste (ILW) in the *SyMo Facility* and immobilise it in an inert matrix that potentially meets the waste acceptance criteria for final disposal in a – yet to be established – disposal facility for ILW. Furthermore, initial considerations of decommissioning of the *ANM Facility* had been made. ANSTO also provided information on contingencies, which essentially entails prolonged storage and immobilisation using conventional and proven technology, such as cementation. I concluded that the information submitted by ANSTO did not raise concerns over safety of on-site waste management in the short to medium term and that contingency planning, e.g. in relation to

[24] See https://www.arpansa.gov.au/news/decision-delegate-ceo-ansto-symo-facility

delays in the establishment of a National Radioactive Waste Management Facility (NRWMF) was satisfactory. ANSTO's accident analysis, and ARPANSA's independent analysis of radiation exposures resulting from accidents provided assurance that off-site exposures would have minor or negligible implications for the health of people and of the environment.

Based on the information, I considered I could proceed with taking a decision to **construct** the *ANM Facility*. However, long-term management of waste, in particular ILW, requires continued regulatory attention. I deal with this in my review of the waste management plan (see section 4.2.3) and in section 4.3 on net benefit.

Responses to issues raised in relation to the licence to construct the ANM Facility

As part of the licence to **construct** the *ANM Facility*, I issued the following licence condition regarding construction of items important to safety:

> *The licence holder must seek the approval of the CEO of ARPANSA for construction of any hot cells/cell containment, hydrogen gas and detection system and any cranes along with items identified as safety category 1 and safety category 2 in the Preliminary Safety Analysis Report (PSAR).*

The licence condition provided further detail to the condition outlined in regulation 54, which states the following:

> *The holder of a licence, or a person covered by a licence, must not construct an item that is important for safety, and that is identified in a safety analysis report, as part of the construction of a controlled facility, unless the CEO has given the holder, or the person, approval to construct the item.*

I also requested ANSTO to consider the following:

> *Just as the current radiopharmaceuticals production facility, the ANM Facility will generate noble gas emissions, where in particular emission of xenon-133 is of interest. At even the low (in terms of radiation dose) emission levels, the emissions are likely to be observed in the monitoring stations ARPANSA operates under the terms of the Comprehensive Nuclear Test Ban Treaty (CTBT). This interference can reduce the efficacy of the CTBT network. To protect the accuracy and sensitivity of the CTBT network ANSTO should aim at incorporating improved technology and operating the ANM Facility such that there is no increase in xenon-133 emissions, despite the approximately four-fold increase in production.*
>
> *When assessing the anticipated operating licence application, I expect plans and arrangements for managing safety at the ANM Facility to demonstrate that it will be operated safely and that, in the event of a process failure or equipment breakdown, can be brought safely to shut down and maintained in a safe shutdown state pending the development of a suitable maintenance recovery process. I expect that the plans and arrangements, including maintenance and recovery processes will be further developed during the commissioning process involving nonradioactive material.*

ANSTO has submitted information in relation to the above. Fourteen applications under regulation 54 were submitted and have been approved. The review of other information has highlighted a number of issues that are dealt with in subsequent sections of this statement of reasons, and that will need to be resolved. This includes the previously identified uncertainties regarding long-term management of operational waste, in particular ILW.

4.1.3 General information relevant to Schedule 3 Part 1 of the Regulations

The general information that may be requested with a licence application is specified in Table 1.

Table 1. General information that may be requested in relation to an application for a licence for a controlled facility, specified in Schedule 3 Part 1 of the Regulations

Item	Information requested
1	The applicant's full name, position and business address.
2	A description of the purpose of the facility that is to be authorised by the facility licence.
3	A detailed description of the controlled facility and the site for that facility.
4	Plans and arrangements describing how the applicant proposes to manage the controlled facility to ensure the health and safety of people, and the protection of the environment including the following information: a) the applicant's arrangements for maintaining effective control of the facility; b) the safety management plan for the controlled facility; c) the radiation protection plan for the controlled facility; d) the radioactive waste management plan for the controlled facility; e) the security plan for the controlled facility; f) the emergency plan for the controlled facility; and g) the environment protection plan for the controlled facility.

Items 1 and 2

Items 1 and 2 of Schedule 3 Part 1 of the Regulations concern the applicant details and the purpose of the facility. The information is unchanged from previous stages of licensing.

The purpose of the *ANM Facility* (in Building 88) is to extract and purify Mo-99 produced through nuclear fission in low enriched uranium (LEU) target plates irradiated in the OPAL reactor, for primarily the Australian and New Zealand markets and also, as opportunities present themselves, to supply Mo-99 to the international market. The quality control (QC) will take place in the Building 2 QC Active Laboratory. Waste will be stored at the facility and managed using other facilities within LHSTC (including the *SyMo Facility*, subject to regulatory approvals), pending further pre-disposal management as necessary and ultimate disposal.

The *ANM Facility* is planned to produce close to 4 000 'six-day curie' per week (approximately 150 terabecquerel) at full capacity, which is about twice the capacity of the current operations in Building 54. The *ANM Facility* is intended to replace the production facility in Building 54, where production will be wound down and eventually cease.

No other purpose than production of the purified Mo-99 product, and activities incidental to the manufacturing of the Mo-99 product, has been stated in the application. Variations that in any way would alter the purpose or have significant implications for safety, require separate approval by ARPANSA.

Item 3

Item 3 of Schedule 3 Part 1 of the Regulations concerns a detailed description of the facility and the site for that facility. ANSTO submitted relevant facility details as part of the approved application for a licence to **construct** the facility, and in applications under regulation 54. Section 4.1.5 considers the facility as built.

Information on site characteristics was submitted with the application to **prepare a site** for the *ANM Facility* and has also been considered in previous regulatory reviews, e.g. in relation the establishment of the OPAL reactor.

ANSTO submitted a referral for the *ANM Facility* to the then Department of Sustainability, Environment, Water, Population and Communities (now the Department of Environment and Energy) as required by the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act). The Department assessed the referral and decided that the proposed action is not a controlled action under the EPBC Act, provided it is undertaken in accordance with its ARPANSA licence, and the documents submitted.

The *ANM facilit*y is co-located with a number of other facilities such as the OPAL reactor and facilities for storage of waste, and for experimental and applied science. It is therefore important to consider implications of an event at other facilities at the site, e.g. the OPAL reactor, for maintaining safety in the *ANM Facility*, as well as common-cause events such as loss of external power and a complete black-out.

Item 4

Item 4 of Schedule 3 Part 1 of the Regulations concerns the plans and arrangements for safety. ANSTO has provided the information relevant to Item 4 with the earlier applications for a licence to **prepare a site** for, and to **construct**, the *ANM Facility*. ANSTO has provided updated information with the application to **operate** the *ANM Facility*. This information is discussed in section 4.2 as well as in other parts of this statement of reasons.

4.1.4 Information relevant to possess or control a controlled facility under Schedule 3 Part 1 of the Regulations

ANSTO has not sought authorisation to possess or control the ANM Facility. However, this may become relevant in case the facility has to be brought to a state of control in the case of events with safety significance, during either hot commissioning or routine operations. This condition may also become relevant when the routine operations have ceased. Table 3 includes information specified in Schedule 3 part 1 of the Regulations that may be requested for such circumstances.

Table 2. Information that may be requested in relation to possess or control a controlled facility, specified in Schedule 3 Part 1 of the Regulations

Item	Information requested
13	The arrangements for maintaining criticality safety during loading, moving or storing nuclear fuel and other fissile materials at the controlled facility.
14	The arrangements for safe storage of controlled material and maintaining the controlled facility.

It is relevant here to reiterate what was stated in section 4.1.2 concerning information I expected ANSTO to submit with an application to **operate** the *ANM Facility*:

> *[…] I expect plans and arrangements for managing safety at the ANM Facility to demonstrate that it will be operated safely and that, in the event of a process failure or equipment breakdown, can be brought safely to shut down and maintained in a safe shutdown state [...].*

ANSTO has provided information that provides a satisfactory level of assurance that the facility can be shut down safely and maintained under control, should an unforeseen event with safety implications occur during hot commissioning. Safe shutdown means that no movement of radioactive material or liquids take place and that cooling and ventilation, if and as required, is provided. The provisions for safe shutdown have been reviewed by the ARPANSA regulatory officers, and considered to be satisfactory for the purpose of commencing hot commissioning. I concur with their assessment.

Any future approval for transitioning to routine operations requires ANSTO to demonstrate that arrangements are in place for safe long-term management in relation to items 13 and 14, i.e. in relation to *possess and control*, should a major event occur that forces prolonged outage. I have specified this requirement in Licence Condition 1(c).

4.1.5 Information relevant to the operation of a controlled facility under Schedule 3 Part 1 of the Regulations

Items 15-19 of Schedule 3, Part 1 of the Regulations specify the information that may be requested in relation to an application for a licence to **operate** a controlled facility (see Table 2).

Table 3. Information that may be requested in relation to the operation of a controlled facility, specified in Schedule 3 Part 1 of the Regulations

Item	Information requested
15	A description of the structures, components, systems and equipment of the controlled facility as they have been constructed
16	A final safety analysis report that demonstrated the adequacy of the design of the controlled facility, and includes the results of the commissioning tests
17	The operational limits and conditions for the controlled facility
18	The arrangements for commissioning the controlled facility
19	The arrangements for operating the controlled facility

Item 15: Description of the facility as constructed

The structures, components, systems and equipment of the facility must be designed and constructed so that they carry out the necessary functions for receiving and dissolving irradiated uranium target plates, and for the subsequent production of a purified Mo-99 product; in a manner that provides for protection of people and the environment from the harmful effects of radiation. This requires the identification of items important to safety and an assessment of the design, construction, performance, operability (including human factors) and possible accident scenarios. The IAEA General Safety Requirements, No. GSR Part 4[25], states:

> ***Requirement 7: Assessment of safety functions***
>
> ***All safety functions associated with a facility or activity shall be specified and assessed.***
>
> *All safety functions[26] associated with a facility or activity shall be specified and assessed. This includes the safety functions associated with the engineered structures, systems and components, any physical or natural barriers and inherent safety features, as applicable, and any human actions necessary to ensure the safety of the facility or activity. This is a key aspect of assessment, and is vital to the assessment of the application of defence in depth […]. An assessment is undertaken to determine whether the safety functions can be fulfilled for all normal operational modes (including startup and shutdown where appropriate), all anticipated operational occurrences and the accident conditions to be taken into account.*

[25] *Safety Assessment for Facilities and Activities.* General Safety Requirements No. GSR Part 4, Rev. 1, IAEA 2016; https://www-pub.iaea.org/MTCD/publications/PDF/Pub1714web-7976998.pdf

[26] From GSR Part 4: **Safety functions** are functions that are necessary to be performed for the facility or activity to prevent or to mitigate radiological consequences of normal operation, anticipated operational occurrences and accident conditions. These functions can include control of reactivity, removal of heat from radioactive material, confinement of radioactive material and shielding, depending on the nature of the facility or activity.

The Specific Safety Requirements No. SSR-4 states with regard to items important to safety of nuclear fuel cycle facilities:

> ***Requirement 13: Safety classification of items important to safety***
>
> ***All items important to safety for a nuclear fuel cycle facility shall be identified and shall be classified on the basis of their safety function and their safety significance.***

Among criteria to be used when identifying items important to safety, SSR-4 includes:

a) *the safety functions to be performed by the item;*

b) *the consequences of failure to perform a safety function;*

c) *the time following a postulated initiating event at which, or the period for which, the item will be called upon to perform a safety function.*

In the preliminary safety analysis report (PSAR), ANSTO identified 29 items important to safety that were grouped into 14 separate applications for approval under regulation 54 (Table 4). The PSAR was a key document considered in granting the licence to **construct** the *ANM Facility*. ANSTO's identification of items important to safety took the above factors into account, including the frequency with which the safety item will be called upon to perform a safety function.

Table 4. Applications for approval to construct items important to safety, pursuant to regulation 54

ID	Description
RFA01	Basement Shielding – decay tanks and enclosures, HEPA/SIAMs/Shielding; concrete walls, floor and roof shielding
RFA02	Liquid waste Decay Tank System Shielding – basement low level liquid waste system/shielding/containment; outside decay tanks and enclosures/shielding containment
RFA03	Concrete shielding for dissolution hot cell, hydrogen conversion hot cell and solid waste (intermediate level and low level) hot cells
RFA04	Lead shielding for purification hot cell, evaporation hot cell, dispensing hot cell, packaging hot cell and in-process sampling hot cell
RFA05	Rear of cells crane
RFA06	Other crane
RFA07	Ground floor shielding
RFA08	Hot cell (HC) and Liquid waste containment system (CS)
RFA09	Active Ventilation System
RFA10	Remaining Shielding Elements
RFA11	Radiation Monitoring System
RFA12	Process Containment (PC)
RFA13	Safety Interlocking System
RFA14	Criticality Assessment

The identification of the items was informed by the operating experience from Mo-99 production in Building 54, where ANSTO has been utilising the alkali-based Mo-99 production process since 2009. The design and the qualification of components to be used in the *ANM facility* has also been informed by the

collective experience of ANSTO and overseas users of the alkaline fission product dissolution process, *e.g.* through ANSTO's technical cooperation with NTP Radioisotopes SOC Ltd. in South Africa.

The RAR deals with the structures, components, systems and equipment as built in further detail. The ARPANSA regulatory officers have taken a graded approach to verification of the facility. This includes review of relevant documentation for safety related items (including but not limited to drawings, test protocols, ANSTO signoff documentation, and documentation provided by suppliers); observations on site; and monitoring of testing and cold commissioning. To the extent the ARPANSA regulatory officers have been able to ascertain, safety related items have been constructed according to plans and using appropriate quality systems, or with minor deviations with negligible impact on safety. The verification has also provided reasonable assurance that structures, components, systems and equipment have been constructed and perform according to the specifications outlined in the requests for approvals under regulation 54. Few deviations from expected performance were noted and were either rectified or found to be well within the tolerable range for safe performance.

In total, ARPANSA regulatory officers performed 28 inspections and site visits during the construction of the *ANM Facility*. Their overarching conclusion is:

> *The structures, systems and components have been constructed in accordance with the approved design, and the design objectives and criteria of all the items important for safety have been achieved. No issues have been identified that may preclude the hot commissioning of the safety related systems*

Items 16 and 17: Final safety analysis report; and operational limits and conditions

The *Final Safety Analysis Report* (FSAR) must be relevant to the facility as built, including the structures, components, systems and equipment that are important to safety, and demonstrate that all the relevant safety requirements are met by the facility design, construction and operations. The *operational limits and conditions* (OLCs) define the parameter values and other conditions, including personnel, within which the facility must operate, based on the design of the facility and the safety analysis.

With regard to safety analysis, the IAEA General Safety Requirements No. GSR Part 4 states:

> ***Requirement 14: Scope of the safety analysis***
>
> ***The performance of a facility or activity in all operational states and, as necessary, in the post-operational phase shall be assessed in the safety analysis.***
>
> *The consequences arising from all conditions in normal operation (including startup and shutdown, where appropriate) and the frequencies and consequences associated with all anticipated operational occurrences and accident conditions shall be addressed in the safety analysis. The analysis shall be performed to a scope and level of detail that correspond to the magnitude of the radiation risks associated with the facility or activity, the frequency of the events included in the safety analysis, the complexity of the facility or activity, and the uncertainties inherent in the processes that are included in the safety analysis. The analysis of accidents shall also be made for the purposes of emergency preparedness.*
>
> *Anticipated operational occurrences and accident conditions that challenge safety shall be identified in the safety analysis.*

ARPANSA assessed the *preliminary safety analysis report* (PSAR) as satisfactory for the purpose of authorising ANSTO to **construct** the *ANM Facility*. The application to operate the facility was supported by

the **ANM Mo99 Facility Final Safety Analysis Report (FSAR), P-50098, Revision 2**[27]. Revision 3 of the FSAR was provided later and takes into account ARPANSA's initial feedback.

The FSAR comprehensively reviews the safety of the facility and its operation, including but not limited to buildings, site, structures, components, systems, equipment, processes, waste management and management for safety. It references relevant technical standards applied in the design and construction of the facility. It is underpinned by the operational risk assessment and other supporting documentation.

The ARPANSA regulatory officers reviewed the FSAR and recorded their observations in the RAR. They are of the view that the FSAR identifies all relevant safety issues and that the principles for safety have been applied in a satisfactory manner. I consider here the risk assessment where I find that improvements can be made; the accident analysis (underpinning the emergency preparedness categorisation); and the OLCs.

Risk assessment: ANSTO submitted the risk assessment supporting the licence application in document **ANSTO/T/TN/2015-20 ANM Mo-99 Operational Risk Assessment rev 1**[28] (March 2017). Risk is an aggregated measure based on the likelihood of an event, and the consequence should the event occur. The estimates of risk may be used to guide decisions on acceptability (as modified by risk appetite and tolerance) and prioritisation of mitigatory actions. ANSTO's risk matrix grades the likelihood of an event in seven categories ranging from extremely unlikely (with a nominal frequency of one in 300 000 years or a range of 10^{-6} to 10^{-5} occurrences in a year); to almost certain (with a nominal frequency of 3 per year, or ranging from 1 per year to anything above one per year). Consequences range from negligible to catastrophic in six separate categories.

As previously mentioned, the risk assessment was reviewed by NSC members and discussed at the Committee meeting on 30 June 2017. The minutes from the meeting recorded the discussions as follows:

> *[…]. The risk assessment does not demonstrate an evaluation of risk control effectiveness and contains unsupported assertions. The Committee noted the need to include frontend workforce involvement in regard to the human factors relating to operation. The appendix of categories does not include the definition of terms such as "incredible".*

In collaboration with NSC members, ARPANSA provided an additional set of questions regarding the risk assessment to ANSTO. The responses to the questions outline the reasoning behind the assessment of specified scenarios being "incredible" (scenarios below the range of assessed likelihoods of occurrence) for a number of potential "high consequence" scenarios. In six applications under regulation 54 (RFAs 05, 06, 09, 11, 12 and 13; *cf*. Table 4), ARPANSA accepted the reasoning behind the scenarios being incredible. Considering the safety function of an item important for safety, reliability of the components comprising this item and the demand for that item in routine operation and abnormal occurrences, a 'Fault Tree Analysis' had been undertaken by ANSTO. For a major or severe radiological consequence of scenarios involving the above items important for safety, multiple failures of the safety systems along with failures of administrative controls must occur concurrently. Such failures were considered to be prevented by the design of the facility, and by engineering and administrative controls. Therefore, the likelihood of the scenarios was assessed as less than 10^{-6} per year.

On further review of the risk assessment, it appears that it does not analyse in great detail the significance of human factors in relation to estimates of the likelihood of an event occurring, which is particularly

[27] See https://www.arpansa.gov.au/sites/g/files/net3086/f/p-50098-r2-safety-analysis-report.pdf

[28] See https://www.arpansa.gov.au/sites/g/files/net3086/f/ansto-t-tn-2015-20-rev1-risk-assessment_0.pdf

important in relation to events of low likelihood. Asked by ARPANSA and NSC, ANSTO referred to NUREG CR-1278 developed for the US Nuclear Regulatory Commission in the 1980s, and to event feedback in ANSTO's internal reporting. In my opinion and for low probability/high consequence scenarios, overreliance on either of these should be avoided and the resulting risk for such scenarios should be considered notional.

A recent event causing overexposure of a worker performing quality control of a Mo-99 product in Building 23, may serve as an illustration of potential overreliance on risk analysis for such scenarios. While it should be noted that regulatory review of this event is not yet concluded, observations from ARPANSA's inspections point to the fact that the risk was underestimated and that the estimate of likelihood was not correctly informed by reporting of events and near misses from similar practices ANSTO-wide.

ARPANSA received Revision 2 of the operational risk assessment in November 2017. It includes 14 recommendations aimed at managing risks. ANSTO also submitted a revised risk assessment for the QC procedures carried out in Building 2 in **ANSTO/T/TN/2016-02 rev 1 Risk Assessment of the B2 Quality Control Laboratory** (December 2017). This risk analysis contains another set of 14 recommendations. It appears that only one of the 28 recommendations specifically addresses human factors:

> *Recommendation 13* [of the risk assessment for Building 2 QC Active Laboratory; clarification added]*: Ensure during high hazard operations, such as sub-dispensing of QC samples, operators work in an appropriate team to ensure adequate checking of operational practices takes place.*

On 19 December 2017, I informed ANSTO that I had found the organisation in breach of sub-section 30(2) of the Act in relation to the contamination event, and requested a corrective action plan. In response, the CEO of ANSTO provided me with the requested corrective action plan and, in addition, committed ANSTO to:

> *"[…] undertake an independent review of all ANSTO Health procedures that have been identified as high risk"*

While I support this initiative, I also believe it should cover all scenarios that have been identified as having 'moderate' or more severe consequence of radiological nature, regardless of likelihood and including a reassessment of "incredible" scenarios. This would include all events that might reach and potentially exceed statutory dose limits. It is highly likely that any such event would also be rated on the *International Nuclear and Radiological Event Scale*[29] (INES), and reported accordingly. A further analysis should take place regarding the contribution by human factors to the likelihood of events and how increased attention to such factors can contribute to lowering of the likelihood of events with moderate and more severe consequences. Licence Condition 1(d-h) are relevant to risk assessment and risk reduction, including the contribution by human factors (see section 5).

Accident analysis: Potentially bounding accident scenarios with severe radiological consequence have been considered in the accident analysis. These include criticality accidents and target meltdown caused by residual heat generation during transfer of the target plates from the OPAL reactor to the *ANM Facility*. The ARPANSA reviewers consider that systems, procedures and controls make a criticality event unlikely. Regarding potential target melt, there is ample experience from the current production of Mo-99 and the handling of target plates. Similar procedures as implemented currently will be followed for the *ANM Facility*; based on the totality of information, ARPANSA reviewers accept that target plate meltdown is unlikely. I agree with the ARPANSA reviewers that neither a criticality accident nor target meltdown appear

[29] See https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/reporting-an-accident/ines-scale

to be a suitable basis for analysis of a 'bounding' accident scenario, i.e. for the purpose of guiding the dimensioning and the arrangements for the facility's emergency response capability.

The *reference accident* for the *ANM Facility* was originally a hypothetical seismic event causing rupture of pipework and subsequent release from two dissolver runs to the atmosphere. ANSTO has recently and in communication with ARPANSA staff analysed a hypothetical 'unspecified energetic event' defined as some event that causes massive damage to the dissolver(s) and building, where the inventory of two dissolvers is assumed to be affected; resulting in a rapid release of radionuclides into the atmosphere which occurs at ground level. This is now in ANSTO's submission referred to as *design extension conditions*[30]. From the IAEA Specific Safety Requirements No. SSR-4:

> ***Requirement 21: Design extension conditions***
>
> ***A set of design extension conditions shall be derived on the basis of deterministic analysis and engineering judgement with complementary probabilistic assessments (as appropriate), in accordance with a graded approach, to further improve the safety of the nuclear fuel cycle facility by enhancing its capabilities to withstand, without unacceptable consequences, accidents that are either more severe than design basis accidents or that involve additional failures. The design extension conditions shall be used to identify the additional accident scenarios to be addressed in the design and to plan practicable provisions for the prevention of such accidents or mitigation of their consequences.***
>
> *[…]. New facilities shall be designed such that the possibility of conditions arising that could lead to early releases of radioactive material or to large releases of radioactive material is practically eliminated. The design shall be such that, for design extension conditions, off-site protective actions that are limited in terms of times and areas of application shall be sufficient for the protection of the public, and sufficient time shall be available to take such actions. The postulated initiating events that lead to design extension conditions shall also be analysed for their capability to compromise the ability to provide an effective emergency response. Only those protective actions that can be reliably initiated within sufficient time at the location shall be considered available.*

As part of the review of documentation and verification on site, the ARPANSA reviewers have considered features events and processes, as well as the assumptions included in the dose assessment of relevance for the accident analysis. They conclude that the features of the facility as built, and as planned to operate, demonstrate considerable capacity to prevent and withstand accidents and their progression, in line with the principle of defence in depth. A formal review explicitly addressing design extension conditions as such has not been performed by ANSTO. However, I concur with the reviewers' conclusions that the features are such that a range of, and combinations of, severe disruptive events are unlikely to lead to significant off-site consequences. Potential consequences include impact on the health of people and the environment, and contamination on site and in surrounding areas.

The first *periodic safety and security review*, which I believe is appropriate to perform after gaining five years of operational experience of routine operations, should include a formal analysis of design extension scenarios. Licence Condition 6 has been issued to that effect (see section 5).

The estimates of radiation exposures following the 'unspecified energetic event' indicate a maximum effective dose to a member of the public of 0.83 mSv; and 4.2 mSv to a worker on site. ANSTO's dose estimates are consistent with ARPANSA's analysis. In further discussions between ANSTO and ARPANSA's regulatory and science officers, ANSTO has stated that there is a potential that protective actions may be

[30] From the *IAEA Safety Glossary*, IAEA 2016: **Design extension conditions:** Postulated accident conditions that are not considered for design basis accidents, but that are considered in the design process of the facility in accordance with best estimate methodology, and for which releases of radioactive material are kept within acceptable limits. **Safety feature for design extension conditions:** Item that is designed to perform a safety function for or that has a safety function for design extension conditions.

justified under certain circumstances outside of the LHSTC perimeter but not outside the residential buffer zone of 1.6 km radius surrounding the site. Such actions would be consistent with recommendations[31] issued by ARPANSA. Assumptions used in the calculations were pessimistic but not unrealistic.

ANSTO has proposed that the appropriate *emergency preparedness category* for the *ANM Facility*, pursuant to the IAEA General Safety Requirements No. GSR Part 7[32], should be category II. GSR Part 7 describes facilities included in emergency preparedness category II as follows[33]:

> *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.*

ANSTO must plan and exercise its emergency response capabilities on the basis that the facility is emergency response category II, using a graded approach. Licence Condition 1(i) addresses this.

Operational limits and conditions: The IAEA Specific Safety Requirements No. SSR-4 states with regard to OLCs:

> ***Requirement 18: Specification of operational limits and conditions***
>
> ***Operational limits and conditions shall be prepared in the design stage, confirmed in the commissioning stage and established before operations of the facility commence.***
>
> *Operational limits and conditions are a set of rules setting forth parameter limits, the functional capability and the performance levels of equipment and personnel for the safe operation of a facility. Operational limits and conditions necessary for safe operation shall be developed in the design stage for a new facility and updated, if necessary, during commissioning to allow time for validation and approval.*
>
> *The safety analysis report shall describe the assumptions and provide the basis for the operational limits and conditions presented in the licensing documentation.*

The operational limits and conditions (OLCs) are outlined in the document **Operating Limits and Conditions P-50099**[34]. The regulatory officers concluded that relevant OLCs have been derived from a number of features, events and processes covered in the FSAR. A subset of OLCs was verified by the ARPANSA regulatory officers during cold commissioning tests. There is, in the opinion of the regulatory officers a sufficiently strong basis for the OLCs in the FSAR and they conclude that:

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[31] *Recommendations for Intervention in Emergency Situations Involving Radiation Exposure*, Radiation Protection Series No. 7 (ARPANSA 2004). See https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/guides-and-recommendations/rps7. **Note** that at the time of this decision, a new RPS Guide on *Radiation Protection in Emergency Exposure Situations* had been released for public consultation. The dose criteria for taking certain actions of relevance for the reasoning in this statement of reasons remain unchanged.

[32] *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

[33] The emergency preparedness categories of GSR Part 7 have replaced the *hazard categories* of the now withdrawn *Regulatory Assessment Principles*. The Principles are archived on ARPANSA's website, see https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides.

[34] See https://www.arpansa.gov.au/sites/g/files/net3086/f/p-50099_r3-operating-limits-and-conditions.pdf

> *[…] the derived OLCs would provide high degree of assurance that the facility will be operated safely and reliably subject to strict adherence to these OLCs and the corresponding surveillance requirements.*

I concur with the view of the regulatory officers and note - as they have done - that the hot commissioning tests will allow for an update of the OLCs and verification of their appropriateness for safe operations, which is in line with Requirement 18 of SSR-4 (see above).

Items 18 and 19: Arrangements for commissioning and arrangements for operations

Documentation and other information underpinning the arrangements for commissioning, including the 'hot' commissioning stage, include the following: the **Commissioning Plan Mo-99 Production Process Mo99_COMM_PROC_CTP_117435; the Commissioning Plan of Safety Related Systems Mo99_COMM_SAFE_PL_157336; and the Commissioning Report Mo-99_COMM_PROC_ER_8156**.

Documentation in support of operations include the **ANM Mo-99 Facility Safe and Secure Operations Manual P-50100**[37] as well as other documentation, e.g. the FSAR and the plans and arrangements for safety considered later in this statement of reasons.

The ARPANSA regulatory officers observed a number of commissioning tests, including 'water runs' (without target) and cold commissioning tests using target plates that had not been irradiated in the OPAL reactor. The officers consider cold commissioning was carried out in accordance with approved protocols captured in the licence to **construct** the *ANM Facility* and are of the view that the results of the cold commissioning tests are satisfactory.

While the ARPANSA regulatory officers are of the view that the safe and secure operations manual and other information available to them indicate that operations can be carried out safely, a decision to authorise routine operations is premature and would, at minimum, require the conditions outlined in Licence Condition 1 to have been fulfilled.

The *ANM Facility* is intended to replace the current production facility in Building 54. While the *ANM Facility* transitions to routine operations, ANSTO plan to continue production of Mo-99 in Building 54. Thus, the two facilities would operate concurrently, which requires the sharing of resources such as experienced and trained staff and a number of services provided by other parts of ANSTO. Transition to routine operations requires ANSTO to demonstrate that the organisation has achieved operational readiness to commence routine operations in the *ANM Facility*, and to gradually increase production in the *ANM Facility* while continuing production in Building 54, so that concurrent production arrangements do not pose concerns over safety. This is addressed in Licence Condition 1(b). A plan for the winding down and eventual cessation of production in Building 54 must be submitted under Licence Condition 1(j).

I consider it prudent and reasonable to cap the production capacity, while concurrent production of Mo-99 takes place in Building 54 and in the *ANM Facility*, at approximately the current capacity of Building 54 (Licence Condition 2). For a period of 18 months after the cessation of production in Building 54, ANSTO may call on Building 54 to sustain Mo-99 production during short-term outages in the *ANM Facility*, subject to ARPANSA's regulatory approval on each occasion (Licence Condition 3).

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[35] See https://www.arpansa.gov.au/sites/g/files/net3086/f/mo99_comm_proc_ctp_1174_b-commissioning-plan-process.pdf

[36] See https://www.arpansa.gov.au/sites/g/files/net3086/f/mo99_comm_safe_pl_1573_b-commissioning-plan-systems.pdf

[37] See https://www.arpansa.gov.au/sites/g/files/net3086/f/p-50100_r2-safe-and-secure-operations.pdf

Provided Licence Condition 1 can be removed and no safety issues have emerged during hot commissioning that require attention, routine operations may be authorised. ANSTO should carefully monitor the safety of routine operations and provide data and observations to ARPANSA with its quarterly reports, or as required. It is reasonable to perform a *periodic safety and security review* (PSSR) after gaining five years of operational experience after the finalisation of commissioning. The scope of the PSSR should be agreed with ARPANSA but should include information on operational experience, review of safety functions against a set of *design extension conditions* (see this section, *Items 16 and 17*), and security. It should also include a plan for implementation of actions identified during the course of the review. Licence Condition 6 has been issued to this effect.

4.1.6 Information relevant to the decommissioning of a controlled facility under Schedule 3 Part 1 of the Regulations

Items 20 - 21 of Schedule 3 Part 1 of the regulations specify information that may be requested in relation to an authorisation to **decommission** a controlled facility.

Table 5. Information that may be requested in relation to the decommissioning of a controlled facility (Schedule 3 Part 1 of the Regulations)

Item	Information requested
20	The decommissioning plan for the controlled facility
21	The schedule for decommissioning the controlled facility

With regard to decommissioning, the IAEA General Safety Requirements No. GSR Part 6[38] include the following relevant requirements:

> ***Requirement 8: Selecting a decommissioning strategy***
> ***The licensee shall select a decommissioning strategy that will form the basis for the planning for decommissioning. The strategy shall be consistent with the national policy on the management of radioactive waste.***
>
> ***Requirement 10: Planning for decommissioning***
> ***The licensee shall prepare a decommissioning plan and shall maintain it throughout the lifetime of the facility, in accordance with the requirements of the regulatory body, in order to show that decommissioning can be accomplished safely to meet the defined end state.***

While no specific information has been requested at this stage, general aspects of safe decommissioning were discussed in the Statements of Reasons underpinning my earlier licensing decisions. Section 13 of the FSAR, relevantly, considers factors important to the safe decommissioning of the facility.

In accordance with international best practice, it is desirable that ANSTO develops a detailed decommissioning strategy and plan for the decommissioning of the *ANM Facility* which takes into account experience from the first few years of operations. The strategy and plan must be aligned with GSR Part 6 and subsidiary IAEA Guides, adopt a graded approach and consider the options for final management

[38] *Decommissioning of Facilities*, General Safety Requirements No. GSR Part 6, IAEA 2014; https://www-pub.iaea.org/MTCD/Publications/PDF/Pub1652web-83896570.pdf

including disposal of the decommissioning waste in accordance with the Australian Government's policy and plans for the full life-cycle management of radioactive waste[39].

It would be reasonable to expect a detailed strategy and plan, as per above, at the time the first PSSR is performed for the facility, as this would allow for the incorporation of several years of operational experience in the decommissioning plan. This is captured in Licence Condition 7 (see section 5).

Items 22–23 of Schedule 3 Part 1 of the regulations concern information relevant to an authorisation to **abandon** a controlled facility. Consideration of abandonment has not been made and would, in any event, have to holistically take into account *all* activities at the LHSTC site. I do not believe it is reasonable to consider abandonment of the site at this stage.

4.1.7 Conclusions

With regard to whether the applicant has submitted the requested information:

The purpose of the ANM Facility has been stated and the verification of safety items performed by ARPANSA's regulatory officers, and observations made during cold commissioning tests, provide a satisfactory level of assurance that the facility has been built, and has the potential to operate, in accordance with approved plans and specifications. The FSAR records the facility as built and its safety features, and its performance within the constraints of the OLCs. Analysis of accident scenarios justify categorisation as an Emergency Preparedness Category II facility. The plans for 'hot' commissioning are adequate and will provide for additional verification of the appropriateness of the OLCs. Transition to routine operations must not commence before 'hot' commissioning data have been analysed and found to be satisfactory from the perspective of safety performance. While this is a normal precaution and good practice, I also consider that other matters must be addressed before transitioning to routine operations can be considered and potentially authorised. The review in this section has identified the approach to risk assessment and the analysis of contribution of human factors to events with safety significance, as such matters. Contingent on the outcome of the review of further matters specified in sub-regulation 41(3), I may, however, proceed with reaching a decision on whether to issue a licence to operate the ANM Facility for the purpose of commencing 'hot' commissioning tests.

4.2 Does the information establish that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment?

Sub-regulation 41(3) requires me to take into account whether the information establishes that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment, when deciding whether to issue a facility licence. At the core of this issue is the management system, which has the following objective as stated in the IAEA General Safety Requirements No. GSR Part 2[40]:

> *Management for safety: this includes establishing and applying an effective management system. This management system has to integrate all elements of management so that requirements for safety are established and applied coherently with other requirements, including those for human performance, quality and security; and so that safety is not compromised by the need to meet other requirements or demands. Safety measures and security measures must be designed and applied in an integrated manner. The*

[39] At the time of this decision, a draft ARPANSA Regulatory Guide: *Decommissioning of controlled facilities*, had been posted on ARPANSA's website for public consultation and the review of received comments was ongoing.

[40] *Leadership and Management for Safety*, General Safety Requirements No. GSR Part 2, IAEA 2016; https://www-pub.iaea.org/books/IAEABooks/11070/Leadership-and-Management-for-Safety

> *management system also has to ensure the fostering of a strong safety culture, the regular assessment of safety performance and the application of lessons from experience. The management system also supports the development of proactive and responsive management.*

Section 4.1.3 specifies the information (based on Schedule 3 Part 1 of the Regulations) that may be requested regarding plans and arrangements for safety that describe how the applicant proposes to manage the controlled facility to ensure that the facility does not cause undue risk to the health and safety of people, and to the environment. ARPANSA has published detailed guidance on plans and arrangements for managing safety[41].

Plans and arrangements for managing safety were submitted with the applications to **prepare a site** for, and to **construct**, the *ANM Facility*. They fall under ANSTO-wide and ANM-specific management systems and were considered generally satisfactory. Some important aspects of the plans and arrangements, in particular as they relate to **operation** of the facility, are considered here.

4.2.1 The arrangements for managing effective control; and the safety management plan

ANSTO's arrangements for managing effective control are outlined in the **Effective Control Plan, Q-50081**[42]. Operation of the facility will be undertaken by the ANSTO subsidiary; ANSTO Nuclear Medicine Pty Ltd, which is a majority owned subsidiary of ANSTO that has been established for the purpose to own and operate facilities built under the licence to **construct** the *ANM Facility*. The 'asset' is intended to be transferred to ANSTO Nuclear Medicine Pty Ltd at the time a licence to commence operations has been issued by ARPANSA, i.e. from the moment 'hot' commissioning is authorised.

In accordance with ARPANSA's guidance for applications where the applicant is not directly involved with day-to-day operations, ANSTO has provided the details of a person in effective control of the nuclear installation, the *nominee*[43]. The General Manager of the *ANM Facility* is the nominee, leads an organisation of approximately 60 staff and reports to the ANM Board. It should be noted, however, that the General Manager is the *only* employee of ANSTO Nuclear Medicine Pty Ltd and thus dependent on the provision of resources (staff, infrastructure, equipment and services) through service level agreements and other ANSTO internal systems. The *responsible person* is the CEO of ANSTO, with responsibility for providing resources for the safe operation of the facility. The *National Directory for Radiation Protection*[44] (*NDRP*) defines the responsible person, and the responsibilities conferred to the responsible person, as follows:

> ***Responsible person*** *in relation to any radioactive source, ionising or non-ionising radiation apparatus, nuclear installation, prescribed radiation facility or premises on which unsealed radioactive sources are stored or used means the person:*
>
> *a) having overall management responsibility including responsibility for the security and maintenance of the source, apparatus, installation or facility*
>
> *b) having overall control over who may use the source or apparatus, installation or facility*
>
> *c) in whose name the source, apparatus, installation or facility, would be registered if this is required.*

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[41] Regulatory Guide: *Plans and arrangements for managing safety*, ARPANSA 2017, https://www.arpansa.gov.au/sites/g/files/net3086/f/reg-la-sup-280b.pdf

[42] See https://www.arpansa.gov.au/sites/g/files/net3086/f/consultation/pdf/q-50081-r3-effective-control-plan.pdf

[43] Regulatory Guide: *How to apply for a facility licence for a nuclear installation*, ARPANSA 2016; https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/guides/REG-LA-SUP-240G.pdf

[44] *National Directory for Radiation Protection* (incorporating amendment 7), Radiation Protection Series No. 6 (ARPANSA 2017); https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/rps/rps6.pdf

On matters that impact compliance with the Facility Licence, the General Manager reports directly to the CEO of ANSTO and the Board is not consulted.

The plans and arrangements for managing safety are approved by the General Manager. As a subsidiary of ANSTO, the *ANM Facility* has adopted ANSTO policies. Management's commitment to maintaining safe and secure operations is generally well documented throughout the effective control plan and at lower level procedures.

The ARPANSA regulatory officers have reviewed the effective control plan and associated documents, including service level agreements. They are of the view that the arrangements are satisfactory, e.g. as regards statutory and regulatory compliance, management's commitment to maintaining safe and secure operations, accountabilities, internal communication including events communication, process implementation, and documentation. I consider that the arrangement with only one employee (the General Manager) leading all activities at the *ANM Facility* but being entirely dependent on ANSTO for resourcing of the activities, may potentially and in a worst-case scenario lead to competing priorities. However, ANSTO is aware that the *responsible person* for the purpose of compliance with the Act, Regulations and licence conditions issued under a facility licence, is the CEO of ANSTO. The resourcing of ANSTO, and the division of responsibilities and accountabilities, are satisfactory for the purpose of the safety of the facility. ANSTO's capacity to comply with the Act, Regulations and licence conditions I may impose, is further discussed in section 4.5.

The **ANM Safety Management Plan Q-50082**[45], in conjunction with other plans, outlines the safety management arrangements that are in place within the *ANM Facility* and the Building 2 QC Active Laboratory. It outlines the commitment to a strong safety culture where a questioning attitude is encouraged and that adopts a rigorous and prudent approach to work incorporating conservative decision making. Importantly, the plan states that safety is not subject to inappropriate commercial pressures. There is separation between ANSTO's safety approval processes and commercial decision-making processes. The ANSTO Safety Assurance Committee (SAC) holds responsibility and authority for granting safety approvals.

The ARPANSA reviewers consider the plans satisfactory and that the measures detailed in the plan and in the accredited quality system provide assurance that an appropriate level of safety can be maintained and that the organisation's goals can be achieved without compromising safety. I generally agree with the reviewers' assessment of both the effective control plan and the safety management plan, noting that the 'art' is in their implementation and – in particular with regard to safety culture – in avoiding complacency. It is necessary for ANSTO to compare the records of achievement with the intentions in the effective control and safety management plans, including identifying lesson-to-be-learned, implementation of relevant actions that make sure that the lessons *will* be learned, and verification they *have* been learned.

4.2.2 The radiation protection plan

ANSTO outlines its plans and arrangements for radiation protection in the *ANM Radiation Protection Plan Q-50083*[46], submitted with the application. Following initial discussions with ARPANSA's regulatory officers, ANSTO later submitted an updated plan, Revision 5.

The General Manager will have overall responsibility for radiation protection during the operation of the facility and the laboratory for quality control at all times. As stated in section 4.2.1 on effective control, the

[45] See https://www.arpansa.gov.au/sites/g/files/net3086/f/q-50082r3-safety-management-plan.pdf

[46] See https://www.arpansa.gov.au/sites/g/files/net3086/f/q-50083-r4-radiation-protection-plan.pdf

CEO of ANSTO in their capacity as *responsible person* for the purpose of the *NDRP*, is responsible for providing adequate resources to execute these responsibilities, and ultimately for the safety of the facility. ANSTO's Radiation Protection Services (RPS) will provide services, via a service level agreement, during the operation of the facility.

Radiation protection principle, in particular optimisation

The international system for radiological protection rests on three principles developed by the ICRP as outlined in *Publication 103*[47] and reflected in the *International Basic Safety Standards*, GSR No. Part 3[48], which have been adopted in Australia (see the *Fundamentals for protection against ionising radiation*[49] and the *Planned Exposure Code*[50]):

- *Justification* i.e. that any action leading to a change in exposure (be it by introducing a source or by making changes to a source or an exposure pathway that alter exposures) should 'do more good than harm' – see further section 4.3.
- *Optimisation i.e.* that exposures to individuals, number of people exposed, and the likelihood of exposures; are kept as low as reasonably achievable, economic and societal factors taken into account.
- *Dose limitation* i.e. that exposures of individuals are kept below dose limits, which will avoid unacceptable exposures of any individual caused by actions to reduce the number of exposed persons. Division 5.2 of the Regulations provide details of the statutory dose limits (see also the *Planned Exposure Code*).

While the practical arrangements outlined in the plan, e.g. as regards work planning, reporting and dose monitoring and surveys are satisfactory, I find the approach taken to implement the principle of optimisation somewhat deficient. I comment on optimisation of worker protection below.

The definition of optimisation used in section 5.2 of the radiation protection plan, under the heading *Optimisation of protection*, is not fully reflective of international best practice as implemented in Australia. ANSTO's radiation protection plan states:

> *ANM is committed to the fundamental radiation protection principle of optimisation by keeping the likelihood of incurring exposures, the number of people exposed, and the magnitude of their individual doses as low as reasonably achievable, taking into account economic and societal factors (the ALARA principle).*

The *Planned Exposure Code* states with regard to optimisation:

> *The principle of optimisation of protection requires that the likelihood of incurring exposures, the number of people exposed and the magnitude of the exposures should be all kept as low as reasonably achievable, taking into account economic and societal factors. The level of protection should be the best under prevailing circumstances and should provide for adequate margin of benefit over harm. The optimisation principle offers*

[47] ICRP *Publication 103*: The 2007 Recommendations of the International Commission on Radiological Protection, Annals of the ICRP, Vol 37 No 2-4, 2007. See http://www.icrp.org/publications.asp

[48] *Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards*. General Safety Requirements No. GSR Part 3, IAEA 2014; http://www.icrp.org/publications.asp

[49] *Fundamentals for Protection Against Ionising Radiation*, Radiation Protection Series No. F-1, ARPANSA 2014; https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/fundamentals/rpsf-1

[50] *Code for Radiation Protection in Planned Exposure Situations* (the Planned Exposure Code), Radiation Protection Series No. C-1, ARPANSA 2016; https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/codes-and-standards/rpsc-1

> *a means to take a graded approach to management of radiation risks and focuses on achieving an ethically acceptable outcome, within the boundaries of the legal system, based on balancing risks and benefits.*
>
> *[…] For occupational exposure the dose constraint is a value of individual dose used to narrow the range of options for managing the exposure such that only options resulting in a dose constraint are considered in the planning process. Actual doses are, thus, expected to be below the dose constraint in normal operation.*

It is important to note that optimisation of occupational exposure should be carried out against a dose constraint that guide the selection of management options among several. This is clarified in *Publication 103* of the ICRP, which states in paragraph 214:

> *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.*

This is not recognised in the radiation protection plan. It appears that actions to reduce doses are entirely focused on "as low as reasonably achievable" or "the ALARA principle", whereas the relevant principle in international best practice is *optimisation*. This would include, but not be limited to, comparison of alternative systems and methodologies, analysis of interdependencies and assessments of costs. The use of language such as "….*ensuring that all radiological exposures are ALARA*" (section 5.1 of the radiation protection plan) detracts from the full meaning of the concept of optimisation.

In the revised radiation protection plan and following initial discussions with ARPANSA officers, ANSTO has with regard to the *ANM Facility* abandoned the generic dose constraint of 15 mSv effective dose per year, previously used site-wide. This is a welcome development and ANSTO has stated that a re-evaluation of the dose constraint for the *ANM Facility* will now be based on the occupational dose assessment in document **Mo99_FACL_OPER_TN_0329_B: Dose Assessment,** submitted with the application[51].

However, the 'ALARA objective' of 2 mSv effective dose per year is still used. While this level of exposure does not give rise to health concerns, it is unclear how it will support the optimisation process, if at all.

I consider ANSTO should update its general approach to radiation protection and revise relevant documents in the management system. This must be carried out for the *ANM Facility* including the Building 2 QC Active Laboratory. Licence Condition 1(d, e) has been issued to that effect (see section 5).

4.2.3 The radioactive waste management plan

The LHSTC is the host of a variety of radioactive waste. ANSTO's waste management facilities are operating under licenses issued by ARPANSA and are subject to ARPANSA's regulatory oversight. This includes waste deposited at the Little Forest Legacy Site and other legacy waste; and, low-level and intermediate level

[51] See https://www.arpansa.gov.au/sites/g/files/net3086/f/mo99_facl_oper_tn_0329_b-dose-assessment.pdf

(LLW and ILW) solid and liquid waste stored and continually generated on site. The waste streams managed by ANSTO at LHSTC are outlined in Figure 1.

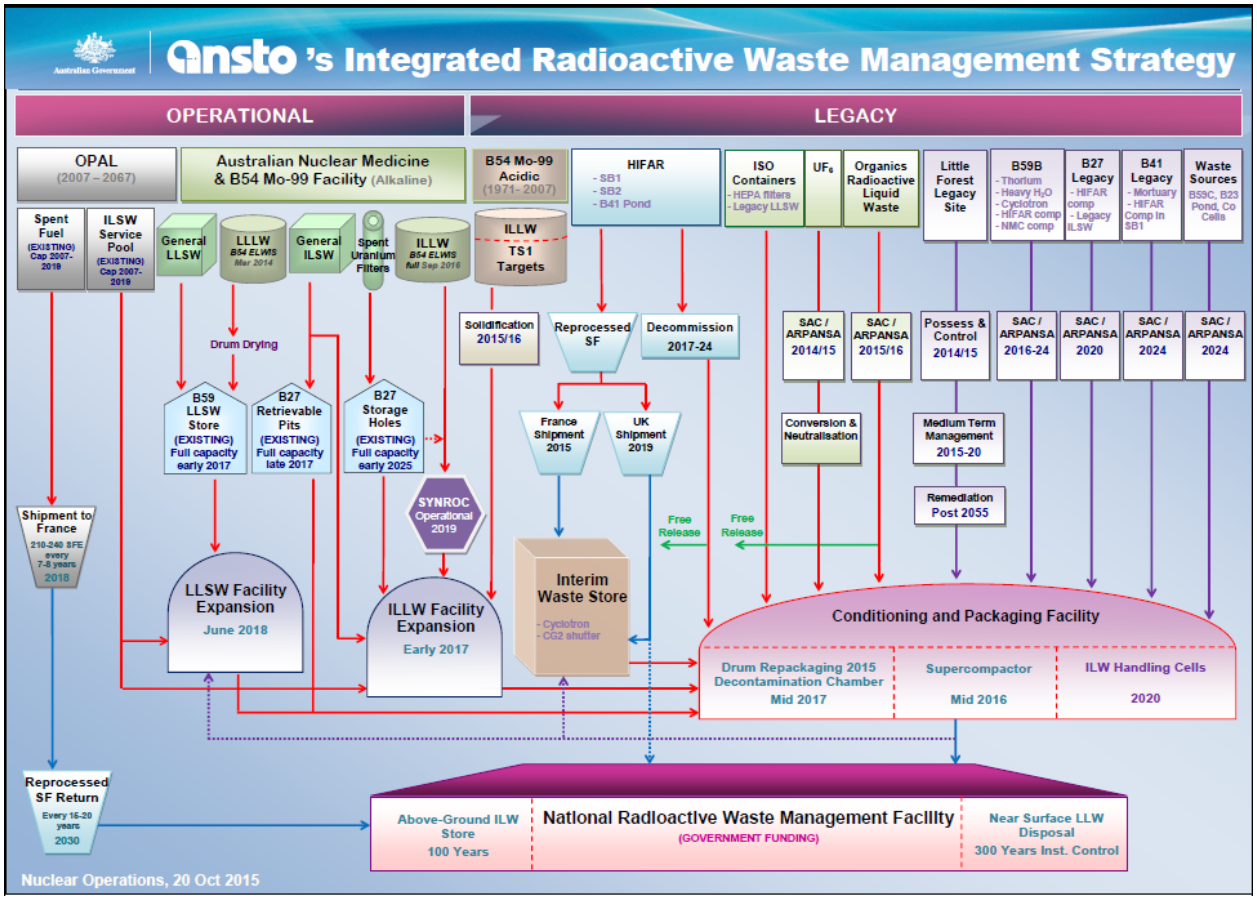

Figure 1. Management of radioactive waste generated and stored at ANSTO (source: ANSTO).

Spent nuclear fuel – while not considered waste *per se*[52] - will add to the ILW streams after it has been reprocessed in overseas facilities and the resulting ILW, less a major part of the fissile material, has been returned to Australia. Waste resulting from reprocessing overseas of fuel from the permanently shut down High Flux Australian Reactor (HIFAR) at LHSTC has already been returned and is stored in the *IWS Facility*, licenced to operate for this purpose in May 2015[53]. Further return shipments are planned by ANSTO in the next few years.

ARPANSA's regulatory officers have reviewed ANSTO's **Waste Management Plan for the ANM Facility, Q-50084,**[54] which covers the management of solid waste (low-level waste, LLW; and intermediate level waste, ILW), liquid LLW and ILW, discharges of liquid waste via the sewer system and gaseous emissions to the atmosphere. The classification of waste is consistent with the nationally adopted waste classification

[52] Spent fuel is considered (high-level) waste if *declared as waste*, i.e. material for which no further use is foreseen. Australia has entered into an agreement with the Government of France to reprocess the OPAL fuel at AREVA's (now ORANO) facilities in La Hague, France. The arrangements allow AREVA (ORANO) to keep the fissile material (mainly uranium and plutonium), which can be used for production of mixed oxide fuel (MOX). For this purpose spent fuel is considered a resource, not waste. The residual product from reprocessing is material for which no further use is foreseen, i.e. waste, and is intended to be returned to Australia.

[53] See https://www.arpansa.gov.au/regulation-and-licensing/regulation/about-regulatory-services/who-we-regulate/major-facilities/interim-waste-store/siting-and-contraction-licence-decision

[54] See https://www.arpansa.gov.au/sites/g/files/net3086/f/q-50084-r3-waste-management-plan.pdf

scheme[55], which builds on the internationally agreed radioactive waste classification scheme published by the IAEA[56].

The waste management plan references relevant national codes and agreements, such as the *Trade Waste Permit* issued by Sydney Water for discharges to the sewer. It details the processes and procedures for waste minimisation, for capturing/collecting, transferring, packaging and storing of solid waste on site, for collection and storage of liquid waste including ILW, and systems for managing discharges to the sewer and gaseous emissions, including systems for delay and decay. Since the facility uses fissile material, criticality assessment has been performed and OLCs specific to criticality have been established.

ARPANSA's regulatory officers are of the view that the plans and arrangements provide assurance that radioactive waste can be managed on site safely and I generally concur. However, there are issues that will require monitoring during commissioning and – subject to successful 'hot' commissioning - routine operations. I deal with solidification of liquid ILW and gaseous discharges below. The long-term management of solid (including solidified) waste and its ultimate disposal, is further dealt with in section 4.3.

Management of liquid ILW

Operation of the *ANM Facility* will likely increase the generation of liquid ILW associated with Mo-99 production. ANSTO's intention is to solidify this waste so that the radioactive substances become immobilised in an inert ceramic matrix, using the so-called Synroc® technique in the planned *SyMo Facility*.

ARPANSA issued ANSTO a licence to **prepare a site** for, and to **construct** the *SyMo Facility*[57] on 13 May 2014, i.e. in the time between the decisions to issue a licence to **prepare a site** for, and to **construct** the *ANM Facility*. The statement of reasons underpinning the decision to licence the *SyMo Facility* outlines the purpose of the facility as it had been stated in the application, being to handle alkaline liquid ILW from current Mo-99 production in Building 54, future alkaline liquid ILW from the *ANM Facility*, and acidic legacy waste stored in the Building 57 liquid ILW tanks. The *SyMo Facility* is a core component of ANSTO's strategy for managing ILW at LHSTC. To date, construction of the *SyMo Facility* has not commenced. ANSTO's estimate is that the facility will become operational in 2020.

In September 2017 ARPANSA approved an application under Regulation 51 (relevant change with significance for safety) regarding changes of the design of the *SyMo Facility*. ARPANSA concluded that the proposed changes to the design of the facility would generally facilitate operations, improve safety and reduce consequences of potential accidents. However, the redesign also means that the existing few cubic meters of acidic liquid legacy ILW that is stored on site cannot be managed in the *SyMo Facility* as originally intended. The legacy waste will have to be immobilised using existing and proven technology, such as conventional cementation. This is captured in the radioactive waste management strategy outlined in Figure 1.

As mentioned earlier, I requested information regarding contingency plans should the *SyMo Facility* be delayed or fail, as part of my decision to authorise ANSTO to **prepare a site** for the *ANM Facility*. The ARPANSA reviewers found the contingency plans to be adequate and I agree that a number of options are

[55] *Classification of Radioactive Waste*, Radiation Protection Series No. 20, ARPANSA 2010; https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/guides-and-recommendations/rps20

[56] *Classification of Radioactive Waste*, General Safety Guide No. GSG-1, IAEA 2009; https://www-pub.iaea.org/books/IAEABooks/8154/Classification-of-Radioactive-Waste

[57] See https://www.arpansa.gov.au/news/decision-delegate-ceo-ansto-symo-facility

available, including prolonged storage at the *ANM Facility*. Four decay tanks, each with a nominal storage capacity for liquid ILW of 6.6 m^3 (corresponding to about 1.5 years of production at full capacity) are available.

I consider that the arrangements for storage of liquid ILW in the *ANM Facility* do not give rise to safety concerns as long as a reasonable margin is maintained to the maximum storage capacity of the waste tanks. However, should the *SyMo Facility* be significantly delayed, storage will reach capacity in only a few years. Unless the storage capacity can be increased, alternative storage and/or solidification solutions will have to be implemented. Transport of solidified waste to a centralised storage and disposal facility, such as the planned NRWMF, will realistically not commence before the second half of the 2020s.

Licence Condition 5 (see section 5) requires ANSTO to (with regard to the *ANM Facility*) report on storage of liquid ILW, projected generation of liquid ILW, projected treatment in the *SyMo Facility*, and plans for final management and disposal of ILW, including contingencies should any of the planned arrangements not go ahead or fail. The report must be submitted by 30 June 2020 and will provide ARPANSA with the information required for any potential regulatory decisions on waste management, in particular regarding liquid ILW, at that time.

Gaseous discharges

Air-borne releases of radioactive substances will be controlled using filters that trap aerosols, particle-bound activity and radioactive iodine. Retention of off-gases in decay tanks and charcoal beds will allow decay of noble gases before they are released to the atmosphere. The ambition for the off-gas management is to limit emissions to levels not exceeding those resulting from current operations in Building 54, despite the new facility's higher production capacity.

The current emissions to the atmosphere have negligible impact in terms of radiation exposure of workers, the public and the environment. However, ARPANSA operates seven monitoring stations for air-borne radioactivity as part of the International Monitoring System established under the Comprehensive Nuclear-Test-Ban Treaty (CTBT). Two of these stations sample noble gases in addition to particle-bound radioactivity. Of particular interest is any detection of xenon-133 (Xe-133) as an indicator of clandestine nuclear weapons testing.

ANSTO co-signed a *Radioxenon Emissions Pledge* in 2013 with the Executive Secretary of the Comprehensive Nuclear-Test-Ban Treaty Organisation (CTBTO). It was reconfirmed in July 2016. The *Pledge* states:

> *ANSTO fully supports the important work of the CTBTO and pledges to work voluntarily to minimise, mitigate, and resolve, where possible, interference of medical isotope radioxenon emissions with monitoring for nuclear explosions.*

It is essential that ANSTO manage emissions of radioactive xenon with the view of not increasing them above current levels associated with activities in Building 54. I made this point already in the statement of reasons supporting the decision to authorise ANSTO to **construct** the *ANM Facility* (see section 4.1.1 of this statement of reasons). The current notification levels for gaseous emissions associated with Mo-99 production at LHSTC have been maintained and will apply to concurrent Mo-99 production in Building 54 and in the *ANM Facility*, and to the potentially close to doubled production capacity at LHSTC assuming the *ANM Facility* will operate at full capacity (Licence Condition 4; see section 5).

4.2.4 The security plan

ANSTO provided ARPANSA with the *ANM Security Plan* as part of their application to **construct** the *ANM Facility*. The submitted information has been reviewed by security experts at ARPANSA.

The ANM protective security encompasses both ANSTO site-wide protective security measures as set out in the *ANSTO Security Plan*; and additional facility-specific protection in the ANM Security Plan. The security plans and arrangements provide appropriate defence-in-depth for transfer of irradiated material between facilities and for operation of facilities. Nuclear security *culture* plays an important role in ensuring individuals remain vigilant to prevent and combat actions with malicious intent. The documentation and procedures developed by ANSTO set out ANSTO's organisational security requirements and responsibilities, and provide security awareness.

The IT systems have adequate physical protection and access controls. There is sufficient dedicated back-up power supply to support the on-going safe operations of *ANM Facility* control systems in the event of an unexpected loss of external mains electricity supply.

The ARPANSA regulatory officers engaged with ANSTO security throughout the licensing process for the *ANM Facility*. ARPANSA regulatory officers conducted verifications on site in January 2018 and concluded that the security features and procedures of the facility corresponded to the approved design, specifications and planned management.

The ARPANSA regulatory officers are of the view that the arrangements provide an appropriate level of protective security that can be sustained during operations of the *ANM Facility*. I agree with their assessment but reiterate that the transitioning arrangements involving concurrent Mo-99 production in Building 54 and in the *ANM Facility* requires sharing of resources. This was considered in section 4.1.5 and has been captured in Licence Condition 1(b).

4.2.5 The emergency plan

The plans and arrangements for managing an emergency in the *ANM Facility* are outlined in the **ANM Emergency Plan, Q-50086**[58]. The Plan delegates the responsibility for safe management of the *ANM Facility* to the General Manager, who will have overall responsibility for the safety of activities at all times, consistent with *ANM Facility* policies and general arrangements. ARPANSA notes, however, that the CEO of ANSTO is the r*esponsible person* for the purpose of the *NDRP*, which includes responsibility for adequate resourcing to deal with an emergency, in the facility and site-wide, consistent with the effective control plan (see section 4.2.1). In an emergency, the General Manager reports directly to the CEO.

The arrangements for an emergency comprise of a facility-specific plan, a site-specific plan and the relevant state plans; all integrated to ensure that both on-site and off-site response personnel and decision makers act in a coordinated manner in an emergency. *ANM Facility* personnel including members of the Production and Quality teams are on site during operations and are trained to perform the initial response activities in the case of an emergency.

ANSTO emergency response team officers are on duty 24/7 and are available to respond to *ANM Facility* emergency events. Through a service level agreement with ANSTO, the *ANM Facility* will adopt ANSTO's emergency management arrangements, which complement facility-specific arrangements. Roles and

[58] See https://www.arpansa.gov.au/sites/g/files/net3086/f/q-50086-r4-emergency-plan.pdf

responsibilities have been defined for nominated ANSTO personnel supporting the response to on site emergencies, the provision of specialist advice, technical assistance and operational support, and resources to assist NSW emergency services organisations response to emergencies with off-site consequences. The plan and overall emergency management arrangements are interoperable with NSW emergency service organisations.

ARPANSA's regulatory officers have reviewed the emergency plan and supporting documentation. As mentioned in section 4.1.5, the *ANM Facility* is an *emergency response preparedness category II* facility, as defined in the IAEA General Safety Requirements No. GSR Part 7. The plans have comprehensively assessed a range of relevant accident scenarios. Section 10 of the FSAR includes a bounding unspecified energetic event analysis, in order to characterise the possible releases of radionuclides into the environment, and to determine what protective actions might be required for both safety- and security-initiated events.

The ARPANSA regulatory officers are satisfied over-all with the plans and arrangements for managing an emergency. They have considered scenarios with multiple initiating events, multiple failures, and the ability to withstand the progression of an accident so that implementation of early or urgent protective actions are not jeopardised.

I consider that the information submitted provides assurance that an emergency at the *ANM Facility* can be satisfactorily managed. However, ANSTO must demonstrate that it has sufficient emergency response capacity for concurrent Mo-99 production in Building 54 and in the *ANM Facility*, before transitioning from hot commissioning to routine operations can be authorised. Licence Condition 1(b) covers this aspect. Also, ANSTO must test the internal arrangements for emergency response in the *ANM Facility* as well as the interface between internal arrangements and site-wide arrangements, in a field exercise observed by ARPANSA before commencement of routine operations. This is addressed in Licence Condition 1(i); see further section 5. ANSTO is encouraged to host site visitations for off-site response agencies, during the field exercise or otherwise, in order to familiarise the response agencies with the facility, strengthen the interoperability of on-site and off-site arrangements, and to enhance awareness of appropriate command post and operational staging configurations.

4.2.6 The environment protection plan

The plans and arrangements for environmental protection are outlined in the **ANM Environment Protection Plan, Q-50323**[59].

The 'environment' under consideration broadly comprises the buffer zone (where no farming takes place) comprising Crown Land or land owned by Commonwealth; as well as residential areas and areas used for recreational purposes adjacent to the buffer zone.

ANSTO considered the following pathways by which radionuclides routinely discharged from ANSTO sites could result in possible exposure to members of the public or to the environment:

- airborne emissions
- rain-out or deposition of airborne radionuclides entering the food chain
- discharge through the Sydney Water sewage treatment system leading to exposure of workers at the sewage treatment plant, uptake by fish and accidental ingestion of seawater by swimmers
- contamination of groundwater or soil.

[59] See https://www.arpansa.gov.au/sites/g/files/net3086/f/q-50323-r0-environment-plan.pdf

Stormwater runoff to the surrounding watercourses does not contribute to any water catchments for public water supply. Wastewater generated in the facility will be transferred to Waste Management Services, which is responsible for ensuring that any liquid discharges from the ANSTO site comply with statutory requirements. The environmental monitoring program considers environmental indicators of relevance to radiological protection of people. It also considers the impact on the environment (or organisms in the environment) *per se*. This is in accordance with international best practice as captured in the *Guide for Radiation Protection of the Environment*[60]. I agree with the conclusions reached by the ARPANSA reviewers that the provisions in the environment protection plan are satisfactory.

4.2.7 Conclusions

With regard to whether the information establishes that the proposed conduct can be carried out without undue risk to health and safety of people, and to the environment:

I consider that the plans and arrangements for managing safety provide assurance that – if properly implemented - 'hot' commissioning tests can commence without undue risk. As discussed in this section, improvements in the approach to optimisation is necessary ahead of routine operations but current practices would not jeopardise the safety of commissioning activities using irradiated material. For the purpose of 'hot' commissioning, the content of the plans and arrangements for managing safety enable me to continue with reaching a decision on whether to issue a licence to operate a controlled facility, being the ANM Facility.

4.3 Has the applicant shown that there is a net benefit from carrying out the conduct relating to the controlled facility?

Sub-regulation 41(3) specifies that, in deciding whether to issue a facility licence, I must take into account whether the applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility.

4.3.1 Justification

Net benefit is related to the radiological protection principle of *justification*, used in the international framework for safety and implemented in Australia. In essence, justification means that no source or activity that poses radiation risks to people and/or to the environment should be introduced, or the way they cause exposure altered, unless there is *net benefit*. This can be understood as an ethical and moral obligation to '*do good*' and to the extent possible '*avoid harm*'[61].

The regulator is often well placed to draw conclusions on net benefit, based on knowledge of the technology and its associated benefits as well as radiation risks. The IAEA safety fundamentals[62] expresses this as follows:

> ***Principle 4: Justification of facilities and activities***
>
> ***Facilities and activities that give rise to radiation risks must yield an overall benefit.***

[60] *Radiation Protection of the Environment*, Radiation Protection Series No. G-1, ARPANSA 2015; https://www.arpansa.gov.au/regulation-and-licensing/regulatory-publications/radiation-protection-series/guides-and-recommendations/rpsg-1

[61] ICRP *Publication 138, Ethical Foundations of the System of Radiological Protection*. Annals of the ICRP, Vol 47 No. 1, 2018

[62] Fundamental Safety Principles, Safety Fundamentals No. SF-1, IAEA 2006; https://www-pub.iaea.org/books/IAEABooks/7592/Fundamental-Safety-Principles

> *3.18. For facilities and activities to be considered justified, the benefits that they yield must outweigh the radiation risks to which they give rise. For the purposes of assessing benefit and risk, all significant consequences of the operation of facilities and the conduct of activities have to be taken into account.*

Proposals to introduce sources and activities may be based on policy decisions of government but this must not limit the regulator's authority to disallow such activities if they in the view of the regulator entail undue risks to the health and safety of people, and to the environment. The IAEA safety fundamentals states:

> *3.19. In many cases, decisions relating to benefit and risk are taken at the highest levels of government, such as a decision by a State to embark on a nuclear power programme. In other cases, the regulatory body may determine whether proposed facilities and activities are justified.*

Regardless of underlying reasons for proposing a facility or activity that poses radiation risks, justification is a cornerstone in the international framework for safety; careful consideration of justification – or *net benefit* - is thus an essential element of the regulatory review and assessment underpinning a regulatory decision**.**

In my view, consideration of net benefit should at least involve:

- the benefits of the proposed conduct, i.e. does the proposed conduct 'do good'?;
- consequences of the proposed conduct including radiation risks and "*all significant consequences of the operation of facilities and the conduct of activities*" (*cf.* the IAEA safety fundamentals), i.e. to what extent does the proposed conduct 'do harm';
- potential alternatives to the proposed conduct, by which the same benefit can be achieved with less harm; and,
- consequences of doing nothing (the 'zero option').

In this context, it is relevant to take into account the content of the submission of the Medical Association for Prevention of War – Health practitioners promoting peace (MAPW) in relation to the application[63]. The MAPW submission addresses a number of issues important to net benefit of the *ANM Facility*. Some of these are considered below. Section 4.7 reviews submissions made by bodies and the public in relation to the successive applications to establish the ANM Facility.

4.3.2 Benefit of the proposed conduct

The extracted Mo-99 will be used for production of Tc-99 generators in Building 23 under an existing ARPANSA licence, or dispatched to customers for their subsequent production of radiopharmaceuticals. In the order of 80% of all nuclear medicine procedures utilise the radiation properties of the metastable Tc-99m, generated during radioactive decay of Mo-99. The beneficiaries are the patients in Australia (about 0.5 million doses are being supplied to patients in Australia on a yearly basis) and elsewhere that require nuclear medicine procedures as part of their cancer treatment.

Benefit was given consideration in my decision to grant ANSTO a licence to **prepare a site** for the facility, where I stated:

> *Justification is about whether the proposed conduct does more good than harm. From a societal perspective, the determination of whether a conduct is justified involves values, policies and priorities. The ANM Facility is an Australian Government initiative. The facility will be used for production of Mo-99, which is the precursor*

[63] www.arpansa.gov.au/news/arpansa-issues-licence-operate-anstos-mo-99-facility#mapw

of Tc-99m, used in a large number of medical procedures carried out in Australia. The beneficiaries would be all people in Australia that undergo, or will undergo, such procedures using the radiopharmaceuticals produced at the proposed facility over its operational life-span. In a global market where much of the supply currently and in the foreseeable future is satisfied through the operation of reactors that are near to the end of their operational life-span, and/or from reactors using highly enriched uranium (HEU) for Mo-99 production, the main benefit may be the sustainability of Mo-99 (Tc-99m) supply, using only LEU. In view of the ageing fleet of reactors globally, a sizeable portion of the international market may also be accessible to ANSTO.

The conclusions regarding benefit were reconfirmed in my decision to grant ANSTO a licence to **construct** the facility.

With regard to the application before me, the benefit of the facility remains the same. As far as I am aware, there is agreement among all parties, including NGOs that advocate alternative technologies for production of Mo-99/Tc-99m, that nuclear medicine procedures utilising Tc-99m are desirable and highly beneficial for cancer patients.

4.3.3 Consequences of the proposed conduct

The ANM Facility is at the front end dependent on the operation of the OPAL reactor, which supplies the neutrons for irradiation of the uranium targets for production of Mo-99 through nuclear fission. The over-all considerations of net benefit of the production of Mo-99 involves the safety of the OPAL reactor as well as the operational safety of the ANM Facility. Likewise, over-all consideration of safety needs to include the back end, which entails all aspects of waste management until its disposal. These aspects are considered below.

Front-end considerations

The operating licence for the OPAL reactor was granted by the then CEO of ARPANSA, Dr John Loy, in 2006; a condition of the licence was that the reactor undergo a *periodic safety review* (PSR) and a *periodic security review* after two years of operation[64]. Because of a prolonged outage associated with issues encountered with the reactor fuel, the PSR was delayed and submitted to ARPANSA in December 2011.

The review by ARPANSA's regulatory officers and my statement of reasons underpinning my decision to consider the PSR closed are available on ARPANSA's website[65]. I concluded that the OPAL reactor had demonstrated satisfactory safety performance up to the time the PSR documentation was finalised, and for some specific areas beyond that point in time. As requested, ANSTO submitted a plan in 2015 for the implementation of actions identified in the PSR; this plan was considered satisfactory by ARPANSA's regulatory officers. A number of safety upgrades have been performed based on lessons learned from the nuclear accident at the Fukushima Daiichi nuclear power plant in 2011. There are no issues of safety concern from the PSR that remain outstanding.

ANSTO is required under the existing OPAL licence to submit a plan for a combined *periodic safety and security review* (PSSR) in 2019, and to deliver a PSSR to ARPANSA in 2021 that meets the requirements of the joint ARPANSA and ASNO (the Australian Safeguards and Non-Proliferation Office) regulatory guide on

[64] See https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/opal/op/oplic_reasons.pdf

[65] See https://www.arpansa.gov.au/news/decision-ceo-ansto-opal-reactor-periodic-safety-review-psr

such reviews[66]. ANSTO is currently liaising with ARPANSA's regulatory officers on the scope and conduct of the PSSR.

ARPANSA's regulatory officers have closely observed the safety (including security) performance of OPAL since the closure of the PSR and performed over 80 inspections and site visits since the completion of ARPANSA's review of the PSR. Breaches of the ARPANS Act have occurred as further detailed in section 4.7. However, notwithstanding occurrences with safety implications since operations commenced in 2006, over-all experience from operations and assessment of information gathered as part of ARPANSA's continual monitoring of safety and staff attitudes to safety, indicate that radiation risks associated with routine operations of the OPAL reactor are small. ARPANSA's assessments also indicate that consequences of accidents are unlikely to have significant implications for health in off-site population centres or likely to cause harm to the environment.

The continued operation of the OPAL reactor, if within its OLCs and adhering to the plans and arrangements for safety, thus has only a small impact on the considerations of net benefit – see however the reasoning on predisposal management and disposal of radioactive waste in the following.

Operation of the ANM Facility

Sections 4.1 and 4.2 of this statement of reasons summarises the conclusions regarding safety features, safety of operations and plans and arrangements for safety. Section 4.3 provides information on occupational exposures based on experience from Mo-99 production in Building 54 and section 4.7 considers the capacity to comply with the Act, Regulations and any licence conditions imposed under section 35 of the Act. While a number of issues have been identified that require ANSTO's attention, the design and operational arrangements provide reasonable assurance of the safety of operations, as well as of radiation protection of staff. The hot commissioning tests will provide an opportunity to verify operational safety; as previously stated routine operations *must not* commence unless ARPANSA is satisfied of their safety, based on experience from, *inter alia*, hot commissioning. The harm associated with the operations would have only minor impact on the considerations of net benefit, with the important proviso that plans and arrangements for managing safety must be strictly adhered to, and staff with managerial responsibilities instil a proper culture of safety including leading by example.

Radioactive waste management – predisposal activities and ultimate disposal

The arrangements for waste management on site were considered in section 4.2.3. It was concluded that they do not cause concern for safety in the short to medium term, but final management requires resolution in order to prevent unnecessary accumulation of radioactive waste on site, which in the longer term may drive costs when (limited) resources could be spent on safe final management including disposal. This also includes waste from decommissioning of facilities on site. The *Australian Nuclear Science and Technology Organisation Act 1987*[67] rules out the LHSTC as a site for a disposal facility; hence waste will have to be transported from the site at some point in the future.

The Government's policy is that Commonwealth radioactive waste, and the waste holdings of states and territories as these jurisdictions see fit and as feasible, is to be managed in a National Radioactive Waste Management Facility (NRWMF), established at an appropriate site in accordance with the site selection

[66] Regulatory Guide, *Periodic Safety and Security Review of Research Reactors*, ARPANSA 2016; https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/regulatory-guides

[67] See https://www.legislation.gov.au/Details/C2017C00304

processes laid out in the *National Radioactive Waste Management Act 2012*[68]. The purpose of the NRWMF is to allow for disposal of solid LLW and storage of solid ILW.

There are currently no policies or arrangements in place in Australia for the disposal of ILW. The Radiation Health and Safety Advisory Council pointed out the absence of concrete plans for management of ILW in 2010, in a report[69] to the CEO of ARPANSA. I summarised the situation, as I saw it in 2013, in my statement of reasons granting ANSTO licence to **prepare a site** for, and to **construct**, the *IWS Facility*[70]:

> *The national policy for management of radioactive waste does not at this point in time include plans for disposal of ILW; it is currently limited to storage of ILW at the planned NRWMF. While this is acceptable during the development of a strategy for the final management of the ILW, I agree with the view expressed by the Radiation Health and Safety Advisory Council in its report to me in 2010 on radioactive waste management in Australia. Council stated as follows with reference to the IAEA Specific Safety Requirements, SSR-5*[71]*:*
>
> *"[…] SSR-5 includes concepts relating to disposal (and storage) of radioactive waste. SSR-5 defines 'disposal' as the emplacement of radioactive waste into a facility or a location with no intention of retrieving the waste. The term disposal implies that retrieval is not intended; it does not mean that retrieval is not possible. By contrast, 'storage' refers to the retention of radioactive waste in a facility or a location with the intention of retrieving the waste. SSR-5 identifies the important difference that storage is a temporary measure following which some future action is planned. This may include further conditioning or packaging of the waste, and ultimately its disposal.*
>
> *Hence, the overall picture of international best practice is that countries should have a policy and strategy for management of radioactive waste, in which storage has a legitimate temporary role provided there is a further strategy for ultimate disposal of the waste. This also leads to the conclusion that Australia's current policy of indefinite storage for intermediate level waste does not appear to be consistent with international best practice*."

Efforts to select a site for the NRWMF have resulted in three sites in South Australia currently being under consideration. Significant work remains for the Department of Industry, Innovation and Science (DIIS) to properly characterise the sites and form a view of which site would be the preferred one (provided satisfactory outcome of the site characterisation(s) and not excluding the possibility that new sites may be volunteered and accepted by DIIS), and to manage the consultation with interested parties. However, it is reassuring that the need for a policy for ultimate disposal of the ILW is being addressed. The most recent National Report[72] under the terms of the Joint Convention[73] makes the following statement regarding the policy for radioactive waste management:

---

[68] See https://www.legislation.gov.au/Details/C2012A00029

[69] *Scoping review of issues related to the management of intermediate level radioactive waste in Australia*. Report of the Radiation Health and Advisory Council to the CEO of ARPANSA, April 2010; http://www.arpansa.gov.au/Publications/RHSAC/rhsac_stat.cfm#rad

[70] See https://www.arpansa.gov.au/regulation-and-licensing/regulation/about-regulatory-services/who-we-regulate/major-facilities/interim-waste-store/siting-and-contraction-licence-decision

[71] *Disposal of Radioactive Waste*, Specific Safety Requirements No. SSR-5, IAEA 2011; https://www-pub.iaea.org/books/iaeabooks/8420/Disposal-of-Radioactive-Waste

[72] Joint Convention: *Sixth National Report of the Commonwealth of Australia*, 2017; https://www.arpansa.gov.au/sites/g/files/net3086/f/jc2017_october_2017.pdf

[73] The Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management; https://www.arpansa.gov.au/about-us/what-we-do/international-collaboration/joint-convention

> *The overall policy objective of the Australian Government in respect to radioactive waste is to ensure the safe and secure management of Australia's legacy and future radioactive waste, noting the waste minimisation efforts of waste producers.*
>
> *Implementation of this policy objective will be through the development of a national facility that is based on best industry practice, conforms to international treaty obligations, and can accept the highest achievable proportion of Australia's legacy and future radioactive waste. The preferred approach for the National Radioactive Waste Management Facility is to have appropriate functionality for:*
>
> - *low level waste (LLW) disposal to cater for the volume of waste reasonably foreseeable for the next 100 years, with a sufficient period of institutional control without causing undue reliance on future generations or harm to the environment.*
> - *ILW storage for a period of time sufficient for the Government to establish a permanent disposal facility.*
>
> *As part of its commitment to the safe and secure life-cycle management of all of Australia's radioactive material, the Government will develop a final disposal facility for Australia's intermediate-level waste in the coming years.*

I have also received correspondence from the then Deputy Prime Minister and Minister for Resources and the Northern Territory, The Hon. Barnaby Joyce MP, stating:

> *The Australian Government is also committed to identifying and developing a permanent disposal pathway for ILW. As part of the work to establish the NRWMF, over the next two years, the department is committed to developing relevant policy and institutional arrangements to effectively manage the full life cycle of waste in Australia, from generation to disposal. A separate process for the disposal of ILW will commence once this work is completed, noting it will occur at a different and geologically suitable site to the NRWMF.*

I consider the commitments and intent expressed in the National Report under the terms of the Joint Convention, and in the letter from the former Deputy Prime Minster, provide confidence that disposal of ILW is now captured in the plans for full life-cycle management of all radioactive waste, and that a process for selecting a site for a disposal facility for ILW will commence in the foreseeable future. An *Australian Radioactive Waste Management Framework* was recently released by DIIS[74]. It sets out the policy, responsibilities, and institutional and funding arrangements that will support the establishment of appropriate systems and facilities for management of radioactive waste in Australia

4.3.4 Alternatives to reactor-based production of Mo-99/Tc-99m and the 'do-nothing' option

As Mo-99 and Tc-99m cannot be stockpiled (the half-lives of Mo-99 and Tc-99m are 66 and 6 hours, respectively), sustained supply of Tc-99m for nuclear medicine procedures requires continuous production, in the case of the *ANM Facility* through reactor-based production of its precursor, Mo-99, through nuclear fission.

74 http://www.radioactivewaste.gov.au/sites/prod.radioactivewaste/files/files/Australian%20Radioactive%20Waste%20Management%20Framework.pdf

The production is based on the use of low enriched uranium (LEU; <20% U-235) nuclear fuel to generate the neutrons required to drive nuclear fission in the LEU targets, i.e. the production at ANSTO utilises LEU/LEU technology as opposed to some other overseas suppliers who base their production on high enriched (HEU; >20% U-235) nuclear fuel and/or targets.

Alternative techniques involve e.g. production in cyclotrons. The techniques have been demonstrated in overseas facilities and the product approved for nuclear medicine procedures. Regulatory approval is pending for overseas production facilities based on non-reactor technology.

Another 'alternative' is to not produce Mo-99 at all in Australia but to rely on importation. This is the 'do nothing' or 'zero' option. The do nothing option will lead to cessation of production of Mo-99 in Australia, as the existing facility in Building 54 reaches the end of its operational life-span, unless alternative production techniques can be implemented that allow large-scale production - which at the present seems to be at least some way off.

As MAPW points out in their submission, the projected forecasts for demand and production of Mo-99 carried out by the OECD Nuclear Energy Agency (NEA) do not foreshadow a shortfall of global availability of Mo-99 in the next five-year period[75]. While episodes of shortage have been experienced in the past, NEA's analysis of production capacity *vs* demand includes a significant capability margin to accommodate for outages of the relatively few production facilities; the NEA considers the desirable margin, or '*outage reserve capacity*', should be set to 35% of the global demand. It can be noted that one of the suppliers (NTP in South Africa), temporarily stopped Mo-99 production in November 2017, which reduced the global overcapacity. The NTP facility has now resumed limited production.

For longer times, naturally, forecasts would be considerably more uncertain and depend on production facilities coming on line that are currently in the planning stage or even just in a conceptual stage. This includes new reactors for 'conventional' production of Mo-99 through nuclear fission and alternatives to reactor-based technology. In addition to uncertainties around production capacity in the long term, the global demand is uncertain. In many countries with less developed infrastructure for health care, far less nuclear medicine procedures are carried out than in developed parts of the world. Countries with less developed infrastructure for health care constitute about 15% of the current market. A legitimate desire and drive for improved cancer treatment may significantly enhance the global demand and create an 'emerging market' – which, in turn, may create an incentive for establishing new production facilities. At minimum, however, 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.

Further consideration to MAPW's submission is given in section 4.7.

4.3.5 Conclusions

With regard to whether the applicant shown that there is a net benefit from carrying out the conduct relating to the controlled facility:

[75] *The Supply of Medical Radioisotopes. 2017 Medical Isotope Supply Review: 99Mo/99mTc Market Demand and Production Capacity Projection 2017-2022*; OECD Nuclear Energy Agency 2017; https://www.oecd-nea.org/med-radio/docs/sen-hlgmr2017-2.pdf

There is health benefit for cancer patients from sustained supply of Mo-99/Tc-99m, in which the ANM Facility will play a role. Irradiation of LEU targets in the multi-purpose OPAL reactor and subsequent extraction of Mo-99 in the ANM Facility will, provided the facilities are maintained and operated safely, not carry with it significant radiation risks. While current projections regarding global production capacity do not forecast any shortage in the next five-year period, operation of the ANM Facility provides additional certainty in availability of Mo-99/Tc-99m for several decades. There remain uncertainties around long-term waste management on site and a national facility for waste management and disposal is not yet available. However, the commitment to develop policies supporting establishment of systems and facilities for full life-cycle management of all radioactive waste is strong. On this basis I may proceed with reaching a decision on authorisation to operate a controlled facility for the purpose of hot commissioning, being the ANM Facility.

4.4 Has the applicant 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 social factors?

Sub-regulation 41(3) specifies that, in deciding whether to issue a facility licence, I must take into account 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 social factors.

The above relates to the optimisation principle, one of the core principles in the international framework for radiological protection. Optimisation was discussed in section 4.2.2 in relation to the radiation protection plan, where I expressed some reservations regarding ANSTO's approach to optimisation.

This section focuses on worker exposures. Exposures of the public and the environment are very low and have negligible or no health impact. Exposures from severe accidents were discussed in section 4.1.5 and are unlikely to lead to significant exposures.

4.4.1 Worker exposure

In order to gain insight in radiation safety of the workers, it is useful to review the dose reports for current activities in Buildings 54 and 23. ANSTO provides ARPANSA with comprehensive dose reports for workers on a quarterly basis. The reports include trends for average and maximum quarterly effective doses; data for equivalent doses to organs; and information on collective doses (average exposure multiplied with the number of workers exposed). Figures 3 and 4 provide data from the third quarterly report for 2017[76], showing trends since the fourth quarter of 2007. Quarterly average effective doses for workers at ANSTO Health (Buildings 54 and 23) have been fairly stable at 0.5 mSv, although with a decreasing trend over the last 10 years (Figure 3). This corresponds to annual effective doses of approximately 2 mSv, considerably below the statutory dose limit of 20 mSv averaged over five consecutive years, or 50 mSv in a single year.

[76] *Personally dosimetry statistics for occupationally exposed employees at ANSTO. Quarter ending September 2017*. Radiation Protection Service, ANSTO, December 2017.

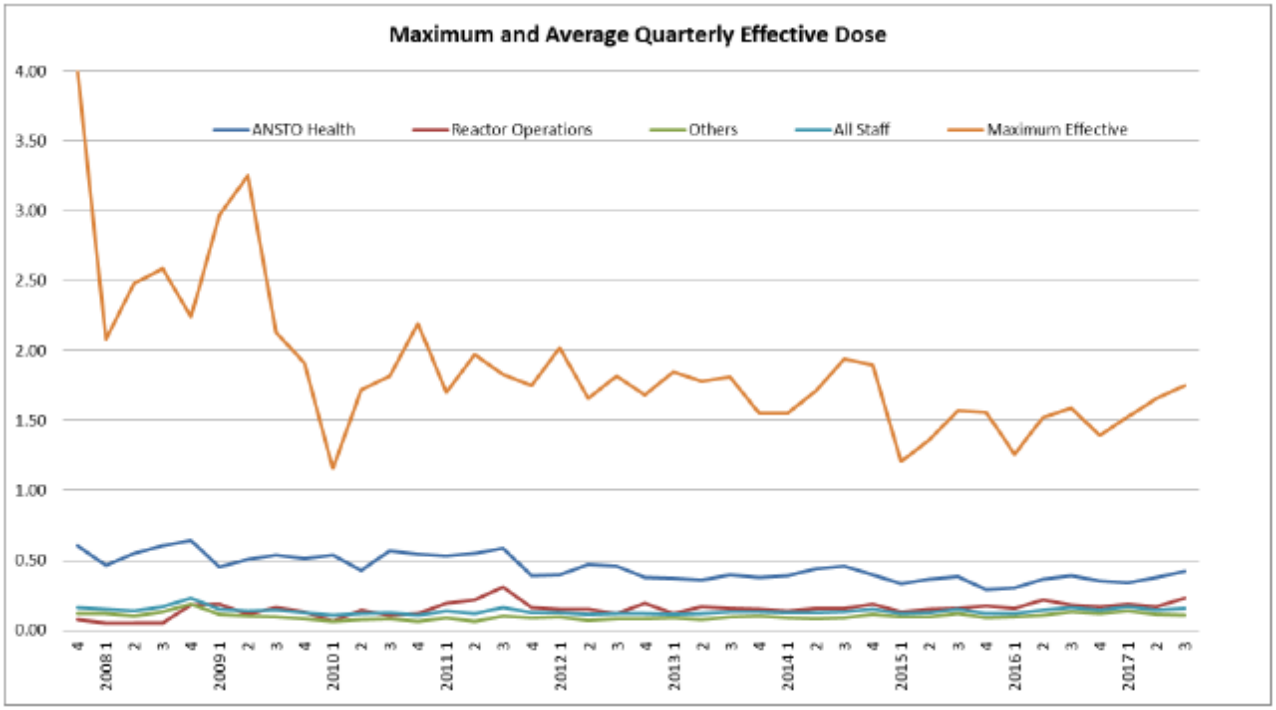

Figure 3. Quarterly effective doses, in mSv, for different worker categories at ANSTO. ANSTO Health (essentially Buildings 54 and 23) is the blue curve (second from the top).

The maximum quarterly effective doses received by *any* worker at ANSTO (i.e. not specific to ANSTO Health) have, since about 2010, been in the range of approximately 1.5 to 2 mSv. Again, annual doses would on the basis of these quarterly recordings be well below statutory limits.

Against the backdrop of the accident in 2017 involving a QC analyst who received a skin dose well above the statutory dose limit (mentioned in section 4.1.5 and discussed further in section 4.5), it is relevant to consider the trends in recorded skin doses. Average equivalent skin doses (Figure 4) are generally higher at ANSTO Health than in other facilities at LHSTC, at about 1 mSv per quarter, which again is considerably below the statutory dose limit. The maximum cumulative equivalent dose to the skin for the first three quarters of 2017 was approximately 25 mSv. Note that the accident in August 2017 referred to earlier has not been included in the statistics but is treated as a separate event.

The trends shown in Figures 3 and 4 demonstrate that Mo-99 production can be carried out with only low exposures of staff. The collective dose during the first three quarters of 2017 was in the order of 0.035 person Sv for the approximately 85 workers that were monitored for radiation exposure.

It is reasonable to assume that occupational exposures associated with Mo-99 production in the *ANM Facility* would remain in the same order as exposures in Building 54. The document **Mo99_FACL_OPER_TN_0329_B: Dose Assessment**[77]*,* which provides the dose assessment for various worker categories at the facility, confirms this assumption. The assessment is cautious in terms of estimated area dose rates, shielding and contact, time taken to perform tasks and dose reduction achieved

[77] See https://www.arpansa.gov.au/sites/g/files/net3086/f/mo99_facl_oper_tn_0329_b-dose-assessment.pdf

through process improvement. The highest doses are expected to be associated with loading and dispatching products, however still within statutory limits with a considerable margin.

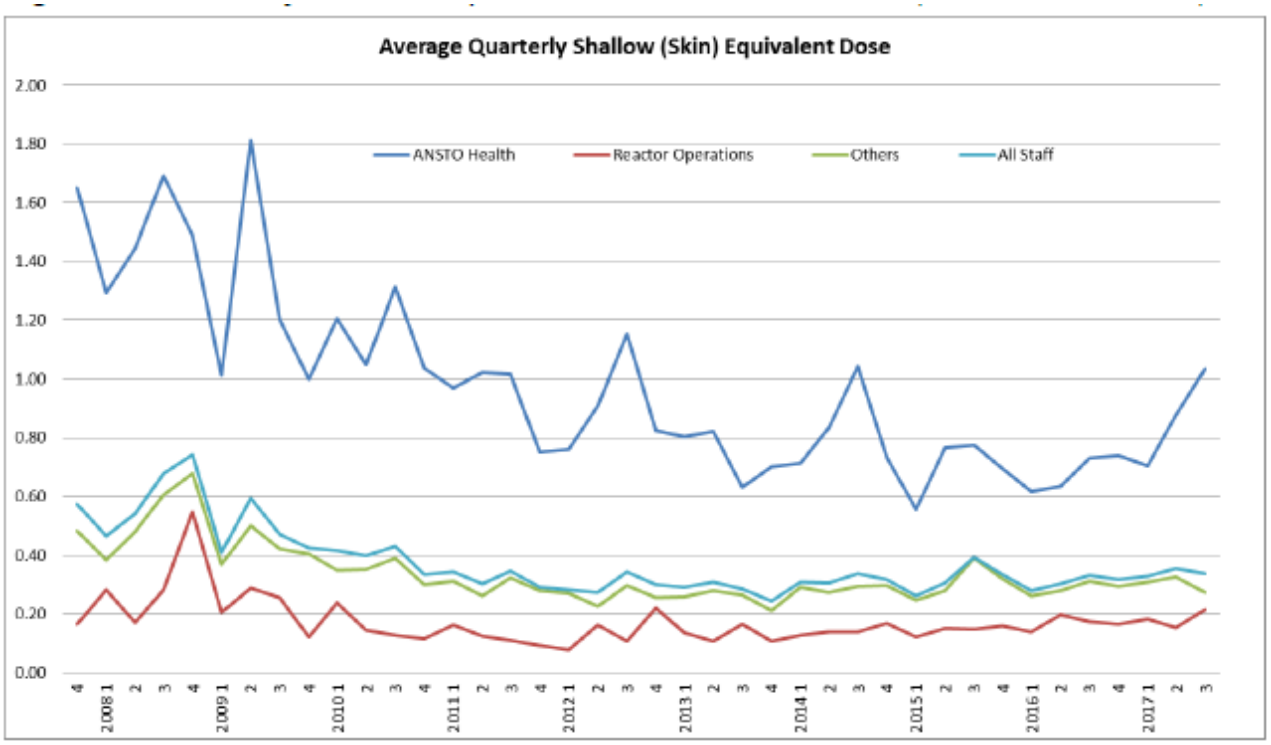

Figure 4. Quarterly equivalent doses to the skin, in mSv, for different worker categories at ANSTO. ANSTO Health is the blue curve at the top.

The exposures are generally below the 'ALARA objective' of 2 mSv annual effective dose, where further dose reduction is not considered justified by ANSTO. As stated in section 4.2.2, I believe there is room for strengthening of ANSTO's approach to optimisation. Further actions to reduce doses may not involve particularly high costs and may also reduce the likelihood of events that could lead to higher exposures. It is important that ANSTO closely monitor occupational exposures with the view of strengthening the optimisation of protection, including the number of exposed people while maintaining the necessary number of workers to perform duties safely and prevent accidents. Actions should be taken within an appropriately defined and approved constraint, as discussed in section 4.2.2.

4.4.2 Conclusion

With regard to whether the applicant shown that there 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 social factors:

It has been concluded in this statement of reasons that the approach to optimisation can be strengthened. Experience from operation in Buildings 54 and 23 demonstrate that production of Mo-99 can take place well within statutory dose limits; however, this should never preclude further actions aimed at optimisation of protection, which includes proactive measures to eliminate processes that may lead to accidental exposures. With the proviso that ANSTO undertakes further work aimed at optimisation, guided by an appropriate constraint before routine operations can commence, I may proceed with reaching a decision on authorisation to operate a controlled facility for the purpose of hot commissioning, being the ANM Facility.

4.5 Has the applicant shown a capacity for complying with the Regulations and the licence conditions that would be imposed under section 35 of the Act?

Sub-regulation 41(3) specifies that I must, in deciding whether to issue a facility licence, take into account whether the applicant has shown a capacity for complying with the Regulations and the licence conditions that would be imposed under section 35 of the Act.

ANSTO is the only holder of licences for nuclear installations under the Act. I have in previous decisions on the *ANM Facility*, as well as in my statement concerning the PSR for the OPAL reactor, drawn the conclusion that ANSTO has the capacity to comply with the conditions established by the Regulations and any additional condition(s) I might impose under section 35 of the Act. Conclusions regarding whether the capacity is fully utilised for fulfilling safety functions can be informed by a review of the compliance history and by observations from ARPANSA's compliance monitoring more broadly, such as inspections[78] and observations of attitudes and approaches to safety among managers and staff, i.e. *safety culture*.

The interface between the technical ('machine'), behavioural and organisational aspects of safety are considered in ARPANSA's guidelines for Holistic Safety[79]. The art of maintaining a culture of safety lies in maintaining what has been termed 'chronic unease' with the technical, procedural, behavioural and organisational contributors to safety.

With regard to the compliance history relevant to Mo-99 production, it is reasonable to look at events at both OPAL and at ANSTO Health. The nature of some events has led ARPANSA to find ANSTO in breach of section 30 of the Act for failing to comply with conditions of the licence. The breaches from 2012 to present time are summarised in Table 6.

The number of breaches is not large enough to allow firm conclusions regarding contributing factors. It can be noted, however, that all events relating to ANSTO Health that subsequently led to findings of breach were self-reported. This includes the previously mentioned accident during a QC procedure in 2017, which was reported as stipulated in sub-regulation 46(2)(c-d). Two of the 13 breaches summarised in Table 6 were considered by ARPANSA to be significant from the safety perspective.

The accident during a QC procedure in 2017 led to an exposure of the hands of a QC analyst, causing tissue reactions consistent with a localised skin dose of in the order of 20 gray (Gy), or 40 times higher than the annual dose limit[80]. The seriousness of the accident led ARPANSA to rate it as Level 3 (serious incident) on the International Nuclear and Radiological Event Scale, INES[81]. This was the first time ARPANSA reported a Level 3 event for a Commonwealth licence holder and the only INES 3 event reported to the INES database in 2017. On 26 February 2017, I tabled a report in Parliament pursuant to section 61 of the Act, summarising the event and breach decision[82].

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[78] ARPANSA's inspection reports are, with some exceptions, posted on the ARPANSA website, see https://www.arpansa.gov.au/regulation-and-licensing/licensing/information-for-licence-holders/inspections/inspection-reports

[79] Regulatory Guide: *Holistic safety*, ARPANSA 2017; https://www.arpansa.gov.au/regulation-and-licensing/safety-security-transport/holistic-safety/guidelines

[80] The annual limit for *equivalent dose* to the skin is 0.5 sievert (Sv), measured over any 1 cm^2 of skin exposed. For radiation exposures of this magnitude, it is more appropriate to use the basic physical quantity *absorbed dose*, with the special name gray (Gy), as in ARPANSA's dose assessment. For the purpose of this specific accident, however, the two units can be used interchangeably. The dose limits are specified in of the Regulations and also in the *Planned Exposure Code*.

[81] The scale ranges from Level 0 (zero) with no safety implications, to Level 7, serious accidents (corresponding to the Chernobyl accident and the accident at the Fukushima Daiichi nuclear power plant.

[82] See https://www.arpansa.gov.au/news/radiation-exposure-worker-ansto-health-report-parliament

ARPANSA performed an 'augmented' inspection in relation to the overexposure, which focused on human and organisational contributors to the accident[83]. Seven observations were made that relate to, *inter alia*, reporting, communication and training. The QC procedure had been identified as a 'high risk' procedure but the risk had not been effectively mitigated. In my letter informing ANSTO of non-compliance with regulations 46 and 48, I stated:

> *The risk assessment available to ANSTO Health identified the specific task as 'high risk'. ANSTO Health management subsequently accepted the risk, and did not require any mitigation measure to reduce it, nor documented any "overwhelming net benefit" (see the ANSTO Risk Analysis Matrix) supporting the decision to accept it. One measure to reduce the risk would have been to reduce the specific activity of the Mo-99. However, this – and other measures to reduce the risk – were only implemented after the accident.*

In my opinion, manual handling of samples that may lead to short-term exposures that cause radiation injuries, should only be accepted under very special circumstances and based on an analysis of justification. This was a routine operation and no (documented) action had been taken to mitigate risks although such actions were available. Although the event must be considered of low probability (several thousand of these QC procedures have been carried out without major documented events that have been brought to the attention of ARPANSA), the potential consequence is such that it should be avoided, in particular as part of a routine procedure.

Fundamentally, this relates to the risk assessment and the analysis of the contribution of human factors to estimates of likelihood of events. This was discussed in section 4.1.5 where I concluded that the risk assessment should be revisited and:

> *[…] should cover all scenarios that have been identified as having 'moderate' or more severe consequence of radiological nature, regardless of likelihood and including a reassessment of "incredible" scenarios. […] A further analysis should take place regarding the contribution by human factors to the likelihood of events and how increased attention to such factors can contribute to lowering of the likelihood of events with moderate and more severe consequences.*

Immediate actions taken by ANSTO have reduced the likelihood of a serious contamination event; the consequence should an event occur has also been addressed by reducing the specific activity of the samples. However, the QC procedure must be reviewed as part of the review of the risk assessment, and the optimisation process should give full consideration to automation of the procedure. Licence Condition 1(d-h) is relevant in this regard (see section 5).

[83] ARPANSA's inspections are planned and carried out according to an annual inspection schedule; or augmented, e.g. carried out in response to an event or observation of safety significance. The report for the ANSTO Health contamination accident in 2017 is at https://www.arpansa.gov.au/sites/g/files/net3086/f/r17-13159.pdf

Table 6. Breaches of subsection 30(2) of the ARPANS Act for the OPAL reactor and for ANSTO Health's activities in Buildings 54 and 23 ('Health'), from 2012 to present time.

Facility	Year	Licence condition	Breach details	Significant Y/N[i]	INES rating[ii]	Action requested
OPAL	2013	Regulation 49 - Non-compliance with plans and arrangements	Use of unauthorised tool during fuel assembly clamping	Y	N/A	Modified work instruction and project raised to redesign the pneumatic tool to eliminate the need for the unauthorised tool.
OPAL	2013	Regulation 49 - Non-compliance with plans and arrangements	One related to clear plastic found during the inspection at Level 13 of OPAL Building 80. One associated with a lack of utilisation staff during a silicon movement.	N	N/A	Recommendations made in associated inspection report.
OPAL	2016	Regulation 50 - Failure to review plans & arrangements	Reactor facility security plan had not been updated	Y	N/A	Update of security plan.
Health	2012	Failure to comply with Operating Limits and Conditions	Sm-151 held in Building 23A exceeded the amount of activity specified in the licence. [Self-reported]	N	N/A	Review and update of Safety documentation to consider updating limits. Completed in 2017.
Health	2012	Failure to comply with Operating Limits and Conditions	I-131 held in Building 23A exceeded the amount of activity specified in the licence. [Self-reported]	N	N/A	Review and update of Safety documentation to consider updating limits. Completed in 2017.
Health	2014	Failure to comply with Operating Limits and Conditions	I-131 held in Building 23A exceeded the amount of activity specified in the licence. [Self-reported]	N	N/A	Review and update of Safety documentation to consider updating limits. Completed in 2017.

Table 6 (continued).

Facility	Year	Licence condition	Breach details	Significant Y/N[i]	INES rating[ii]	Action requested
Health	2015	Regulation 49 - Non-compliance with plans and arrangements	Surveillance requirements for sampling of liquid waste, as required by the criticality certificate, not followed. [Self-reported]	N	N/A	Recommendations made in associated inspection report.
Health	2015	Failure to comply with Operating Limits and Conditions	Failure to comply with operational Limit and Condition 11.8 - SIAM filter bank fire suppression system. [Self-reported]	N	N/A	SIAM filter bank changeover procedure and work instruction updated to prevent reoccurrence after non-compliance discovered.
Health	2016	Failure to comply with Operating Limits and Conditions	Mo-99 held in Cell 3 in B23 exceeded the amount of activity specified in the licence. [Self-reported]	N	N/A	Review and update of Safety documentation to consider updating limits. Completed in 2017.
Health	2017	Regulation 44 – Failure to prevent a breach	Failed to prevent the activity of Mo-99 in Cell 3 in B23 from exceeding the amount specified in the licence. [Self-reported]	N	N/A	Review and update of Safety documentation to consider updating limits. Completed in 2017.
Health	2017	Regulations 46 – Failure to prevent accidents, and 48 – Failure to comply with code or standard	Accident, contamination during a QC procedure resulting in a skin dose of about 20 gray, and tissue reactions [Accident reported]	Y	3	Action plan requested to prevent recurrence of the scenario. Matter still under regulatory consideration

[i]Based on ARPANSA's graded approach to non-compliance[84]

[ii]N/A, INES rating not relevant

[84] Regulatory Guide: *Graded approach to dealing with licence holder non-compliance*; https://www.arpansa.gov.au/sites/g/files/net3086/f/reg-com-sup-270j.pdf

4.5.1 Conclusion

With regard to whether the applicant has shown a capacity for complying with these regulations and the licence conditions that would be imposed under section 35 of the Act:

Information available to ARPANSA demonstrate that the resourcing (financial and personnel) of safety at ANSTO is adequate and has supported a past record of safe operations. The reporting to ARPANSA, e.g. self-reporting of non-compliances, is indicative of a satisfactory reporting culture. However, a number of non-compliances with the licence conditions have been recorded and observations recounted in this statement of reasons demonstrate that further actions to mitigate risks, including analysis of the contribution by human factors, must be undertaken by ANSTO, before transition to routine operations can be authorised. With this reservation, and bearing in mind that this decision authorises hot commissioning, not routine operations, I may proceed with reaching a decision on authorisation to operate a controlled facility, being the ANM Facility.

4.6 Has the application been signed by an office holder of the applicant, or a person authorised by the office holder of the applicant?

Sub-regulation 41(3) requires me to determine whether the application has been signed by an office holder of the applicant, or a person authorised by the office holder of the applicant.

The application was signed by the CEO of ANSTO, an office holder for the purpose of the Act. It was originally signed on behalf of ANSTO Nuclear Medicine Pty Ltd. However, I have subsequently received correspondence from ANSTO that explicitly states that the applicant, and the licence holder should a licence be granted, appropriately is ANSTO. I agree that this is an appropriate arrangement and my decision is predicated on my understanding, confirmed by ANSTO, that ANSTO is the *applicant* and the *licence holder*, and the CEO of ANSTO the *responsible person*.

4.6.1 Conclusions

With regard to whether the application has been signed by an office holder of the applicant, or a person authorised by the office holder of the applicant:

The CEO of ANSTO signed the application on behalf of ANSTO. The CEO is an office holder for the purpose of the Act. On this basis I may proceed with reaching a decision on authorisation to operate a controlled facility, being the ANM Facility.

4.7 The content of submissions relevant to the application

Sub-regulation 41(3) requires me, in my decision on whether to issue a licence for a *nuclear installation*, to consider the content of any submissions made by members of the public about the application. Regulation 40 requires me to advertise my intention to make a decision on a facility application as soon as practicable after the receipt of the application, and – if the application relates to a nuclear installation - invite people and bodies to make submissions about the application. The invitation to make submissions can be supplemented with other means of consultation, such as public meetings.

As the *ANM Facility* would constitute a nuclear installation, consultation has been carried out in relation to all three licence applications, as summarised in Table 7. Copies of the licence applications submitted by

ANSTO were in all cases made publically available, along with advice on how and when submissions could be made.

Table 7. Overview of consultation in relation to the successive licensing stages for the *ANM Facility*.

Application	Received	Invitation to make submissions[i]	Public meetings[ii]	No. of submissions or comments	Decision[iii]
A0270 'siting'	25/10/12	8/5/12	16/5/13	30[iv]	4/10/13
A0285 'construction'	22/11/13	2/1/14	None	None	27/6/14
A0309 'operation'	7/4/17	28/4/17	22/6/17	1	6/4/18

[i)] In the Australian Government *Gazette*, in The Australian newspaper, on the ARPANSA website and usually in local newspapers such as the St George and Sutherland Shire Leader

[ii)] In the Engadine Community Centre, Sutherland Shire

[iii)] Advertised on the ARPANSA website

[iv)] The submissions covered the siting application for the *ANM Facility*, the siting and construction application for the *IWS Facility*, and the siting and construction application for the *SyMo Facility* (see text for explanation)

4.7.1 Submissions in relation to siting and construction

The first consultation covered the application to **prepare a site for** the *ANM Facility*, and applications to **prepare a site** for, and to **construct,** a facility for storage of radioactive waste arising from reprocessing of fuel used to operate the High Flux Australian Reactor (the *IWS Facility*, being a nuclear installation), and the the *SyMo Facility*.

The *SyMo Facility* would be a prescribed radiation facility and as such is not covered by the obligation to invite submissions under regulation 40. However, considering the linkages between, in particular, the *ANM* and *SyMo Facilities*, I invited submissions in relation to all applications simultaneously. For the subsequent licence applications for the *ANM Facility*, submissions were invited for that facility only.

The submissions in relation to the application to **prepare a site** for the *ANM Facility* often covered more than one, sometimes all three, facilities under regulatory review by ARPANSA at the time (i.e. the *ANM*, *IWS* and *SyMo Facilities*). The issues raised in the submissions, ANSTO's responses and comments from the ARPANSA assessors are posted on ARPANSA's website[85]. Below is the summary of issues, which was included in my statement of reasons to authorise ANSTO to **prepare a site** for the *ANM Facility*.

a. ***Alternative techniques for Mo-99 production, or for medical procedures (question/comment 2, 6, 14, 18):*** *I consider ANSTO's responses satisfactory. Alternatives (importation, production technique, and location of production facility) were discussed in section 3.3 where I reached the conclusion that, based on the evidence before me, there is net benefit from the proposed conduct, considering the small risks associated with the ANM Facility and the benefit from sustained radiopharmaceutical production to the Australian, and global, population. Submission 14 does not consider alternatives directly but the cost of the facilities, which is one consideration in establishing net benefit of a conduct.*

[85] See https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/responses.pdf

b. ***Generation of waste, particularly plutonium, and its implications for nuclear proliferation; and Synroc® technique for waste management (question/comment 1, 3, 4, 5, 7, 8, 9, 10, 13, 19, 20, 22, 24, 26, 27, 28, 29):*** *Many of the questions raised on waste management relate to the return of intermediate level waste from France and UK. This issue is considered in ARPANSA's regulatory review of the application from ANSTO to prepare a site for, and construct, an interim store for such waste at LHSTC, and is not directly relevant to the application considered in this statement of reasons. With regard to waste arising from operation of the ANM Facility I consider ANSTO's responses generally satisfactory. Waste generation and the waste management plan, including contingencies in the case the SyMo plant is inoperable and in view of the uncertainty as to when the planned NRWMF may become operational, were discussed in 3.3.2. I have there stated that improved contingency plans need to be developed ahead of, or as part of, an application to construct the ANM Facility. I have also requested further information on decommissioning and management of decommissioning waste (see 3.1.2).*

c. ***Security (question/comment 16):*** *I consider ANSTO's response satisfactory. Security was considered in section 3.2.1.2.*

d. ***Transport, emergencies and liabilities (question/comment 11, 12, 15, 17, 25):*** *I consider ANSTO's responses satisfactory. I expect to again consider the emergency arrangements following further analysis of the reference accident, ahead of or as part of an application to construct the ANM Facility.*

e. ***General aspect of the site, such as population density and risk for bushfires (question/comment 21, 22, 23, 30):*** *I consider ANSTO's responses satisfactory; however, I expect further consideration of demographic factors being part of the further analysis of the reference accident, as stated under (d) above.*

No submission was received in relation to the application to **construct** the *ANM Facility*.

4.7.2 Submission from MAPW in relation to the application to operate the ANM Facility

As mentioned in section 4.3, one submission was received in relation to the application to **operate** the *ANM Facility*, from the Medical Association for Prevention of War – Health professionals promoting peace (MAPW). I also received further correspondence from MAPW on the same issue, dated 29 January 2018, although this correspondence does not constitute a formal submission in relation to the application. The submission highlights a number of issues:

- *No shortage of Mo-99 (Tc-99m) is projected for the next five-year period.*

  MAPW quotes the projections of the OECD Nuclear Energy Agency (NEA) for the period 2017 to 2022. As discussed in section 4.3.3 of this statement of reasons, NEA's analysis is based on a number of different scenarios and none of them predicts that the irradiation and production capacity will fall short of global demand during this period. This includes an operational outage capacity which is 35% of the projected demand of 9 000 six-day curie (the projected demand has decreased from 12 000 a number a years ago). MAPW concludes that the *ANM Facility* is not essential for maintaining a production capacity that satisfies the global demand.

- *Uncertainties regarding the profitability of Mo-99 production for ANSTO and Australia.*

  The reactor-based production of Mo-99 is expensive and subsidised by taxpayers. Furthermore, the full life-cycle costs are not accounted for, including the costs for waste management.

- *The generation of ILW will increase if ANSTO is authorised to operate the ANM Facility, while the plans for its management on site remain uncertain and are predicated on the successful commissioning of the SyMo Facility.*

- *The system for full life-cycle management of ILW is incomplete.*

Both dot points above concern radioactive waste management, which I have dealt with in sections 4.2.3 and 4.3.3. MAPW points out that Mo-99 production will lead to generation of ILW for which no final disposal solution is yet available in Australia, and that construction of the *SyMo Facility* has not yet commenced.

- *Alternatives to reactor-based technology for production of Tc-99m are available.*

  This was considered in section 4.3.4.

The issues raised by MAPW are relevant and as such have been dealt with in previous sections in this statement of reasons.

On the point of supporting the Australian demand for Mo-99 through importations rather than through indigenous reactor-based production, Dr Loy reasoned in his 2006 decision to grant ANSTO a licence to **operate** the OPAL reactor[86]:

> *I accept that it would be feasible for Australia to rely upon imports for reactor-produced radioisotopes. There would be some consequences in terms of the availability of some pharmaceuticals and certainly some risks of the disruption from time to time. The Government has chosen not to accept these limitations and risks and this is properly a decision for Government. The production of isotopes for medical application – both diagnosis and treatment – is a benefit to Australia. When weighed against the radiological risks arising from normal operation of the reactor and the management of its radioactive waste, which I believe ANSTO has established to be small, there is clear net benefit to Australian society as a whole.*

The Australian Government's policy has not changed with regard to domestic capability for Mo-99 production. The Commonwealth has lent ANSTO $168 million to establish both the *ANM facility* and the *SyMo Facility*, out of which $110 million have been earmarked for the *ANM Facility*. This loan is to be repaid through dividends of the Commonwealth's shareholding in the *ANM Facility*. The *ANM Facility* is intended to continue production in Australia for the next 30 to 40 years and replace production in Building 54, which will be wound down, whether the *ANM Facility* receives regulatory approval or not.

Assessment of viability of the business model is not within ARPANSA's competence and outside of my mandate. With regard to the global market, the NEA's assessment for the next five years does not, as MAPW points out, project a shortfall. Also, the demand as forecasted in NEA's most recent analysis is now reduced compared to just a few years ago, e.g. at the time I decided to authorise ANSTO to **prepare a site** for the *ANM Facility*. However, as discussed in section 4.3.4, the NEA report also points out the considerable uncertainties of the projections and the vulnerabilities of the production capacity. Hence, NEA intends to update the projections on a yearly basis. There is particular uncertainty regarding potentially 'emerging markets' which currently constitutes only a small fraction of the basis for NEA's projections. Projections over the operational life-time of the *ANM Facility* are therefore highly uncertain, but it seems reasonable to assume that some countries with large populations may aspire to considerably increase their use of nuclear medicine, including Mo-99/Tc-99m, for the benefit of the health of the population. Whether that will happen and constitute an 'emerging market' remains to be seen. However, it is clear that the *ANM Facility*, subject to regulatory approval for routine operations, will be able to satisfy the Australian market for considerable time.

On a final point, the issue of net benefit may be viewed from the reverse perspective, i.e. would there be net benefit from discontinuing reactor-based production of Mo-99 in Australia, e.g. from the time the Building 54 production facility shuts down. Unless other technology can be introduced to sustain the

[86] See https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/opal/op/oplic_reasons.pdf

national demand, Australia would then be dependent on importations. On balance I consider there is merit in sustained domestic Mo-99 production and that the technology in use at LHSTC carries with it small risks, noting also that the OPAL reactor is multipurpose including materials production and research using neutrons. I agree with MAPW that full life-cycle management of radioactive waste remains an issue that requires policies, plans and facilities that, as MAPW correctly points out, are currently lacking. However, I find the risks associated with current practices manageable and – while without doubt solutions for final disposal are needed – storage can be carried out safely in the short to medium term. There is a need to continue monitoring the accumulation and storage of ILW at LHSTC, in the light of both uncertainties around the *SyMo Facility* and the NRWMF. Licence Condition 5 has been issued to that effect (see section 5).

4.7.3 Conclusions

With regard to the content of submissions made by members of the public about the application:

The successive submissions through the licensing stages of the ANM Facility largely focused on questions around the justification for increased reactor-based Mo-99 production that partly targets an international market, which may be saturated over at least the next five-year period; and an increased generation of radioactive waste for which the final management remains uncertain. The above questions are relevant and important. While the arguments challenge continued reactor-based technology for Mo-99 production, it seems that sustained production fulfils a purpose while risks are small. I agree that policy and plans for full life-cycle management of resulting radioactive waste are not in place but I consider that the commitments made in that regard provide assurance that these matters will be addressed and eventually resolved. I consider that on that basis I may proceed with reaching a decision on authorisation to operate a controlled facility, being the ANM Facility.

5. Overall conclusions and licence conditions

5.1 Conclusions

The ARPANSA regulatory and science officers have reviewed and assessed the application and documented their observations in the RAR. I have used the application, the RAR, and other information available to me as detailed in section 3 of this statement of reasons, in reaching my decision.

As stated in section 4.1, normal practice for a facility of this kind is to differentiate between cold and hot commissioning. Cold commissioning can be completed for certain items that are important for safety where the performance is unaffected by the radiological properties of the material being handled. 'Hot' commissioning tests in this case involves tests using uranium target plates that have been irradiated in the OPAL reactor. As this is akin to operations, it is reasonable to review, assess and if appropriate authorise hot commissioning as part of the decision on a licence to **operate** a facility. As can be inferred from the Regulations, operations for the stated purpose (extraction and purification of Mo-99 from irradiated uranium target plates for the Australian and international markets), can only commence after the facility is fully commissioned, *including* hot commissioning, and require separate authorisation.

The reasoning and conclusions underpinning my decision have been outlined in sections 4.1 – 4.7 of this statement of reasons. In conclusion (*cf*. section 2.2), ANSTO has in my view provided a satisfactory level of assurance that:

- the facility has been built as approved;

- commissioning activities using irradiated target plates (hot commissioning) can commence and be carried out safely;
- the facility can be brought to a safe controlled state in case of events with safety significance during commissioning; and,
- the purpose, risk analysis, safety analysis, safety features, safety arrangements and end-of-life arrangements provide for no undue risks, net benefit, and for protection of people and the environment from the harmful effects of radiation.

I have considered international best practice and the submissions made by bodies and members of the public in relation to the application, in reaching my decision.

On the basis of all evidence at hand, I have decided to issue a licence to **operate** the *ANM Facility* that authorises ANSTO to commence hot commissioning. The licence remains in force (as amended under section 36 of the Act, if relevant) until it is cancelled or suspended under section 38 of the Act or until it is surrendered under section 39 of the Act.

While I am of the view that ANSTO has demonstrated that the *ANM Facility* can be commissioned safely, a number of areas for improvement have been identified in the regulatory review and assessment that must be addressed before ANSTO can commence routine operations for the stated purpose. I have chosen to capture those in a set of conditions that need to be fulfilled before routine operations can be considered and potentially authorised. The conditions are outlined below.

5.2 Licence conditions

Section 35 of the Act, Part 4 Division 4 of the Regulations, and Part 5 of the Regulations, prescribe conditions that apply to the licence. These, and the standard licence conditions generally applied across facility licences, are not discussed further here.

Under section 35(1)(c) of the Act, I have issued a number of licence conditions that are specific to the *ANM Facility* and apply to Building 88 and to the Building 2 QC Active Laboratory. Under section 36 of the Act, I may amend the licence conditions imposed by me, at any time.

The numbering of the licence conditions below is not the same as in the licence; this is because the standard licence conditions have not been included here.

Licence Condition 1 (LC1) concerns the hot commissioning stage.

> ***LC1.*** *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*
>
> *(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*
>
> *(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*

(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)

(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)

(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

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

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

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

Provided LC1 can be removed, and depending on what potential new information with safety significance that has come to light that needs addressing, at minimum the licence conditions outlined in the following apply (LC2 – LC7).

The *ANM Facility* is a replacement facility. Production of Mo-99 in Building 54 will be wound down whether or not the *ANM Facility* transitions to routine operations. Production of Mo-99 in Building 54 may continue while production in the *ANM Facility* gradually increases, contingent on the safety of the operations in both facilities. When production of Mo-99 for the market takes place in both facilities, it is prudent to cap the total production of Mo-99. Unless other information has come to light that would justify a more stringent cap, total production must be capped at the current capacity in Building 54. LC2 has been issued to that effect.

***LC2**. 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.*

Following cessation of routine operations in Building 54 and for 18 months after that time, temporary production of Mo-99 for the market may take place in Building 54 to compensate for shortfall in production capacity during temporary interruptions of Mo-99 production in the *ANM Facility*, subject to approval by ARPANSA. This is captured in LC3.

> ***LC3**. 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.*

It is not anticipated that emission of radioactive substances to the atmosphere from Mo-99 production will increase in terms of annual averages as a result of operations at the *ANM Facility*. The notification levels for emissions to the atmosphere are therefore kept at the same level as for current practices in Building 54. This is captured in LC4.

> ***LC4.** The licence holder must*
>
> *(a) report the airborne discharges from Mo-99 production at the Lucas Heights Science and Technology Centre to the CEO annually as percentages of the notification levels set out in Table A*
>
> *(b) report the airborne discharges from the ANM facility to the CEO quarterly as percentages of the notification levels set out in Table B. The quarterly report must contain the results of 4-weekly discharge measurements*
>
> *(c) notify the CEO of any release in excess of a notification level, within seven days of detection. Details of the cause of release, radiological consequences, and actions taken to limit the release must be provided*
>
> *(d) notify the CEO within 24 hours or the next working day, as appropriate, if a notification level is exceeded by a factor of five. Details of the cause of release, radiological consequences, and actions taken to limit the release must be provided.*

The production of Mo-99 at the *ANM Facility* will generate radioactive waste, including liquid ILW. The storage capacity for liquid ILW corresponds to approximately six years of Mo-99 production at full capacity. ANSTO plans to start treating liquid ILW at the *SyMo Facility* about two years after commencement of routine operations of the *ANM Facility*. In view of the uncertainties associated with management of ILW discussed in this statement of reasons, it is reasonable to request ANSTO to submit an update on liquid ILW generation and holdings at the *ANM Facility*, by 30 June 2020. The report must also include information on projected generation of ILW, projected treatment in the *SyMo Facility*, and storage and disposal of the ILW generated in the *ANM Facility* and its alignment with the national policy and plans for full life-cycle management of radioactive waste. It must include contingency plans for the case that elements of the planned system for ILW management do not go ahead or fail. The report can, at ANSTO's discretion, be combined with the report on plans for removal of ILW from the *IWS Facility*, due 30 June 2020[87].

[87] The statement of reasons underpinning my decision to operate the IWS Facility (https://www.arpansa.gov.au/sites/g/files/net3086/f/legacy/pubs/regulatory/ansto/SOR_operationIWS.pdf) states as follows: *The licence is not limited in time; however, the purpose of the facility is temporary storage of the waste, pending solution for its final management. The length of storage is contingent on the establishment of the NRWMF, or any alternative final management solution that may be considered in the future. It is therefore reasonable to request, at appropriate times, updated information as regards the performance of the IWS Facility, and projections for the future. I have therefore included the following licence condition:*

The licence holder must submit to the CEO, no later than 30 June 2020 and in a form acceptable to the CEO, plans for the removal of waste stored in the facility.

This is now LC5 of Facility Licence F0292 (the *IWS Facility*).

***LC5**. 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.

A periodic safety and security review (PSSR) report must be submitted to the CEO of ARPANSA that builds on five years of operational experience from the time commissioning activities had finalised. The operational experience will also inform the plans for decommissioning of the facility; a decommissioning plan must be submitted no later than the PSSR. This is captured in LC6 and LC7. The time for the subsequent PSSR and updated decommissioning plan will be decided after ARPANSA has completed its review of the submissions.

***LC6.** The licence holder must undertake the first Periodic Safety and Security Review (PSSR) of the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The PSSR must:*

(a) summarise the operational experience including any abnormal occurrences as well as provide an account of contributing factors to such occurrences, risk mitigation, occupational radiation exposures including contamination events, and public radiation exposures

(b) review the capability of the safety functions under a range of design extension conditions agreed by ARPANSA

(c) consider the security of the facility

(d) include a plan for implementation of actions identified during the course of the review.

The PSSR report must be submitted to ARPANSA by 31 December 2024 or at a time agreed by the CEO.

***LC7.** The licence holder must submit a decommissioning plan for the ANM facility after gaining five years of operational experience from the finalisation of commissioning activities. The decommissioning plan must be submitted to ARPANSA by 31 December 2024 or at a time agreed by the CEO and take into account the national policy and plans for full life-cycle management of radioactive waste.*

5.3 Notification levels for gaseous emissions from Mo-99 production

The notification levels given in Tables A and B below apply to LC4.

Table A. Notification levels for annual emissions to the atmosphere resulting from Mo-99 production at the Lucas Heights Science and Technology Centre, NSW.

Kr-85m TBq	Kr-87 GBq	Kr-88 GBq	I-131 GBq	I-132 GBq	I-133 GBq	Xe-133 TBq	Xe-135 TBq	Xe-135m TBq	Gross alpha MBq	Gross beta MBq	All other
10	300	400	10	7	2.15	1350	400	100	When detected	1000	500

Table B. Notification levels for annual emissions to the atmosphere resulting from Mo-99 production at the Lucas Heights Science and Technology Centre, NSW.

Notification period	Percent of values in Table A
Quarterly	50
Monthly	20