REGULATORY IMPACT STATEMENT: PROPOSED CHANGES TO RADIATION PROTECTION LEGISLATION

Statement of the Nature and Magnitude of the Problem and the Need for Government Action

The major source of exposure to radiation in New Zealand is from medical x-rays. X-rays are also used by dentists, chiropractors, podiatrists and veterinarians. Other medical uses of radiation include the injection of radioactive materials as tracers (for example in bone scans) and non-ionising radiation devices such as lasers and ultrasound. Industrial uses of radiation include the use of radioactive materials for measurements during manufacturing processes (for example, to determine thickness or whether a hopper is full), gamma or x-rays to check welded joints or other mechanical components for cracks or defects, high doses of radiation for processing materials or goods (for example, changing the internal structure of plastics), and high-powered lasers. Radiation is also used for research purposes (for example, to trace the flow of ground water) and many consumer goods contain radioactive materials (for example smoke alarms) or generate ionising or non-ionising radiation (lasers).

The use of radiation in New Zealand is regulated by the Radiation Protection Act 1965 and the Radiation Protection Regulations 1982. The legislation is outdated, does not reflect the current use of radiation sources and is inconsistent with international standards and best practice legislation.

For example:

- The legislation does not enable the regulation of non-ionising radiation and practices involving exposure to naturally occurring sources of radiation. This is inconsistent with the Australian National Directory for Radiation Protection. New Zealand is a member of the panel developing the Directory;
- The legislation places responsibility for the safety of radiation sources on individual users, which is no longer appropriate in the current environment where large organisations (such as hospitals, companies or research institutes) are likely to be the owners/managers of a source. International standards and agreements (including the International Basic Safety Standards for Protection Against Ionizing Radiation and for the Safety of Radiation Sources, the International Atomic Energy Agency (IAEA) Code of Conduct on the Safety and Security of Radioactive Sources, and the Joint Convention on the Safety of Spent Fuel Management and on the Safety of Radioactive Waste Management) require that the primary responsibility for the safety and security of radiation sources be placed on the person or organisation responsible for the overall management of the source;
- The legislation does not enable the Ministry of Health to prohibit the use of a radiation source if it is unsafe or has been obtained illegally, to take control of an orphan source (a source for which there is no licensee) or a source stopped by Customs, or to intervene in a dangerous situation where the immediate health and safety of people or the environment may be at risk. The IAEA Code of Conduct requires that the Ministry, as the regulatory authority, have adequate powers of enforcement, including the power to recover and restore control over orphan sources and deal with radiological emergencies.
- There is no legislative provision for the preparation of safety, security and emergency plans by licensees, nor for the registration of radiation sources, as required by the IAEA Code of Conduct. There is potential for New Zealand to face difficulties in

importing radioactive materials, as it is currently not possible to give effect to the security provisions of the IAEA Code of Conduct.
- The exemptions and dose limits specified in the Radiation Protection Regulations are inconsistent with the International Basic Safety Standards.

Statement of the Public Policy Objectives

The public policy objectives are to protect the health and safety of individuals and the environment from the harmful effects of radiation, to ensure the safe and secure management of radiation sources and their uses, and to bring New Zealand into line with international best practice and international obligations with respect to the safety and security of radiation sources and their use.

Statement of Feasible Options (Regulatory and/or Non-Regulatory) That May Constitute Viable Means for Achieving the Desired Objectives

Status quo

The Radiation Protection Act 1965 and the Radiation Protection Regulations 1982:
- Regulate ionising radiation sources (radioactive materials and irradiating apparatus);
- Place primary responsibility for the safety and security of radiation sources on individual licensed users (approximately 3000 people);
- Enable the Ministry of Health to place conditions on licences, which may include mandatory compliance with locally written Codes of Safe Practice;
- Require users to renew their licences annually, and pay a fee of $190-$300 (incl GST), depending on the complexity of the licence;
- Require the Ministry of Health to keep a register of licences but not radiation sources;
- Enable the Ministry of Health to suspend or cancel licences;
- Provide for exemptions from all or some regulatory requirements, such as the requirement to hold a licence;
- Establish requirements for protection from exposure to radiation, including specified dose limits;
- Provide for a maximum penalty for offences against the Act of a fine of $10,000 plus a further fine of up to $500 for every day that the offence continues; and
- Provide for a Radiation Protection Advisory Council.

It is no longer appropriate to maintain the status quo as the current legislation does not meet the public policy objectives.

Preferred option: New radiation protection legislation

A new Radiation Safety Act would be drafted, which would:
- extend the scope of the legislation to include harmful non-ionising radiation and practices involving enhanced exposure to naturally occurring sources of ionising radiation;
- establish a Director for Radiation Safety with defined functions and duties;
- shift the primary responsibility for the safety and security of radiation sources to the person or organisation responsible for the overall management of the source and require them to apply to the Director for Radiation Safety for a "licence to possess" a

radiation source (approximately 2000 individuals or organisations). As under current legislation, a fee would be payable and licences would be renewed annually.
- require that radiation safety plans (covering safety, security and emergency plans) be prepared, as appropriate, as part of the process of applying for a licence;
- update controls on the import and export of radiation sources in line with international agreements. For example, the IAEA Code of Conduct requires States to authorise the export or import of certain radiation sources only if the destination State has the administrative and technical capacity to manage the source in line with the Code;
- establish a formal process to enable the Director for Radiation Safety to develop and approve new Codes of Safe Practice while allowing continuance of existing Codes;
- require the registration of (approximately 7000) radiation sources and (approximately 200) premises or establishments on which unsealed sources are used or stored with the Director of Radiation Safety;
- enable the Director for Radiation Safety to issue compliance orders, seize a radiation source, stop a vehicle and take control in the event of a radiological emergency;
- increase the maximum penalty for offences against the legislation to a fine of $500,000 plus a further $50,000 for every day that the offence continues;
- enable information about an offence to be laid within two years of the matter of the information arising;
- provide for the accreditation of providers undertaking radiation safety services;
- update provisions on the Radiation Protection Advisory Council to reflect the proposed functions of the Director for Radiation Safety;
- update radiation safety standards in line with the International Basic Safety Standards through Codes of Safe Practice and new regulations on exemptions from regulatory requirements and dose limits with respect to individual exposure to radiation; and
- provide for regular review of the legislation.

While it would be possible to amend current legislation and regulations, the nature and extent of changes required mean that it would be more efficient to draft new legislation.

Statement of the Net Benefit of the Proposal, Including the Total Regulatory Costs (Administrative, Compliance and Economic Costs) and Benefits (Including Non-Quantifiable Benefits) of the Proposal, and Other Feasible Options

Government

The primary benefit to the government is that New Zealand will be in line with international best practice and will be able to give effect to relevant international agreements and standards, thus enhancing New Zealand's international credibility. Benefits to government will also arise from the regulatory authority having defined functions and powers, including a legislative mandate to approve Codes of Safe Practice and enhanced enforcement and emergency powers, and from the establishment of a clear point of responsibility for the safe and secure management of sources.

There will be increased government workload in the implementation of the new licensing framework, and possibly long-term from increased enforcement of regulatory requirements, but there will be an overall reduction in the number of licences (although they will be more complex). Government resources and infrastructure needed to support the new legislation are expected to be greater than is presently the case but in overall terms this represents an enhancement of present activities rather than significant new interventions.

A preliminary analysis undertaken by the National Radiation Laboratory indicates that funding from the current licensing regime would be inadequate to fund the proposed regulatory structure, especially with respect to the management of radiation safety plans and the increased level of safety and security surveillance programmes likely to be required. It is suggested that the total revenues appropriated from licensing and other regulatory fees will approximately double from the present level of $650,000 to an estimated $1,400,000 (both exclusive of GST). While this is a reasonable increase in percentage terms, it is however considered to be small with respect to the total overall risks associated with radiation use and the commercial revenues associated with the application of radiation in society. It is anticipated that through a greater recovery from core regulatory activities through fees and other services activities that the Ministry of Health will be able to support the overall radiation safety infrastructure of the proposed new regime within current departmental appropriations.

Industry

The proposed changes to the licensing framework will establish a clear point of responsibility for the safety and security of radiation sources by shifting responsibilities from multiple users of a radiation source to a single person or organisation with overall responsibility for the management of the source. This is likely to result in a safer working environment, and individual employees will no longer carry the burden of legal responsibilities without the authority to act. Giving effect to the IAEA Code of Conduct, through for example a requirement to register sources, will also mean that New Zealand businesses can continue to import radioactive material without concerns of non-compliance with the security provisions of the Code. Accreditation of service providers will assist licensees to identify those able to safely provide radiation safety services.

There are likely to be some increased costs to radiation users resulting from the requirements to apply for a licence to possess, to prepare a radiation safety plan, and to register radiation sources. While businesses may be required to put in place additional measures to ensure the security of sources, it is not anticipated that any significant additional safety measures will be required. Increased costs to radiation users may also arise through the possible regulation of non-ionising radiation sources and practices involving exposure to naturally occurring sources of ionising radiation. Costs will include those directly attributable to the payment of fees and compliance costs associated with new procedures and information requirements. Compliance costs are discussed in more detail in the Business Compliance Cost Statement. There will not initially be any costs associated with non-ionising radiation because the Australian National Directory of Radiation has not yet prescribed any particular apparatus that needs to be controlled. At a later time this is likely to include high-powered lasers.

The proposed new legislation will have a wider range of authorisations, registrations and accreditations for which fees will be charged than the current Act. Therefore it will be necessary to re-evaluate the levels at which the various fees should be set, in accordance with Treasury guidelines, so that the costs are spread equitably over the industry and as far as possible are commensurate with the degree of risk that must be regulated in each case. As stated previously it is expected that the total revenue from regulatory fees approximately double (from $0.65million to $1.4 million, excl. GST), but with the risk weighting to fees, small users (e.g. dentists, veterinarians, etc) may not experience a large increase, if any. Licence fees are expected to be in the vicinity of $200 incl. GST for a simple application (for example, a dentist) and $3000-4000 incl. GST for more complex applications such as a private radiology practice with many machines and registrants. (Dentists currently pay $190 per year each for individual user

licences, and radiologists $300, both inclusive of GST.) Under the new legislation there will generally be a single licence to possess to possess a radiation source that will have a fee derived from the number and size of radiation sources to be possessed. Costs will therefore be offset to some extent as many businesses will only have to apply for a single licence for the whole organisation, rather than many individual licences for their employees. As well as the possession licence there will fees to import/export, buy/sell, and register individual radiation sources. It is not possible to quantify these fees at this stage, but they will be set in regulations under the new Act and will be subject to a Regulatory Impact Statement/Business Compliance Cost Statement at that stage. However it should be noted that the expected increase in regulatory costs to users is small compared to the total revenues from radiation usage and considering the magnitude of potential risks that the regulatory control addresses.

Society
The major benefit of the proposal is increased public safety through improved security of sources (and hence reduced potential for misuse), and greater safety of sources as a result of extending the scope of the legislation, establishing clear responsibilities, updating safety standards, improving the ability of the regulatory authority to enforce regulatory requirements and respond to emergencies, and increasing the incentives for licensees to comply with requirements. There may be a very small indirect cost to the public in the extent that businesses pass on any increased costs of meeting regulatory requirements.

Statement of Consultation Undertaken

A discussion paper on radiation protection legislation was released in November 2002 that outlined key deficiencies of the legislation and proposed a new legislative framework. Sixty nine submissions were received from a range of government agencies, industry bodies, health organisations, universities, individuals, and other interest groups. In general, submissions supported the need for new legislation in line with international safety standards and, as appropriate, moves toward uniformity of legislation in Australia. Comments stressed the need for regulation to be commensurate with the degree of risk, which has been a key principle underlying proposed new legislation.

The following government agencies have been consulted on the proposed legislative changes: Ministry of Justice, Ministry for the Environment, Department of Labour (OSH), New Zealand Police, New Zealand Customs Service, Ministry of Foreign Affairs and Trade, Ministry of Transport, Department of Prime Minister and Cabinet, The Treasury, State Services Commission, Ministry of Women's Affairs, Te Puni Kokiri, Civil Aviation Authority, Land Transport Safety Authority, and Maritime Safety Authority.

Consultation highlighted a number of issues: the need to clarify the fact that non-ionising radiation will only be subject to regulations when it poses a significant potential health risk; the need to clarify the boundaries of the proposed legislation against the Health and Safety in Employment Act and the Hazardous Substances and New Organisms (HSNO) Act; and the need for ongoing discussion with the Ministry of Justice with regard to Bill of Rights Act issues. Police have requested ongoing input regarding the proposed role of the Director of Radiation Safety in emergency situations, and specifically the ability of officers (Police and potentially Fire Service) to exercise emergency powers in the event of the declaration of a radioactive emergency. Health officials will continue to liaise with Police on these matters as the legislation is developed. Treasury are happy with the

stated financial implications provided the Ministry of Health is able to implement the proposed legislation within current departmental appropriations.

Business Compliance Cost Statement

Compliance costs will arise from businesses understanding the new legislative requirements and the time taken to gather information for, and complete, licence consent and registration applications, prescribed records and, where relevant, radiation safety plans. Note that many of these changes are already underway as a result of the requirement for radiation safety plans that has been introduced in the most recently written Codes of Practice and licence conditions, so further changes with the implementation of the new regime will be minimal. There will not be increased costs from technical safety requirements because these are contained in current Codes of Safe Practice that will be adopted under the new legislation.

It is estimated that approximately 2,200 organisations will require a licence to possess a radiation source. This includes approximately 1,500 small businesses such as chiropractors, podiatrists, vets, dentists and general practitioners, 300 medical establishments such as hospitals and private radiology clinics, and 400 other organisations including industry users and universities.

It is anticipated that the costs of compliance will reduce over time as businesses become more familiar with the application requirements. The NRL is committed to using technology to facilitate applications, reports, notifications, etc, and will prepare detailed guidance and model radiation safety plans to assist businesses to understand regulatory requirements and minimise compliance costs.