



The New Gamma Sterilisation and Decontamination Plant, Queensland

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SUMMARY: Steritech Pty Ltd operates the only three industrial gamma sterilisation and decontamination plants in Australia. A plant in Dandenong Victoria has operated since 1971 and a second in Wetherill Park from 1985. In August 2003, a third facility started commercial operation in Narangba, 40km north of Brisbane. Each plant represents a generational change in operating features, although the basic design of the irradiation room, storage pool and shielding remains substantially the same.

This paper discusses some of the key design features of the Queensland plant, the complex approval and licensing process and some of the complications caused by perceived terrorist threats.

1. Introduction

Australia has a long history in radiation processing, the world's first commercial sterilisation plant started in 1959 in Dandenong, a south-western suburb of Melbourne. It was used solely for sterilising goat fibres for carpet manufacture.

Tasman Vaccine Laboratories opened a plant, also in Dandenong for the irradiation of Medical products such as rubber gloves. After having several owners, Steritech Pty Ltd was formed as a privately owned Australian company to take over the facility as a contract sterilising service in 1991.

The Dandenong plant has operated successfully since 1971 and the facility in NSW since 1985.

By 1999 it was apparent to the company that there was a commercial need for a third plant in Queensland. After advice from the Queensland Department of State Development, a green-field site, part of an existing 'Industrial Estate' was settled upon.

The proposal was to build a 'State of the Art' facility with a ⁶⁰Co capacity of 5×10^6 Ci (185PBq).

The design chosen was an MDS Nordion Two-Pass Parallel Row Pallet Irradiator.

The two irradiators that were already operated by Steritech Pty Ltd are both MDS Nordion (or its predecessor) designed plants.

In mid 1999 the Application/Licensing/Approval process was started.

The facility finally started commercial operation in August 2003 with an initial loading of 3×10^5 Ci (11PBq).

2. The Narangba Design (MDS Nordion IR217)

The basic design of any gamma irradiation plant is: An office block; a warehouse; plant room(s); an irradiation cell and a storage system to shield the

radiation source when it is not in use; a maze (or mazes), used for personnel/product access and designed to eliminate any direct beams of radiation emerging from the irradiation chamber.

Important features of the Narangba plant include:

- A product conveyor system that automatically indexes the pallets around the ⁶⁰Co source.
- A single spacious product/personnel access maze.
- Photoelectric detectors at the personnel entrance, the product entrance and the product exit points.
- A programmable logic controller including a data logger for ease of troubleshooting by plant operators.
- A comprehensive function monitoring system that provides immediate information, at the control console, on the operational state of the irradiator.
- A video screen that displays, as red warning, any one of the 32 faults.
- A total of 21 safety interlocks and devices installed for the protection of personnel.

3. The Australian Licensing Regime

The major Australian agencies with radiation safety responsibilities are:

Commonwealth Government

1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) whose documents include:
Radiation Protection Series Number 1:
(Radiation Exposure Limits)
Radiation Protection Series Number 2:
(Transport Code)

Code of practice for the design and safe operation of non-medical irradiation facilities (1988).

2. The Department of Environment & Heritage [DoEH]; responsible for administering the: *Commonwealth Environment Protection and Biodiversity Act (1999).*

This EPBC Act provides for control over various radioactive materials and defines what Steritech proposed as a 'Nuclear Action'.

Queensland Government

In Queensland, the responsible regulatory agency is the Department of Health through its sub-branch Queensland Radiation Health.

At various times both the Queensland Environmental Protection Agency and Queensland Emergency Services also took a keen interest in the proposal.

4. The Approval/Licensing/Certification Process

In early 2000, after considerable debate, Caboolture Shire Council gave planning approval for the construction of the necessary buildings and associated site works on an existing Industrial Estate. The building approval carried several conditions, not the least of which was that the facility must comply with the relevant Queensland Radiation Safety Legislation.

Almost before the ink was dry on the approval document several local protest meetings were held.

The protestors made application to the Queensland Planning and Environment Court to have the Shire Council decision overturned. The principal grounds were that:

- The proposal represented an unwanted and unnecessary risk to the local populace [The nearest house is 750m away and a primary school is about a 2km distance].
- The transport of ⁶⁰Co is an especially hazardous activity and the value of property along the transport route would plummet.
- Caboolture Shire is a 'Nuclear Free Zone' and, therefore, the operation of the Steritech Gamma Sterilisation plant would be contrary to Council Policy, if not illegal.
- The proposal is part of a long-term plan to start a 'nuclear industry' in Queensland.
- The plant was being built to irradiate massive amounts of food products that would be harmful to consumers.

The court hearing took 6 1/2 days during which every possible relevant and irrelevant issue was canvassed from the biological effects of exposure to ionising radiation, through lack of insurance cover for radioactive contamination, to the use of depleted

uranium in Kosovo. The protestors had no qualified legal representation and were represented by a 'bush lawyer'. During the hearings the Judge exercised considerable leniency but was finally condemnatory of the actions of the opponents to the proposal and in his judgment he upheld the Caboolture Shire approval.

Department of Environment and Heritage:

To satisfy the requirements of the EPBC Act, Steritech had to make a detailed submission to the Department specifying all the actions it proposed to take to build and operate the plant. This was then posted on the Company's website and public comment invited. Copies were also placed, for public scrutiny, in the Queensland State Library, the Caboolture Shire Council and the local Library.

Of 156 submissions received, 155 objected to the proposal, with one in favour.

The Department of Environment and Heritage gave its approval on September 26 2001, subject to five conditions. The most important of these was that Steritech comply with the legislative requirements of Queensland Health.

5. Queensland Legislation:

Queensland has an extremely comprehensive Radiation Safety Act and associated Radiation Safety Standards. Four of these had varying degrees of relevance covering almost 50 individual Compliance tests.

These documents, in turn, are the foundation of a complex licensing regime.

Before being able to operate commercially, Steritech had to:

1. Obtain a *Licence to Possess Radioactive Sources* (an exceedingly tedious process discussed later), then;
2. Obtain an *Approval to Acquire Radioactive Sources* (which has to be referred to ARPANSA for import purposes), then;
3. Obtain *Licences to Use Radioactive Sources* (for both Steritech employees and MDS Nordion engineers carrying out the installation), then;
4. Obtain *Radiation Safety Officer's Certificate* for the RSO, then;
5. Obtain a *Certificate of Compliance* that confirms that the plant satisfies all the compliance tests specified in the relevant Radiation Safety Standards, then;
6. Submit the Certificate of Compliance with the Licence to Possess to the Chief Executive, Queensland Health to finally receive approval to commercial operations.

The key document is the **Licence to Possess Radioactive Substances**.

To obtain this, Steritech was required to submit a Radiation Safety and Protection Plan for the facility. This document, which runs to 75 pages, had to adhere to a very precise format. The document went through something like 15 to 20 alterations, before it satisfied the very specific content and language requirements of the Queensland regulator. It is now the *de facto* 'Condition of Licence'.

Some of the decisions made by Queensland Radiation Health can at best be described as unusual.

For Example:

Although Steritech successfully operates two other plants in Australia, because they are outside Queensland's jurisdiction any reference to them was considered to be irrelevant. An early draft of the application quoted personal radiation exposures from the existing plants, as an indicator of the company's excellent radiation safety practice. The SPL was advised that the numbers were '*little more than distracting*'.

The Queensland radiation exposure limit for members of the public is set at 10uSv per week or 50% of the recommended Annual Limit recommended by ICRP (as included in the Queensland Radiation Safety Regulations). It was deemed by Queensland Radiation Health that this limit would apply to any accessible point outside the building, not at any site boundary fence, and it would be based on 168 hours per week exposure.

Without providing any details of their calculations, QRH notified Steritech that an additional 280mm of concrete shielding would be required on the north wall and 270mm on the west wall to '*ensure that the requirements for radiation doses set out in RSS PR009 will be met if the completed facility is loaded with the maximum inventory of ⁶⁰Co*'.

As one internationally experienced engineer observed '40 countries are out of step with Queensland'.

Steritech finally received approval to start commercial operations in August 2003, over 4 years after the initial approach was made to Caboolture Shire Council.

5. Terrorist Threats

In March 2002, Dr Henry Kelly, President of the Federation of American Scientists, presented a paper to the US Senate Committee on Foreign Relations. In it he discussed the threat posed by *radiological attacks* in which quantities of radioactive materials are exploded in city centres, thus releasing '*nuclear materials without using a nuclear explosive device*'.

In his paper, which has been much quoted, and often misunderstood, Kelly discussed the potential impact of '*a single piece of cobalt from a food irradiation plant being dispersed by an explosion at the lower tip of Manhattan*'. He admitted that

'acquisition of such material is less likely than' getting hold of a medical caesium source or an oil well americium survey source.

On these and other grounds the determined and disruptive protest group, camped opposite the construction site and vowed that the cobalt would never be allowed to enter Steritech's facility.

The Queensland Emergency Services who controlled the transport of the cobalt within Queensland treated this threat very seriously. Information on the actual transport was very tightly controlled and over 60 police from various sections participated. In the event the movement took place without any difficulty, the cobalt arrived on site at about 3am and was installed in the source racks by midday.

6. Discussion:

At various times during the licensing process, Steritech was faced with:

- A Commonwealth Department that did not appear to distinguish clearly between radioactive decay and nuclear fission.
- A State Department that believed that a transport vehicle carrying ⁶⁰Co would adversely affect the value of the properties the vehicle passed.
- Another State Department that appeared to be as much concerned with process as outcome (a Radiation Safety and Protection Plan of 75 pages is not a particularly useful document for a busy Plant Operator, no matter how beautifully phrased).
- The same State Department that imposed dose constraints at odds with their own legislated radiation exposure limits and interpreted those constraints in an interesting but costly manner.
- A local newspaper that delighted in printing any shock/horror story linking the plant with Chernobyl, nuclear weapons, terrorist threats etc, etc, but was reluctant to print any considered responses.
- A small but extremely vocal group of local residents, assisted by hard core violent protestors, prepared to attend meetings to shut down the proposal but not prepared to allow informed debate and discussion.

7. The Linear-No Threshold Theory

It is sometimes easy to overlook the fact that the great edifice of radiation safety regulation is based very largely on the Linear-No Threshold Theory of radiation risk.

Since first advanced in the 1950's, the L-NT has become the touchstone for radiation protection

practice yet there is no evidence that the theory is valid at doses less than 50mSv. Epidemiological studies of populations living in areas of naturally high background radiation have not detected adverse genetic or carcinogenic effects.

However, if the LN-T is valid down to the maximum allowable radiation dose imposed by the Queensland Radiation Safety Standards and the ICRP risk factor of $5 \times 10^{-5} \text{mSv}^{-1}$ is correct then the individual risk to a member of the public from exposure to radiation based on continuous exposure would be: $0.5 \times 5 \times 10^{-5}$, i.e. 1 in 40,000 per year

This in a country where a real risk, the road toll is approximately 1 in 10,000 per year

8. Conclusion

This paper has outlined the difficult and at times tedious process that Steritech has had to go through to begin operating a gamma sterilisation and decontamination plant in a new State in Australia.

This process has not been without cost in time, effort and money. It has been estimated that establishing the plant in Queensland has cost about \$250,000 more than a similar plant would have cost in another jurisdiction.]

There is an urgent need for national uniformity in, not only legislation, but also interpretation and implementation. Although a committee working under the ARPANSA banner is developing a uniform legislative approach, progress is slow.

Users of ionising radiations such as those gathered at this ANA Conference have a role to play both in promoting more widely the beneficial uses of ionising radiation and ensuring that such uses are not restricted by excessive regulation.

Failure to do so will inevitably lead to more and more restrictions being placed on such inherently safe activities as radiation processing.