Revolution in New Zealand’s Radiation Protection Legislation and Evolution and Continual Improvement in its Regulatory Authority

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Abstract  
The safe use of ionising radiation in New Zealand is regulated by the Radiation Protection Act 1965 and the Radiation Protection Regulations 1982, which are administered by the National Radiation Laboratory (NRL). This legislation is now out of date and creates difficulties for New Zealand in meeting international standards of radiation safety and security, and complying with obligations under international treaties. These problems can be addressed by new legislation that would change the powers and functions of the regulatory authority, and change the responsibilities of licensees under the Act. However historically NRL has provided radiation services as well as acting as regulatory authority. This has the potential to create a conflict of interest in making regulatory judgements. Over the preceding 50 years NRL has undergone an evolution that has resulted in a clarification of the regulatory functions, and development of a quality management system that is now accredited to ISO standards. This paper presents a possible structure of a new Act, and discusses the role of quality management in maintaining the independence of regulatory authority.

1. Introduction  
Radiation protection is undergoing a major revolution in New Zealand. It is moving away from the paternalistic culture of the 1950’s to the risk-management based legalistic culture of the 2000’s. Because under the new culture safety standards are maintained by the force of law rather than advice from “trust me and do what I say” experts, the legal system must be robust, and the regulators must be seen to be impartial and trustworthy.

There are good reasons for making the cultural changes, but also difficult decisions that must be made. It is a process that is underway in many countries, but the fact that New Zealand is a sparsely populated country of only 4 million people means that some of the problems must be approached in a different way in comparison with larger countries.

This paper discusses the pressures to change both the legislation and the regulatory authority, and explores the reasons for and against the various options open to New Zealand for dealing with them. The views and proposals presented here are only those of the author and do not represent the policy of the New Zealand Government.

2. The Radiation Protection Legislation  
This section will present the historical background to the legislation that is currently in force. It will discuss the inadequacies and problems caused by the legislation, and the drivers for new legislation. It will conclude with an overview of proposed new legislation that will satisfy the needs of the foreseeable future.

2.1 History  
The safe use of ionising radiation in New Zealand is currently regulated by the Radiation Protection Act 1965 (RPA). This is administered by the National Radiation Laboratory (NRL). The Act is closely based on the previous Radioactive Substances Act 1949. This former Act was originally drafted in the early 1940’s at the request of radiologists who were concerned about the safety of staff using radiation. At that time the most common use of radiation was the use of x-rays for medical
diagnosis and therapy, radium, radon, and some I-131 for therapy, and unsealed radioactive materials for research. Radioactive materials and x-ray machines were generally owned by the person using them. In the early 1960’s the Act was revised in order to address mainly technical details. The new Act was passed in 1965, but was not brought into force until 1973 to coincide with the Radiation Protection Regulations 1973. The regulations were revised in 1982, but again this was a minor technical revision.

2.2 **How the RPA operates**

2.2.1 *Regulatory powers under the RPA*

The RPA gives the powers of authorization and approval to either the Minister of Health, or the Director-General of the Ministry of Health. Most of these powers are delegated to NRL. The Ministry of Health also funds and sets high-level policy for the public health system, which includes all of the country’s radiation therapy facilities, and about half of the diagnostic x-ray facilities. In this respect the Ministry can be considered the major user of radiation in New Zealand.

2.2.2 *The Radiation Protection Advisory Council*

The RPA establishes the Radiation Protection Advisory Council (RPAC) consisting of the Director-General and a group of experts appointed by the Minister. There is no lay membership, nor any direct representation by members of interested parties. The functions of the RPAC are to advise the Minister and Director General in respect of their powers and functions under the RPA.

2.2.3 *Licences to use radiation*

The primary control of the safe use of radiation is through licensing of individual users. Everyone using radiation has either to have a licence, or to work “under the supervision or instructions” of someone with a licence. Considerable time has been spent debating what “under the supervision or instructions” means. Licences can be made subject to special conditions. Generally there is a requirement for the user to comply with a Code of Safe Practice, written by the NRL for that particular use of radiation. It has never been tested in Court whether this is valid under the section of the Act empowering conditions on licences.

2.2.4 *Controls on obtaining radiation sources*

The prior consent of the Minister is required for the acquisition of radioactive material. There is however, no formal registration of radiation sources or on-going licensing of the owner. In the case of irradiating apparatus, the seller must notify the regulatory authority of a sale, but no prior consent is required. Furthermore, irradiating apparatus can be sold only to a person holding a licence allowing the use of it. Because licences can be held only by individual people, this strictly speaking prohibits corporate ownership of irradiating apparatus!

2.2.5 *The Radiation Protection Regulations*

The Radiation Protection Regulations 1982 attempt to set up safety standards and responsibilities, but there is considerable doubt as to whether the powers under the Act are sufficient to give them legal force. The regulations require the owner (even though the “owner” is not identified in the Act) to ensure there is always a suitably licensed person to take responsibility for the radiation sources. Once this is done almost all of the responsibility for the safety and security of the sources rests with the user licensee rather than the owner. This includes ensuring secure storage, and that other users are suitably trained. If there are several licensees at one site the “employer” (again a term not defined in the Act) must either designate respective areas of responsibility or appoint one to “supervise the regulatory compliance by the others”. There is uncertainty as to how this should be administered, or even exactly what it means.
2.3 The problems

2.3.1 Lack of regulatory independence
The RPA was written at a time when the public accountability of government departments was not held under as great a scrutiny as it is now. It was quite clearly the intention that the priorities both of the political party of the day through the Minister, and of the (then) Department of Health should be considered in administering the RPA. Even the advisory body, the RPAC is not independent in that it consists of Ministerial appointees together with the Director-General. There is no provision for an independent watchdog role. It can be argued (and indeed is strongly) that a Ministry of Health will have a primary concern for the health of the nation, and that any conflict of interest will be benign, compared, say, to a Ministry of Atomic Energy (which does not exist in New Zealand). However there is still the possibility (either perceived or real) that the political need to win votes by, for example shortening waiting lists for radiotherapy, could lead to cutting corners in radiation safety. While it is sensible that the overall health perspective be maintained, to ensure that resources are not being squandered on trivial radiation hazards, the directives from Health, or indeed any other interested party should be transparent and open for public scrutiny.

2.3.2 Lack of managerial liability
Corporate use of radiation, for example in large hospital departments or manufacturing plant, causes ambiguities in liability under the RPA. In a hospital department there may be many licensed users. Most of the regulatory requirements for a radiology or radiation oncology department involve equipment and procedures rather than individual use. These are prescribed in the Code of Safe Practice that all of the licensees must comply with. If there is an incidence of non-compliance it may be ambiguous who is responsible for remedying it.

In an industrial plant that uses installed sealed radioactive sources, it is very ambiguous who the “user” is. It could be the general manager, or the service engineer, or the operator of the part of the plant that uses the sources. If a source is lost everyone blames someone else. If the licensee responsible at the time has left the country then nobody can be held liable. This has happened.

2.3.3 Other problems
There are other technical problems as well. Transport is not controlled well. It is unclear who is responsible if a package containing radioactive material becomes lost during transit. There are no powers of intervention in case of a dangerous situation, and no power to seize or take control of a dangerous radiation source. The only immediate power of intervention available is cancellation of a licence. But most offences involve an unsafe radiation source rather than an individual, and since the licence is only a user licence there is nothing technically stopping another person who still has a licence from using the offending item of equipment. There is the power to confiscate a radiation source after a successful conviction of the owner for an offence under the Act, but this process can typically take months or years, and is not effective for addressing an immediate hazard.

2.4 Outside drivers

2.4.1 BSS
The IAEA Safety Series No. 155 (International Basic Safety Standards for Protection against Ionizing Radiation and for the Safety of Radiation Sources) lays out fundamental principles of the control of radiation safety. Two of these are that the primary responsibility for the safety of a practice using radiation must rest with the legal party carrying out the practice, and that any practice using radiation must be subject to prior authorisation of the regulatory authority. The NZ regulatory system fails on both of these. There is considerable international pressure for States to strengthen their regulatory control of radiation safety in order to avoid major radiation accidents, or radiation sources becoming lost or getting into the wrong hands.
2.4.2 Code of Conduct
More recently the IAEA has drafted a Code of Conduct on the Safety and Security of Radioactive Sources. This places obligations on regulators to maintain a formal register of radiation sources, to ensure that for each source there is at all times someone responsible for security, and any radiation sources exported go only to jurisdictions where safety and security can be assured. New Zealand is under political pressure to adopt this Code, but fully compliance is not technically possible under the present regulatory system.

2.4.3 Other international conventions
Convention on the Physical Protection of Nuclear Material – the Convention establishes requirements for the protection of nuclear material during international transport and requires States to incorporate offence provisions in their national law relating to the theft of nuclear material. New Zealand has signed the Convention but not yet ratified it.
Adoption of both of these Conventions would require changes to the Act.

2.4.4 Uniformity with Australia
The Australian Radiation Protection and Nuclear Safety Act 1998 requires the CEO of the Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) “to promote uniformity of radiation protection and nuclear safety policy and practices across jurisdictions of the Commonwealth, the States and the Territories”. The National Uniformity Implementation Panel (Radiation Control) has been set up under the ARPANS Act to oversee the harmonisation of the Australian State jurisdictions. New Zealand has a formal place on the NUIP(RC) and there is a Ministerial commitment for NZ to take account of any resolutions when our legislation is reviewed. The NUIP(RC) is formulating a National Directory of Radiation Protection that prescribes all the regulatory elements that each jurisdiction within Australia must align with to achieve acceptable uniformity.

2.5 The options
Given that the NZ legislation has deficiencies, both in its effectiveness and in comparison with international standards, the Ministry is faced with the following options:

1. Continue with the present legislation, being aware of the inadequacies and potential problems. We have survived for nearly 40 years by adapting the present system and relying mainly on Codes of Safe Practice, and this has not up till now been challenged legally. But society has become more litigious. It is now more likely that an expensive requirement under the RPA would be challenged in Court. Simply waiting for this to happen is not seen as a responsible option.

2. Attempt to rectify some of the deficiencies by amending the regulations but not changing the Act. Changing regulations is much simpler than changing Acts. But this is not a viable option for a technical reason. It is only possible to write regulations that are empowered by section 31 of the RPA. It is the fundamental structure of the RPA that is wrong, and it would not be possible to improve this significantly given the limited provisions of section 31.

3. Initiate a fundamental review of radiation protection and re-design the regulatory system from first principles. This option is provided as an alternative to the next one, namely accepting the consensus regulatory model that is be implemented in other countries as being the best solution.

There has been a considerable amount of work gone into refining the regulatory control of radiation safety, and now there is a widespread call for uniformity. This paper will expand on Option 4 above to demonstrate how this would successfully address the problems listed above.

2.6 Proposals for Legislative Change

2.6.1 Establish a Director for Radiation Safety with defined functions and duties
The IAEA Code of Conduct and Basic Safety Standards require that national legislation establish a regulatory authority whose regulatory functions are effectively independent of any Government department or other agency that promotes any of the practices regulated. Currently all of the regulatory powers lie with either the Minister or Director-General of Health. In order not to pre-empt future policy development on the structure and governance of the regulatory authority, it is proposed that the legislation formally establish a Director for Radiation Safety, with provision for the appointment of a suitable person by the responsible department. This would provide maximum flexibility about future organisational arrangements (including initially accommodating the present arrangement) and allow the new legislation to be progressed independently.

2.6.2 Amend provisions on the Radiation Protection Advisory Council
It is proposed that new legislation continue to provide for a Radiation Protection Advisory Council as it is important as a source of independent advice and for demonstration of the impartiality of the actions of the Director of Radiation Safety. However, the Council currently consists only of the Director-General of Health and a group of experts appointed by the Minister of Health. The composition of the Council needs to be adjusted to reflect the need for effective independence from the Ministry of Health and to represent a wider range of interests. Specifically, it is proposed that the Director-General of Health be removed from the Council and that provision be made for a layperson to be appointed to the Council. It is also proposed that the functions of the Council be updated with the Council advising the regulatory authority and responsible Minister on general matters of radiation safety and standards rather than on applications for licences.

2.6.3 Introduce a new licensing framework
It is proposed that a new licensing framework be introduced that places the primary responsibility for radiation safety on the person or organisation responsible for the management of a radiation source, with that person or organisation being required to apply for a “licence to possess” a radiation source. This would ensure that there is a clear point of responsibility and would be consistent with other New Zealand legislation on safety in the workplace. It is also necessary to give effect to the IAEA Code of Conduct, and would be consistent with the Australian National Directory of Radiation Protection (see above). It is proposed that a licence to possess a radiation source also be required in situations where a third party is temporarily in control of a radiation source for a particular purpose, including importers and servicing companies.

It is proposed that, as part of their application for a licence to possess, applicants may be required to submit a “radiation safety plan”, appoint a radiation safety officer and comply with a Code of Safe Practice (discussed below). Provision for radiation safety plans is necessary to give effect to the IAEA Code of Conduct. Plans would set up a formal responsibility structure, standard safety procedures and record keeping requirements, and would cover (i) a safety assessment and plans for the safe use of the radiation source, (ii) a security plan, and (iii) emergency plans as appropriate.

2.6.4 Enable the development of Codes of Safe Practice
It is proposed that the Director for Radiation Safety be empowered to approve Codes of Safe Practice to provide mandatory requirements for the safe and secure use of radiation sources. The National
Radiation Laboratory has already developed Codes of Practice, compliance with which may be made a condition of a licence. However, it is not clear whether compliance with the codes is enforceable under current legislation. Explicit legislative authority is therefore necessary. The advantage of setting out mandatory requirements for safe practice in codes rather than in the regulations is that it enables international radiation safety developments (on what are largely technical matters) to be adopted relatively quickly.

2.6.5 Require registration of radiation sources
The IAEA Code of Conduct places a strong emphasis on the security of radiation sources and requires that a national register of radioactive sources be established that includes, at a minimum, Category 1 and 2 radioactive sources listed in the Annex to the Code. It is proposed that a broader approach be taken with the Director for Radiation Safety being required to maintain a national register of all radiation sources and premises on which unsealed radioactive materials are used or stored. As required by the IAEA Code of Conduct, it is proposed that the register be confidential and not available to the public for reasons of public and national security.

2.6.6 Introduce new enforcement and emergency powers
The IAEA Code of Conduct and the Australian National Directory require that the regulatory authority have the capacity to take appropriate enforcement actions and to take control in a radiological emergency. It is proposed that the Director for Radiation Safety have the following powers:

(a) compliance orders – it is proposed that the Director be able to issue a compliance order to a possession licensee, requiring the licensee to either do something or refrain from doing something in order to ensure compliance with regulatory requirements and/or protect the health and safety of people and the environment.

(b) power to seize a radiation source - it is proposed that the Director have the power to seize and take control of a radiation source if the source is not under the control of an appropriately licensed person or organisation, it is unregistered, it has been stopped by Customs, or if the Director believes it is necessary to avert a serious radiation hazard.

(c) power to stop a vehicle - it is proposed that the Director have the power, in conjunction with the Police, to stop a vehicle if there are reasonable grounds to suspect that the vehicle has been involved in an offence, something in the vehicle may provide evidence of an offence against the Act, or a person’s health and safety may be adversely affected by exposure to radiation because of the transport of radioactive material in the vehicle.

(d) emergency powers - it is proposed that the Director be able to declare an emergency in situations involving actual or imminent danger to the health and safety of people or the environment as a result of exposure to radiation, and that the Director have emergency powers that would enable the Director to enter a site without consent or a warrant, to give directions and take control of any property in order to limit or mitigate any adverse effects.

2.7 The path forward

The discussion in the previous sections represents the opinions of the authors about the structure of legislation that would meet both international and national requirements. A formal review of the Act is currently underway, and the response to a public discussion document released in December 2002 was generally supportive of drafting new legislation. Government approval has been received to proceed with policy development in consultation with interested parties. It is hoped that presentation of this paper will widen consultation to the international community.
3. The Regulatory Authority

This section traces how the New Zealand radiation protection regulatory authority, the National Radiation Laboratory (NRL) has evolved and changed in its focus and modus operandi to meet the changing style of national management of radiation safety.

3.1 Historical development

In the 1940’s the Laboratory (“The Radio Physics Laboratory”, then in 1947 “The Dominion X-Ray and Radium Laboratory” and then in 1963 the “National Radiation Laboratory”) was mainly involved in calibration and maintenance of the 18 clinical dosemeters in NZ, measurement of X-ray therapy output, and advice to radiotherapists. As well it ran a radon plant, supplying over 3 curies per year to the radiotherapy profession in gold needles, or gold seeds, or ointment.

From an annual report published in the 1960’s the Laboratory aimed “at stimulating and maintaining the interest of radiation workers in safe working habits and conditions and in advising and teaching people how to protect themselves and others from the harmful effects of radiation rather than confine itself to acting as ‘enforcer’ of the letter of the law.” NRL played a paternal role of looking after the safety of the radiation users. The first Codes of Safe Practice, written in the 1970s, were advice on basic radiation safety and good practice for an industry that was largely ignorant of these. “Field officers” from NRL would visit users and advise them on safe practice, and also check and calibrate equipment. This was all provided as a service free to users, but funded by the taxpayer. There was no suggestion of enforcing the Codes, and they were not written in a form that would allow compliance to be readily determined.

Not only did NRL play a paternal role, but also the users played an adolescent role. The industry was not capable of taking responsibility for its own radiation safety because it did not have either the corporate knowledge or the infrastructure. All of this at that stage resided within the early NRL. Between 1950 and 2000 a number of developments took place. With the increasing sophistication of radiation therapy came a new group of professional medical physicists in the medical area. They took over responsibility for radiation dosimetry, shielding design, and general radiation safety in the medical area. Later on the same trend occurred in the diagnostic x-ray area. By the end of 2000 NRL was no longer performing any routine medical physics work, only spot checks in order to audit the in-house work. During the same time, there was a move for company management to take responsibility for occupational health and safety, under the Health and Safety in Employment Act 1992. It is the employer’s responsibility to ensure a safe work environment and to ensure that workers are suitably trained to be able to work safely. In this legal environment it was sensible that the site Safety Officer include radiation safety his/her portfolio. We have reached the stage where NRL no longer provides routine services of quality assurance, safety advice, or dosimetry to the industry. This is now provided either by in-house expertise or by private contractors.

3.2 NRL today

NRL currently has a staff of 30 and still retains some advisory and service functions as well as the administration of the RPA. The following is a brief summary.

3.2.1 Administration of national radiation protection legislation.

- Licensing of competent operators of sources of ionising radiation.
- Issuing consents to import, sell, or export radioactive materials and receive and record notifications of sale of irradiating apparatus.
- Monitoring compliance with the requirements of the Act, Regulations and Codes of Safe Practice.
- An emergency response capability is maintained to ensure that public safety is maintained in real or suspected radiation exposure situations (such as a road accident where radioactive
materials are being transported or a fire in a building in which radioactive material is housed). This activity is coordinated with other emergency response services.

3.2.2 Provision of advice on radiation safety issues
- Advice is given on request to the Government and the public on general matters of radiation safety.
- NRL also maintains expertise in non-ionizing radiation, and can advise and do measurement surveys and assessments for radio transmission towers, lasers, etc.
- NRL also publishes Guidance Notes to assist in compliance with the Codes of practice.

3.2.3 Environmental radioactivity services
- Monitoring the environment for radioactive fallout. This is a practice that was established by Parliament at the time of atmospheric atomic weapons testing in the Pacific.
- Analysis of radioactivity content of a variety of environmental and food samples.
- Comprehensive Nuclear Test Ban Treaty (CTBT) monitoring station operation. NRL has been involved in site surveys, installations and continuing station maintenance.
- CTBT radionuclide laboratory operations. The Treaty establishes 16 laboratories around the world to support the activities of the radionuclide monitoring stations and NRL is named as one of these.
- CTBT National Data Centre operations. National data centres are established to advise Governments about the meaning of data coming from the CTBT monitoring station network in order to assist in the political process described in the treaty when a weapons test is suspected.

3.2.4 Radiation Protection Services
- The Personal Dosimetry Service, which provides a means of measuring an individuals exposure to radiation encountered during the course of their work.
- Calibrations and Standards, which provides calibrations of radiation measuring instrumentation to ensure that the readings they give are accurate.
- Radio Frequency (RF) and Extremely Low Frequency (ELF) radiation and field measurements, to assess human exposure to radio transmitters and power sources.
- Education and Training is about the delivery of specialised training programs related to radiation safety.
- Waste management, which provides a means for owners to transfer unwanted sources into a managed store.

3.3 NRL and the optimum regulatory model

An optimum regulatory model would attempt to achieve clarity of function and responsibility, and minimise conflict of interest by separating all of the component parties. Thus in this model the policy makers, the regulatory authority, the third party verifiers or auditors, and the regulated parties are all separate and independent. This is a system that works well in an area with large numbers and a well-integrated infrastructure like the motor vehicle safety. In this example, in New Zealand top level policy is formulated in the Ministry of Transport, licensing and the Road Code are dealt with by an independent Government body the Land Transport Safety Authority, vehicle inspections are done by private contractors, and compliance with road rules is carried out by the NZ Police.

However in its present form NRL performs the functions of each of the above components. We assist the Ministry of Health on policy development, we are the licensing authority, we do compliance monitoring, and we are ourselves licensed users of radiation (for example the calibration laboratory, and waste management). It will be clear from previous discussion that the present combination of regulator-advisor-service provider is the result of the historical development of NRL, rather than any systematic setting up of an agency of this type. The question must be asked as to whether a different structure would have advantages.
In contrasting the structure of NRL with the optimum model, it is important to consider what problems the model is addressing, and whether it is the only solution when other factors come into play. The problems are in separating political interests, commercial interests and public good interests, and also ensuring that all of the administrative processes are not susceptible to any conflict of interest. In the case of NRL the most important other factor that must be considered is that in a country the size of New Zealand there is not a large pool of experts in radiation safety. The IAEA documents make it clear that the regulatory authority must have sufficient in-house expertise to assess independently applications for authorization or safety reports. There is a strong argument for continuing with an integrated regulatory authority and service provider model in order to maintain a critical mass of experienced and skilled staff.

If the regulatory authority is to continue in its present integrated form, it will be necessary to show that the issues that lead to the optimum model have been satisfactorily addressed. It is proposed here that this will be true as long as:

(a) The powers and functions are vested in a person appointed under the new legislation, who is not either a Minister of Parliament or a chief executive of a government department.
(b) There is an independent watchdog advisory council with representation from interested parties, including the public that reports independently to the responsible Minister.
(c) The administrative procedures of the regulatory authority are all transparently documented and audited in accordance with Quality Management principles.

The proposed new legislation would satisfy (a) and (b). The third prerequisite has already been dealt with through the adoption of a quality management system for all of the functions carried out at NRL.

### 3.4 Quality Management

In recent years continual improvement and the adoption of quality management systems have been key motivators as NRL has progressed through a period of considered and managed change. NRL’s commitment to quality, high standards and continual improvement is demonstrated by its having recently achieved external certification of its quality management system to ISO 9001:2000 ‘Quality Management Systems – Requirements’. In addition, NRL’s Environmental Laboratory in 2003 achieved accreditation to NZS/ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories).

The principles of quality management are transparency of process and consistency of policy across the organisation. We feel that a commitment to quality management will be essential to both achieving and demonstrating an absence of conflict of interest in an integrated regulatory/service agency.

### 4. Conclusion

This paper has been an attempt to map out a possible path for the revolution/evolution of New Zealand’s radiation safety regulatory system in order to meet the internationally agreed standards of radiation safety and security in the context of a country the size of New Zealand. The proposed path contains regulatory change and review of the function and structure of the regulatory authority. While the proposals are solely the views of the authors, we feel that there is value in analysing the surrounding issues and drivers in depth so that when decisions are made they are based on a sound understanding and more likely to achieve the desired goal.