Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

Ref: R25/30986

Statement of reasons of the CEO of ARPANSA – F-01098

I refer to the facility licence application for Siting of the Nuclear Medicine Manufacturing Facility (NMMF), which was received on 29 November 2024 from the Australian Nuclear Science and Technology Organisation (ANSTO) in a form approved by me as the Chief Executive Officer of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). The application was assessed in accordance with the ARPANSA Review and Assessment Manual.

Under section 32 of the *Australian Radiation Protection and Nuclear Safety Act 1998* (the Act), I have decided to issue Facility Siting licence F-01098. This licence decision is subject to the review provisions in section 40 of the Act. See Appealing decisions made by the CEO for further information. My reasons for issuing the licence are set out below.

Statement of reasons

I have decided to issue a facility licence authorising siting of the NMMF after reviewing the Regulatory Assessment Report (RAR) prepared by ARPANSA's regulatory staff, which assessed the application against all matters specified in the Act and the Australian Radiation Protection and Nuclear Safety Regulations (2018) (the Regulations) that I must consider in making a decision to issue a facility licence and having made my own enquiries where necessary. I agree with the findings and conclusion of the report that all of these matters have been complied with. For example:

1. The RAR lays out how matters required under section 53 of the Regulations have been met including that:
    - The information asked for by the CEO was provided by the applicant
    - The information provided in the licence application has established that the proposed conduct can be carried out without undue risk to the health and safety of people, and to the environment.
    - The applicant has shown that there is a net benefit from carrying out the conduct relating to the controlled facility.
    - The information provided in the licence application 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 (ALARA), having regard to economic and societal factors.
    - The applicant has considered interactions between technical, human and organisational factors in the management of safety.
    - The applicant has shown a capacity for complying with the Regulations and the licence conditions that are imposed under section 35 of the Act for the conduct specified in the licence application before me.
    - The application was signed by Mr Shaun Jenkinson, Chief Executive Officer (CEO) of ANSTO. In accordance with paragraph 45(b) of the Regulations. As the CEO of ANSTO, Mr Jenkinson is

authorised to submit the application. Persons covered by the licence are the licence holder, employees of the licence holder, Commonwealth contractors, employees of Commonwealth contractors, and Permitted Persons.

I concur with the findings of the RAR in relation to the mandatory considerations contained in the Regulations.

2. The RAR lays out how subsection 32(3) of the Act, which requires the consideration of international best practice (IBP) in relation to radiation protection and nuclear safety, has been met. In their assessment, regulatory staff have identified what are considered to be relevant IBP criteria regarding radiopharmaceutical processing facilities, and assessed the information provided in the licence application against those criteria, concluding that the proposed facility and lifecycle activities will be in line with these practices. I agree that relevant IBP has been identified and adequately addressed for siting.

3. The application contained information required by section 46 of the Regulations, including provision of a description of the purpose of the facility, a description of the facility and its site, a detailed site evaluation establishing the suitability of the site including for the characteristics of the site, the impact of external events, and review of environmental impact statement requirements provided in a Department of Climate Change, Energy, the Environment and Water decision dated 8 May 2024. Requirements under section 46 were also met for the required plans and arrangements for managing safety, a preliminary safety analysis report with details of the proposed facility conceptual design. A bounding reference accident consequence assessment was provided as required for siting assessment and for use with emergency planning and response arrangements in future operation.

   Regulatory staff have documented their assessment of this information against relevant regulatory guidance, and I concur with their findings that the site evaluations and impacts, plans and arrangements, safety analysis report, and reference accident consequence assessment are satisfactory for this siting stage of the facility life cycle. I also concur with the assessment that the submitted information provides adequate assurance that proposed activities under future licence stages occurring at the facility can be undertaken safely over the whole life cycle of the facility without undue risk to people or the environment from the harmful effects of radiation.

4. The RAR lays out how the submission provides an adequate level of detail to assure the sustained requisite level of protective security for the application to prepare a site.

As required under section 53 of the Regulations, the CEO invited public comment in relation to the siting licence application for this nuclear installation. Consultation ran from 16 April 2025 to 28 May 2025 and included a community information session held on 30 April 2025. I have taken into account the community feedback received during the information session, noting that no formal public submissions were received. There were no public submissions, questions or comments received that would justify me refusing a licence for the siting of the facility.

In making a decision I also considered the views and advice of the Nuclear Safety Committee (NSC) following briefings and discussions during NSC meetings in 2025 where the siting of NMMF was discussed. No significant issues were raised by the NSC in its advice to the CEO. The minutes of past NSC meetings are available on the ARPANSA website.

Licence conditions

In issuing the licence, I have decided to impose the standard licence conditions that apply to this kind of facility, and to impose special licence conditions for siting.

Dr Gillian Hirth AO

CEO of the Australian Radiation Protection and Nuclear Safety Agency

19 December 2025