



Senator Jane Hume
Chair
Senate Economics Legislation Committee
Parliament House
CANBERRA ACT 2600

Dear Senator Hume

On reviewing the Proof Hansard of the testimony I gave on behalf of the Australian Nuclear Science and Technology Organisation (ANSTO) at the Senate Estimates hearing on 25 October 2018, we have found that some of the information provided to the Committee would benefit from clarification.

The following exchange occurred between you and I:

CHAIR: The findings of the safety report pointed to the age of the facility that you're in. I'm wondering how long ANSTO has been aware that the facility was going to need upgrading? Obviously, you've been in there for a very long time; I'm sure this isn't the first time this has dawned upon you.

Dr Paterson: There has been an emphasis on the age of the facility, and I would emphasise that it was one of the first facilities built on the site. But the original purpose in the late fifties, when it was built, was not the purpose it serves today. As we have gone through various generations of activities in the **Atomic Energy Commission** through into the transition to ANSTO and now with the development of a much keener interest in nuclear medicine globally, that facility has been through a number of changes of function and upgrades. It is not, however, purpose built as a nuclear medicine production facility. And from a production point of view, it lacks features that you would build into a facility if it were started today, such as redundancy and equipment, if you don't want breakdowns to interrupt supply.

The full name of the organisation was the Australian Atomic Energy Commission, or AAEC.

The following exchange occurred between Senator Kim Carr and I:

Senator KIM CARR: When will we see production start?

Dr Paterson: **The production will start within the next two weeks.** The original dates have slipped considerably, as you are aware. In order to mitigate the risk of those dates slipping, ANSTO worked to expand the capacity of building 54, which is the current facility, which is coming to the end of its life as well. That's why the investment in the A&M facility was so important and remains very important. The building 54 facility at the time we started the construction of the A&M facility was producing between three and five per cent of global supply, and it now supplies around 16 per cent of global supply as a result of us taking some of the technologies that were developed for the A&M building and retrofitting them into building 54. That's been a considerable benefit to our international reputation because we have been able to cover a number of international supply shortages over the last two years. In fact, there's an ongoing shortage due to a long outage of the South African production facility. So we have mitigated the delays in the construction to a very considerable degree. But it is true to say that the method that we used to construct this did not allow us to control the time scale to the extent that we should have. We have changed how we do this sort of procurement for the future. These types of time delays are not to do with the quality of the facility or its integrity in any way; the time delays will be mitigated in the future projects.

The ANM facility recently completed hot commissioning as part of the staged approach to commissioning the facility to demonstrate that it meets the safety criteria set by the safety regulator, the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Separately, the sale of the nuclear medicines produced in the facility requires approvals from the Therapeutic Goods Administration (TGA) and overseas counterpart regulators. In line with my above statement, the first production run for those purposes was undertaken on 14 November 2018. Product has been supplied to domestic and international customers, who are responsible for obtaining the necessary approvals from the relevant medical regulator. The results from Australian validation runs are then supplied to the TGA to inform their decision on the registration of the product. At this stage, ANSTO is anticipating the commencement of commercial production in early 2019.

I apologise for any inconvenience caused, and ask that you alert other members of the Committee to the above clarifications.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Adi Paterson', with a stylized flourish extending to the right.

Dr Adi Paterson
Chief Executive Officer

26 November 2018