



Australian Government
**Australian Radiation Protection
and Nuclear Safety Agency**



Statement of Reasons

Decision by the CEO of ARPANSA on Facility Licence Application A0339 from the Australian Nuclear Science and Technology Organisation to prepare a site for the Intermediate Level Waste Capacity Increase (ILWCI) Facility



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This Statement of Reasons has been authored by the CEO of ARPANSA with the assistance of ARPANSA staff to describe the decision made under section 32 the *Australian Protection and Nuclear Safety Act 1998* (the Act) in response to a licence application made under the Act by the applicant identified in this statement.

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This Statement of Reasons does not form part of Facility Licence F0339.

In the event of any inconsistency between the Licence and this Statement of Reasons, Facility Licence F0339 will prevail.

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1. The licence decision

On 16th March 2022, I issued facility licence F0339 under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act¹) to the Australian Nuclear Science and Technology Organisation (ANSTO), authorising the licence holder to prepare a site for a **controlled facility** at Lucas Heights in New South Wales, namely, the Intermediate Level Waste Capacity Increase (ILWCI) Facility.

The purpose of the planned facility is to store² radioactive waste, mainly from the production of nuclear medicine at the Lucas Heights site, with the intention of its future removal from the site. No other function of the ILWCI Facility is authorised under this licence.

Under Division 3 of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations³), the proposed facility is a **nuclear installation**, intended for storage of radioactive waste with an activity content above the level specified in the Regulations.

The licence is subject to general conditions applicable to all licences as prescribed in section 35 of the Act and in Division 6 of Part 5 of the Regulations. Additionally, under paragraph 35(1)(c) of the Act, I have prescribed compliance with Part 6 of the Regulations as a licence condition and, further, issued specific licence conditions and requested evidence of compliance to be submitted with any future application for a licence to construct the ILWCI Facility, or earlier where that is feasible.

2. Reaching the decision

2.1 Receipt of application

On 23 July 2021 I received a licence application (A0339) from ANSTO to prepare a site for the ILWCI Facility. Supporting documentation was submitted in accordance with the application form for nuclear installations⁴, and the appropriate fee was paid.

2.2 Documentary evidence and references

The evidence before me in reaching the decision was:

- the application and supporting documentation, including supplementary documentation provided on ARPANSA's request
- the Regulatory Assessment Report⁵ (RAR) R21/07969 developed by the ARPANSA reviewers⁶
- recommendations, codes, and standards representing international best practice (IBP)

¹ [Australian Radiation Protection and Nuclear Safety Act 1998 \(legislation.gov.au\)](https://www.legislation.gov.au)

² Defined as "the holding of radioactive sources, radioactive material, spent fuel and/or radioactive waste in a facility that provides for their/its containment, with an intention of retrieval", see [Code for Disposal Facilities for Solid Radioactive Waste \(arpansa.gov.au\)](https://www.arpansa.gov.au), RPS C-3, ARPANSA 2018.

³ [Australian Radiation Protection and Nuclear Safety Regulations 2018 \(legislation.gov.au\)](https://www.legislation.gov.au)

⁴ [Regulatory Guide - Applying for a licence for a nuclear installation \(ARPANSA-GDE-1795WEB\) | ARPANSA](https://www.arpansa.gov.au)

⁵ See <https://arpansa.gov.au/ANSTO-ILWCI>

⁶ Lead reviewer was Ms Francesca Wigney, Facility Safety Section, Regulatory Services Branch (RSB). Ms Julie Murray reviewed the Security aspects of the application. Contributions were made by RSB regulatory officers and by staff of ARPANSA's Radiation Health Services Branch and by the Office of the CEO. The RAR was peer reviewed by Mr Andrew Wulf and Dr Samir Sarkar, and was approved by Mr Jim Scott, Chief Regulatory Officer. Mr Martin Reynolds, General Counsel, reviewed the Statement of Reasons and the licence. No interest was declared by anyone involved in the review and assessment, or in the decision, that materially conflicts with, or could be perceived to conflict with this decision.

- the Radiation Protection Series⁷ (RPS) Codes and Guides developed to support and promote uniformity in radiation protection and nuclear safety policies and practices across Australian jurisdictions
- ARPANSA's regulatory guidance⁸, developed for applicants and reviewers
- advice and submissions in relation to the application.

2.3 The Nuclear Safety Committee

The Nuclear Safety Committee is established under the Act to, *inter alia*, provide advice to the CEO of ARPANSA on matters relating to nuclear safety and the safety of controlled facilities⁹. The Committee was provided an orientation of the ILWCI Facility application at its meeting on 26 November 2021. Committee members subsequently provided advice on the RAR, the safety analysis report and the safety assessment, which were considered in ARPANSA's review and assessment, and in the licence decision.

The Committee reviewed a draft of this Statement of Reasons at its meeting on 25 February 2022. Members in attendance supported my preliminary decision to approve the application, subject to conditions of licence as further outlined in this Statement of Reasons. The minutes from the meeting will be published online in due course.

2.4 Consultation

In accordance with section 48 of the Regulations, ARPANSA published a notice of intent to make a decision on 1 September 2021. The notification was posted on ARPANSA's website together with ANSTO's submission¹⁰. The notification was also published in *The Australian* newspaper, and in the *St George Leader* and *Sutherland Shire Leader*.

As the application was for a nuclear installation, the notice included an invitation for interested third parties to make submissions in relation to the application with a closing date of 15 November 2021. ARPANSA organised a public forum (virtual due to the COVID-19 pandemic) on 13 October 2021 to provide information on different aspects of the proposed facility and on ARPANSA's review and assessment of the application¹¹.

The submissions are available from ARPANSA's website¹², unless a request for confidentiality had been made. Appendix 3 to the RAR provides an analysis of the submissions and addresses the issues raised. I also address key parts of the submissions in section 3.8 of this report.

2.5 Matters that must be taken into account when reaching a decision

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, as well as matters outlined in section 53 of the Regulations that are specific for a facility licence.

2.5.1 International best practice

In my view, consideration of international best practice involves the following:

⁷ [Radiation Protection Series | ARPANSA](#)

⁸ [Regulatory guides | ARPANSA](#)

⁹ For information on membership, advice, and meeting minutes, see [Nuclear Safety Committee | ARPANSA](#)

¹⁰ [Notice of intention to make a decision on a facility licence application | ARPANSA](#)

¹¹ [ARPANSA public forum on ANSTO licence application – Intermediate Level Waste Capacity Increase - YouTube](#)

¹² See <https://www.arpansa.gov.au/notice-intention-make-decision-facility-licence-application>

- 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 and documented in international standards
- technical standards for construction, materials and other matters relevant to safety
- experience from siting, construction, operation, and decommissioning of similar facilities in Australia and in other countries with an advanced infrastructure for safety.

The main elements of the international framework for safety, which I consider to be relevant international best practice, are laid out in, *inter alia*, the Safety Fundamentals and Safety Requirements and Safety Guides published by the International Atomic Energy Agency (IAEA); in the IAEA Fundamentals and Recommendations on Nuclear Security, and in the Recommendations of the International Commission on Radiological Protection (ICRP). The framework is supported by assessments of health and environmental risks from radiation, including the scientific evaluations carried out by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

ARPANSA's regulatory guides 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. ARPANSA maintains information on a selection of relevant international standards and risk assessments on its website.¹³

2.5.2 Specific matters

Section 53 of the Regulations specifies matters that I must take into account in deciding whether to issue a facility licence. These are:

- a. whether the application for the licence complies with subsection 46(1) of the Regulations
- b. whether the applicant for the licence has given the information asked for by the CEO
- c. whether the application, together with the information (if any) given as described in paragraph (b), establishes that the conduct proposed to be authorised by the licence can be carried out without undue risk to the health and safety of people, and to the environment
- d. whether the applicant has shown that there is a net benefit from carrying out the conduct proposed to be authorised by the licence
- e. whether the applicant has shown that the magnitude of individual doses, the number of people exposed and the likelihood that exposure will happen are as low as reasonably achievable, having regard to economic and societal factors
- f. 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
- g. whether the application has been signed by an office holder of the applicant, a person authorised by an office holder of the applicant or, if the licence is for a Commonwealth entity mentioned in section 45 of the Regulations, someone described in paragraph (b) of that section
- h. if the application is for a facility licence for a nuclear installation—the content of any submissions made by members of the public about the application.

I deal with the issues specified in section 53 of the Regulations in sections 3.1 – 3.8 hereunder, considering IBP where relevant.

¹³ [International best practice | ARPANSA](#)

My decision is also informed by ARPANSA’s ongoing oversight and regulatory experience with ANSTO, in particular ANSTO’s waste operations; by the waste management strategy of ANSTO (under preparation); and by the Australian Radioactive Waste Management Framework¹⁴. The considerations contained in this Statement of Reasons follow the intent and principles outlined in ARPANSA’s Regulatory Activities Policy.¹⁵

For the purpose of this Statement of Reasons, health and safety refers to *protection of people and the environment from harmful effects of ionising radiation*¹⁶ and includes consideration of radiation (radiological) protection and safety, 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 work health and safety legislation, is outside of my mandate.

3. Reasons for the decision

3.1 Does the application for the licence comply with subsection 46(1) of the Regulations?

Subsection 46(1) lists the following documentation that must be included in any application for a facility licence:

- (a) the applicant’s full name, position and business address
- (b) a description of the purpose of the facility to which the licence is to relate
- (c) a detailed description of the facility and the site of the facility
- (d) the applicant’s plans and arrangements for managing the facility to ensure the health and safety of people and the protection of the environment, including the following:
 - (i) arrangements for the applicant to maintain effective control of the facility
 - (ii) the safety management plan for the facility
 - (iii) the radiation protection plan for the facility
 - (iv) the radioactive waste management plan for the facility
 - (v) the security plan for the facility
 - (vi) the emergency plan for the facility
 - (vii) the environment protection plan for the facility
 - (viii) the decommissioning plan for the facility
- (e) for each activity to be authorised by the licence—a safety analysis report that is as complete as possible.

ANSTO has provided information relevant to all items specified in sub-section 46(1) of the Regulations.

This section of the statement will only consider general aspects of the purpose of the facility; of plans and arrangements for managing safety; and of the safety analysis report and underlying safety assessment. The purpose of the facility is also considered in relation to justification in section 3.4; paragraph 46(1)(c), sub-

¹⁴ [Australian Radioactive Waste Management Framework | Department of Industry, Science, Energy and Resources](#)

¹⁵ [Regulatory Activities Policy | ARPANSA](#)

¹⁶ Section 3 of the Act specifies its object; “... to protect the health and safety of people, and to protect the environment, from the harmful effects of radiation”.

paragraphs 46(1)(d)(i–viii) and paragraph 46(1)(e) are discussed in relation to undue risk (section 3.3); and paragraph 46(1)(a) is discussed in relation to authorised signatory (section 3.7).

3.1.1 Considerations

Purpose

The purpose of the planned ILWCI Facility is to increase the storage capacity for intermediate level solid waste (ILSW) from production of nuclear medicine and scientific research activities at the ANSTO Lucas Heights site. The current ILSW storage facility operating under ARPANSA licence F0260 is estimated to reach capacity in 2027.

The waste streams associated with production of nuclear medicine (mainly reactor-based production of molybdenum-99 [Mo-99] decaying to metastable technetium-99 [Tc-99m] used in nuclear medicine procedures) at the Lucas Heights site are schematically illustrated in Figure 1. Three major waste streams contribute to the generation of intermediate level waste¹⁷ (ILW):

- reprocessing of used fuel from the OPAL reactor in overseas facilities, with the resulting waste returned to Australia and (currently) stored in the Interim Waste Store (IWS) Facility at Lucas Heights (ARPANSA licence F0292)
- dissolution of irradiated uranium targets in the ANSTO Nuclear Medicine (ANM) Facility (F0309) for extraction and purification of Mo-99, with the residual waste (spent uranium filter cups; SUF cups) and general consumables used in the extractions stored in the existing ILSW facility
- liquid ILW generated and stored at the ANM Facility with the intention of solidifying the waste in the SyMo Facility currently under construction (ARPANSA licence F0266), and subsequent proposed storage of canisters with the solidified waste in the ILWCI Facility.

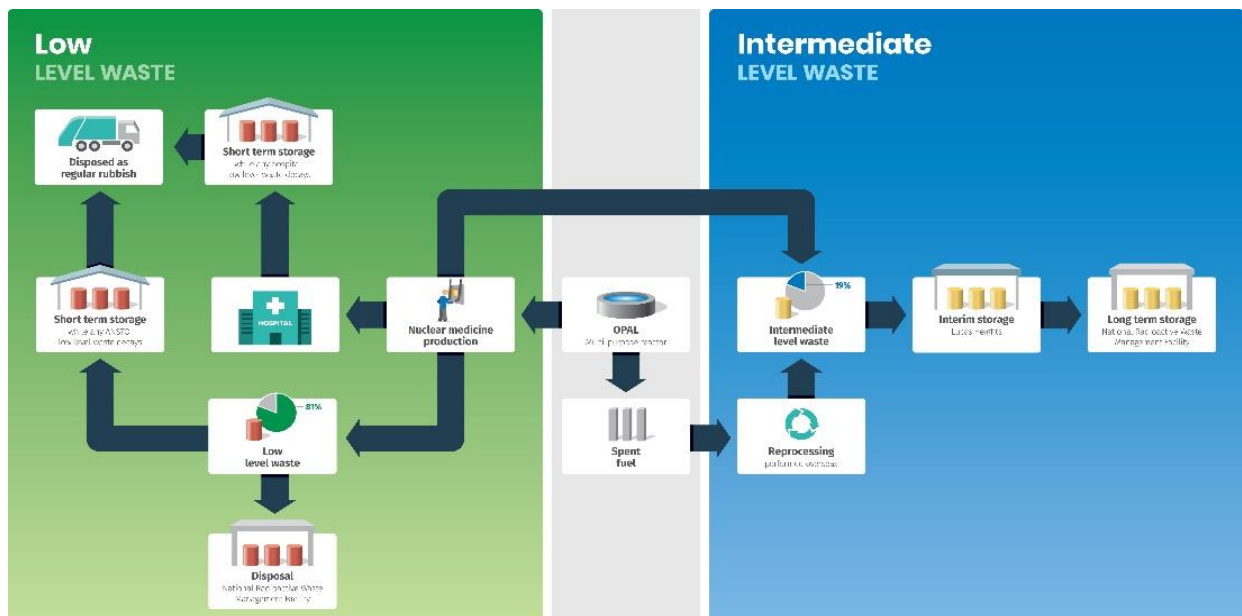


Figure 1. Overview of waste streams generated by nuclear medicine production at the ANSTO Lucas Heights site. Illustration provided by ANSTO and shown during the public forum held on 13 October 2021.

The ILW will, according to current plans, be transported to the National Radioactive Waste Management Facility (NRWMF) for storage pending ultimate disposal at another site. A site in South Australia near Kimba

¹⁷ See *Guide for Classification of Radioactive Waste*, RPS G-4, ARPANSA 2020 [Radiation Protection Series G-4 | ARPANSA](#) for information on waste classification

has been declared as the site for the NRWMF¹⁸; however, it will likely not receive any waste until the end of the 2020s at the earliest, if approved. The ILWCI Facility can be considered a contingency interim measure similar to the IWS Facility pending establishment of facilities for final management and disposal of ILW generated by ANSTO.

The planned ILWCI Facility is to be located within the 'Waste Precinct' of the Lucas Heights site. The facility will be separate from the existing ILSW facility, including its footprint and inventory (several tens of PBq),¹⁹ justify regarding it as a new nuclear installation to be covered by a separate licence. The ILWCI Facility will increase the storage volume for SUF cup storage vessels and other waste stored in aluminium retrievable bins (ARB) by 112 and 176% respectively. It will also provide storage capacity for waste canisters produced in the SyMo Facility. ANSTO estimates that capacity will be reached in 2037 i.e., the ILWCI extends the period during which waste can be received by appropriately designed storage facilities on site by 10 years.

Licence F0339 only authorises activities for the purpose outlined in the application. I have received confirmation from the ANSTO CEO that no other purpose is foreseen for the ILWCI Facility.

Completeness of information

It is implicit in the legislation that licensing of a facility normally occurs in stages, with each stage (to *prepare a site* for a facility; to *construct, operate, have possession or control of, decommission, or abandon* a facility) covered by a separate licence application (section 46 of the Regulations). Staged project development and licensing that require sequential applications and regulatory decisions mitigate the risk of problems arising from issues detected late or at the end of the project and that had been overlooked at the onset of the project. However, a prerequisite for a successful staged licensing process is that ultimate purpose, design, operation and decommissioning of the facility are understood in sufficient detail *at the initial stage of preparing a site for a facility* to avoid costly and time-consuming rectification work and a re-start of the regulatory review and assessment process.

In relation to the ILWCI Facility, some of the submitted documentation is necessarily generic in nature and lacks full detail at this stage of the facility lifecycle. However, the site characteristics documentation, the design, the risk assessment, and the safety analysis report (SAR) provide meaningful information and allow conclusions to be drawn about safety and security with reasonable certainty and appropriate to the site licensing stage. Other plans and arrangements for managing safety must be considerably more developed in advance of submitting an application to construct the facility and at later stages of the facility lifecycle. See further section 3.3.

3.1.2 Conclusions

Does the application for the licence comply with sub-section 46(1) of the Regulations

Information has been provided relevant to all areas itemised under sub-section 46(1) of the Regulations. The main purpose is to store ILW from nuclear medicine production and research activities; no other purpose has been stated. Plans and arrangements for managing safety currently lack detail. However, information on site characteristics and design, the risk assessment and the safety analysis report, are adequate and appropriate for the current stage of licensing, allowing meaningful reasoning and conclusions on safety of the ILWCI Facility.

¹⁸ [Minister declares Napandee as the site for the National Radioactive Waste Management Facility | Department of Industry, Science, Energy and Resources](#)

¹⁹ 1 petabecquerel (PBq) = 10¹⁵ Bq or 10¹⁵ atomic disintegrations per second.

3.2 Has the applicant given the information asked for by the CEO?

Sub-section 46(2) of the Regulations specifies documentation that the CEO may require from an applicant for a facility licence, noting the CEO may determine to request only some of the listed documentation and/or request other relevant documentation in addition to what is listed.

Notwithstanding what was stated above about the need for a fulsome albeit preliminary understanding of the life cycle of the facility when initially preparing a site for the facility, I consider the following (excerpts from sub-section 46(2) of the Regulations) most relevant for the present licensing decision:

1. Preparing a site for a controlled facility:
 - (i) detailed site evaluation establishing the suitability of the site for the facility
 - (ii) the characteristics of the site, including the extent to which the site may be affected by natural and human events
 - (iii) any environmental impact statement (however described) requested or required by a Commonwealth, State, Territory or local government agency in relation to the site or the facility, and the outcome of the environmental assessment.
2. Constructing a controlled facility
 - (i) the design of the facility, including ways in which the design deals with the physical and environmental characteristics of the site
 - (ii) any fundamental difficulties that will need to be resolved before any facility licence relating to the facility is issued.
3. Decommissioning a controlled facility.

ANSTO has provided information relevant to the above and has not communicated any fundamental issue to ARPANSA that needs to be resolved before a facility licence decision can be made.

ARPANSA has received the outcome of the notification under the *Environment Protection and Biodiversity Conservation Act 1999* (the EPBC Act; cf. item 1(iii) in the list above). On 13 October 2021, the Department of Agriculture, Water and Environment (DAWE) determined that the referral does not constitute a controlled action provided that certain conditions are met²⁰. ARPANSA supports the conditions imposed by DAWE; they correspond to ARPANSA's licensing basis and conditions issued with this licence.

²⁰ Referral decision (EPBC 2021/9025) conditions:

1. Remote Handled Solid Wastes (RHSW), other than filter cups, must be stored within aluminium retrievable bins, and liquid waste must be immobilised.
2. Filter cups must be stored within vessels approved for this purpose by Australian Radiation Protection and Nuclear Safety Agency (ARPANSA).
3. RHSW must be stored in concrete storage areas approved in accordance with all Regulatory Approvals.
4. RHSW within the Australian National Science Technology Organisation (ANSTO) site must be transported to the Intermediate Level Waste Capacity Increase (ILWCI) facility in a transport (shielded) flask.
5. The person taking the action must not transport any RHSW within the ANSTO site to the ILWCI facility until it has obtained all the Regulatory Approvals.
6. The ILWCI facility must not be operated for RHSW storage outside the licensed operating period specified by the Regulatory Approvals.
7. The person taking the action must comply in all respects with all the Regulatory Approvals for the location, construction, maintenance, operation and decommissioning of the ILWCI facility.

3.2.1 Considerations

The site

The site characteristics of the Lucas Heights site have been assessed on several occasions for the purpose of establishing new facilities licensed under the Act including the detailed assessments preceding the construction of the OPAL reactor. However, underground storage of waste requires analysis of the specific site for the ILWCI Facility, new knowledge may emerge, and experience may have been gained that furthers the understanding of the site characteristics and its impact on systems, structures, components and equipment important to safety.

For the purpose of preparing a site for the ILWCI Facility, ANSTO submitted an analysis of site characteristics and site related design basis, as well as design documentation. The characterisation study was supplemented by geotechnical investigations specific to the proposed location of the ILWCI Facility. Site characteristics have also been considered in the safety assessment and SAR.

Two feasible locations within the Waste Management Precinct were considered. The preferred site (Site A) scored higher than the other (Site B) on a number of criteria, including risks posed by bushfires (where the preferred site is outside of the flame zone) and facilitation of workflow. It only scored lower on one criterion being expandability (3 out of 5) compared to Site B (4 out of 5). ARPANSA agrees with the preference for site A.

The site characteristics analysis identifies the following areas for further consideration in the design of the facility: bushfire; drought; high summer temperature; lightning; low water supply; seismic activity; soil shrink – swell consolidation; extreme wind; ventilation air quality; and water supply quality.

The ILWCI Facility is an integral part of the activities at the site and interfaces with facilities and activities on site that give rise to ILSW that requires remote handling. ARPANSA's review has considered the impact of co-location of facilities and the interaction between different facilities on the Lucas Heights site. The reviewers have also considered ANSTO's assessment of the safety significance of human activity (e.g., road, rail and air transport; other industrial activity; military activity) for safety of the ILWCI Facility. The scenarios applicable to the ILWCI Facility are not different from those considered for other facilities on site and possibly carry less risk because the main purpose of the facility is storage with little handling and with predominantly passive safety features. No industrial activity that would preclude siting of the ILWCI Facility as proposed has been identified.

ARPANSA's regulatory officers have concluded that the site characteristics would not preclude location of the ILWCI Facility at the selected site while also acknowledging that the design of the facility is conceptual and that some risks should be given future consideration in the design of the facility. The selected site appears a logical choice and is suitable based on available documentation. I agree with the reviewers that the information submitted on the site characteristics provides reasonable assurance that the facility can be established and operated safely at the proposed site with the caveat that the design must carefully consider certain safety aspects already identified by ANSTO.

Design and Decommissioning

Design options have been developed by a consultant and submitted with the application. Broadly, the design is very similar to that of the existing ILSW Facility with holes and pits for SUF cup storage vessels and ARBs below floor level and covered with concrete lids. The ARPANSA reviewers have considered the conceptual design and are satisfied the documentation provides assurance of sound design and safety for the purpose of issuing a licence to authorise ANSTO to prepare a site for the ILWCI Facility. I agree with the reviewers.

ANSTO's plan for decommissioning of the ILWCI Facility is, at this stage, preliminary and as such lacks detail. However, I agree with ANSTO that for a facility of this nature (and provided no significant incident causing spread of radioactive material occurs) *the decommissioning operations should not present significant technical challenges*. The ARPANSA reviewers consider, and I concur, that the decommissioning plan should provide significantly more detail in the next licensing stage.

While the decommissioning plans lack detail there is an in-principle commitment by ANSTO to the 'immediate dismantling' option in accordance with international guidance. This is commendable but contingent on careful planning and adequate funding. Planning for decommissioning and integration of decommissioning in the over-all strategy for managing radioactive waste are required at a sufficiently early stage to assess the implications for various waste streams and the associated funding for managing such waste streams. This should be considered in ANSTO's waste management strategy which is currently under development.

3.2.2 Conclusions

Has the applicant for the licence given the information asked for by the CEO

The submitted information is sufficient in terms of scope and breadth to provide reasonable assurance that the selected site is suitable for the proposed ILWCI Facility, logical in terms of interface with other facilities on site, and - if the facility is designed and constructed as intended – that the facility would be able to withstand adverse environmental conditions and events as well as accidents associated with human activity. However, the facility design is at a conceptual stage and the site evaluation has identified external factors that should be considered in the final design.

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

3.3.1 Considerations

The issue to be considered is whether the applicant has demonstrated that risks have been identified, assessed, and mitigated; and that the management system provides reasonable assurance that the facility can be constructed with appropriate consideration of safety, and subsequently operated and decommissioned safely (the requisite plans and arrangements for managing safety are listed in sub-section 46(1) of the Regulations).

Safety Assessment (preliminary), Safety Analysis Report (SAR) and reference accident

Consistent with sub-section 46(1) of the Regulations and aligned with guidance from ARPANSA²¹, ANSTO submitted a SAR with the application *as complete as possible* considering the stage of licensing (*cf.* sub-section 46(1) of the Regulations). As concluded in section 3.1, ANSTO provided sufficient information for meaningful assessment of the major safety aspects of the proposed facility and activities. ANSTO submitted a safety assessment²² underpinning the SAR including hazard identification (HAZID) and assessment of incident²³ scenarios in terms of likelihood and consequence, in radiation protection terminology referred to as potential exposures that could be approached through risk constraints²⁴. In addition, a reference

²¹ [Regulatory Guide - Preparation of the safety analysis report for non-reactor facilities \(ARPANSA-GDE-1924WEB\) | ARPANSA](#)

²² The terms safety analysis report and safety assessment may have similar meanings, see IAEA Glossary 2018 edition [PUB1830_web.pdf \(iaea.org\)](#). ARPANSA's regulatory guidance considers the safety assessments a component of the broader SAR. This difference in terminology has no material consequence for the understanding of the safety of the ILWCI Facility.

²³ [Advisory Note: Use of the term 'incident' as defined in the Planned Exposure Code | ARPANSA](#)

²⁴ The Planned Exposure Code (RPS C-1 Rev 1), ARPANSA 2020, [Code for Radiation Protection in Planned Exposure Situations \(arpansa.gov.au\)](#) provides the following definitions:

accident assessment was submitted for the purpose of establishing the relevant emergency preparedness category for the ILWCI Facility.

The SAR makes the following claim:

On the basis of the site characteristics information and the specific site-related design basis considerations, it is concluded that the proposed site for the storage facility, within the Lucas Heights site, does not have any negative features which cannot be overcome by the high standard and quality of engineering design and construction which are required by ANSTO.

The radiological risks to the population from accident conditions, including those that may require mitigation measures, are acceptably low and in accordance with national requirements. This facility will be designed to meet the safety objectives, and the appropriate external events, codes, standards, and design methods have been considered in the design.

ANSTO used a workshop approach with a team representing several specialist competencies with a variety of roles and backgrounds to identify incidents that, should they occur, would have non-negligible radiological or WHS-related impact on workers, the public or the environment. Estimates of likelihood and impact informed the estimates of inherent risk. Controls were identified and the residual risks were estimated with controls in place. The controls were generally designed to reduce the likelihood of the incident. The controls were either 'critical' (requires ongoing monitoring) or 'other'.

The risk assessment methodology has further developed compared to what was used in previous licence applications. It is generally reliant on managing residual risks by limiting their probability of occurrence to levels where the occurrence (annual or over the lifetime of the facility) is inherently uncertain and not easily supported by observation and experience. Certain scenarios are, based on their low likelihood, eliminated from further management as they are considered 'incredible' using a probability threshold of 10^{-6} per year.

Inherent catastrophic or severe radiological impact²⁵ and residual risks after considering the estimated frequency after mitigating the risk were identified for incidents as follows:

1. Dropping the general purpose (GP) flask used for transportation of SUF cups during transport (catastrophic impact) – considered not credible and therefore not further assessed.
2. Dropping the retrievable waste flask during transport (severe impact) - the residual risk was calculated as 'low'.
3. Dropping the GP flask due to crane failure (catastrophic impact) – considered not credible and therefore not further assessed.

Potential exposure: *Prospectively considered exposure that is not expected to be delivered with certainty but that may result from an anticipated operational occurrence or accident at a source or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors.*

Dose (risk) constraint: *A prospective and source related value of individual dose (dose constraint) or of individual risk (risk constraint) that is used in planned exposure situations as a parameter for the optimisation of protection and safety for the source, and that serves as a boundary in defining the range of options in optimisation. For occupational exposures, a constraint on individual dose to workers used by Responsible Persons to set the range of options in optimising protection and safety for the source. For public exposure, the dose constraint is a source related value established or approved by the relevant regulatory authority, with account taken of the doses from planned operations of all sources under control.*

²⁵ 'Catastrophic' refers to whole-body exposure >1 sievert (Sv); 'severe' to whole-body doses of 0.1 to 1 Sv. Whole-body doses above 1 Sv lead to tissue reactions and potentially to severe injury or death. In the range 0.1 to 1 Sv, transient health impact can be expected with severity increasing in proportion to the dose. There would also be an expectation of increased frequency of cancers attributable to radiation in a population exposed at such levels. See further Publication 103 of the ICRP, 2007 [P103 The 2007 Recommendations of the International Commission on Radiological Protection \(sagepub.com\)](#)

4. Dropping the retrievable waste flask due to crane failure (severe impact) – residual risk calculated as ‘low’.
5. Worker falling into an open pit inside the facility (catastrophic impact) – incident with significant physical injury in addition to the radiological.

The residual consequence was not altered by the risk mitigation actions, but the residual risks were assessed to be reduced to acceptable levels (see the RAR for discussion). The potential exposures are below, or in many cases much below, the 2×10^{-4} annual risk constraint (below which protection should be optimised) for fatal cancer, which is recommended for occupational exposure by the ICRP²⁶. Critical controls included crane and flask scheduled maintenance. Three recommendations were made with regard to reducing the likelihood of a worker falling into an open pit. So far, no credit has been taken for mitigating actions for this incident, pending the recommendations being actioned, and the risk thus remains ‘high’. It is expected that the mitigating actions for this risk will reduce the residual risk but more details on the design are required before this can be fully assessed.

The SAR and underpinning risk assessment have been reviewed by the ARPANSA reviewers against the relevant regulatory guidance. Their conclusion is that the SAR and risk assessment provide a reasonable level of assurance of safety of the ILWCI Facility for the purpose of preparing a site for the facility. I agree with the reviewers.

However, and notwithstanding the fact that there is reasonable confidence in safety of the facility, doses up to and above the annual dose limit (20 mSv as a five-year average) have been identified for several incidents but with low to very low likelihood of occurrence. I note that the estimates of likelihoods appear conservative in some cases, but caution should be exercised against placing confidence in purportedly low likelihoods as they remain uncertain and mistakes caused by distraction, unawareness, negligence, or other factors can be made even by trained and experienced staff. While human and organisational factors have been considered in the risk estimates, information has been taken from sources that are over 30 years old. It is expected that a future safety assessment will consider more up to date data sources where they are available for human factors. In addition, in some cases where engineering judgement has been applied for probability of failure, no explanation/justification has been documented.

Furthermore, an unlikely, or even an incredible incident may still be *possible* and if it happens, it is the impact that matters. For high-impact incidents, the likelihood that it will happen during the operational lifespan of the facility is also of importance. I recommend that ANSTO considers the application of a risk constraint for systematic optimisation of protection addressing likelihoods and impacts over the operational lifespan of the facility and carefully considers options to reduce the impact of incidents where they are rated severe or higher.

The recommendations made in the SAR should be actioned by ANSTO and evidence provided to ARPANSA at the latest with an application to construct the ILWCI Facility.

ANSTO conducted a reference accident analysis to support classification of the ILWCI Facility in terms of Emergency Preparedness Category. The facility has been classified as Emergency Preparedness Category III in accordance with national and international guidance²⁷; not requiring early or urgent protective actions

²⁶[P103 The 2007 Recommendations of the International Commission on Radiological Protection \(sagepub.com\)](#)

²⁷ The Emergency Preparedness Categories can be found in *Guide for Radiation Protection in Emergency Exposure Situations – The Framework*, RPS G-3 Part 1, ARPANSA 2019, [RPS G-3 Emergency Exposure Guide - PART 1 \(arpansa.gov.au\)](#). Category III: Facilities, such as industrial irradiation facilities or some hospitals, for which on-site events are postulated that could warrant protective actions and other response actions on-site to achieve the goals of emergency response in accordance with international standards, or for which such events have occurred in similar facilities. Category III (as opposed to category II) does not include facilities for which events are postulated that could warrant urgent protective actions or early protective actions off-site, or for which such events have occurred in similar facilities.

off-site. ARPANSA accepts this category for the purpose of preparing a site for the ILWCI Facility and will perform independent accident analysis based on updated design and inventory information to be submitted with an application to construct the ILWCI Facility.

Plans and arrangements for managing safety

In support of the application, ANSTO has submitted plans and arrangements for managing safety at the ILWCI Facility in accordance with sub-section 46(1) of the Regulations. The Decommissioning Plan was briefly considered in section 3.1; the Radiation Management Plan will be considered further in section 3.5 on optimisation.

The Effective Control Plan, Safety Management Plan, Radioactive Waste Management Plan, Security Plan, Emergency Plan and Environment Protection Plan have all been submitted with the application. They build on existing practices and documentation at ANSTO. The ARPANSA reviewers have considered the plans in detail as regards their general content and acknowledge that at this stage of licensing the documentation meets the intent of the ARPANSA regulatory guidance,²⁸ but are currently not detailed enough for a fulsome review.

In the next iteration, expected in support of an application to construct the facility, ANSTO should concretely outline and explain how the different elements of the plans and arrangements have been tailored to the specific requirements of the ILWCI Facility, i.e., focus on the specific aspects that differ from or that establish interfaces with existing site-wide plans and arrangements at the ANSTO Lucas Heights site. The plans and arrangements should be presented in a way that makes them useful for ANSTO staff.

3.3.2 Conclusions

Can the proposed conduct be carried out without undue risk to the health and safety of people, and to the environment

The material transported from facilities within the Lucas Heights site to the ILWCI Facility for storage is inherently hazardous and capable of causing serious radiation-related health effects on workers engaged in the operations. The SAR considers the risk assessments for several identified hazards. The risk mitigating measures applied to handling and storage provide reasonable and sufficient assurance of safety, commensurate with the current licensing stage. The recommendations from the SAR, and the human and organisational aspects of incidents with higher inherent risk must be considered in the lead up to applying for authorisation to construct the ILWCI Facility. The plans and arrangements should clearly identify how the site-wide plans will be applied to the design and operations of the ILWCI Facility.

3.4 Has the applicant shown that there is a net benefit from carrying out the proposed conduct?

3.4.1 Considerations

Net benefit relates to the principle of justification. In the international framework for safety, justification for the establishment of a waste management facility cannot be judged in isolation from the purpose of the practice that generates the waste. The reasoning around net benefit needs to take into account the benefit from nuclear medicine production *and* any negative impact on health, society and economy. In my decision of 12 April 2018²⁹, which authorised ANSTO to commence ‘hot commissioning’ of the ANM Facility for fission-based production of Mo-99, I concluded:

²⁸ [Regulatory Guide - Plans and arrangements for managing safety \(ARPANSA-GDE-1735WEB\) | ARPANSA](#)

²⁹ [statement_of_reasons_sor_-_anm_operations.pdf\(arpansa.gov.au\)](#)

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.

In my decision of 24 May 2019 to amend the licence for the ANM Facility³⁰, allowing routine operations to commence, I reiterated this view in the light of updated projections of global demand for Mo-99 in relation to production capacity. However, the supply depends on a fairly small number of processing facilities and while there is an expectation that new facilities for non-reactor nuclear medicine production will come online in the next few years, some existing facilities may retire. The ANM Facility will likely remain a cornerstone in the nuclear medicine supply chain in Australia and could also play a significant role globally; however, the actual production may be impacted by changes in supply and demand on the international market. This, in turn, may have consequences for the projected time (years) for the ILWCI Facility to reach capacity. This should be considered in an analysis of different scenarios as it is of fundamental importance for the understanding of when other measures for waste storage must be implemented or the generation of waste must cease.

Successive licensing decisions have emphasised the need for careful planning of waste management at the Lucas Heights site and for contingency planning. ANSTO is developing its Waste Management Strategy and an initial draft has been made available to ARPANSA. The ILWCI Facility is an element of this strategy and offers an opportunity to extend safe management of the waste streams associated with the operation of the ANM Facility 15 years into the future and possibly beyond³¹. It is desirable that the Waste Management Strategy separates the individual ILW streams and that the planning considers predisposal management and disposal for those waste streams separately including contingencies should there be delays or changes to ANSTO's preferred option(s) for final management of the different ILW streams.

3.4.2 Conclusions

Has applicant shown that there is a net benefit from carrying out the proposed conduct:

The benefit of the ILWCI Facility is based on the production of nuclear medicine. The ILWCI Facility could extend the ability to safely manage ILW resulting from nuclear medicine production to 2037 assuming no major changes to the projected production rates over the next 15 years. I consider that the ILWCI Facility has a role in securing the domestic availability of nuclear medicine. While this is a contingency brought about by the current lack of a disposal solution for ILW leading to prolonged storage, either at the ILWCI Facility or elsewhere, I continue to consider the risks associated with prolonged storage at the Lucas Heights site manageable based on information available to date.

³⁰ [anm-sor-24052019.pdf \(arpansa.gov.au\)](#)

³¹ A further prerequisite for sustained operations of the ANM Facility in accordance with the draft Waste Management Strategy is the successful finalisation of the construction and subsequent commissioning of the SyMo Facility for solidification of liquid ILW currently accumulating in the ANM waste tanks. Construction work carried out under ARPANSA licence F0266 is at its final stage.

3.5 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 societal factors?

3.5.1 Considerations

Once an activity is deemed justified, dose limits apply, and protection must be optimised. Optimisation means, in essence, that all reasonable (from the cost and societal perspectives) efforts should be made to reduce exposures, the number of people exposed and the likelihood of exposure. To prevent significant exposures of individuals, dose constraints should be established below the dose limit by an appropriate margin. It would be considered unacceptable to plan a conduct so that the constraint is exceeded. This is captured in the Radiation Protection Plan and in ANSTO's Radiation Safety Standard, the latter stating with regard to optimisation:

Optimisation of protection at ANSTO 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 resonates with the recommendations of the International Commission on Radiological Protection³² and the International Basic Safety Standards³³ (BSS) and should be considered in the design of a facility (safety by design) and in planning for its subsequent operations. ANSTO's Radiation Safety Standard does not explicitly address optimisation against a risk constraint. I recommend ANSTO consider adopting the risk constraint concept in the risk assessment methodology, including incorporating the actual risk of harm in the impact analysis for the higher exposures, using appropriate dose coefficients and exercising some caution with regard to possible overinterpretation of numerical values for health risks (actual or inferred).

I emphasise that optimisation must be considered in the planning and design stage. At the construction application stage, I expect specific documentation regarding the way optimisation has been considered in the design of systems, structures, and components, and in the arrangements for workflow and processes; using a graded approach that focus on the major risks and health impacts.

Experience from the current operations of the ILSW Facility have not revealed significant exposures of staff of ANSTO's Waste Management Services. A review of worker doses for the last 10 years shows that maximum effective doses for individual years typically range between 1.5 and 2.5 mSv for about 10% of the workforce, with the rest of the workforce incurring lower or negligible doses. Skin, eye, and extremity equivalent doses are correspondingly low. Possible internal contamination is below detection limits providing an indication that committed effective doses are of low concern. Airborne discharges, which are

³² 2007 [P103 The 2007 Recommendations of the International Commission on Radiological Protection \(sagepub.com\)](#)

³³ General Safety Requirements No. GSR Part 3, IAEA, 2014. [Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards | IAEA](#)

reported quarterly to ARPANSA have remained well below regulatory limits with the off-site dose demonstrated to be negligible through modelling.

It is reasonable to assume that the doses incurred currently will not be exceeded in the ILWCI Facility, but potentially be lower as a result of further optimisation. A preliminary dose constraint (or constraints) should be provided with an application to construct the ILWCI Facility.

3.5.2 Conclusions

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 societal factors

Experience from the current storage of spent uranium filters and from waste operations in general demonstrate that radiation exposures during normal operations are low. The safety analysis report indicates a potential for significantly higher exposures as the result of certain incidents with localised impact, but the likelihood is low. While information and evidence on optimisation in design considerations, including preliminary dose constraints, should be provided with an application for a construction licence, existing documentation and experience provide assurance that normal operations result in only low exposures. Reasonable optimisation measures should be put in place.

3.6 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?

3.6.1 Considerations and conclusions

Waste Management Services currently operates under five licences issued by ARPANSA; operations of the Interim Waste Store Facility for returned waste from the overseas reprocessing of spent OPAL and HIFAR fuel assemblies (F0292), ANSTO Waste Operations including the existing ILSW Facility (F0260), a licence to possess or control the permanently shut down HIFAR reactor (F0184), a licence to possess or control the Little Forest Legacy Site (F0293) and a licence to site and construct the SyMo facility (F0266).

Over the last 10 years, there have been 7 breaches of licences managed by Waste Management Services. Six had minor or negligible safety significance and one was considered to be potentially safety significant although no doses were actually received. As noted in section 3.5, radiation exposures of staff in the existing ILSW Facility are low. ARPANSA is not aware of any resource limitation that would negatively impact the ability to comply with legislation and licence conditions. Additional resources have been made available to ANSTO to establish the ILWCI Facility and once it is established and starting to receive waste, existing workforce will be diverted from the currently operating store to the ILWCI Facility.

I believe ANSTO and - in this case - its Waste Management Services and Waste Operations, have the *capacity* to comply and carry out the functions safely. Human and organisational factors will determine how well this capacity will be utilised in day-to-day routines and in non-routine work. These are not issues specific to the proposed ILWCI Facility but apply across all licensed activities within the Lucas Heights site. ARPANSA's reviewers have not identified any issue that would challenge the view that ANSTO through Waste Management Services and Waste Operations has the capacity to manage the ILWCI Facility safely. I agree and urge ANSTO to maintain strong vigilance of the human and organisational factors that govern safety, including the culture for safety.

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

Experience from the existing ILSW Facility including compliance with licence conditions and occupational radiation exposure provide reasonable assurance that ANSTO, through Waste Management Services, has the capacity to comply with the Act, Regulations and licence conditions.

3.7 Authorised signatory

3.7.1 Considerations and conclusions

Mr Shaun Jenkinson, CEO of ANSTO, submitted the application on 19 July 2021. Mr Jenkinson is authorised to submit the application under sub-section 45(b) of the Regulations.

Persons covered by the licence are the licence holder³⁴, employees of the licence holder, Commonwealth contractors, employees of Commonwealth contractors, and Permitted Persons.

Authorised signatory

The CEO of ANSTO is an authorised signatory.

3.8 Content of submissions about the application

The process for consultation was briefly outlined in section 2.3 of this Statement of Reasons. Five submissions were received, in some cases extensive and drawing on other documentation such as previous submissions to Senate inquiries. Comments and questions put forward at the Public Forum on 13 October 2021 were largely similar.

ARPANSA wishes to thank the individuals and, where relevant, their parent organisations for the time and effort in expressing their views on the application submitted by ANSTO. Consultation enables informed decision-making and ARPANSA recognises the value of consultation and stakeholder engagement in enhancing institutional strength-in-depth³⁵.

Very little input was received that related to safety of the ILWCI Facility *per se*. However, many comments were received in relation to the position of the ILWCI Facility in the national framework for managing radioactive waste, in particular as regards the plans for establishing a storage facility for ILW as part of the NRWMF. These comments are relevant. Any waste facility is part of a *system* for waste management that includes predisposal management (for example storage and conditioning), transport and disposal. The need for this system is related to the purpose of the facilities and activities that give rise to radioactive waste and thus intrinsically linked to justification.

The ARPANSA reviewers grouped the issues into themes and evaluated them as recorded in appendix 3³⁶ to the Regulatory Assessment Report. ANSTO was consulted in cases where the factual correctness had to be verified. In this section, I consider the comments in an aggregated form where some of the nuances will have been lost, although – in my view - the ‘essence’ is captured. I refer a reader to the previously mentioned appendix to the RAR for full detail. Some of the views recorded in the submissions express perceptions based on conjecture; I have not commented on those.

³⁴ For the purposes of this licence, the licence holder is the ‘responsible person’ as defined in the *Code for Radiation Protection in Planned Exposure Situations* (2020) RPS C-1 (Rev. 1) [Radiation Protection Series C-1 \(Rev. 1\) | ARPANSA](#). Responsibility for ensuring the safety of the ILWCI Facility lies collectively with the CEO and senior management team of ANSTO.

³⁵ *Ensuring Robust National Nuclear Safety Systems, Institutional Strength-in-Depth*, INSAG (International Nuclear Safety Group) 27, IAEA 2017, [P1779 web.pdf \(iaea.org\)](#)

³⁶ See <https://arpansa.gov.au/ANSTO-ILWCI>

One submission was made with the request that the contents remain confidential. While the content has been reviewed by ARPANSA and considered in the decision, the RAR and this Statement of Reasons do not make specific reference to any details of the submission to prevent inadvertent disclosure of the identity of the person or body making the submission. Broadly, it related to the financial justification of continued nuclear medicine production at ANSTO and therefore the need for the ILWCI Facility. It did also raise questions regarding the appropriateness of the proposed NRWFM facility in relation to alternative site options.

3.8.1 Considerations

The forecast for reaching capacity of the ILWCI Facility (2037)

One submission questioned the precision of ANSTO's estimate of when the ILWCI Facility is expected to reach capacity. ANSTO considers that the ILWCI Facility will be able to receive waste until 2037. ARPANSA considers it desirable to explore different scenarios regarding national and international supply and demand of nuclear medicine and the possibility that existing production facilities may retire and/or new facilities come online. A licence condition has been issued to gain more certainty regarding the time during which the ILWCI facility may receive waste and, as a consequence, nuclear medicine production can be sustained without the need for further contingency measures.

Storage of ILW until disposal

Several submissions raised questions around the need for a storage facility for ILW as part of the NRWFM. The questions are summarised in italics below, followed by my response.

- *ARPANSA should require that all ILW remain at Lucas Heights until a disposal facility has been established*

ARPANSA's mandate is not to plan for the management of radioactive waste at ANSTO or in Australia, but to review and assess such plans with emphasis on safety and protection, based on the safety case put forward by the proponent as well as contingencies and a thorough understanding of the system for waste management. ARPANSA's view is that for some ILW, safe storage can continue for decades³⁷, confirming the views expressed by ANSTO³⁸. A waste management strategy is under development by ANSTO. The strategy should consider all waste streams, including legacy waste, and the different options for predisposal management and disposal. This matter is subject to ongoing discussions between ARPANSA and ANSTO.

- *ARPANSA should prepare for a decision that a ILW store (as part of the NRWFM) may not be licensed and that licence applications for a disposal facility for low-level waste and for storage of intermediate level waste must be separate*

Because of fundamentally different purposes, the safety case for disposal of LLW would reasonably differ significantly from the safety case for ILW disposal and require separate reviews and assessments. It is, therefore, also reasonable to consider storage and disposal at a proposed NRWFM under separate licensing in the regulatory decision-making process, potentially reaching different conclusions.

- *The process for siting of the NRWFM does not take into account advice, jurisdictional legislation and the views of the traditional owners of the land*

³⁷ see https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Economics/RadioactiveWaste/Submissions

³⁸ See Appendix 3 of the RAR

ARPANSA has closely followed the successive steps in the process for selecting a site for the NRWMF. Since 2016, at a stage when the process had narrowed down to one site and subsequently broadened to three specific sites in South Australia, ARPANSA has reached out to local communities, organisations and individuals to provide information about ARPANSA, the process for regulatory review and assessment, safety requirements, requirements for protection of health and safety of people and the environment, and provisions for engaging stakeholders.

This outreach has not been part of formal consultation under the Act, which will only commence if and when ARPANSA receives an application for a licence. Among the issues ARPANSA will consider during review and assessment are: whether there are unresolved legal or technical matters; the safety case put forward by the proponent; optimisation of protection while taking the system for radioactive waste management into account and including economic and societal factors; any environmental impact assessment requested by any other agency (such as under the EPBC Act which among other things considers matters relevant to heritage), and the content of submissions made in relation to the application.

- *Requests for explanation of current federal policy and preparations for disposal of ILW*

It is not ARPANSA's place to provide this explanation. The Australian Government has recently established the Australian Radioactive Waste Agency³⁹ for the purpose of providing policy advice to the appropriate policy department, the Department of Science, Innovation, Energy and Resources; and to prepare for seeking authorisation to establish the necessary waste facilities.

- *Lucas Heights is not suitable for long-term storage of intermediate level waste*

The Sutherland Shire Council has for many years voiced their reservations in regard to plans for storage of radioactive waste at Lucas Heights. In its submission, the Council argues strongly for an expedient establishment of the NRWMF to, *inter alia*, enable transport of ILW from Lucas Heights for subsequent storage until a solution for final disposal has been developed and implemented in practice. The Council acknowledges the safety of radioactive waste storage at the Lucas Heights site but expresses deep dissatisfaction with the time it has taken to establish the NRWMF, which has led to continued accumulation of radioactive waste at Lucas Heights.

Even under optimistic assumptions regarding the timing for which the NRWMF facility can commence receiving waste, increased storage capacity at Lucas Heights will be required unless the waste is a) transported to another site (no such contingency plans are known to ARPANSA), or 2) production of ILW (and hence nuclear medicine production) ceases at a time when the existing ILSW Facility has reached capacity.

ARPANSA is aware of this dilemma. This decision seeks to deal with this dilemma in a pragmatic way, where I consider the continued supply of nuclear medicine to be a priority and that the waste management issues it raises to be manageable over the next decades. This view was previously expressed in the decision to authorise the operation of the ANM Facility, thus securing sustained production after the retirement of the production facility in Building 54⁴⁰; this decision also refers to a commitment by the Australian Government to establish a *disposal* facility for ILW at a site different to that of the NRWMF.

³⁹ [Australian Radioactive Waste Agency | Department of Industry, Science, Energy and Resources](#)

⁴⁰ [statement_of_reasons_for_anm_operations.pdf\(arpansa.gov.au\)](#)

I also reiterate that storage is not the ultimate solution but, by definition, only an *interim* measure. In this regard, it is relevant to reiterate what was stated in ARPANSA's submission to the Senate Economics Legislation Enquiry into the National Radioactive Waste Management Bill 2020⁴¹:

ARPANSA wants to emphasise that national solutions should be sought, plans developed, and facilities established for all radioactive waste stored, and over the coming years generated, in Australia; this will contribute to elimination of the need for specific storage facilities where radioactive waste may accumulate over long periods of time without a defined disposal pathway – or any disposal facility in sight.

I am aware that development of conceptual models for ILW disposal is under way, and facilities exist in other countries from which experience can be drawn when developing the Australian solution. I am convinced that this will occur and it is desirable that this process commences as soon as practicable, but is given great care and the necessary time required to receive the requisite technical approval and 'social licence'.

The establishment of Waste Acceptance Criteria should be expedited and should be the responsibility of ARPANSA

The Waste Acceptance Criteria (WAC) are required for the predisposal management of the waste, including for transport and ultimate disposal. Early establishment of WAC supports final management of the waste characterised by 'no surprises'. I consider the development of WAC the responsibility of the operator of a storage or disposal facility, which is in accordance with international best practice. However, I acknowledge the role ARPANSA has in carefully reviewing the appropriateness of the WAC. If ARPANSA were to develop the WAC, the division of responsibilities between the operator and regulator would be blurred; the operator must develop the WAC with the view of the long-term safety of the operator's own facility, with regulatory oversight and as necessary, approval provided by ARPANSA. The WAC must be informed by, and appropriately aligned with, the safety features of the disposal facility.

Progress in relation to recommendations by the independent review into safety practices at ANSTO

Based on recurrent incidents, including contamination of workers, ARPANSA directed ANSTO in June 2018 to initiate an independent review into the safety practices of nuclear medicine production at ANSTO. The review resulted in 85 recommendations and ANSTO's action plan was approved by ARPANSA in December 2019. ARPANSA is generally satisfied with the implementation of changes based on the recommendations⁴² and progress on outstanding recommendations continues to be the subject of six-monthly reports from ANSTO to ARPANSA.

The submission queried whether there had been an improvement in safety culture. In response I would note that 'culture' is a trait that is hard to quantify but where implemented measures, staff awareness, incidents and attitudes observed through ARPANSA's inspection program (with increased attention to human and organisational factors), site visits and meetings with executive management, provide meaningful information. The observations indicate ongoing and continuous improvement.

Integrity of ARPANSA's decision-making and recruitment of the Chief Executive Officer

Concerns have been expressed about the integrity of ARPANSA's regulatory decisions, which to some extent seem to be based on perceptions around the process to appoint the first CEO of ARPANSA. The inclusion of the major licence holder (ANSTO) in the selection panel during the recruitment of ARPANSA's

⁴¹ See https://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Economics/RadioactiveWaste/Submissions

⁴² [Progress on actions from ANSTO safety review | ARPANSA](#)

first CEO appears to have raised perceptions around the integrity of the process that could have been avoided at the time.

The integrity of ARPANSA's decision-making should be judged on facts and not on conjecture. Specifically, to the extent a critical and evidence-based regulatory approach to a proposal to establish a waste management facility is a relevant indicator of regulatory integrity, a reader may take some comfort from a recent article⁴³ by Professor Ian Lowe⁴⁴.

While accepting that regulatory decision-making, just as any other human activity, is never infallible, I believe ARPANSA's decisions as a rule are well informed, characterised by integrity and underpinned by sound judgement and evidence, in accordance with ARPANSA's Regulatory Activities Policy⁴⁵. I am pleased to see that the submission expressed general confidence in the current state-of-affairs. A recruitment process is underway for the recruitment of ARPANSA's third CEO, managed by the Department of Health. I have full confidence in the integrity of the recruitment process.

3.8.2 Conclusions

Content of submissions about the application

ARPANSA invited and reviewed submissions about the application. The submissions predominantly concerned the position of the ILWCI Facility in the national radioactive waste management system. The diversity of opinions regarding the NRWMF, in particular storage of ILW at the NRWMF, are well known to ARPANSA. No new information emerged that materially challenges ARPANSA's view that continued production of nuclear medicine provides significant benefit to Australia's health care system; this inevitably leads to continued production and increased storage of ILW at Lucas Heights. In my opinion and as argued in this Statement of Reasons, this can safely continue over the next decades pending the establishment of facilities for final management of radioactive waste, including a disposal facility for ILW for which no concrete plans are currently available.

4. Licence conditions

Under section 35 of the Act, I impose the following licence conditions regarding specific matters that must be addressed in sufficient detail and in a form that clarifies the safety aspects of the issue. The information must be submitted with an application for a licence to construct the ILWCI Facility, or earlier where feasible. Failure to comply may result in a licence application to be deemed incomplete and not reviewable.

4.1 Time until reaching capacity of the ILSW stores

Sections 3.1 and 3.4 of this Statement of Reasons discuss the projections provided by ANSTO, which indicate that the existing ILSW Facility will reach capacity in 2027 and the ILWCI Facility in 2037. There are associated uncertainties, and these may have significant consequences for long-term production and national availability of nuclear medicine, as well as for the establishment of new waste management facilities at ANSTO or elsewhere. An analysis of scenarios must be submitted with an application to construct the ILWCI Facility or before, as detailed below. The information provided to ARPANSA must consider both waste volume and activity.

⁴³ [3 reasons the announcement to dump radioactive waste in South Australia is extremely premature \(theconversation.com\)](https://www.theconversation.com/3-reasons-the-announcement-to-dump-radioactive-waste-in-south-australia-is-extremely-premature)

⁴⁴ Professor Emeritus Ian Lowe of Griffith University was the Chair of the Australian Conservation Foundation 2004 – 2012. He was also a member of the Radiation Health and Safety Advisory Council established under the ARPANS Act 2002 - 2014, to which he was appointed by the Minister as "a person to represent the interest of the general public".

⁴⁵ [Regulatory Activities Policy | ARPANSA](#)

Licence condition: ANSTO must, as part of the supporting documentation for an application to construct the ILWCI Facility or earlier, provide

- (i) Updated information on expected progression of emplacement of ILW in the existing storage facility for ILSW and in the ILWCI Facility, and expected timing for reaching capacity for storage of SUF cups, ARBs, and SyMo waste canisters at these facilities, building on:
 - a. assumed continued production of ILW from nuclear medicine production at the time the supporting documentation is submitted
 - b. other plausible scenarios for future demand and production capacity for Mo-99/Tc-99m for nuclear medicine procedures, in Australia and globally
 - c. scenarios under (a - b) and assuming contribution by ANSTO to the Outage Reserve Capacity recommended by the OECD/NEA High-Level Group on the Security of Supply of Medical Radioisotopes⁴⁶
 - d. activity of waste stored under the scenarios defined in (a) – (c).

4.2 Influence of site characteristics and optimisation of protection in the design of the ILWCI Facility

Section 3.2 refers to the site characteristics and site-related design basis for the ILWCI Facility. A number of areas were identified in by ANSTO as requiring consideration in further design works.

Licence condition: ANSTO must, as part of the supporting documentation for an application to construct the ILWCI Facility or earlier, provide:

- (i) Updated information on design considerations and design decisions that have been made about
 - a. bushfire
 - b. drought
 - c. high summer temperature
 - d. lightning
 - e. low water supply
 - f. seismic activity
 - g. soil shrink and swell
 - h. extreme wind
 - i. ventilation air quality
 - j. water supply quality
- (ii) Updated information on considerations of optimisation of protection in the design including
 - a. design, workflow and processes
 - b. preliminary dose constraints and projected airborne discharges relevant to the facility and/or certain aspects of the facility.

⁴⁶ [Nuclear Energy Agency \(NEA\) - High-level Group on the Security of Supply of Medical Radioisotopes \(HLG-MR\) \(oecd-nea.org\)](https://www.oecd-nea.org/)

4.3 Safety assessment and safety analysis report

Section 3.3 of this Statement of Reasons considers the SAR and underpinning risk assessment, including the recommendations for further actions. In addition, the approach to risk assessment was discussed, in particular screening out certain incidents as not credible, and the human factors.

Licence condition: ANSTO must, as part of the supporting documentation for an application to construct the ILWCI Facility or earlier, provide:

- (i) Responses to the recommendation in Appendix B to the SAR 'Disposition of the Risk Assessment Recommendations' which considers:
 - a. structural integrity of the shielding of the GP flask and retrievable waste flask following impact
 - b. crane failure while storage pit shielding is compromised
 - c. rescue plan for person falling inside a pit
 - d. safety measures for operators or maintenance staff while in the vicinity of an open pit.
- (ii) ANSTO must as part of the supporting safety assessment provide expanded written justification for initial screening of postulated events as not credible.
- (iii) ANSTO must explain the reasoning behind engineering judgement applied where analyses of frequency of events involving human factors and probability of failure have been estimated instead of referenced data sources.

4.4 Waste Management Strategy

ARPANSA acknowledges ANSTO's ongoing development of a Waste Management Strategy. Further clarity should be provided by ANSTO with regard to the different forms of ILW to be stored in the ILWCI Facility and timing, conditioning, and contingency plans for management of the different waste streams and waste forms until such time a disposal facility is able to receive such waste.

Licence condition: ANSTO must, as part of the supporting documentation for an application to construct the ILWCI Facility or earlier, provide:

- (i) An updated plan for the future management of the waste stored in the ILWCI Facility that considers:
 - a. timing of different steps of the future management of the waste in the ILWCI, separately for the waste streams that have contributed to the inventory of the ILWCI
 - b. contingency plans for the ILW managed in the ILWCI Facility.

4.5 Decommissioning

As discussed in section 3.2, current plans for decommissioning lack detail, but make a commitment to timely decommissioning. ANSTO must provide considerably updated information, albeit conceptual, on plans for decommissioning of the ILWCI and how this, in broad terms, fits with decommissioning of other facilities at the Lucas Height site, which is part of ANSTO's Waste Management Strategy currently in development.

Licence condition: ANSTO must, as part of the supporting documentation for an application to construct the ILWCI Facility or earlier, provide:

- (i) An updated decommissioning plan for the ILWCI Facility that considers:

- a. *indicative timing for different phases of the ILWCI decommissioning*
- b. *management of decommissioning waste; this could be part of ANSTO's site-wide Waste Management Strategy.*

5. Conclusions

The information submitted with the application, while in some cases lacking in depth and specifics, addresses the requirements under the legislation and broadly meets the intent behind the regulatory guidance issued by ARPANSA for this stage of the licensing process. The documentation has been reviewed by ARPANSA's regulatory officers and other subject matter experts at ARPANSA. The reviewers have concluded that the documentation provides reasonable assurance of the safety of the ILWCI Facility, commensurate with the requirements for preparing a site for the facility.

Submissions were received during the consultation period and a public forum was organised in a virtual format for information exchange. The issues raised were mainly unrelated to the safety of the ILWCI Facility *per se* but still relevant as they considered the *system* for management of radioactive waste by ANSTO and in Australia, in which the ILWCI Facility has an important role.

I have assessed all information before me, and I conclude that there is a case for establishing the facility and that, on the basis of the submitted documentation and operational experience from a similar facility at the Lucas Heights site, the facility can be sited as proposed and that there is reasonable prospect that the facility can be constructed, operated and decommissioned in a way that provides assurance of safety of the workers, the public and the environment.

Carl-Magnus Larsson
CEO of ARPANSA