



NRL
National Radiation Laboratory

A Review of the New Zealand Radiation Protection Legislation

Summary of Submissions

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Executive summary

The discussion paper “Review of the New Zealand Radiation Protection Legislation” was released by the Ministry of Health for public comment on 5 December 2002. The closing date for submissions was 15 March 2003. A total of 69 submissions were received.

The majority of submissions expressed confidence in the consensus scientific understanding of the health risks from radiation. Those that disagreed were mainly concerned with the effects of electromagnetic radiation from transmission towers and cell phones. Some felt that the potential risk from technologically enhanced naturally occurring radioactive material and from cosmetic use of sun-beds needed to be acknowledged.

Submissions on the various occupational groups using radiation in New Zealand focussed largely on the difficulties in defining “user” in the context of medical use, and the potential interfacing or overlapping between the Health Practitioners Competency Assurance Bill and any new radiation protection legislation.

There was general agreement that ionising radiation should be regulated but a widely divergent range of opinions on whether non-ionising radiation should be.

While there were some suggestions that other legislation could be brought into play to cover for the deficiencies in the Radiation Protection Act, there were no suggestions that it was not seriously deficient. There was generally a preference for following the examples and standards given by international and, where appropriate, Australian models.

There were many comments stressing the need in any new system for the degree of regulatory control to be commensurate with the degree of risk being regulated. Many submissions were in favour of the inclusion of some elements of risk management or performance-based regulation so that compliance costs could be optimised at the discretion of the user.

The suggestion that New Zealand should have a single integrated specialist radiation protection agency was strongly supported. There was also support for the agency being associated with the Ministry of Health. The overall consistent message was that the public must have confidence that the agency is independent of both business and political pressures.

There was unanimous agreement that New Zealand needs new radiation protection legislation. The opinions expressed in submissions will be used to formulate policy directed towards drafting instructions for a new Bill.

1. Introduction

The discussion paper “Review of the New Zealand Radiation Protection Legislation” was released by the Ministry of Health for public comment on 5 December 2002. The closing date for submissions was 15 March 2003. A total of 69 submissions were received. These were distributed as follows:

- 11 Government Departments, Crown Research Institutes, and Crown Entities
- 4 Regional Councils
- 7 Industry
- 23 Health professional colleges and other bodies
- 15 Individuals
- 2 Universities
- 7 Other interest groups.

The discussion paper contained a set of consultation questions that covered the issues raised. Not all of the submissions addressed the questions directly. However, for the sake of drawing conclusions from the submissions, this summary analysis arranges all of the comments under the most appropriate consultation question, and where possible interprets the comments as an affirmative or negative answer.

This summary is set out in the same sections as the discussion document. Each begins with a set of dot points summarising the issues raised in the section. Then follows discussion of the responses to each question relating to that section.

The Ministry of Health is not responding to the comments submitted at this stage. The comments will all be given careful consideration when formulating policy on future developments of the radiation protection legislation.

The Ministry of Health would like to express its appreciation of the time and work evidenced by submissions.

2. What are the health effects of radiation?

Summary of Section 2

- Radiation may be either ionising (x-rays, gamma rays, etc) or non-ionising (visible light, UV, radio waves, etc).
- Radioactive material emits ionising radiation continuously. Irradiating apparatus produces radiation only when switched on.
- The health effects of exposure to large amounts of both types of radiation have been thoroughly researched and are generally well known.
- It is generally accepted that the risk of health effects from exposure to low levels of ionising radiation is proportional to the amount of exposure, and that there is a threshold to the exposure level of most types of non-ionising radiation below which there are no harmful health effects.
- There is still some uncertainty about the health effects of very low levels of exposure to radiation, and research is continuing.

Question 2.1 Do you feel that the consensus understanding of the health effects from radiation is correct? If not, why not?

A total of 29 of the submissions addressed this question.

Of these, 20 agreed in principle with the current understanding of risks but four stressed the need to continue investigations, particularly in the area of non-ionising and low-level radiations. Submissions also made the point that while the scientific and radiation safety communities may have reached some level of consensus there was considerable confusion on the part of the general public. This led to suggestions that it is an integral part of regulation of radiation safety to inform and educate the public on what the true risks are.

There were six submissions claiming that the health effects of low levels of electromagnetic radiation are significantly underestimated. Another three had concerns about microwave ovens, Chernobyl-contaminated food from Europe, and low levels of ionising radiation.

Question 2.2 Are there other types of radiation that have been missed and should be included? If yes please give details.

A total of 20 submissions addressed this question.

Eleven were satisfied that all types of radiation that could be a risk were covered in the discussion document.

The others gave particular examples of non-ionising radiation that could be covered by the Bill proposed in the discussion document, and at least could potentially be covered by regulations empowered by the Bill.

Interesting suggestions were NORM/TENORM (naturally occurring radioactive material and technologically enhanced naturally occurring radioactive material) and cosmetic use of ultraviolet radiation (sunbeds). Currently it is ambiguous how the Radiation Protection Act applies to manufacturing processes that as a by-product concentrate naturally occurring radioactive material to a degree that it may be hazardous. The use of sunbeds is subject to a voluntary standard but is currently unregulated in New Zealand.

3. Who uses radiation in New Zealand?

Summary of Section 3

- The use of radiation in New Zealand is typical for an industrialised country
- Radiation is used in (for example):
 - medical diagnosis (x-rays, nuclear medicine, MRI, pathology testing) and therapy (medical linear accelerators, surgical lasers);
 - industry (radioactive gauges, cutting lasers);
 - research (DNA forensic testing, genetic engineering);
 - entertainment (display lasers);
 - consumer products (smoke alarms).

Question 3.1: Are there any other groups or sectors that should be included?

A total of 17 submissions addressed this question.

Nine submissions agreed that all significant user groups were covered.

There was concern about drawing the regulatory lines in the right places in the case of medical use, where generally the people who refer patients for a procedure, prescribe the procedure, carry out the exposure, and follow-up or report the results can all be different.

There were concerns about the safety of cosmetic use of lasers and tanning equipment. These are currently unregulated.

There was also a comment about users of medical MRI and diagnostic ultrasound. These modalities are generally used by a sector that is already well regulated, by the Medical Auxiliaries Act, soon to be replaced by the Health Professionals Competency Assurance Act (HPCA Act). However, there were concerns about the new HPCA Act extending use to other less well-trained groups.

4. Who is at risk from radiation?

Summary of Section 4

- The health risk from radiation may be due to the planned exposure to controlled small amounts of radiation, or to the possibility of an accident or deliberate misuse leading to an uncontrolled exposure.
- An individual may be at risk from exposure to radiation as a worker, a medical patient, or as a member of the public.
- Effective legislation needs to control the risks in each of these categories.
- Natural background radiation is with us all the time. The fact that there are limits as to how much it can be controlled sets limits to the practical degree to which any legislation can control either natural or man-made radiation.

Question 4.1: Are there other groups of people at risk from radiation who have not been discussed, and if so, why?

A total of 20 submissions addressed this question.

Ten of the submissions felt that all groups at risk were adequately covered.

Among the other submissions there was a range of useful suggestions, but none predominant.

There was concern expressed about the following groups:

- Classes of health practitioners who may be able to use x-rays as part of a new scope of practice under the new HPCA Act.
- Family and other care-givers exposed to patients who have been treated with radioactive materials and released to go home.
- People involved in management of emergencies that may have radiological hazards (transport accidents, “dirty bomb” incidents, etc).
- People who have brief but intensive contact with radiation, such as students, or research workers who use radiation in association with a single project.
- Aircrew flying long hours at high altitude.

Question 4.2: Are there any particular radiation risks that you feel should be regulated, and if so, why?

A total of 26 submissions addressed this question.

None of the submissions were *not* in favour of regulating ionising radiation. One submission stressed regulation of the security of radiation sources as well as safe use.

Another submission suggested regulation of NORM and TENORM (naturally occurring radioactive material and technologically enhanced naturally occurring radioactive material), possibly through building design. This is because the most likely exposure to this is from building materials or from the lack of ventilation in buildings concentrating naturally occurring radioactive radon gas.

Submissions on non-ionising radiation were ambivalent.

There were requests for regulation of non-medical (cosmetic) use of ultraviolet radiation and lasers because voluntary use of a standard is not effective, and also medical ultrasound and MRI.

One submission reflected the aim of good legislation – that all man-made sources of radiation should be regulated to ensure that benefit exceeded risk, but to a degree commensurate with the degree of risk.

Question 4.3: Are there any particular radiation risks that you feel should not be regulated, and if so, why?

A total of 23 submissions addressed this question.

Five submissions insisted that all forms of radiation should be regulated.

The suggestions for exclusion of ionising radiation were restricted to natural background (including air travel) and patients released from hospitals after treatment with radioactive materials.

There were requests for the exclusion of a variety of forms of non-ionising radiation on the basis that either the risk was too small or that existing control under other legislation was sufficient (Health and Safety in Employment Act, Resource Management Act, Medical Registration Boards, etc)

Two submissions asked that extremely-low-frequency electromagnetic fields should be excluded because they are not technically radiation.

5. How does the New Zealand radiation protection legislation function, and why should it be changed?

Summary of Section 5

- The Radiation Protection Act 1965 is out of date. The responsibilities that it sets up do not reflect the structures of the present day organisations that use radiation.
- There are areas where it is doubtful whether the RPA could be effectively used to prosecute or lay charges if someone were using radiation dangerously or irresponsibly.
- There is an international move towards the adoption of consistent radiation safety standards and regulatory systems, sponsored by organisations and agencies to which New Zealand is a signatory. New Zealand should review its own regulatory system in relation to the international standards.
- There is also a move towards radiation safety regulatory uniformity in Australia, following the international model. The process is coordinated by a panel of which New Zealand has formal membership. The Minister of Health has agreed to take account of the panel's decisions.

Question 5.1 Do you agree that the Radiation Protection Act may be ineffective in some cases in prosecuting persons using radiation dangerously or irresponsibly? If not then why?

A total of 22 submissions addressed this question.

Eighteen of the submissions agreed that there were serious areas where the RPA is ineffective. Some pointed out quite rightly that it was ineffective in the area of non-ionising radiation because it did not regulate it.

There were suggestions that other legislation could be brought into use in some cases. So the situation may not be as precarious as portrayed in the discussion document, but this does not detract from the claim that the RPA is ineffective.

Question 5.2 Do you feel that New Zealand has an obligation to implement standards that are recommended by international bodies (like WHO, FAO, ILO) to which we belong? If not then why?

A total of 34 submissions addressed this question.

Twenty-eight of the submissions were in agreement with the principle of adopting international consensus standards, particularly if they are endorsed by organisations of which New Zealand is a participating member. Some of the support was conditional on the standards being close to what the people of New Zealand would find acceptable.

A group of submitters lobbying for stricter controls on electromagnetic radiation claimed that international standards are driven by the interests of big business, and are not to be trusted. They feel that standards (maximum exposure levels in particular) should be set at a local community level on the advice of experts they are confident are independent of business interests.

There was a comment from the telecommunications industry that care must be taken to adopt standards in line with our major trading partners to ensure that we are not disadvantaged commercially.

Question 5.3 Do you agree that NZ should develop legislation that sets up controls and standards that harmonise with Australia?

A total of 30 submissions addressed this question.

All but one of the submissions were in general agreement with the principle of uniformity with Australian legislation. However, a third of these expressed some reservations about wholesale adoption of Australian standards.

Some submitters felt that international standards should be followed where they disagree with Australian standards. Others were concerned not to lower New Zealand standards just to fall into line with Australia.

The one dissenting submission claimed that Australian standards for electromagnetic radiation are too lenient because of the dominant influence of business interests at the expense of safety.

6. What is the best way to regulate the risks from radiation?

Summary of Section 6

- The more restrictive a regulatory system is the greater the cost to the industry, the customer, and the public as a whole. The cost of regulation must be justified by the benefits it produces.
- Regulatory control can use the following methods:
 - command and control, through restriction to authorised practices and operators only, and requiring compliance with prescriptive standards;
 - performance based legislation that gives the user greater freedom to set safety practices as long as certain criteria are not violated;
 - risk management based legislation that sets up procedures for surveillance, analysis and optimal management of risks to be carried out by responsible and empowered agencies;
 - deregulation, and reliance on market forces and other broad-based safety legislation to control risks.
- An internationally endorsed regulatory model favours the command and control mechanism, with the primary responsibility for the safety of any practice placed on the person or company carrying it out. The Ministry of Health would prefer the New Zealand legislation to follow this model.
- The Ministry believes that the most effective regulatory authority for radiation safety in New Zealand would be an integrated specialist unit incorporating both regulatory and service functions, and that the options for the radiation safety regulatory authority being a separate body outside the Ministry of Health should be explored.

Question 6.1: Which regulatory model do you think is the most appropriate for regulation of radiation risks?

A total of 30 submissions addressed this question.

Twenty-seven of the submissions opted for the prescriptive “command and control” style of legislation, including seven that suggested this should be in combination with elements of risk management or performance based requirements. This suggests that at least some standards (safe levels and methods) should be mandatory, but particularly in areas of lower risk the person carrying out the practice can be given some freedom as to how the risks are managed.

Many of the submitters stressed that a prescriptive regulatory system gave the public greater confidence when it came to their own safety.

Question 6.2: If the model that you expressed a preference for in Question 6.1 were adopted, do you think this would raise any compliance cost issues for regulated parties or anyone else?

A total of 22 submissions addressed this question.

Half of the submitters saw compliance costs as a significant issue. Most saw the costs of a sensible regulatory system as necessary and should be accepted. There was no comment explicitly on the cost of one regulatory model over another. Feelings were divided as to whether the costs of regulation should be borne totally by the user, or subsidised so as to discourage avoidance of licensing or registration just for cost-cutting reasons.

There were comments about how potentially expensive to the country a radiological disaster could be, and that a strong regulatory system could be seen as a form of insurance.

Question 6.3: Do you feel that the radiation safety regulatory authority should be a single integrated specialist unit that provides both regulatory and support services, or do you think the functions should be split? Please give details.

A total of 36 submissions addressed this question.

Thirty of the submissions indicated that a single integrated specialist radiation safety agency was appropriate for New Zealand. Many submitters saw the role of the agency as advisory and educative as well as regulatory. There is a perceived need for an expert body that is seen to be independent of business and pressure groups to give impartial advice to the country on radiation risks.

There was discussion of the possibility of conflict of interest between regulatory and service/advice functions within an integrated unit. Two submitters preferred to solve this by splitting the unit into separate bodies. But amongst the submissions in favour of a single unit this was not seen as a big problem. One suggested that the finances should be kept separate so that it was transparent what it was that the regulatory fees were funding, and that there was no subsidisation of what should be commercial services.

One submission recommended that the structure of the regulatory authority should not be prescribed in a new Act. This would allow flexibility to modify the structure if it proved to be necessary.

Question 6.4: Should the regulatory authority be part of the Ministry of Health or part of a Crown-owned entity?

A total of 26 submissions addressed this question.

Sixteen submissions indicated a clear preference for the regulatory agency remaining within the Ministry of Health. One reason given for this was confidence in the Ministry treating health issues as a priority, rather than a possibly more commercially oriented stand-alone unit having other priorities. However, in many comments it was acknowledged that not all radiation issues are directly concerned with health. There were also commercial and international treaty interests that must be considered.

The main concerns expressed were that the agency should be free of both political and commercial pressures.

7. What are the options for achieving a satisfactory regulatory system?

Summary of Section 7

- The Radiation Protection Act has serious deficiencies. There are four possible courses of action to consider:
 - continue with the present legislation;
 - leave the Act as it is but amend the Radiation Protection Regulations;
 - start with a clean slate and develop our own unique New Zealand radiation safety legislation;
 - draft a new Act and regulations modelled on recent international examples.
- The Ministry has a preference for drafting a new Radiation Safety Bill to bring the New Zealand legislation into uniformity with international models and, particularly, recent Australian legislation.

Question 7.1: Do you agree that NZ should have a new Radiation Safety Act?

A total of 38 submissions addressed this question.

There was unanimous agreement that New Zealand needs a new radiation protection Act of some form. There was no suggestion that anything less than this would suffice.

Question 7.2: If your answer to 7.1 was “no”, which of the other options should be taken? Please give reasons for your choice.

Because of the unanimous answers to question 7.1 there were no answers to this question.

Question 7.3: If we should have a new Act, do you think other regulatory models should be considered? Please give details.

A total of nineteen submissions addressed this question.

Fifteen more or less supported following the international standard or Australian model.

The others wanted to see more elements of risk management or performance regulation developed in preference to the largely prescriptive standard regulatory model.

8. Outline of possible new radiation safety legislation

Question 8.1: Is there anything else you would like to see in a new Act? Please give details.

A total of 43 submissions addressed this question.

This question was treated as a “catch all” for suggestions on what submitters wanted to see in new legislation.

The Act should designate as a duty of the regulatory agency to investigate radiation risks and inform the public on issues as they arise. One of the tasks would be to keep abreast of new scientific knowledge on radiation risks and incorporate these in regulation.

There were also comments that the legislation should be sufficiently flexible to allow changes for new knowledge or technology to be implemented in a timely fashion. This would suggest an Act that sets up powers and responsibilities, and leaves more prescriptive detail to regulation or Codes/Rules that are adopted by Gazette Notice. There was a call for public involvement in any changes to controls on radiation.

There was support for the primary responsibility for safety resting with a single “licence to possess” a radiation source, rather than distributed among individual users. This was particularly the case in low risk use areas such as airport security x-ray systems. One submission was concerned about the possession licensee not having the safety knowledge of a qualified licensed user.

There was mixed enthusiasm for user licences. Some submissions liked the way in which user licences could set a minimum standard of training for categories of use. On the other hand some submissions were in favour of the possession licensee taking full responsibility for ensuring users were adequately trained and experienced. This was felt to be appropriate in low-risk areas of use. There was concern that the difficulties in the present Act concerning who is responsible and who should be licensed in the medical process of referral-prescription-treatment-follow-up should be avoided. There was also concern that the decision to licence a class of users be primarily informed by the degree of risk in that category of use.

There was a perceived need for controls of potentially dangerous radiation sources to begin at importation and follow the sources through to disposal or export. Any currently ambiguous responsibilities such as seizure by Customs, or loss during transport, would need to be clearly circumscribed in new legislation. Advice from a submission from the Ministry of Foreign Affairs and Trade indicates that a considerable strengthening in this area will be necessary if New Zealand is to comply with an upcoming International Security Code of Conduct.

A submission from the New Zealand Police suggested that the enforcement and emergency powers missing from the current Act could well be obtained by developing a working relationship with the Police. The radiation safety agency would request and advise, but any forced entry or detention would be undertaken under Police powers.

A comment from the Justice Department indicates that a substantial case would need to be made for increasing the default period of statutory limitation from six months to a longer period.

There were comments about the relationship between new legislation and existing other legislation (Civil Defence and Emergency Management Act 2002, Health Act, Public Health Bill, Health Professionals Competency Assurance Bill, Health and Safety in Employment Act, Hazardous Substances and New Organisms Act, Resource Management Act etc). There were concerns that there be consistency so that a single solution would satisfy all, and that liability under more than one Act would not create a “multiple jeopardy” situation.

There was concern that non-ionising radiation would be a “poor cousin” and be inappropriately regulated by being forced to fit into a framework better suited to ionising radiation. It was suggested that non-ionising radiation should have a distinct separate section within a new Act.

Question 8.2: Is there anything you would not want to see in a new Act? Please give details.

A total of 19 submissions addressed this question.

This question serves the purpose as the other side of the previous question. It has been used as the collection point for everything submitters do not want a new Act to have.

There was a submission asking that there should be no individual user licences where a particular activity was a scope of practice under the new HPCA Act. This is partly because it is felt that licences would be redundant, and partly a response to the difficulties experienced under the present RPA in determining who should be licensed.

There were requests for exclusion of some classes of non-ionising radiation because regulation is either unnecessary or adequately covered by other legislation.

It was claimed that occupational exposure to non-ionising radiation is well controlled by the Occupational Health and Safety service (OSH) under the Health and Safety in Employment Act.

The New Zealand Association of Radio Transmitters requested exclusion because amateur radio transmitters are never powerful enough to be a health hazard.

The telecommunications industry wanted to make sure that they would not be captured by legislation designed around ionising radiation, involving individual licences and registration of individual pieces of equipment.

There was a plea for the new legislation not to regulate (in particular require licensing or registration of) categories of use that are already adequately controlled. This could be interpreted as a statement of the principle that any regulatory system must produce a benefit that outweighs its cost.

Question 8.3: Is there anything you would particularly like to see covered by a code of practice or in regulations?

A total of 24 submissions addressed this question.

This question attracted an interesting list of radiation risks that submitters particularly wanted to have standards prescribed for. This list comprises:

- Ultrasound, MRI, medical lasers;
- Training requirements, continuing education and safety refresher courses;
- The Ministry for the Environment Guidelines for radio transmitters;
- Restrictions on the siting of radiotransmission towers;
- Mandatory quality control procedures for x-ray equipment;
- Emergency planning, requirements for liaison with local emergency authorities;
- Use of cosmetic tanning equipment and lasers;
- Existing voluntary standards that the industry in question believes should be mandatory;
- Handling of radioactive corpses;
- Risks from high natural background radiation that can be controlled through building practices;
- TENORM (technologically enhanced naturally occurring radioactive materials).

Question 8.4: If the legislation outlined above were to be enacted do you think this would raise any compliance cost issues for regulated parties or anyone else? If you think this would affect you please elaborate.

A total of 19 submissions addressed this question.

Only seven suggested that compliance cost would be a concern. Many accepted that there may be significant costs but accepted this as a necessary part of using radiation. Generally comments were somewhat ambivalent, because the present system is prescriptive and not particularly equitable in terms of cost. So it is not clear whether another system that is also prescriptive would cost more or less.

There were many expressions of dissatisfaction with the present system of user licensing. There were also many submissions stressing then need for the degree and cost of regulation to be commensurate with the degree of risk.