REGULATION REVIEW COMMITTEE

Parliament of New South Wales

REPORT DRAWING THE SPECIAL ATTENTION OF PARLIAMENT TO THE RADIATION CONTROL REGULATION 1993 PUBLISHED IN THE GOVERNMENT GAZETTE OF 27TH AUGUST 1993 AT PAGE 5006 AND RECOMMENDING THAT CLAUSE 9 AND CLAUSE 15 BE DISALLOWED

REPORT No. 22 November 1993

REGULATION REVIEW COMMITTEE

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The Regulation Review Committee was established under the <u>Regulation</u> Review Act 1987. A principal function of it is to consider all regulations while they are subject to disallowance by Parliament.

In examining a regulation the Committee is required to consider whether the special attention of Parliament should be drawn to it on any ground, including any of the following:-

- (a) that the regulation trespasses unduly on personal rights and liberties;
- (b) that the regulation may have an adverse impact on the business community;
- (c) that the regulation may not have been within the general objects of the legislation under which it was made;
- (d) that the regulation may not accord with the spirit of the legislation under which it was made, even though it may have been legally made;
- (e) that the objective of the regulation could have been achieved by alternative and more effective means;
- (f) that the regulation duplicates, overlaps or conflicts with any other regulation or Act;
- (g) that the form or intention of the regulation calls for elucidation; or
- (h) that any of the requirements of sections 4, 5 and 6 of the Subordinate Legislation Act 1989, or of the Guidelines and requirements in Schedules 1 and 2 to that Act, appear not to have been complied with, to the extent that they were applicable in relation to the regulation.

The Committee may, as a consequence of its examination of a regulation, make such reports and recommendations to each House of Parliament as it thinks desirable including reports setting out its opinion that a regulation or portion of a regulation ought to be disallowed and the grounds on which it has formed that opinion.

RADIATION CONTROL REGULATION 1993

Objects of Regulation

This Regulation replaced the Radioactive Substances Regulations 1959 which was repealed by the Radiation Control Act 1990. The matters with which the Regulation deals include the following:

- (a) the licensing of persons to use certain radioactive substances and radiation apparatus;
- (b) prescribing activities which may only be carried out by an accredited radiation expert;
- (c) regulating the use of radiation apparatus and radioactive substances in the workplace and requiring employers to supply certain information to persons who are likely to be exposed to radiation in the course of their employment;
- (d) requiring the radiation doses received by persons in the course of their employment to be monitored;
- (e) regulating the disposal and transport of radiation apparatus and radioactive substances and the discharge of radioactive substances;
- (f) requiring employers to take certain action in the event of a radiation accident;
- (g) enabling the Director-General to direct an employer to appoint a radiation safety officer or radiation safety committee or both for a workplace;
- (h) exemptions from certain provisions of the Act and the Regulation.

Clause 9 - Supervision of certain licensees

This clause reads:

- "9. (1) When granting a licence under section 6 of the Act to a person who is a nuclear medicine technologist, the Authority must impose a condition on the licence to the effect that the person must not carry out:
- (a) any nuclear medicine diagnostic procedures using scintigraphy; or
- (b) any nuclear medicine therapeutic procedures using unsealed radioactive sources,

otherwise than under close supervision.

(2) In this clause:

"Close supervision" means supervision by a qualified person who is in close proximity and is capable, if required, of observing the person being supervised and directing the person in the carrying out of the procedures referred to in subclause (1);"

Several public submissions have expressed concern that the regulation requires close supervision by a qualified person of any nuclear medicine technologist who is carrying out the following procedures:

- (a) any nuclear medicine diagnostic procedures using scintigraphy; or
- (b) any nuclear medicine therapeutic procedures using unsealed radioactive sources, otherwise than under close supervision.

Under the regulation close supervision means supervision by a qualified person who is in close proximity and is capable, if required, of observing the person being supervised and directing the person in the carrying out of these procedures. The qualified person must be a person who holds a relevant licence which allows him to provide close supervision or who is a medical registrar at a hospital that provides training in nuclear medicine.

Some of the public submissions maintain that this would result in a huge extra cost burden and in fact there may not be enough "qualified persons" available to provide supervision in close proximity.

The Health and Research Employees' Association of NSW produced to the Committee a submission from the Nuclear Medical Technologists, which states that in many teaching hospitals the ratio of nuclear medicine physicians to technologists is about 1:7, and with more than one site for performing scans, a severe limitation would be placed on the resources. Moreover technologists working in country centres and in small metropolitan hospitals would become highly restricted in their practice as the number of nuclear medicine physicians to provide the prescribed level of supervision is not enough in those places. The submission concluded:

"Nuclear Medicine Technologists are highly trained applied science graduates. The course teaches them cognitive, affective, and psychomotor skills.

Some technologists such as those described above are working successfully in situations where there is no supervision by medical physicians.

Recent advances in communications technology such as modem-computer links will mean that more practices will rely on a Nuclear Medicine Technologist to acquire the scan and transmit the information to the Nuclear Medicine physician at another location.

There is an inadequate number of physicians to provide "close supervision". If technologists were to work-to-rule the Department productivity would be severely compromised as not all staff or equipment could be functioning at the same time.

Our peers in NSW the Radiation Therapists and Diagnostic Radiographers are not required to be supervised by medical physicians.

Nuclear Medicine Technologists in other states of Australia are not required to be supervised by medical physicians."

The regulatory impact statement that accompanied this regulation did not assess the costs and benefits of the proposed regulatory controls now set out in Clause 9. As a result the Committee on 28th October 1993 wrote to the Minister asking for his advice on this issue. On 11th November 1993 the Committee received a reply from the Minister which indicated that the level of supervision had been an issue of much concern and debate. He advised the Committee that submissions had been received by the Radiation Advisory Council and that a number of alternative options had been evaluated on the basis of advice received by that Council. He said that the regulation would be carefully evaluated to determine if it provided an effective balance between the need to ensure safe practices and the availability of supervisory staff. He concluded by saying that the Environmental Protection Authority would seek to amend the provisions at a later date if they proved unsuitable.

However the evaluation that the Minister is now going to undertake on the impact of the regulation should have been carried out in advance of it so as to conform to the requirements of the Subordinate Legislation Act and to ensure that it is in the best interests of the community. The Minister's response appears to the Committee to be completely unsatisfactory as he has neither demonstrated the inadequacy of the previous controls nor justified the need for the new provisions in Clause 9. It may well be therefore that the public concern expressed in regard to Clause 9 may turn out to be fully justified. It is the Committee's opinion that Clause 9 should be disallowed.

In the event that the Minister would be willing to give an undertaking to the Parliament to amend Clause 9 to reinstate the previous supervisory provision and then to carry out a satisfactory regulatory impact assessment of a close supervision requirement, then the Committee is of the view that the motion for disallowance could be withdrawn.

Clause 15 - personal monitoring devices

Clause 15 reads:

15. (1) An employer must ensure that all occupationally exposed persons in his or her employ who are involved in the use of ionising radiation for any one or more

of the following purposes are issued with approved personal monitoring devices for detecting and measuring cumulative exposure to ionising radiation:

- (a) radiotherapy;
- (b) industrial radiography;
- (c) nuclear medicine;
- (d) scientific research in laboratories classified as medium or high level laboratories (within the meaning of Part 4 of Australian Standard 2243.4-1986, Safety in Laboratories, published by the Standards Association of Australia) where unsealed radioactive sources are used.

Maximum penalty: 15 penalty units.

(2) An occupationally exposed person to whom an approved monitoring device has been issued in accordance with this clause must wear the device while involved in the use of ionising radiation in the course of the person's employment.

Maximum penalty: 15 penalty units."

Approximately 29 submissions were received in regard to this clause expressing concern that it operated to exclude from protection certain categories of workers who were formerly covered by the requirement of personal monitoring devices. In a submission dated 14 September 1993 the State Secretary of Health and Research Employees' Association stated:

"Our first concern with the Regulation is the deletion of requirement of personal monitoring devices for Diagnostic Radiographers, Nurses, Radiologists, Cardiologists, and other support staff in Diagnostic Radiology. There is a grave concern that, as a back up, there are no inspection checks for faulty X-Ray equipment in the Regulation. The wearing of personal monitoring devices (PMD) has been a Legislative requirement since 1959.

The withdrawal of PMD's will mainly effect Radiologists, Nursing Staff and Radiographers. The decision ignores the realities of modern radiological practice.

- * PMD's are used to identify trends in doses received by staff. This allows corrective action to be taken even if the dose received falls short of the maximum permissible dose for occupationally exposed personnel (20mSv). Corrective action involves:
 - (a) identifying poor work practices by staff
 - (b) identifying equipment emitting excessive radiation (affecting patients as well as staff)

The Regulations set a dose limit of 2mSv for pregnant employees. This limit is often exceeded and without PMD's the employee and the employer have no way of recognising this danger. "

A separate submission from that Association also stated:

"Hospital Radiology Departments have begun carrying out interventional procedures such as embolizing tumours in the brain. These cases can take up to 7 hours and result in patients receiving doses of radiation comparable to Radiotherapy doses. They are an alternative to surgery and an important medical breakthrough, however staff involved, nurses, doctors and radiographers must stay in the room with the patient and they will not be able to determine what level of radiation they have received.

("Diagnostic Imaging" August 1993 Page 68 "Radiation exposure risk haunt X.") Appendix 2.

- . Radiographers wishing to work overseas in countries such as United Kingdom are required to furnish their previous records of doses received. This will no longer be possible. All other states of Australia issue PMD's to Radiology Departments.
- . In future employees who contact diseases that could be related to exposure to radiation (such as leukemia) will not be able to review their accumulated dose readings to see if their condition could be work-related.

In summary the PMD's are recognised as a cost effective tool for Radiology Departments in keeping radiation doses to staff at the lowest possible level. A badge costs \$9 to read and is usually read 4 times a year for a cost of \$36 per year per employee."

The Committee in its letter to the Minister dated 28th October 1993 advised him that the RIS had inadequately considered this aspect and sought his advice on it. In his reply the Minister stated that the choice of categories was based on statistical evidence collected over many years of the risk levels of various types of occupationally exposed persons. The Committee considers that this evidence should have been fully presented in the regulatory impact statement.

The regulatory impact statement that accompanied the regulation estimated the cost of using the personal monitoring devices (PMD) by the prescribed four categories of workers and of the record keeping activities at approximately \$80,000 a year. This is less than 10% of the cost of \$879,000 for implementing the licensing and the registration requirements. The cost of a PMD is reported by the Environment Protection Authority to be approximately \$20 with \$10 for each reading. The readings are required to be taken monthly for the prescribed categories of workers. Personal monitoring devices have a strong bearing on the safety and health of the persons occupationally exposed to radiation and

appear to be useful means of protecting the workers from excessive exposure to harmful radiations.

The Committee is of the opinion that Clause 15 should be disallowed.

In the event that the Minister would be willing to give an undertaking to the Parliament to amend Clause 15 to include the additional categories of diagnostic radiographers, nurses, radiologists, cardiologists and support staff in diagnostic radiology as recommended by the Health and Research Employees' Association, then the Committee is of the view that the motion for disallowance could be withdrawn.

Chairman, Regulation Review Committee