

A Review of the New Zealand Radiation Protection Legislation

A Discussion Document

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MANATŪ HAUORA

Preface

The Ministry of Health is reviewing the way the risks from radiation are regulated in New Zealand. This document discusses the problems with the present regulatory system and the possible options for solving these.

Submissions expressing comments and suggestions are invited from interested persons, whether representing organisations or as individuals. When sent on behalf of an organisation, the submission should include the position within the organisation of the person making or signing the submission and an indication of the extent of consultation, discussion, and support within the organisation for the options, opinions and advice expressed in the submission.

To assist with the analysis of submissions, clearly worded, and brief dot points with question, page and paragraph references would be helpful in reviewing content. However please do not feel limited to addressing only the questions provided.

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The closing date for submissions is 15 March 2003.

All submissions received will be considered before the development of policy advice to the Minister of Health.

Please note that correspondence may be the subject of a request under the Official Information Act 1982. In the event of possible future such requests to the Ministry if there is any part of your correspondence that you consider could *properly* be withheld under the Act, please include comment to that effect and give reasons why you would want it withheld.

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Executive summary

1. The New Zealand radiation protection legislation is based upon an Act that was originally passed in 1949. Since then there have been significant changes in the way radiation sources are used in New Zealand. Similarly, there have been equivalent changes internationally in the way radiation safety is regulated. The Ministry is concerned that the safety standards in New Zealand are not uniform with the rest of the world, including many developing countries.
2. There are two categories of radiation that are capable of causing health effects, namely ionising and non-ionising radiation. These effects have been extensively researched. Large doses of ionising radiation can produce immediate symptoms of radiation sickness; smaller doses are associated with an increase in the likelihood of cancer or genetic disease in the decades or generations following exposure. There are also well known effects from exposure to intense non-ionising radiation. Although there is a general consensus that long-term exposures to relatively weak levels of non-ionising radiation do not cause health effects, research in this area is still proceeding.
3. The use of radiation in New Zealand is typical for a developed country. Medical procedures are the most common source of radiation exposure, but there is also the potential for exposure in the workplace in industries that use radiation, and to the public from some consumer items or from other uses if they are not adequately controlled, especially hazardous non-ionising radiation, such as medical lasers.
4. The Radiation Protection Act 1965 has a number of serious deficiencies due to recent changes in the use of radiation. In particular, application of the Act to present day corporate structures generates ambiguities that severely reduce the effectiveness of the legislation in defining legal liability for the control of radiation sources.
5. There are pressures both from Trans-Tasman developments and international health and safety organisations, of which New Zealand is a signatory, to move to an internationally consistent radiation safety regulatory system. A widely sponsored regulatory model has been developed internationally and has been adopted in Australia and many other countries. Many developing countries are actively proceeding along similar lines, and New Zealand has participated as an expert advisor in a number of these programmes.
6. Safety and risk can be controlled using a variety of regulatory styles. After reviewing the options with respect to cost, efficiency, and the level of safety assured, the Ministry is provisionally recommending that the prescriptive style exemplified by the international model be followed in New Zealand as well.
7. Given that the New Zealand legislation has deficiencies, both in its effectiveness and in comparison with international standards, the Ministry is considering the following options:

- continue with the present legislation, being aware of the inadequacies and potential problems;
 - attempt to rectify some of the deficiencies by amending the regulations but not changing the Act;
 - initiate a fundamental review of radiation protection and re-design the regulatory system from first principles;
 - draft new legislation based upon the accepted international model of best practice
8. The Ministry would like to propose that the last option be developed. The suggested structure of a new Act along these lines is presented to provide a focal point for comment.

1. Introduction

- 1.1 Radiation is a controversial subject. The Ministry of Health is aware of the public's concerns. The New Zealand radiation protection legislation is based on an Act that was originally passed in 1949. There have been significant changes in the way radiation sources are used in New Zealand since then, particularly in industry and medicine. Similarly, there have been consistent changes internationally in the way radiation safety is regulated. The Ministry is concerned that the safety standards here in New Zealand are not harmonised with the rest of the world.
- 1.2 This document initially attempts to present a balanced discussion of our present consensus understanding of the health risks from radiation. This is followed by a review of the various uses of radiation in New Zealand, and parties who could be exposed to radiation as a result.
- 1.3 The shortcomings of the present Radiation Protection Act 1965 (RPA) and Radiation Protection Regulations 1982 (RPR) are discussed, and the legislation is compared with developments overseas. There is significant pressure, both internationally and from Australian jurisdictions, for the RPA to be harmonised with current regulatory standards.
- 1.4 In order to put any suggested changes into context this paper discusses the various ways that risk might be regulated. Any regulatory system is a balance between the degree of protection and the cost of achieving it, both to the user and to the community as a whole. However the Ministry believes it would be prudent to follow international best practice and continue to regulate radiation within a prescriptive regulatory framework.
- 1.5 A range of options for changing the New Zealand legislation, from doing nothing, to writing a new Act, is presented for consideration and comment. The Ministry would prefer to draft a new Radiation Safety Act, and is very interested in whether there is general support for this option.
- 1.6 The possible content of a new Act is developed in some detail. The Ministry encourages submissions from all interested parties, on the suggested structure and content, to ensure that the new Act will:
 - provide coverage for all types of radiation that necessarily should be controlled;
 - place the responsibility for safety with the appropriate persons;
 - provide for empowerment and processes that enable appropriate safety standards to be set and enforced.

2. What are the health effects of radiation?

There are two categories of radiation that are capable of causing health effects, namely ionising and non-ionising radiation. Ionising radiation is high-energy radiation and includes x-rays, alpha particles, beta particles, and gamma rays that have ionising capability (by removing atomic or molecular electrons) and hence can cause chemical or molecular changes to interacting bodies. Non-ionising radiation is electromagnetic energy and includes laser light, electromagnetic fields, and radio waves. These cannot directly cause chemical change through ionisation, but can produce heating and electrical effects. Ultrasound, as an example, is also considered to be a type of non-ionising radiation. The effects of each category are discussed separately. The present RPA controls ionising radiation but not non-ionising radiation.

2.1 Ionising radiation

- 2.1.1 There has been considerable research on the effects of ionising radiation. The International Commission on Radiological Protection (ICRP) has been in existence since 1928, and continuously reviews worldwide evidence of the effects of radiation. It has published numerous recommendations on radiation protection since then (e.g. ICRP 1977, ICRP 1991). The most recent set of general recommendations is endorsed by most regulatory authorities (ICRP 1991). ICRP has also drawn from the research carried out by other international bodies such as the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).
- 2.1.2 Every few years since its formation in 1955, UNSCEAR has produced a substantial report based on information gathered from all UN member states (see UNSCEAR, 2000). The data used comes both from the follow-up of survivors of the bombing of Nagasaki and Hiroshima, and from the large numbers of other people who have been exposed to radiation for medical purposes.
- 2.1.3 The medical effects of an extreme exposure to ionising radiation are well known, and typically produces symptoms of “radiation sickness”. Such a level of exposure would only happen in a major accident and is very rare worldwide. At lower levels of exposure the damage is subtle, and the body may be able to repair damage caused. The effects are typically an increased likelihood of cancer in later life or genetic abnormalities passed on to offspring. The degree to which the likelihood increases depends on the degree of the radiation dose received. At the lowest levels the effect is not measurable because we live in an environment of natural ionising radiation all the time that varies over a wide range depending upon where we live. However it is assumed for the purposes of radiation protection that the radiation risk is simply proportional to the dose, right down to the lowest levels of dose. That is to say, if you halve the dose you halve the risk, no matter how small the dose is. This is referred to as the “linear no-threshold” risk model.

- 2.1.4 It is important to understand the differences between radioactive materials and radiation. Radioactive materials are unstable matter that emit ionising radiation of various types, as they decay. They are a continuous source of radiation that cannot be terminated. They may be lost or spilt, and ingested so that the body is irradiated internally until the material decays away or is excreted. However ionising radiation can also be produced electrically, such as in x-ray machines or linear accelerators. These machines do not contain any radioactive material, and once they are switched off they produce no radiation. They can produce intense radiation when operating, but are not hazardous when switched off or disconnected from a power supply. A piece of equipment that generates radiation without the use of radioactive material is commonly referred to as an “irradiating apparatus”.

2.2 Non-ionising radiation

- 2.2.1 Generally speaking, the risks from non-ionising radiation are simpler to quantify. They take the form of some type of direct injury, such as burns, eye damage from a laser, or heating from a radio-frequency field. The thresholds for these effects are well established, and at levels below the thresholds there is generally assumed to be no credible risk.
- 2.2.2 There may, however, be exceptions to this. Some research suggests that there may be effects from levels of electromagnetic fields or radiation below the thresholds for thermal effects, which might result in small increases in the risks of developing some diseases, such as leukaemia and other cancers. The fact that there is still uncertainty after a considerable amount of research and re-analysis of results suggests that if there are real effects they are likely to be very small. Any uncertainty must nevertheless be taken into account when considering societal concerns and how such concerns are best managed.
- 2.2.3 There is a general consensus that ultrasound imaging does not carry any significant risks. On the other hand, it is acknowledged that other types of ultrasound, such as Doppler scans (used to measure blood-flow), have the potential to cause injury if not carried out with due care.

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 current understanding of the health effects from radiation is correct? If not, why not?

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

3. Who uses radiation in New Zealand?

There are about two and a half thousand importations of radioactive material into New Zealand each year (not including domestic smoke alarms), nearly a thousand people licensed to use radioactive material, and over two thousand people licensed to use irradiating apparatus (mainly x-ray equipment). New Zealanders receive on average about 20% of their annual exposure to radiation from human-made sources. This may seem surprising in “nuclear free” New Zealand, but it is quite normal for a developed country.

Who uses all of this radiation?

3.1 Medical, dental, veterinary

- 3.1.1 The major source of exposure to radiation is from medical x-rays. X-rays are also used by dentists, chiropractors, podiatrists, and veterinarians. These groups account for most of the licences held to use these machines. Radioactive materials are also used for medicine. Bone scans, for example, use an injection of a small amount of a particular radioactive material that seeks areas of high bone metabolism, and can be imaged using a special camera. Trace amounts of radioactive material are used in some medical laboratories for certain types of blood tests.
- 3.1.2 Lasers have many medical applications, and electromagnetic fields are used in magnetic resonance imaging scanners. Ultrasound is used both for diagnosis and therapy in medicine.

3.2 Industry

- 3.2.1 Radiation is very useful for taking measurements during some manufacturing processes. By measuring the amount of scatter or penetration, for example, estimates can be made of thicknesses, composition, whether a hopper or drink can is full, or whether pipe welds are intact. This generally makes use of small amounts of radioactive material (that emit the desired type of radiation) which are securely encapsulated so that the material cannot leak out.
- 3.2.2 Industrial radiography uses gamma rays or x-rays to take pictures of welded joints, metal castings, or other mechanical components to check for defects or cracks. Because gamma rays are generated from radioactive material (caesium-137 or iridium-192) rather than mains electricity, the cameras are quite portable and can be used on site to inspect joins in cross-country pipelines.
- 3.2.3 Radiation is also used for processing materials and goods. Very large doses can be used to sterilise medical equipment or change the internal structure of plastics.

This application requires the use of either large amounts of radioactive material or an electron accelerator.

- 3.2.4 High-powered lasers are also used for some industrial processes. Radiofrequency fields are used in broadcasting and communication and for heating and welding. Lower frequency fields are found around any electrical equipment.

3.3 Research, education

- 3.3.1 Because radiation can be easily detected in very small quantities, radioactive material is ideal for use as a tracer to investigate some physical or biological processes. It can be used to trace the flow of ground water, and is used extensively in molecular biology.
- 3.3.2 One of the common methods of DNA testing uses fragments of DNA tagged with radioactive phosphorus or sulphur. Other uses include x-ray machines for crystallography analysis and research into the effects of radiation on cells and physical matter.

3.4 The public

- 3.4.1 There are many consumer goods that contain radioactive materials or generate ionising or non-ionising radiation. Smoke detectors for instance utilise a small amount of radioactive material.
- 3.4.2 Cell phones, microwave ovens, television transmitters and many other common devices produce non-ionising radiation. High-powered lasers are used for displays in the entertainment industry.

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?

4. Who is at risk from radiation?

In order to know how to regulate radiation safety, we need to know who requires protecting from radiation risks. There are two categories of risk that must be considered:

- the risks from normal, every-day exposure to radiation that must be controlled to be at a “safe” level, and
- the risk from a radiation accident that must be minimised by regulating any circumstances where such an accident could occur.

4.1 Workers

4.1.1 In New Zealand there are about 4000 people who use radioactive material or ionising radiation as a normal part of their work. Many work in hospitals where they take x-rays, or look after patients who have had radioactive materials injected or implanted. Others use nuclear density meters to measure the composition of the ground surface during road construction, or take radiographs of pipe welds. Others use very small amounts of radioactive material for medical and other scientific research. Non-ionising radiation is widely used in communications and broadcasting and industrial applications such as radio-frequency heating and welding.

4.1.2 Under normal circumstances the routine occupational exposure to radiation is low and may even be effectively non-existent. According to internationally agreed standards the risk from this low level of exposure is acceptable. Every industry has its hazards and risks that must be managed, and radiation risks should be seen in context. As long as nothing goes wrong and correct procedures are followed, radiation workers are considered to be no less safe than other workers. However, if something does go wrong workers may be exposed to dangerous levels of radiation. Because radiation cannot be sensed by humans this may not be discovered until long afterwards. There is no reflex response to radiation that prompts people to get out of danger.

4.1.3 The risks of accidental occupational over-exposure come from faulty equipment, inadequate training, not following correct procedures, loss of radiation sources, accidents, etc. Occupational risks are kept to a minimum by good safety management, the fostering of a “safety culture” and regulatory control. Conversely the risks are greatly increased where there is disregard for regulatory requirements, complacency, cost cutting, poor training, lack of appreciation of risk, or lack of management concern for safety.

4.2 Medical patients

4.2.1 Medical patients are a special case in that they are deliberately exposed to radiation. There is always an associated radiation risk, even when the procedure is performed as intended. However, as long as the patient is in the care of someone suitably trained, and using equipment that is functioning properly, the benefit from

the treatment or diagnosis should always be greater than the risk of adverse health effects from the radiation.

- 4.2.2 The real risks to medical patients therefore involve incompetence, mistakes, equipment failure, or accidents. Risks are minimised by ensuring that only fully competent people are allowed to practise, and that every medical clinic has a safety management approach that includes continuing professional development of staff, maintenance of equipment, safe procedures that reduce the likelihood of errors, etc.

4.3 General public

- 4.3.1 The public has a right to expect that if they are in a place of unrestricted access they should be safe from all types of radiation, and they should not have to bear the risk from radiation associated with someone else's business. Society should feel confident that any permitted exposure of the public to radiation is at a safe level, and that the chance of any accidental radiation exposure or accidental release into the environment is negligible.

- 4.3.2 In the absence of regulatory control, some of the possible ways in which members of the public could be exposed to a higher level of either ionising or non-ionising radiation than they would consider acceptable are:

- loss or theft of a radioactive source allowing it to fall into the hands of someone unaware of the hazards or with the intention of deliberate misuse;
- installation of an x-ray machine or linear accelerator with insufficient shielding, so that areas of public access are irradiated to a higher degree than is acceptable;
- release of radioactive waste into the environment at levels that may be a health hazard;
- release of patients from a hospital too soon after radioactive materials have been administered;
- sale of consumer goods containing radioactive materials that are unsafe to be used or disposed of without following special instructions;
- insecure premises where radiation is used, including hospital wards with inadequate restriction of public access;
- an accident during the transport of radioactive material;
- installation of radio transmitters producing high exposures in areas which are publicly accessible;
- poor control of lasers used for displays and entertainment, or for general sale.

4.4 Acts of terrorism

- 4.4.1 Since the terrorist acts of 11 September 2001 and the subsequent anthrax scares, there have been growing fears internationally that radioactive material may be used in a so-called "dirty bomb". Considerable social and economic disruption would ensue if a large radioactive source were dispersed over an urban area by means of an explosive device. It is possible that a large enough source could create a real health hazard in the contaminated area, but more realistically the level of contamination would probably be small but measurable. Regardless of the level of

radioactive contamination that might occur, it is accepted that civic disturbances would be considerable, and any clean up operation expensive and time consuming.

- 4.4.2 The degree of actual risk to the people of New Zealand from such an act of terrorism can only be speculated upon. The ensuing damage would possibly be from the response to the perceived risk just as much as any direct harm from the radiation. Nevertheless society will always desire protection where it perceives itself to be vulnerable.
- 4.4.3 Following the USA terrorist attacks the International Atomic Energy Agency has developed an action plan to strengthen the security of nuclear material and large radioactive sources worldwide, and to prevent the illegal trafficking in radioactive material. As well as this, a United Nations Security Council Resolution in September 2001 provides an important framework for the international response to the terrorist attacks. New Zealand is in the process of enacting the necessary legislation to become party to the various treaties for prevention of terrorism, including the Convention on the Physical Protection of Nuclear Material.
- 4.4.4 However, the radiation protection legislation has primary responsibility for border control of radioactive material, and ensuring it is not misappropriated and that it remains securely under the control of persons with a legitimate use for it. Any deficiency in this area within New Zealand would have to be seen as a risk to both the public of New Zealand and to the international community.

4.5 Natural background radiation

- 4.5.1 Everyone is continuously exposed to both ionising and non-ionising radiation from natural sources. Most of the non-ionising radiation is well below the level that could cause any health effects. The exception is ultraviolet radiation from the sun. But the ionising radiation in some parts of the world can be at levels sufficiently high to cause health concerns.
- 4.5.2 The typical sources of exposure to natural background radiation include:
- cosmic radiation: generated beyond the earth and penetrating through the atmosphere;
 - terrestrial radiation: from naturally occurring radioactive materials in rocks, soil, building materials, etc;
 - radon: a radioactive gas that emanates from the ground or other materials rich in natural uranium or thorium;
 - ingestion: from the naturally occurring radioactive materials in foods.
- 4.5.3. The relative contributions from natural background radiation (ionising) are shown in the diagram below. The diagram also shows the average contributions from human-made radiation. The main contribution is from medical procedures (mostly x-rays). There is still some residual fallout in the environment from the atmospheric testing of atomic weapons, but this is now so small it is becoming difficult to measure.

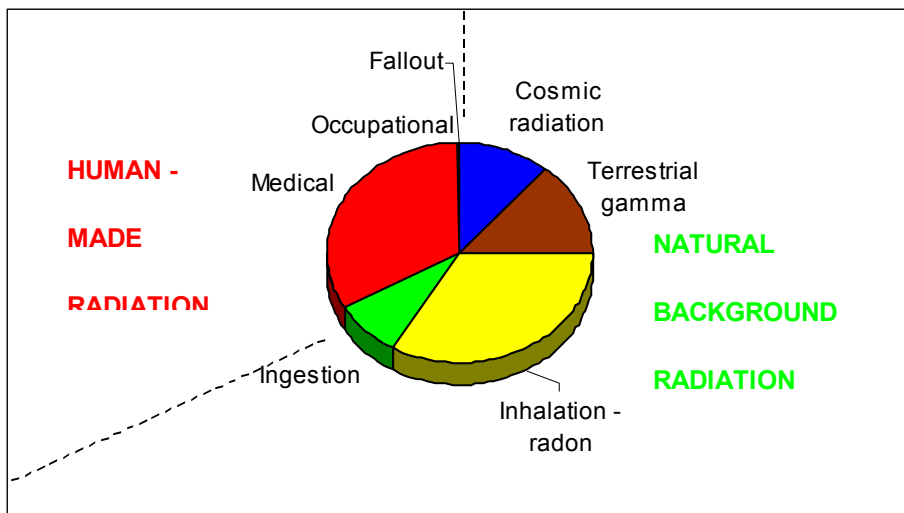


Diagram of the proportion of radiation dose to the average member of the public from natural and man-made sources

4.5.4 Generally, the exposure to naturally occurring radiation is exempted from regulatory control on the basis that it has always been there, and there is little that can be done about it anyway. However, there are some exceptions to this. Aircrew flying for long hours at high altitude get a much greater exposure to cosmic radiation than people at ground level, in many cases greater than regulatory limits for members of the public. The length of flying time at altitude, particularly for pregnant flight staff, is regulated in some countries. In some parts of the world building materials or local geology lead to a significant radon hazard in poorly ventilated buildings. A survey of radon in New Zealand houses by the National Radiation Laboratory in 1988 (Robertson et al 1988) suggests that would be unlikely here.

4.5.5 There are two points that arise from the consideration of natural background radiation:

- whether it is necessary to have the provision to be able to regulate the conditions that lead to an enhanced level of exposure to naturally occurring radiation (it is not possible under the RPA); and
- that the normal levels of exposure to natural background give a useful benchmark for what should be achieved by the regulatory control of man-made sources.

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?

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

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

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

5.1 The Radiation Protection Act 1965

5.1.1 The 1965 Radiation Protection Act (RPA) is an amendment, in detail only, of the original 1949 Radioactive Substances Act. The RPA is administered by the National Radiation Laboratory (NRL), a unit within the Public Health Directorate of the Ministry of Health. It covers only ionising radiation (radioactive materials and irradiating apparatus) and does not control any harmful non-ionising radiation sources. The most recent regulations under the RPA are the Radiation Protection Regulations 1982 (RPR). The RPA and RPR have the following control mechanisms:

- the manufacture, importation, and sale of radioactive material requires the prior consent of the Minister of Health;
- sale of irradiating apparatus is only permitted to a (natural) person holding a licence under the RPA to use it, and must be notified forthwith to the Director-General of Health;
- the use of radioactive material or irradiating apparatus is restricted to a person holding a licence under the RPA or someone acting under the supervision or instructions of a suitably licensed person;
- consents and licences may be subject to any conditions that are considered necessary at the time of issue;
- the RPR place obligations on owners to ensure that as far as practicable there is always a suitably licensed person responsible for the safety of a radiation source, and that any safety features or equipment requested by the licensee are provided;
- the transport of radioactive materials must comply with the Regulations for the Safe Transport of Radioactive Materials, published in Vienna by the International Atomic Energy Agency (IAEA 2000);
- the RPA sets up the Radiation Protection Advisory Council, consisting primarily of independent radiation experts, to advise the Minister and the Ministry on any aspects of policy or administration of the RPA, independently of the NRL.

5.2 Deficiencies of the RPA

5.2.1 The technology of radiation use and the type of establishment using radiation have changed dramatically in the last fifty years. NRL is having increasing difficulty applying the provisions of the RPA to present day use. In some cases the ambiguities are large enough to lead to doubts about whether some of the requirements are in fact legally binding.

- 5.2.2 In 1949, the typical use of radiation was by a single owner-licensee. The equipment was unsophisticated and the establishment structures were simple. The consent-notification-licence mechanism worked effectively and efficiently because there was no ambiguity as to who was responsible. Notification of the sale of irradiating apparatus gave adequate control because this would have applied only to medical x-ray machines. In 1973, and again in 1982 when the regulations were drafted, there is evidence of attempts to address increasing inadequacies. Work structures had become more complex, and so the RPR require “employers” to designate respective responsibilities among licensees, and for responsibilities to be apportioned between owners, licensees and “radiation safety officers”, without making it clear how this can be achieved. There is no continuing control of the actual radiation sources other than consent-notification process relating to change of ownership. There is no formally registered person who continues responsibility for ownership.
- 5.2.3 Furthermore, it is still a requirement that irradiating apparatus (hospital x-ray machines, medical linear accelerators etc) can only be sold to *an individual* with a licence to use the apparatus. There is no provision for corporate ownership. This is clearly inappropriate in the case of a large hospital department, university, CRI etc.
- 5.2.4 In any establishment using radiation, the person with the primary responsibility under the RPA is a user licensee (or several licensees). It is not technically possible for a body corporate to apply for a licence. Therefore it is almost never the case that the responsible licensee is the “employer” with responsibility under the Health and Safety in Employment Act 1992.
- 5.2.5 The RPA requires a user either to have a licence or to work under the “supervision or instructions” of a licensee. These latter terms are not defined in the RPA, so it is ambiguous in many cases as to who must have an individual licence. A person charged with the offence of using radiation without a licence can often use as a defence that they were “instructed in use or supervised” by a licensee even when this is intuitively inappropriate e.g. one dentist over another in the same practice but different location.
- 5.2.6 Under the RPR the owner of any radiation source needs only assign a licensed person to take care of the source. After this the owner has no further responsibility for security, safe use, or actions in the event of loss. These are all detailed in the RPR as responsibilities of the licensee. But the licensee may not be contractually responsible to the owner, or may simply leave and go to another country. There are serious ambiguities and questions of who is liable for the continuing security of the source. This is unacceptable, particularly as the world strives for greater security of radiation sources in the face of possible acts of terrorism.
- 5.2.7 The IAEA Transport Regulations deal mainly with packaging and documentation. They assume sufficient local regulatory control exists with respect to other safety aspects. If a radioactive source is lost or damaged during transport neither the RPA nor RPR indicate whose responsibility this is. If it is being transported from one

owner to another by a third party, then it is very unclear who should bear responsibility for remediation, which in some cases might be an expensive exercise.

5.2.8 The powers available under the RPA for enforcement are:

- the right of entry;
- the right to take samples and measurements; and
- the power to cancel or suspend a licence if a breach of the legislation has resulted from the actions of an individual licensee.

There is no provision for emergency powers such as taking control in a situation that may be dangerous. Equipment or material may only be confiscated following a successful conviction for an offence under the RPA. This may take months or years. In the meantime, cancellation of a licence can easily be circumvented by employing another licensed user. Examples given later illustrate this concern.

5.2.9 Section 14 of the Summary Proceedings Act 1957 limits the time after any offence in which information about the offence may be used for prosecution to 6 months from the offence being committed, unless another time limit is specified in the Act against which the offence was committed. Most Acts have extended this time to several years, but this has not happened in the case of the RPA. If a radioactive source goes missing, and its loss is not discovered until more than 6 months have elapsed, *it is not possible to lay any prosecutions*, no matter who was responsible for the loss.

5.3 Examples of situations when the RPA does not work

5.3.1 A radiation oncology department in a hospital

This is a multi-disciplinary team consisting of radiation oncologists, radiation therapists, medical physicists, nurses, technicians, servicemen, etc. While there is other legislation intended to protect patient safety, such as the Hospitals Act 1957, the Health and Disability Commissioner Act 1994, and the Medical Practitioners Act 1995, the primary responsibility for safety from the harmful effects of radiation is with the RPA.

The legal owner of the linear accelerators used in cancer therapy will generally be a body corporate. In some cases the owner may be a charitable organisation that donated funds. In any case it is not a natural person holding a licence to use the apparatus, as the RPA requires (see 5.2.3 above). So there is a problem with the RPA even before any safe use issues are considered.

The radiation oncologists and most of the medical physicists hold licences under the RPA. However the people who use the linear accelerators are the medical radiation technologists. They are considered to be acting under the instructions of one of the licensed radiation oncologists. The most likely serious radiation accident in an oncology department is the delivery of the wrong radiation dose to a patient, possibly due to non-observance of checking procedures following installation or maintenance of equipment, or following an error somewhere in the treatment prescription, planning, and delivery process, or even failure to identify the right patient. This is a failure in the quality system.

But the department will have devolved responsibility for safe use of radiation to the individual licensees (see section 5.2.6 above). So there is no individual person responsible under the RPA for the quality system, and it could well be that the mistake was made by someone planning the treatment. This person does not operate a treatment machine, so does not “use” radiation, and is not subject to licensing control. The ICRP stresses the importance of regulations requiring radiotherapy departments to implement a comprehensive quality assurance programme (ICRP, 2000). *Not only can the RPA not accommodate a corporate department owning irradiating apparatus, it provides for little direct control over the implementation and maintenance of the departmental quality system.*

5.3.2 A medical x-ray department

The department typically consists of a number of rooms with x-ray machines installed in them, operated by medical radiation technologists, under the instructions of a group of radiologists each of whom is licensed under the RPA. As in the previous section, owning x-ray equipment corporately is not legal under the RPA.

The responsibility for the equipment is attributed to one licensee designated the “principal licensee”. The role of principal licensee has no status under the RPA. However the RPR requires the employer of more than one licensee to appoint one to “supervise” regulatory compliance of the other licensees (regulation 9(3)(b)). There is some doubt whether the RPA empowers this regulation, and it may not stand testing in court.

The safety of the equipment and processing is maintained by a quality assurance programme set up and checked by a licensed medical physicist. The safety features and quality assurance procedures are requirements in an NRL Code of Safe Practice. Compliance with such a Code is required as a condition on all of the licences at the department. The legality of making a Code mandatory as a condition on a user’s licence is not clear from the RPA. The most frequent item of regulatory non-compliance in an x-ray department is that a particular x-ray machine or room does not satisfy the requirements of the Code of Safe Practice. Who is liable for remedying a breach of the Code? Possibly the owner, possibly the principal licensee, possibly every licensee because they must all comply with the Code. This ambiguity severely weakens the effectiveness of the legislation. Diagnostic x-rays are the greatest source of exposure to radiation of the New Zealand population and yet the RPA and RPR do not specify how patient safety can be unambiguously managed in an enforceable way.

5.3.3 An industrial plant using radioactive gauges

Many industrial processes use radioactive gauges to monitor production parameters, such as the fullness of hoppers, or the thickness of plating, etc. They are fixed in place, and do not generally require attention other than during installation, servicing, and decommissioning. During normal operation, they remain unattended.

The only regulatory controls on the radioactive sources in gauges are the consent to import or export them, and through a licensed user. But who is the “user”? The plant operator? The serviceman? The (corporate) person who should hold the licence for the continued safe use of the sources is the company. The company is responsible for worker safety

under the Health and Safety in Employment Act 1992, and for not polluting the environment and complying with any conditions of a resource consent under the Resource Management Act 1991. However the RPA does not license or register the owner, and can only license an individual user.

The main risk from an operation like this is that radiation sources may become misplaced, possibly during decommissioning of old plant. Who is responsible for going to the (possibly considerable) expense to find lost sources? There is no registered owner. The user licensee at the time of loss might have left the business. Who would be liable? The owner could argue that the problem was not one for the body corporate as at the time a licensed person was employed, and thus owner obligations were effectively discharged. Furthermore because of the 6 months limitation on information, if the loss was not disclosed until more than 6 months after the event, nobody could be prosecuted!

5.4 Outside pressures to change the RPA

Clearly the present Radiation Protection Act is difficult to administer and implement, it is ambiguous how it should be interpreted in the 21st century, and it carries the probability of being unenforceable in many circumstances. Radiation safety is also a global issue rather than just a national one. There are numerous factors that put pressure on New Zealand to regulate radiation safety more effectively.

5.4.1 The international models

Because there are cross-border issues such as illicit trafficking in radioactive materials, import/export, and environmental releases, there has been a considerable amount of work put into establishing internationally accepted safety standards, particularly for transportation, and for strengthening the regulatory systems in each country to be able to enforce the standards. This was the motivation behind the international multi-party sponsored Basic Safety Standards (BSS) (described in detail below). The expectation following the endorsement of the BSS by each of the sponsoring bodies was that member states of each of the bodies should enact legislation embodying the standards.

The Council of the European Union has acted on the expectation, and issued a series of Euratom Directives setting down standards for radiation protection that member states must follow. In particular, Directive 96/29/Euratom (European Communities 1996) gives effect to both the BSS and the recommendations of the ICRP. The Directive has an Article stating "Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive before 13 May 2000." In the UK for example, a new set of regulations (Great Britain 1999) was passed to implement the changes in the new directive.

As discussed below, there are fundamental differences between the BSS model of regulation and the New Zealand radiation protection legislation. New Zealand is a signatory to the IAEA, WHO, FAO and the ILO, bodies that sponsored and endorsed the BSS. This would seem to place an onus on New Zealand to honour the endorsement of the BSS.

5.4.2 Trans-Tasman obligations

New Zealand already has a number of cooperative arrangements with Australia. In 1983 the Closer Economic Relationship (CER) Trade Agreement was signed to simplify the flow of trade between the two countries.

In 1996 Australia and New Zealand signed a Treaty establishing a joint system for developing food standards in Australia and New Zealand. This is the first example, under CER, of the two sovereign nations joining together to create a common set of standards in the interests of enhancing both public health and trade. Under the Treaty, food standards developed by the statutory body Food Standards Australia New Zealand (formerly Australia New Zealand Food Authority, ANZFA) will be adopted by reference and without amendment in New Zealand and the Australian States and Territories. The purpose behind the Treaty is:

- protecting public health and safety;
- providing adequate information to enable consumers to make informed choices and to prevent fraud and deception;
- promoting fair trading in food;
- promoting trade and commerce; and
- promoting consistency between domestic and international standards where these are at variance.

Then in 1997, New Zealand enacted the Trans-Tasman Mutual Recognition Act. This followed an agreement between New Zealand and the States and territories of Australia to legislate for the mutual recognition of controls on goods for sale and on the registration of occupations. The objective of the agreement was to remove regulatory barriers to the movement of goods and service providers across the Tasman and reduce compliance costs to industry, but at the same time to maintain the effectiveness of the regulatory controls. Currently New Zealand is considering the establishment of a joint Australia/New Zealand agency for the regulation of therapeutic products (which include prescription and over-the-counter medicines, medical devices, complementary medicines, and many dietary supplements).

In the area of radiation safety regulation, Australia is moving towards a system of national uniformity. Under Section 15(1)(a) of the Australian Radiation Protection and Nuclear Safety Act 1998, the Chief Executive Officer of the regulatory authority set up by the Act is responsible for the promotion of “uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, States and Territories”. The Radiation Health Committee, which was established under Section 22 of the same Act, has among its functions the following:

- to develop policies and to prepare and draft publications for the promotion of uniform national standards of radiation protection;
- to formulate draft national policies, codes and standards in relation to radiation protection for consideration by the Commonwealth, the States and the Territories;
- from time to time review national policies, codes and standards in relation to radiation protection to ensure that they continue to substantially reflect world best practice.

To achieve this the National Uniformity Implementation Panel (Radiation Control), or NUIP(RC), has been formed as a working group under the Radiation Health Committee comprising senior officers of agencies of all jurisdictions that are responsible for the administration of their respective radiation protection legislation. The NUIP (RC) has recommended the consolidation of radiation protection standards and administrative guidelines into a document called the “National Directory for Radiation Protection”, following extensive consultation and agreement by jurisdictions. The jurisdictions would use the provisions contained in the National Directory when undertaking amendments to their Acts, regulations and policies.

On 17 November 2000, the New Zealand Minister of Health formally agreed to a proposal that a New Zealand representative be appointed as a participating member of the NUIP(RC) and that any review of the radiation protection legislation should take into consideration Trans-Tasman mutual recognition issues and the recommendations of the NUIP(RC). The National Directory is being drafted in close conformity with the BSS. This therefore adds further weight to the New Zealand obligation to review and update the radiation protection legislation along these lines.

To date the Trans-Tasman agreements have been motivated by efficiency, increased consumer confidence, and reduced compliance costs. Australia is developing the national uniformity process for the regulation of radiation safety for all the same reasons. This is a strong argument for New Zealand to participate in the process as well. However it should be noted that there is no suggestion at this stage of the establishment of a single radiation safety regulatory authority similar to the Food Standards Australia New Zealand. In Australia, uniformity in radiation safety is being developed through the co-operation of autonomous State jurisdictions, which each retain the functions of licensing and authorisation within their own State.

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?

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?

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

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

6.1 The fundamental principle of regulation

6.1.1 There are two steps in the process of controlling the risks from radiation:

- the first is to set up a framework of controls that allow the placing of restrictions on who can carry out particular activities, or designate certain individuals responsible for maintaining safety standards;
- the second is to determine what level of risk is acceptable, and what safety standards should be adopted and enforced.

Most regulatory systems operate using an Act to set up responsibilities and prohibitions, and then make or adopt regulations, Codes of Safe Practice, Rules, or Standards to set the safety standards.

6.1.2 It is important to bear in mind that any regulatory controls come at a cost. Someone must pay for the licences, approvals, authorisations, administration, as well as the mandatory requirements of the legislation. The more heavily regulated an activity is, the greater the cost to the participants, and generally the customers and public as a whole. *It is a fundamental principle that the cost of a regulatory system should be justified by the benefits it achieves.*

6.1.3 From the discussion in the previous sections, it is clear that what a regulatory system must achieve is to ensure that all planned exposures of people to radiation are at a suitably low level of exposure, and that the likelihood of an accident occurring that results in a greater exposure than this is also suitably low. In a perfect world we could rely on everyone to be responsible, considerate of others, and not have accidents. The real world of course falls short of this. The question is - how much should we curtail people's freedom to make decisions and have accidents for the sake of the safety of others?

6.2 Command and control type regulation

6.2.1 This is the most restrictive type of legislation and is the type most commonly used for regulating the use of radiation. Only approved practices involving radiation can be carried out. Only approved people who can demonstrate they are suitably trained and experienced are permitted to carry out critical tasks. The radiation equipment is subject to mandatory safety requirements.

6.2.2 A recent Australian review of whether the State radiation protection legislations restricted competition unduly or unfairly concluded that the prescriptive style as a basis for regulation was justified and generally supported by the community as long as there were uniform standards between the States (see ARPANSA 2001). The IAEA sample Act and regulations also follow the prescriptive model (see IAEA-TECDOC-1067).

6.2.3 There is very little choice left to the operator or user. There may be other practical ways of doing things safely, but only the way prescribed in the legislation is allowed. There are very few opportunities to cut corners or take chances. If the legislation is kept up to date and subject to consultation with the industry and any other affected parties, it should represent the industry standard for safe practice. It is the safest regulatory system, but it is also the most inflexible and most expensive to administer. There is always a danger of it getting out of date and so placing unreasonable burdens where practices or equipment have changed to become intrinsically safer.

6.3 Performance-based regulation

6.3.1 In this type of legislation the desired outcomes are set in regulation, but individuals are given freedom as to how to achieve the specified outcome. The only offence is to breach a particular safety standard. In the case of radiation it could be made an offence for anyone owning a source of radiation to expose anyone to more than a given dose limit. As long as they stay within that limit they can do what they like. This is rather like getting rid of all of the rules of the road but making it an offence to have an accident.

6.3.2 This style of regulation is promoted where possible. There is a minimum of administration, no mandatory requirements to check compliance with. It encourages personal responsibility and gives the individual the opportunity to solve problems in the most efficient and appropriate way.

6.3.3 The disadvantage with this type of regulation is that each individual can decide what level of risk of not meeting the required performance level is acceptable. Some are prepared to (or must, because of cost constraints,) take bigger risks than others. This may be acceptable as long as the consequences fall mainly on the individual or a few others who can be compensated. It is not acceptable if the consequences are borne by the public or may be catastrophic.

6.3.4 Given that it may be unacceptable to use performance standards as a basis for regulation, it is always possible to incorporate elements of it as acceptable compliance with prescribed standards, once a licensing or registration regime has been set up. The Australian national competition review (ARPANSA 2001) recommends that a performance-based approach be used wherever possible.

6.4 The risk management principle

6.4.1 This system is focused on dealing with risks directly. Rather than prescribing particular safe practices, or setting particular outcomes in legislation, it places responsibility on anyone wishing to carry out any practice involving radiation to manage the risks in the most effective way. It is usually set in the legislation how this must be done; by notifying and consulting with anyone who may be affected, and by using whatever risk assessment methods are appropriate.

6.4.2 It is common to invoke the “precautionary principle” when there is any uncertainty about the risks involved. The Hazardous Substances and New Organisms Act 1996 is an example of this approach:

“All persons exercising functions, powers, and duties under this Act, including but not limited to, functions, powers, and duties under sections 29, 32, 38, 45, and 48 of this Act, shall take into account the need for caution in managing adverse effects where there is scientific and technical uncertainty about those effects.”

6.4.3 The basic elements are:

- a “duty of care” requirement for anyone to avoid doing something that may put others at risk;
- a surveillance/response and assignment of controls role of the regulatory authority to manage the risks that may arise within the domain of regulation;
- the obligation of any individual to demonstrate that the risks associated with any proposed actions are being managed in a way acceptable to anyone who may be implicated.

6.4.4 The advantage of this type of regulatory control is that it is responsive to any changing circumstances or new directions, and it allows continuous reassessment of what is acceptable risk and reasonable costs for management. It ensures that any affected parties have an opportunity to be consulted, and it should result in standards that the community as a whole is satisfied with.

6.4.5. However the approach can be very wasteful of resources if the applications are all similar and can be more efficiently covered by regulation or standards. The end result can sometimes generate more controversy than agreement when the issue in question is subject to widely held differences of opinion. Unfortunately radiation can often fall into this category as evidenced by the continuing cell phone tower debate.

6.4.6 As with the use of performance-based regulation, it is possible to incorporate elements of risk management within a prescriptive regulatory system. The Australian national competition review (ARPANSA 2001) recommends that risk management methodology be used where possible.

6.5 Deregulation

6.5.1 In any review of legislation at some stage the question must be asked: is it necessary to regulate at all? There are always compliance costs associated with any legislation, and these costs must be borne by consumers or society. Are there already factors that are sufficient to maintain an acceptable level of safety without adding another layer of legislation? There may be commercial factors, such as a poor safety record reducing competitiveness in the market. Or if the individual engaged in the activity is likely to be the only one to suffer then voluntary education together with common sense may be sufficient. This is the case with recreational boating, where no licences or registrations are required.

- 6.5.2 There is another factor to regulation of radiation safety. Most other hazards produce immediate consequences. The likelihood of immediate and dire consequences always makes people careful. However many of the effects of radiation are long-term, and cannot be sensed immediately. If there is no perceived effect it is difficult to maintain safety procedures. It is universally accepted that at least some regulatory control of radiation safety is necessary to enforce safe practice.
- 6.5.3 Is there other safety legislation already in place that duplicates any regulation of radiation? There is already legislation governing health and safety in the workplace, medical practice, hospitals, transport, safety of hazardous substances, and protection of the environment. In principle, each could deal with the risks of radiation and radioactive materials within its own area without the need for a separate radiation safety regulatory authority. To an extent this already happens.
- 6.5.4 The International Atomic Energy Agency in a study of the national infrastructure required for radiation safety (IAEA-TECDOC-1067) does accept that in some countries there may be a division of regulatory responsibilities among two or more authorities. However a single organisation is given as the ideal, and in any case it is stressed that there must be a regulatory authority responsible for authorisations and notifications (registration and licensing) of the ownership and use of radiation sources. There is a considerable advantage in having a licensing or registration process that places the ultimate responsibility for all aspects of the “cradle to grave” safety of a radiation source on the natural or corporate person carrying out the practice.
- 6.5.5 In the New Zealand situation there may potentially be many ways of dividing the regulation of radiation safety. Each would have its advantages and disadvantages. For the purpose of this review the following points must be considered:
- The desirability of a “cradle to grave” regulation to ensure hazardous radiation sources do not get lost or are not vulnerable to trafficking;
 - The degree to which radiation requires specialist expertise that would need to be duplicated in each agency with regulatory responsibility;
 - In every State of Australia there is a single specialist radiation safety regulatory authority;
 - New Zealand is a small country so there will necessarily be a small number of radiation safety experts; are they better spread thinly among a number of different organisations, or is it better to maintain a “critical mass” of expertise in a single organisation?

6.6 The internationally recommended model for regulating radiation safety: the Basic Safety Standards

- 6.6.1 The International Atomic Energy Agency published the IAEA’s Basic Safety Standards (BSS, IAEA 1996) to assist countries developing or reviewing their legislation and to set a common internationally agreed framework for radiation

protection legislation. The BSS set out the basic principles and requirements for ionising radiations to achieve effective radiation protection and safety for the full range of practices and sources that could give rise to radiation exposure. It includes recommendations made by the International Commission on Radiological Protection (ICRP) and also takes into account the findings of the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR).

- 6.6.2 The BSS was jointly sponsored by the IAEA, International Labour Organisation (ILO), the Nuclear Energy Agency of the Organisation for Economic Co-operation and Development (OECD/NEA), the Pan American Health Organisation (PAHO), the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO). It reflects the consensus of experts from over fifty countries who participated in drafting the document.
- 6.6.3 The BSS continues to be a major source of international support for the regulatory approach to achieve radiation safety objectives. In 1999 the IAEA published a document to assist member states that wished to strengthen their regulatory control of radiation (IAEA 1999). This was jointly sponsored by FAO, IAEA, OECD/NEA, PAHO, and WHO, and gives an example of model legislation to assist drafting authorities.
- 6.6.4 The essential features of the model Act are:
- establishment of the regulatory authority that is independent of any department or body that uses or promotes the use of radiation;
 - definition of the practices and activities that are subject to authorisation by the regulatory authority;
 - definition of the powers, functions, and duties of the regulatory authority;
 - designation of the responsible parties under the Act as:
 - principal parties – those authorised by licence or registration, and employers;
 - other parties with subsidiary responsibility – users, suppliers, servicemen, advisors, etc.
 - prescription of the duties of the principal parties to establish, develop and implement a radiation safety programme commensurate with the nature and extent of the risks associated with the practice;
 - empowerment of the regulatory authority to make regulations.
- 6.6.5 The sample regulations are based on the most recent recommendations of the International Commission on Radiological Protection (ICRP 1991). The fundamental principles of protection recommended by the ICRP are as follows:
- justification: no practice that uses radiation should be adopted unless the benefits to the exposed individuals or society as a whole outweigh any detriment the radiation causes;
 - optimisation: in relation to any practice that uses radiation the individual radiation doses received, the number of people exposed to radiation, and the likelihood of incurring exposure should be as low as reasonably achievable, economic and social factors being taken into account;
 - individual dose and risk limits: limits of dose and risk should be set to ensure that no individual is subjected to an unacceptable level of risk.

- 6.6.7 In terms of the previous sections, this is mainly “command and control” type legislation. However the main thrust is to define responsibilities and safety goals. There is room within this for risk management and performance based elements. As written by the IAEA the model legislation includes only ionising radiation. However any prescribed category of non-ionising radiation could be included by defining the apparatus that generates it as a “radiation source” (or whatever term is used in a new Act).

There is the provision to exempt certain practices or sources if control is not considered to be necessary for safety. But essentially, no practice can be carried out unless an appropriate person has been authorised by the regulatory authority to take full responsibility for safety of the practice as a whole, and unless the practice complies with all of the requirements set down by the regulatory authority.

The principal parties referred to here are the corporate owner or employer. *This is fundamentally different from the New Zealand RPA.*

6.7 Options for the structure and location of the regulatory authority

- 6.7.1 Whatever type of regulatory system is chosen, it must be implemented and administered by an agency (or agencies) empowered by the legislation and funded by whoever gets the benefit from the legislation. Any agency must have the resources and expertise to carry out the administrative functions of processing applications for authorisations, licences, registrations, etc. Other functions such as investigations, provision of advice, compliance monitoring, and enforcement can in principle be performed by third party contractors. There may even be arguments for several agencies, each regulating an aspect of radiation safety. This section discusses the options.
- 6.7.2 The first option is the “one-stop-shop”. A single regulatory agency carries out all of the functions associated with the radiation safety legislation, and provides support and advisory services as well. This has the advantages of concentrating the expertise in a single establishment rather than as isolated individuals in other establishments. Maintaining all of the expertise in the subject in one place for professional support may be the only way of attracting and developing the skills essential to intelligent and informed administration of the legislation. There is also benefit for the industry in having a single point of contact for advice, administration, and services.
- 6.7.3 But there are some disadvantages to the one-stop-shop model. There is a potential for conflict of interest between the regulatory and service functions. For example, where support services have to be approved by the agency, that must include the agency’s own services. Also, the concentration of radiation safety in one agency under the Ministry of Health results in a corresponding fragmentation in other safety control agencies. So, for example, occupational safety and health is split between the Occupational Safety and Health Service (OSH) under the Department

of Labour and the radiation safety agency (which would cover the occupational use of radiation).

- 6.7.4 There are two possible alternatives to the one-stop-shop. The first is that the agency could be split into separate regulatory and service parts. There is then no conflict of interest and the services can be operated as a user-pays commercial business. However there is a resulting fragmentation of expertise and the loss of some efficiencies through sharing of overheads, skills, and equipment.
- 6.7.5 The second alternative is that the agency is distributed among several other bodies that deal with safety. Thus the Land Transport Safety Authority could be fully responsible for enforcing the safe transport of radioactive materials under a new Rule under the Land Transport Act 1998. Similarly all of the other legislation dealing with some aspect of safety could include radioactive material, or the use of radiation, and the corresponding authority would enforce it. This has the advantage of integrating radiation into these authorities, but fragmenting the overall control of radiation. The regulatory wisdom of doing this was discussed in the previous section. But whether either of these scenarios has merit in terms of the regulatory agency/agencies depends crucially on to what degree radiation is unique and needs to be dealt with by a specialist unit, and the need to achieve “critical mass” for the agency to attract and foster the required expertise.
- 6.7.6 The regulatory authority that currently administers the RPA is the National Radiation Laboratory (NRL). It is a business unit within the Public Health Directorate of the Ministry of Health. NRL has been in existence for over 50 years, and provides a “one-stop-shop” for radiation safety in New Zealand. It has the following functions:
- administration of legislation – licensing and other authorisations, compliance monitoring;
 - provision of advice to the government, public, and third parties;
 - environmental radioactivity monitoring – fallout monitoring, food certification, involvement in the Comprehensive Test Ban Treaty monitoring sites;
 - radiation protection services – personal dosimetry service, calibration and standards laboratory, other miscellaneous services.

The structure and location of NRL has been reviewed many times over the last 20 years, in the context of health, occupational safety, hazardous substances, resource management, and ideal regulatory models. The outcome of all of these reviews is that the structure of NRL has remained more or less unchanged from 50 years ago. For a country the size of New Zealand it was consistently concluded that the benefits from having a single specialist unit able to provide services, advice, and regulatory functions outweighed any disadvantages. The international regulatory model places great importance on the competence of the regulatory authority (see IAEA 1999), and in the New Zealand context this must be seen as supporting the integrated unit.

- 6.7.7 While reviews of NRL all recommended that the regulation of radiation safety was best administered by a single unit within the health sector, there were some suggestions that the regulatory agency should be an independent body responsible to the Minister of Health but outside the Ministry. This would avoid conflicts of interest, both in terms of enforcement and funding. Thus NRL could be part of a

Crown entity and have the functions of promoting, enforcing, and setting standards of radiation safety, as prescribed by the empowering Act. The Ministry of Health would retain policy-making functions concerning radiation safety. A Crown entity would satisfy the Basic Safety Standards model (see next section).

- 6.7.8 The location of NRL inside or outside the Ministry is not a simple issue. A conflict of interest situation would be more likely if NRL was for example within a ministry of nuclear energy rather than a health ministry. Furthermore, the Ministry of Health has other aspects of health regulation amongst its core business, so NRL is not unique in this respect. This is an issue that must be debated fully.

6.8 The Ministry's preference for regulatory style

- 6.8.1 After reviewing the radiation safety regulatory systems in many countries and holding discussions with many of the regulators, the Ministry has a provisional preference for the way it would like to see radiation safety regulated in New Zealand.
- 6.8.2 Because of the risks to the public from radiation, the Ministry does not feel that performance-based legislation would provide sufficient protection. Commercial pressures can lead operators to make economies that compromise safety to a level that would not be acceptable. None of the other regulatory systems reviewed placed the primary control on achieving a prescribed level of performance. In each case radiation practices, sources, and operators must be licensed or registered, after satisfying strict prerequisites, before any use of radiation could begin. Once responsibilities and safety standards are established in law there is room for a performance-based approach.
- 6.8.3 The Ministry considers that unlike areas such as public health, where risk management principles may be appropriate as a basis for regulation, radiation protection is more effectively regulated under a largely prescriptive system. However, the methodology of risk management should be used where appropriate within the framework set up by the legislation.
- 6.8.4 The Ministry also considers that deregulation and total reliance on other health and safety legislation is not a plausible option. Existing health and safety legislation cannot be guaranteed to cover all possible uses, and such fragmentation always carries the danger of things “falling through the cracks”. In other countries regulatory systems are based on a single regulatory authority that maintains jurisdiction over the use and ownership of sources of radiation from cradle to grave.
- 6.8.5 Because effective implementation of radiation safety legislation and other support services requires specialist knowledge and experience, the Ministry is in favour of keeping the regulatory authority in its present form as an integrated unit. However

any decision on whether it should remain within the Ministry of Health or not will depend on the outcome of the present review.

6.8.6 The preferences expressed in this section are only provisional and will be reviewed after opinion has been canvassed before definite policy is developed.

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?

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?

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.

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

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

The previous section discussed which regulatory system the Ministry of Health believes would be the best for New Zealand. However changing legislation comes at a cost, both in terms of resources and in disruption to all those affected by new administrative systems and costs that may be set up. It is necessary to review whether there are other options that may achieve a satisfactory result at less cost.

7.1 Do nothing at all

For some time now, NRL as the regulatory authority administering and implementing the RPA has endeavoured to extend the applicability of the legislation through Codes of Safe Practice. Compliance with a Code is made a condition on licences, and this brings the Codes into force. However the legal robustness of this has never been tested.

Furthermore, most of the requirements in the Codes concern installations, equipment, and procedures. But the Codes are binding only on individual user licensees, not the owner of the facility or business. NRL has developed the concept of a “principal licensee” who has overall responsibility for compliance with the Code. This may be a plausible interpretation of regulation 9(3)(b), but there is some doubt about whether the RPA can empower this regulation. This is obviously a very shaky structure for a regulatory system.

Choosing not to change any of the legislation means continuing to live with this system. It is certainly the easiest and cheapest option in the short term but there is a serious risk of embarrassment if the legislation is challenged and fails.

7.2 Do nothing to the RPA but change the RPR

It is easier to change regulations than rewrite an Act. But regulations can be made for a specific purpose only if the Act allows for this. There are parts of the RPR that are ambiguous, out of date, and possibly not even empowered by the RPA. If the RPA is not changed then the RPR certainly must be. But any new regulations would still be restricted to what is empowered by the RPA. It is not possible to change the fundamental responsibilities that the RPA sets up.

While a careful revision of the RPR would be the fallback position in case it becomes impossible to rewrite the RPA, it cannot be seen as a solution to all the RPA’s inadequacies, and would not produce legislation that took account of the Basic Safety Standards, or the Trans-Tasman uniformity goals. The Ministry does not consider this option to be anything other than a last resort.

7.3 Develop a new Act from first principles

Any review of legislation must ask whether we should accept that everyone else is right and follow their example, or whether to look at the problem with fresh eyes and start with a clean slate from the New Zealand perspective. There are types of legislative structure other than the standard international model, as discussed in a previous section.

However the desire to be original has to be set beside a consensus arrived at after a considerable amount of effort by major multi-national bodies whose prime concern is health and safe working conditions. Is it likely to come up with anything different, after all of the previous reviews, conferences, reports, etc? Is it a wise commitment of resources, when adopting the international model will at least provide what a very large part of the world already finds satisfactory? The Ministry thinks not.

7.4 Adopt and adapt international best practice

There is little argument about what constitutes international best practice in the regulatory control of radiation safety. The principles of best practice have been thoroughly worked out and clearly set down in the Basic Safety Standards. This includes the establishment of a single radiation safety regulatory authority. Examples of legislation that satisfy the principles have been published by the IAEA, and are embodied in the Australian National Directory for Radiation Protection.

The most recent legislation passed in Australia is the Queensland Radiation Safety Act 1999 and Radiation Safety Regulation 1999. This was intentionally drafted to comply with the international model. There would be a considerable efficiency gain in starting with these examples when formulating drafting instructions for the new legislation. The Ministry considers this is prudent and robust, and supports the approach.

Summary of Section 7

- The RPA has serious deficiencies. There are four possible courses of action to consider:
 - continue with the present legislation;
 - leave the RPA as it is but amend the RPR;
 - 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 New Zealand should have a new Radiation Safety Act?

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.

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

8. Outline of possible new radiation safety legislation

The following is the outline of a regulatory structure that would be consistent with the Basic Safety Standards and Trans-Tasman recommendations. It follows similar lines to the Queensland Radiation Safety Act 1999. Note that the Act sets up the powers and responsibilities of the various parties. The actual safety standards that are to be enforced are prescribed in the standards or codes of practice that may be adopted, or in the regulations made under the Act. Both of these processes would take place after the Act has passed. Initially the codes of practice that are currently used as licence conditions (see <http://www.nrl.moh.govt.nz/publish.html#codes>) would probably be adopted. A list of suggested items to be included in regulation is given below.

Radiation Safety Act

Purpose of the Act

The Act should have a clearly stated purpose that will be the basis for the interpretation of all other provisions. An example is:

“The purpose of the Act is to protect the health and safety of all people and the environment from the harmful effects of ionising and non-ionising radiation.”

Coverage

The Act should cover radioactive materials, and apparatus that generates either ionising or hazardous non-ionising radiation. The specific apparatus to be included can be prescribed in regulations.

Establishes the regulatory authority

The Act should establish a regulatory authority that has the powers, functions and duties defined in the Act. This authority may be the Minister who then delegates some or all of the administration of the Act to a section of the Ministry as at present. Consideration should be given to establishing the regulatory authority as part of a Crown entity.

Licences to possess

Any legal person (either an individual person or a legally established corporate entity) wishing to own a source of radiation must first be granted a licence to possess. The applicant for a licence will be required to supply details of how radiation safety will be managed. The licensee will then be responsible for the overall management of the safety of the source.

Licences to use

Any individual person wishing to use radiation must first be granted a licence to use. The applicant for a licence will be required to demonstrate sufficient training and experience to be able to carry out the proposed use of radiation safely. The licence will then both authorise the licensee to use radiation subject to appropriate conditions, and make the user responsible for safety during the use.

Licences to transport

Any individual person in charge of a vehicle transporting radioactive material must hold a licence to transport. An applicant will be required to have appropriate safety training and will be responsible for the safe custody of the radioactive materials while they are in his or her care.

Registration of radiation sources and facilities

When a radiation source is acquired (by a person holding a suitable possession licence) it must be registered in the name of the licensee. The registration will be subject to the source meeting prescribed safety standards. Any prescribed facility where radiation is used and where the design of the facility is an intrinsic part of safety must be registered in the name of the possession licensee, or the owner of the facility if there may be more than one possession licensee.

Importing, exporting, buying, selling, and disposal of radiation sources

Each of these activities will be controlled through requirements to hold possession licences together with prompt notifications. They will not need to be discretionary, requiring the consent of the regulatory authority, because approval is already effected through the possession licence. Disposal must be in accordance with regulations, a code, or a standard specified in a condition on the licence.

Accreditations

The Act should give the regulatory authority the power to accredit persons or suppliers to carry out roles that are a necessary part of radiation safety management. These may include radiation safety officers, safety inspectors, or radiation dosimetry services.

Standards and Codes of Safe Practice

The regulatory authority may produce or adopt Standards or Codes of Safe Practice that may then become mandatory conditions on licences or registrations. The process of adoption or production will be required to include due consultation with all interested parties.

Establishment of an advisory council

The regulatory authority must appoint an advisory council that includes radiation safety experts, and industry and consumer interests to provide advice to the regulatory authority on:

- policy concerning the administration and implementation of the Act;
- any applications for licences or registrations referred to it by the regulatory authority;
- standards or codes of safe practice;
- regulations under the Act;
- any other matters of radiation safety that may be of regulatory concern.

Rights of appeal

Any person who is not satisfied with a decision of the regulatory authority may appeal in the first instance to the advisory council, and then to the District Court to have the decision reconsidered.

Enforcement and investigations

The Act will enable an authorised person to enter premises, to take samples, measurements or data, to seize or embargo equipment or materials, to stop a vehicle, and to have emergency powers, for the sake either of investigating an offence against the Act or other potentially hazardous situation, or of mitigating a dangerous situation.

Power to make regulations

The Act should empower the regulatory authority to make regulations for any of the following purposes:

- defining radioactive materials, ionising radiation sources, and hazardous non-ionising radiation sources;
- providing for exemptions from some or all of the regulatory requirements;
- prescribing requirements for disposal of radioactive materials;
- setting limits of radiation dose;
- providing for restrictions on buildings, structures, or installations that cause an increase in the exposure of the public or environment to radiation;
- setting fees;
- providing for any other requirements necessary for implementation of the Act.

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

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

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

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.

Glossary

Alpha particles: high-energy particles that are emitted from some types of radioactive material when it decays.

ARPANSA: The Australian Radiation Protection and Nuclear Safety Agency (set up by the Australian Radiation Protection and Nuclear Safety Act 1998).

BSS: The International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources. (See IAEA 1996).

Electromagnetic fields: electric and/or magnetic force fields that are generated when electric current flows in conductors.

FAO: Food and Agriculture Organization of the United Nations.

Gamma rays: high-energy electromagnetic radiation (photons) produced by radioactive decay.

Half-life: The time it takes for the activity of a sample of a particular radioactive material to reduce to half of its initial activity.

IAEA: International Atomic Energy Agency; an inter-governmental forum for scientific and technical cooperation in the nuclear field. New Zealand was one of the founding members when it was created in 1957. There are currently 132 member countries.

ICRP: International Commission on Radiological Protection.

ILO: International Labour Organisation of the United Nations.

Ionising radiation: radiation with sufficient energy to ionise (knock electrons from their orbitals within) atoms or molecules and hence change chemical or molecular structure.

Irradiating apparatus: any equipment (powered by electricity) that is capable of generating radiation.

Laser: a device for generating an intense narrow beam of monochromatic light (from the acronym for *light amplification by stimulated emission of radiation*).

Linear accelerator: a machine that generates high-energy radiation by accelerating electrons along a straight wave-guide; used either to produce an electron beam or to generate x-rays from the electrons. This is the most common treatment machine used for medical radiation therapy.

Natural background radiation: the radiation that occurs naturally in the environment from solar and cosmic radiation or natural radioactive materials in the environment.

Non-ionising radiation: radiation of insufficient energy to cause ionisation. It is mainly absorbed as heat, but may produce induced electrical effects as well.

NRL: National Radiation Laboratory.

NUIP(RC): National Uniformity Implementation Panel (Radiation Control); a panel set up under the Radiation Health Committee formed under the Australian Radiation Protection and Nuclear Safety Act 1998; responsible for facilitating the development of uniform regulatory standards among the Australian States.

Radiation: any type of energy or particles that travels outwards from a source.

Radioactive gauge: a sealed radioactive source that is used for measuring some parameter during an industrial process.

Radioactive material: material formed from nuclei that are unstable and spontaneously decay into other more stable nuclei, emitting radiation in the process.

Risk: In the context of this discussion document, the risk of *something happening* means the likelihood of it happening (usually referring to an undesirable event); but the term on its own (eg, “Exposure to radiation may involve a health risk.”) should be interpreted as the combined weight of the likelihood and the severity of the event.

RPA: Radiation Protection Act 1965.

RPR: Radiation Protection Regulations 1982.

Source (radiation source): Any item that generates radiation; it may be radioactive material or irradiating apparatus.

UNSCEAR: United Nations Scientific Committee on the Effects of Atomic Radiation; a specialist committee that reports annually to the United Nations.

WHO: World Health Organization. A body set up under the United Nations; New Zealand is a member.

X-rays: ionising radiation generated by directing a beam of electrons that has been accelerated up to high energy onto a metal target. The resulting radiation is electromagnetic (photons) and differs from gamma rays only because of the type of source.

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Consultation questions

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

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

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

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

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

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

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?

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?

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

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

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?

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.

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

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

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.

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

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

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

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.