Australian Government
Australian Radiation Protection and Nuclear Safety Agency

arpansa

Attachment: Statement of Reasons

The issue

On 12 April 2018, I issued Facility Licence F0309. The licence authorised ANSTO to commence hot commissioning of the ANM Facility using irradiated uranium target plates. However, routine operations for the stated purpose, i.e. to produce nuclear medicine for the domestic and international markets, was not authorised. A number of licence conditions (LC), collectively captured under LC8, were issued that must be actioned to ARPANSA's satisfaction before routine operations can commence.

Production of Mo-99 is currently being undertaken in Building 54, under Facility Licence F0262. ANSTO's intention is to cease production in Building 54 once the ANM Facility is fully operational.

ARPANSA has received documentation addressing LC8 over a period of several months, and on 12 March 2019, ANSTO applied under section 63 of the Australian Radiation Protection and Nuclear Safety Regulations 2018 (the Regulations) for LC8 to be removed. The application and supporting documentation is currently under regulatory review and assessment.

During March 2019, ANSTO informed ARPANSA of problems encountered with the two hydrogen convertors in Building 54. During a period of just over one month, functionality of three heaters, which are essential to the performance of the convertors, was irrecoverably lost. Only one of the converters is currently functional. No replacement parts are readily available or can be fitted within reasonable time. Production of Mo-99 has been reduced to a maximum of three batches per week and failure of one more heater in the remaining functional converter would cause production to cease altogether

On 20 March 2019, ANSTO applied for authorisation to carry out 30 production runs over a period of six weeks at the ANM Facility, as a contingency. In the application under section 63 of the Regulations, ANSTO:

> *"… seeks approval to commence production of Mo-99 for a maximum of thirty manufacturing batches for six weeks using the model ANM Operational Transition Plan P-50603 supplied during the licence conditions submission"*

ANSTO also states that approval would allow for fine-tuning of the operational procedures, and optimisation of radiation protection for operational staff.

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

Reaching the decision

ANSTO submitted the application to carry out a limited number of production runs in the format required by ARPANSA, supported by a letter from the CEO of ANSTO. Supplementary information has been requested and received. The application refers to evidence or documentation received by ARPANSA in support of the previously mentioned application to remove LC8. This information is under regulatory review and has preliminarily been deemed sufficient for reaching a regulatory decision on whether or not to remove LC8 by the end of April or early May 2019.

ARPANSA performed a site visit to examine the status of the hydrogen convertors in Building 54 on 25 March 2019.

ARPANSA's regulatory officers have reviewed the available information and have recommended approval of the application to carry out up to 30 runs, with conditions. Their review and recommendations, submitted documentation, the status of ARPANSA's review of the application to remove LC8, and certain matters specified in section 53 of the Regulations have been taken into account in reaching the decision.

Undue risk and optimisation

ARPANSA reviewed the plans and arrangements for managing safety ahead of authorising ANSTO to commence hot commissioning. ARPANSA has since received an updated radiation protection plan detailing improved optimisation arrangements, and has also reviewed occupational exposure data from the hot commissioning tests. In addition, ARPANSA has observed an emergency response exercise involving the ANM Facility. At ARPANSA's request, ANSTO has commenced revision of its risk assessment methodology with increased emphasis on managing scenarios characterised by having moderate or more severe consequences. The quality control procedure for high activity Mo-99 solutions has been re-engineered in a manner that has satisfied ARPANSA's regulatory officers that contamination events are less likely. Human factors have also been addressed.

ARPANSA's regulatory officers observed a number of the hot commissioning test runs, and have reviewed the results of these runs and supporting documentation provided by ANSTO. A number of actions have been taken by ANSTO to rectify issues that were encountered during the hot commissioning; however, no issue with significant safety implications was identified.

The staff transitioning plan (ANM Staff Transition Plan P-50603) that was submitted with the application to remove LC8 covered the period February to June 2019 and is now out of date. Information on staffing arrangements must be provided to ARPANSA prior to commencing production and subsequently on a weekly basis (see amended LC9).

ANSTO has committed to:

> *"… on a fortnightly basis, provide ARPANSA with a report highlighting any deviations to the process, manufacturing results, Health Physics measurements undertaken, noble gas emissions tracking, areas for improvement observed and event reporting."*

The amended LC9 formalises this commitment.

Net benefit

The current production capacity, although reduced, in Building 54 satisfies the Australian demand for Mo-99, as well as part of the international demand. As noted earlier, if the remaining hydrogen converter fails, production will cease altogether. With the NTP Facility in South Africa not operating since the end of February 2019 and not likely to resume operations in the near future, there are no backup arrangements for supply to the Australian market that can be activated expediently. This would at least in the short term lead to disruptions in the supply of Mo-99/Tc-99m to Australian customers. In the longer term it is likely that other suppliers to the global market could compensate for the discontinued production at ANSTO.

Considering the low risks associated with a limited number of production runs in the ANM Facility, it is reasonable to conclude that there is net benefit from carrying out a limited number of production runs at the ANM Facility, to mitigate the risk for disruptions in supply of Mo-99/Tc-99m to Australian customers.

ANSTO states as new benefit:

> *"Granting approval will give ANM and ANSTO the ability to gather further data which will lead to optimising operations for the future once ANM is granted a Facility Licence to commence routine operations. The approval will help ANM in optimising the linkage between ANM-B2 and ANM-B23 ANSTO Health for Product Quality Control and generator manufacturing for domestic supply at the anticipated ANM production levels; and, help Improve functionality, dose optimisation and operability of the new QC laboratory at B2 will be achieved, reducing operational requirements for QC in B23."*

While this is true and commendable, and should be encouraged, it does not in itself provide sufficient justification for authorisation of production runs. The actions described could have been undertaken at a time when LC8 had been removed.

Capacity to comply

ANSTO's application refers to safe operations of licensed activities at the Lucas Heights Science and Technology Centre as evidence for capacity to comply. There should in my opinion be little doubt that ANSTO has capacity to comply with the Act, the Regulations and licence conditions imposed by the CEO of ARPANSA. Recent events have, however, called into question whether this capacity has always been utilised to the best effect in relation to production of nuclear medicine[1].

Following a direction to initiate an independent review of safety practices at ANSTO Health, in particular in Building 23, and in response to the recommendations of that independent review, ANSTO submitted an action plan to ARPANSA in December 2018. I have encouraged ANSTO to implement the actions identified in the first iteration of the plan. An updated plan was received on 20 March 2019 and is currently undergoing regulatory review and assessment.

I find it reasonable that ANSTO should consider the relevance of the findings of the independent review, and of the action plan, for nuclear medicine production in general, including in the ANM Facility. At minimum, I would have expected a stated intention to consider and, as appropriate, implement learnings from the independent review report. The production imperative must never even be possible to perceive to be overtaking the safety imperative, consistent with ANSTO's own plans and arrangements for safety.

[1] Information on safety events and safety review is available at ARPANSA's website, https://www.arpansa.gov.au/news/arpansa-receives-report-independent-review-team-ansto-approach-safety

Conclusion and amended licence condition

ANSTO has requested early commencement of routine operations, albeit limited to 30 production runs over a six-week period. ANSTO is also planning to further refine its processes and optimise protection. While the latter is valuable, it should be clear that the application primarily seeks to sustain Mo-99/Tc-99m supply to ANSTO's customers, which is akin to routine operations for the stated purpose and should not be confused with 'extended hot commissioning'.

Under the circumstances, I find it reasonable to approve the application. I do so only after careful examination of the current status of ARPANSA's review of the application to remove LC8. While not completed, it gives me enough confidence that a limited number of runs can be carried out safely, just as I concluded that the plans for hot commissioning could be implemented safely in my decision of 12 April 2018. In all, 27 runs were performed for hot commissioning and product testing.

I do not see any particular reason to limit the production *time* to six weeks. The combined production capacity (Building 54 plus ANM) will be capped as per LC9.

Licence condition 9, issued on 2 April 2018, reads as follows:

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

The amended licence, issued on 2 April 2019, provides for no more than 30 production runs and specifies the associated conditions. Licence condition 9 now reads:

> ***LC9**. Total Mo-99 production must be capped, and reported on, as follows:*
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> ***(a)** during initial routine operations of the ANM Facility with simultaneous Mo-99 production in Building 54: the total production of Mo-99 must be capped at 2 400 six-day curie per week as a four-week average, and not increased beyond that level until production in Building 54 has ceased and operational experience of the ANM Facility provides evidence of safe operations*
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> ***(b)** notwithstanding the restriction on routine operations imposed by licence condition8; the licence holder may carry out a total of no more than thirty production runs to compensate for planned outages or unplanned disruptions in the production of Mo-99 in Building 54, before removal of licence condition8. The cap on total production remains as in 9(a)*
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> ***(c)** the licence holder must give ARPANSA prior notice of their intention to carry out production as specified in 9 (b) including information on weekly staffing arrangements for safe operations of the ANM Facility and, as relevant, Building 54*
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> ***(d)** the licence holder must for production specified under 9 (b) on a fortnightly basis, and within a week after the end of the preceding two-week period, provide ARPANSA with a report on operational experience in the ANM Facility highlighting any deviations to the process, manufacturing results, Health Physics measurements undertaken, noble gas emissions tracking, areas for improvement observed and event reporting*

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

I encourage ANSTO to inform its customers of the current status of Mo-99 production at ANSTO's facilities and to plan for contingency measures to maintain supply to the market as necessary.