Australian Government

Australian Radiation Protection and Nuclear Safety Agency

Regulatory Impact Statement
Public Consultation Draft

Code of Practice
Safe Use of Fixed Radiation Gauges

Comment on the draft Regulatory Impact Statement should be forwarded by 14 October 2005 to:

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Table of Contents

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Background & Issues

Ionizing radiation and fixed radiation gauges

1 Fixed radiation gauges (FRGs) that incorporate either radioactive sources, X-ray tubes or neutron generator tubes are commonly used throughout industry to measure thickness, level, density, mass, volume and also provide control over manufacturing processes. The principle of operation for a radiation gauge depends on the detection of a radiation beam transmitted through or scattered by the item or material of interest.

2 Many different industries use FRGs to determine the various parameters including petroleum manufacturing, metal producers, drink canning and cigarette manufacture to name only a few. The following table lists the number of gauges and premises where gauges are used in each jurisdiction in Australia. The total number of these devices in use throughout Australia has remained relatively steady over the last 5-years or so.

Jurisdiction	No. of Gauges (inc radioactive source, X-ray, neutron generator tube)	No of premises with gauges
ACT	No gauges.	Not applicable.
Commonwealth	2	2
NSW	646	112
NT	179	9
Qld	933	82
SA	331	20
Tas	222	18
Vic	422	135
WA	1591	121
TOTALS	4324	497

3 FRGs containing radioactive sources have been used for many years in Australia. The use of these devices has been governed by the *Code of Practice for the Safe Use of Radiation Gauges*, which was published by the National Health and Medical Research Council (NHMRC) in 1982 as Radiation Health Series (RHS) No. 4. This Code is not legislation in its own right however, most Australian jurisdictions adopt the Code either directly into their legislation or indirectly as a condition of licence, registration or both. In this way, the Code becomes regulatory as all users must comply with the working rules and the devices must comply with the equipment standards therein.

4 FRGs containing X-ray tubes or neutron generator tubes were not covered by any similar Code of Practice. Regulatory authorities have only been able to use the general safety requirements in the 1982 Code of Practice as a guide for FRGs that contain X-ray or neutron generator tubes.

5 The 1982 Code of Practice established standards of safety with the view to providing an acceptable level of control of the radiation associated with the use of these devices, albeit FRGs that contained radioactive sources only.

6 The 1982 Code of Practice was however, based on radiation protection limits prescribed in ICRP Publication No. 26 and the transport requirements on a 1973 edition of the IAEA Regulations for the Safe Transport of Radioactive Material.

7 The 1982 Code of Practice was written in a prescriptive format. Modern Codes of Practice are more outcome based in their format.

Problems

Outdated information

8 The radiation sources used in FRGs could, if used or transported improperly or if involved in a serious accident, cause radiation exposure leading to radiation injury. Further, personnel required to work near FRGs might not necessarily be trained in their use nor would they necessarily be familiar with the properties and potential hazards associated with radiation. The need for appropriate warning signage is also an important consideration.

9 The dose rates associated with some of the more ‘powerful’ FRGs can be quite significant. A high degree of safety needs to be engineered into the design of FRGs to ensure that exposure is kept to a minimum and that, in the event of an incident or accident, the likelihood of exposure is minimal. Consequently, any person that might be required to work on the gauge or the apparatus on which it is installed needs to be aware of the potential risks involved with their use to ensure that doses received are kept to a minium.

10 The 1982 NHMRC Code does not have an expiry date but it is over 20 years since it was published. The NHMRC does not wish to continue the RHS publications and recently handed the responsibility for the review of these publications to ARPANSA. ARPANSA needs to review the 1982 NHMRC Code to ensure that workers and the public are able to obtain reliable information on the measures to take to avoid radiation exposure that might exceed permissible levels.

11 The 1982 NHMRC Code was based on radiation protection limits specified in the International Committee for Radiation Protection (ICRP) Publication No. 26 in 1977. Also, the transport requirements in the 1982 NHMRC Code were based on the 1973 edition (revised and amended in 1979) of the International Atomic Energy Agency (IAEA) Regulations for the safe transport of radioactive material. The ICRP and IAEA publications have been significantly revised since the 1982 NHMRC Code was published. Since the introduction of the 1982 Code, an Australian Code of Practice that covered transport of radioactive material has been introduced (originally in 1982) and replaced in 1990 and 2001 to reflect the changes to the IAEA requirements. As such, the 1982 NHMRC Code needs to be reviewed to ensure that the dose limits specified by the ICRP in its 1990 recommendations are not exceeded.

12 This variation of the requirements of 1982 Code from the current international recommendations could result in a lack of uniformity across Australia. This could cause confusion for users, manufacturers, suppliers and service technicians, and a lack of clarity as to which provisions apply to FRGs if some regulators were to still use the 1982 Code as its provisions are inconsistent with the 2001 Australian Transport Code and Radiation Protection Series No. 1 (RPS1). Increased costs could be experienced as each stakeholder group attempts to find out the requirements that they must comply with in each jurisdiction.

13 Also, the 1982 NHMRC Code only covered FRGs that incorporated radioactive sources. This meant that gauges utilising X-ray tubes and neutron generator tubes were not covered by any Code of Practice. While these latter types of gauges are not as common as those that contain radioactive sources, they do exist and therefore need safety requirements to be specified.

Externalities

14 The uncontrolled use of FRGs represents a risk of radiation exposure and injury to users of the devices, workers at the premises, the public, and represents a risk of contamination of the environment. The social costs that can result from uncontrolled exposure to radiation, eg. from a lost radioactive source, could be serious. Relying on market mechanisms for affected parties to directly negotiate with the company that causes these externalities would involve transaction costs that may not be reasonable for users and members of the public to bear.

15 The Australian Radiation Incidents Register (ARIR) lists 24 incidents involving FRGs dating back to the early 1970s. There was no common cause of these incidents and the degree of exposure to humans varied from negligible to above the annual dose limit for members of the public. Any improvement to current work practices would be expected to decrease the frequency of such events. Further, the introduction of requirements for X-ray equipment and neutron generator tubes should ensure uniform and ongoing safe use of these type of gauges. It is therefore considered essential that work practices and equipment design requirements for FRGs continue to be stringent.

Desired Objectives

16 To cost-effectively protect persons, property and the environment from the adverse effects of radiation during, and as a result of, the use of FRGs containing radiation sources.

Possible Options

17 Three options were considered:

- *status quo* — this option entails doing nothing and leaving the 1982 Code of Practice in place for adoption by each jurisdiction as is currently the case;
- self-regulation — this option would allow the industry to set its own safety requirements, subject to other occupational health and safety (OH&S) obligations; and
- update the 1982 Code — this option entails re-writing the 1982 Code and updating it with current radiation protection requirements and philosophies.

Impact Analysis

Affected Parties

18 The parties who are likely to be affected by the use of these type of devices include:

(a) companies that use FRGs covering all industry sectors including large multinational companies and small local industries;

(b) employees of the companies that use FRGs;

(c) service technicians;

(d) suppliers of the equipment;

(e) Government regulators (State, Territory and Commonwealth); and

(f) the community.

Companies that use FRGs need to know correct procedures to ensure the safety of their employees who may be required to work on or near equipment that have FRGs affixed to them. Companies also need to ensure a duty of care to the wider community. Employees of companies that use FRGs need to be protected from potential harmful effects of exposure to radiation while at the same time not perform any act that might compromise the safety of a FRG or its installation.

Service technicians need to know the correct radiation protection procedures to ensure their own safety and that of their employees or fellow workers while servicing or repairing a FRG. Service technicians also need to ensure a duty of care to the wider community.

Suppliers of the equipment need to ensure that all equipment supplied to users is consistent with international standards and is safe to use.

Governments and the public are stakeholders insofar as any incident involving the use of these devices impacts on public perception of radiation safety generally.

Cost benefit analysis for each option

19 The aim of this assessment is to provide a clear exposition of the nature of the costs and benefits associated with each option, and to quantify these impacts where possible.[1]

Status quo

Costs

Compliance

20 There are ongoing compliance costs associated with complying with the 1982 Code. In particular, the 1982 Code sets out a series of requirements related to the:

- allocation of responsibility for all safety procedures and for the provision and maintenance of all safety equipment;
- design, construction and testing of radioactive sources used in radiation gauges;
- design, construction, testing and maintenance of source containers for radiation gauges;
- siting and installation of radiation gauges and provision of protective barriers and other safety features;
- provisions of suitable storage areas for radiation gauges not installed;
- consistent and informed use of personal monitors to measure and assess personal doses and of suitable radiation measuring instruments to measure radiation exposure from radiation gauges and to assess potential hazards;
- formulation of comprehensive safety procedures, including working rules, emergency procedures and procedures for accounting for radioactive sources;

[1] While cost-benefit analysis requires all costs and benefits associated with the options to be measured quantitatively in common units (either in monetary units or physical units) to the fullest extent possible, to the extent that quantification is not possible, a comprehensive list of the costs and benefits together with a strong qualitative analysis can often provide a simple but still compelling case. Indeed, this approach is preferable to one where unreasonably broad assumptions are made to generate quantified impacts which provide a false sense of accuracy.

- the initial and continued instruction of all persons involved in use and maintenance of radiation gauges;
- provision and display of warning labels, notices and markings; and
- recording and keeping of all relevant data.

21 Clearly these requirements place a compliance burden on the range of stakeholders specified. In this regard, a number of observations are possible:

- firms and their employees are already subject to a range of general and specific OH&S duties of care and requirements as well as the radiation protection regulations of the Commonwealth, States and Territories, many of which would effectively impose similar (but more general) requirements on firms with gauges. This suggests that at least some of the compliance costs associated with radiation protection activities are not solely attributable to the 1982 Code;
- while a significant majority of FRGs are operated by large firms, and hence can be expected to have broad safety systems in place, some FRGs are operated within smaller firms. Regulatory compliance costs are generally disproportionately borne by smaller firms because they lack the scale to average costs down;
- inconsistent implementation of the 1982 Code between jurisdictions could result in increased compliance costs for firms operating in more than one jurisdiction; and
- FRGs that incorporate X-ray tubes or neutron generator tubes are not consistently regulated throughout Australia as they were not included in the requirements of the 1982 Code. This could also result in increased compliance costs for firms operating in more than one jurisdiction.

22 As industry is already used to operating under the 1982 Code, there is an expectation that compliance is strong (enforced by State and Territory regulators), although for smaller firms compliance costs tend to be relatively higher, as those costs are disproportionately larger for small firms.

Administration

23 There are administration costs associated with monitoring and enforcing compliance with the 1982 Code, but these are considered slight because such administrative costs tend to be bundled/subsumed within each regulatory agency's general budgets. That is, it is not possible to disaggregate administrative costs associated with the 1982 Code in comparison to other OH&S and radiation-related enforcement costs.

24 Because each jurisdiction has implemented the 1982 Code in their own laws in somewhat different fashions it is likely that there are some additional ongoing administrative costs in dealing with firms operating in more than one jurisdiction and in addressing any issues that arise as a result of a lack of a nationally consistent approach. This is particularly the case with FRGs with X-ray tubes or neutron generator tubes, which are currently regulated differently in each State and Territory.

Health and safety

25 The 1982 Code has not reduced radiation incidents to zero, and so there are health and safety costs borne under the *status quo* regulatory arrangements.

26 The Australian Radiation Incidents Register (ARIR) — see table 1 (next page) — lists twenty one incidents involving FRGs since the introduction of the 1982 Code[2], of which six had confirmed exposures (although exposures for nine other incidents were unknown).

27 Putting a cost on these incidents is problematic because the incidents identified in the ARIR are not necessarily serious, although the full extent of the costs of some incidents may not be experienced until well after the incident.

28 Also, under the *status quo*, there is a risk that compliance with other health and safety standards may be compromised (or achieved at greater cost) if inconsistencies between the 1982 Code and other regulatory controls create confusion as to which standard is relevant in any particular situation. For example, the:

- 1982 Code is inconsistent with the lower annual dose limits (i.e. 20 mSv per year averaged over 5 consecutive years for occupationally exposed persons) currently in RPS1; and
- transport requirements in the 1982 Code are inconsistent with the Australian Transport Code (which was updated most recently in 2001 to reflect revisions of the IAEA Transport Regulations).

Dynamic efficiency

29 Regulatory regimes should seek to provide a framework that:

- allows industry to respond flexibly in meeting their obligations; and yet
- can adjust to best practice developments.

30 The NHMRC has rescinded all of its health based codes that are over 10-years old and has no mechanism for renewing or updating them. As such, there is currently no up to date information for FRG users on radiation safety issues. This lack of flexibility and currency suggests that dynamic efficiency is compromised under the *status quo*.

[2] It is important to note that it is likely that the ARIR understates the number of radiation-related incidents.

TABLE 1 – EXTRACT FROM AUSTRALIAN RADIATION INCIDENTS REGISTER – RADIATION GAUGE INCIDENTS

Date	Industry	Jurisdiction	Incident description	Equipment/Source	Exposures/Doses
12 June 1973	Sewerage treatment	NSW	Damage to density gauge containing 1.5 Ci (55.5 GBq) of caesium-137.	Density gauge caesium-137 1.5Ci (55.5GBq)	Whole body radiation dose <5 μSv. Hand dose <10 μSv. Effects/doses negligible.
27 October 1975	Private house	NSW	Rupture of a container of strontium-90 powder while servicing a thickness gauge. Subsequent dispersal of radioactive material.	Thickness gauge strontium-90 15mCi (555MBq)	Contamination of premises, clothing, etc. estimated radiation doses to 2 people of 200 mSv & <10 mSv respectively.
November 1978	Nickel mining	WA	Loss of caesium -137 source from density gauge causing contamination of smelted scrap metal.	Density gauge Caesium-137	No reported contamination or irradiation of personnel.
18 December 1984 – 24January 1985		SA	Removal of cobalt-60 source from container of a bin level gauge during repair. The source was left unshielded for several weeks near occupied work areas.	Bin level gauge cobalt-60 500MBq @ August 1976	Whole body radiation doses to 3 people of 10, 1.2 & 0.5mSv respectively.
3 March 1986		QLD	Weld on mounting bracket failed causing radiation gauge to fall 1.5m. The radiation gauge remained in the 'beam on' condition for up to 5 days.	Industrial radiation gauge	Unknown
30 July 1986	Steel	VIC	Radiation gauge used at steel mill fell apart. Source and gauge parts lost. Source subsequently found to have be sold with Iron scale and crushed in ball mill. 98.5% of source crushed in cement. 1.5% recovered from ball mill.	Radiation gauge. americium-241 1Ci (37GBq)	Negligible
1987		VIC	Radiation gauge shutter shielding block fell out. Four screws, which held the lead shutter block to the shaft, worked loose due to vibration of the gauge over time.	Radiation gauge	Unknown
1988		SA	Radiation gauge sent to SA from NSW with the source in the 'on' (exposed) position.	Radiation gauge	Unknown
1988		Not known	A source in a radiation gauge had been held in place by short bolts made of low tensile steel. These had sheered off in use.	Radiation gauge	None
7 or 8 February 1989	Steel	VIC	Radiation gauge accidentally damaged when molten steel poured over the gauge housing. Inspection of gauge showed no reduction in shielding effectiveness.	Radiation gauge	None

Date	Industry	Jurisdiction	Incident description	Equipment/Source	Exposures/Doses
24 February 1989	Steel	VIC	A tundish, used for directing flow of molten steel from a smelter to a cast, was damaged causing molten steel to flow onto a radiation gauge. Gauge removed and placed in lead-lined cylinder. No contamination detected.	Radiation gauge	None
20 March 1989	Steel	VIC	A tundish, used for directing flow of molten steel from a smelter to a cast, was damaged causing molten steel to flow onto a radiation gauge. Gauge removed and placed in lead-lined cylinder. No contamination detected.	Radiation gauge	None
1989		WA	At site 1, a person came within close range of radiation gauge that was switched on.	Radiation gauge	Unknown
1989		WA	At site 2, a person came within close range of radiation gauge that was switched on.	Radiation gauge	Unknown
1989		WA	At site 3, a person came within close range of radiation gauge that was switched on.	Radiation gauge	Unknown
1991		NT	Density meter was removed from a pipe with the source exposed. Several people carrying out repairs had worked in close proximity for several hours.	Density gauge	Blood samples sent for chromosome analysis showed no abnormalities.
23 February 1994	Steel	VIC	Radiation gauge, which had been in storage for 4 months, found to have unusually high radiation levels around it. Gauge sent in lead-lined box for analysis. Found that lead shielding within the gauge had split due to manufacturing fault.	Radiation gauge	Unknown
1995		NSW	Two service engineers received small radiation doses to their hands and fingers when servicing a faulty radiation gauge.	Radiation gauge	Small radiation doses to hands and fingers of two service engineers.
10 February 2002	Coal Processing	Qld	A routine radiation survey around a fixed industrial gauge revealed radiation gauge higher than normal radiation levels. The routine survey in this instance was more rigorous and discovered that the radiation emanating from the top of the gauge was in excess of that expected. Subsequent investigation by the manufacturer of the gauge revealed a defect in the gauge due to faulty manufacturing processes. The manufacturer has advised that all similar gauges are being investigated.	caesium-137 3.7GBq	Unknown –expected to be low
31 March 2003	Mining	WA	Contract fitter loosened bolts on a radiation gauge, allowing it to slide approximately 1.5 metres, resulting in a misalignment of the source with its detector. A boilermaker/welder was in the immediate vicinity at the time and was exposed to low level radiation levels for 45 minutes. The maximum dose rate the worker was exposed to was 13 µSv per hour.	Fixed gauge – Density caesium-137	10 µSv to a non-radiation worker estimated from dose rate of 13 µSv per hour for 45 minutes.

Date	Industry	Jurisdiction	Incident description	Equipment/Source	Exposures/Doses
19 April 2003	Mining Exploration	QLD	A permit to work was signed to clear a blockage in a pipe. The blockage was within 1m of a radiation gauge. Unfortunately, the radiation item on the checklist was overlooked by both the permit issuer and the permit recipient, which resulted in the radiation gauge not being isolated before the work commenced. Signs in area were also ignored.	Industrial radiation gauge caesium-137	0.09 µSv based on a 1 hour exposure and 0.5 m from the gauge (worst case).
8 August 2003	Metal Processing	QLD	During a compliance assessment audit, an industrial radiation gauge was found to have a jammed shutter. In addition to this, the shutter indicator lights were not working. Due to the inaccessibility of the installation site, it was unlikely that any person had been exposed to radiation. Further access control measures have been put in place until the next plant shutdown, at which time the gauge will be removed from service and repaired.	Industrial radiation gauge caesium-137 6.9 GBq @ 09/071997	Unknown.
15 September 2003	Sawmill	QLD	The device housed 4 industrial radiation gauges, each containing a 7.4GBq Americium-241 source. One of the gauges (gauge No.2) was jammed open (in the "exposure on" state, but the LED & system indicated that the shutter was closed) due to a faulty micro-switch. The problem was rectified by replacing the switch. However, two of the remaining 3 gauges showed evidence that their shutter had been jammed. Also, the device requires modification in order to be able to clearly identify the shutter state. The only person exposed was the company's radiation safety officer, who received an equivalent dose of about 0.25 µSv (extremities), resulting from un-jamming the gauge. There was no radioactive contamination resulting from the incident.	Industrial radiation gauge americium-241 29.6 GBq (4 × 7.4 GBq) @ 16/12/2002	Un-jamming the shutter of gauge took approximately half an hour. The radiation dose at the surface of the source exit port through a lead sheet was measured to be 0.5 µSv per hour. The company's radiation safety officer estimated the equivalent dose was less than 0.25 µSv (extremities).

Source: Australian Radiation Incidents Register

International standing and consistency

31 Because there have been cross-border issues such as illicit trafficking in radioactive materials, import/export, and environmental releases, there has been a considerable international effort 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).[3] 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. As Australia is a signatory to bodies that sponsored and endorsed the BSS, this would seem to place an onus on Australia to honour the endorsement of the BSS and provide standards consistent with international best practices.[4]

Benefits

Health and safety

32 Radiation protection regulations are often assessed in terms of their impact on average or collective annual effective dose[5]. Based on the latest available information — material published by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR)[6] — the average annual effective dose for all workers in Australia is estimated to be 0.24 mSv per year.[7] In comparison, the average annual effective dose received by FRG users in Australia, including installation and maintenance personnel, was reported as 0.075 mSv per year[5,8]

33 Relative to the 1982 Code, which allows for a maximum occupational exposure limit of 50 mSv per year, the average annual effective dose for workers is over 650 times lower than current exposure limits. Clearly, radiation protection standards generally, and the 1982 Code in particular, provide health benefits in relation to FRGs.

34 The significant difference between actual exposure and maximum limits, suggests that there are other factors that encourage low effective dose levels than simply mandating exposure limits. In fact, radiation protection has for some time now promoted the concept of optimisation and the ALARA principle.[9] Coupled with the general broader regulatory

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3 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.

4 G. Dicus 1998, Why we need to harmonize radiation Protection regulations, Nuclear Regulatory Commission paper presented at the Women in Nuclear Global Annual Meeting, Taipei, Taiwan, 24 April, http://www.nrc.gov/reading-rm/doc-collections/commission/speeches/1998/s98-13.html.

5 N.D. Morris, P.D. Thomas and K.P. Rafferty 2004, *Personal Radiation Monitoring and Assessment of Doses Received by Radiation Workers (2004)*, Technical Report 139 prepared for ARPANSA, Australian Government, Yallambie.

6 This figure is based on a weighted average of average annual effective annual dose for workers monitored. The data was taken from United Nations Scientific Committee on the Effects of Atomic Radiation 2000, *Sources and Effects of Ionising Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes*, United Nations, New York.

7 This is based on a weighted average of the average effective dose and the number of workers monitored over the period 1975 to 1994.

8 It should be noted that few users of FRGs in Australia are actually monitored on a regular basis as radiation protection is engineered into the design of the equipment and dose rates are usually very low.

9 The ALARA principle encourages users of radiation to ensure that radiation exposure is kept as low as reasonably achievable (ALARA) after taking into account economic and social factors.

requirements — such as registrations, licensing, monitoring, reporting, and so on — the application of ALARA is the most likely explanation for low effective dose levels.

35 It is worth noting though that without change, health and safety benefits may be constrained under the *status quo* option, specifically:

- the *status quo* option promotes exposure limits and regulatory approaches which are inconsistent with other areas of radiation protection — such as the National Directory — and hence may serve to undermine the ALARA principle;
- as modern FRGs have been designed to operate with lower emissions than specified in the 1982 Code (largely because of higher international standards and technological improvements), firms may be inclined to operate FRGs beyond the equipment life suggested by the manufacturers so long as the FRG still met the dose requirements of the 1982 Code. It is not unreasonable to assume, therefore, that there would be an upward trend in collective dose over time by maintaining the 1982 Code. In effect, the existence of the 1982 Code may actually result in a deterioration in health outcomes over time; and
- the 1982 Code has a somewhat narrow field of regulatory coverage — the 1982 Code does not cover FRGs incorporating X-ray tubes or neutron generator tubes. Safety requirements for such FRGs have been left up to individual jurisdictions to implement and the development of safety requirements for these types of devices would have taken place on an *ad hoc* and potentially non-uniform basis across Australia.

36 These factors are not health costs *per se*. Rather, they are caps on the health benefits achievable under the 1982 Code.

37 While the 1982 Code clearly has workplace safety as its focus, the existence of an explicit code for FRGs brings the FRGs to the attention of the firm. Thus, the aim is also to ensure that FRGs are not a problem to the health and welfare of the broader community and the environment. The problem is that:

> Although safe in design, such sources [FRGs], once they become orphans, hold the large possibility of being dismantled or publicly accessible.[10]

Similarly, without regulation there is a greater possibility that:

> The locations of such devices or sources within a facility may not be recognized, since the devices may be connected to process control equipment. This lack of recognition may result in a loss of control if the facility decides to modernize or terminate operations.[11]

Self-regulation

38 Industry self–regulation describes a regulatory system whereby it is industry participants who primarily determine the type of actions or procedures that constitute appropriate conduct.

39 To develop some concept as to what are the costs and benefits of a self-regulatory regime it is necessary to make a judgement as to what the self-regulatory arrangements will look like.

[10] P. Ortiz, V. Friedrich, J. Wheatley and M. Oresegun 1999, 'Lost & Found Dangers: Orphan Radiation Sources Raise Global Concerns', *IAEA Bulletin*, vol. 41, no. 3, pp. 18-21, p. 20.

[11] International Atomic Energy Agency 2000, *Categorization of Radiation Sources*, Attachment 3, Annex, GOV/2000/34-GC(44)/7, 10 July, p.8.

40 The most likely self-regulatory regime that would evolve with respect to FRGs is what Priest[12] calls 'firm-defined regulation' — see table 2. This is largely because there is no single peak industry body that could organise itself to participate in the development of an industry standard. Many different types of companies including bottling plants, cigarette manufacturers, oil refineries, metal fabrication works, plastics and material producers, electroplating workshops and many others use these devices. A body representing any of these industries could conceivably have their own idea on safety that would, in turn, result in non-uniform requirements.

TABLE 2 – THE 'FIRM-DEFINED REGULATION' MODEL OF SELF-REGULATION

Characteristic	Description
Government involvement	Government requires (or permits) private industry to establish regulatory structure, often at firm level
Source of power	Primarily the firm's control over its own processes and employees. Secondarily found in legislation that mandates self-regulation
Involvement of the public	Depends. The structure may remove rulemaking from public consultation process
Accountability	Government monitoring of private rule enforcement. Employee accountability to firm; firm to shareholders
Rulemaking	Rules made at firm or industry level specific to firm or industry requirements. May be approved by government regulator
Adjudication	Initial stage of firm discipline/labour relations. Secondarily through courts or tribunals
Sanctions	At first instance at firm level. May include fines, employment sanctions, dismissals; the emphasis is remedial. Second instance, fines and other regulatory sanctions imposed by government
Offences	Offences in regulatory legislation continue to exist. Adjudication in civil courts continues. First step is private enforcement
Membership/coverage	The overall legislation covers an industry, the tailored rules cover a firm or smaller industry group

Source: M. Priest (1997-98), 'The privatization of regulation: Five models of self-regulation', *Ottawa Law Review*, Vol. 29, p. 233.

Costs

Compliance

41 Under most self-regulatory regimes, compliance costs (i.e. the costs associated with complying with general OH&S-related standards) are reduced compared with having to operate under a specific regulatory regime for FRGs. This reduction is generally a function of two factors:

- the flexibility associated with a self-regulatory regime means that firms can develop least-cost compliance approaches; and

12 See M. Priest (1997-98), 'The privatization of regulation: Five models of self-regulation', *Ottawa Law Review*, Vol. 29, p. 233.

- some firms will reduce their compliance costs by seeking to minimise their self-defined control of the problem.

42 Given the second of these responses, workers may need to undertake more effort to satisfy themselves that they are not unduly exposed (possibly with the greater involvement of unions as employee representatives).

43 In some cases however, a self-regulatory regime in place of the 1982 Code will not reduce compliance costs significantly (if at all). For example, each jurisdiction in Australia requires service technicians to be licensed although there is no uniform set of requirements for service technicians across the country. Safety requirements for service technicians are covered under the licensing conditions that apply to them within their own jurisdiction. Thus, abolition of the 1982 Code would still require that service technicians comply with their licensing conditions.

44 It is difficult to quantify how any compliance cost changes will flow through the industry because they will be highly dependent upon the individual strategies of each participant.

Administration

45 As indicated in table 2, enforcement of safety standards will be through:

- the public enforcement of more general OH&S standards; and
- private actions for damages in the event that firms do not take appropriate steps to ensure the safe operation, transportation, disposal etc of FRGs.

46 While there is a temptation to suggest that these responses indicate higher public and private expenditure on litigation, in practice, experience in self-regulatory regimes indicate that regulators will not see FRGs as a regulatory priority (because the lack of a regulatory regime indicates this) and so it is unlikely that there will be an ‘explosion’ in public litigation costs.

47 Self-regulation could involve some transitionary administrative costs if jurisdictions are required to amend Acts and/or Regulations that refer to the 1982 Code. The difficulty occurs in determining how jurisdictions would respond to self-regulation. For example:

- If jurisdictions accept a move to self-regulation, then the amendments may be classified as being ‘machinery of government’ and the costs of the minor amendments may be slight, and are not considered as costs for the purpose of inclusion in a RIS.
- If, however, some jurisdictions sought to amend their own Acts and/or Regulations to compensate for an agreed national move to a self-regulatory environment, the one-off costs may be in the vicinity of $400 000 to $3.6 million.[13]

48 For the purpose of this RIS it is assumed that legislative-related costs are minimal, as reduced regulatory requirements do not usually require detailed analysis and tend to be passed or made quickly without significant resources.

Health and safety

49 Governments would have no direct control over exposure limits and safety procedures. This could be detrimental to the health and safety of occupationally exposed persons, and ultimately to the public, in the event of an incident involving a FRG.

50 There is also a concern that health and safety outcomes will not be supported because of the existence of information asymmetries in a self-regulatory environment:

13 The basis for this cost estimate is set out in the Proposed Code of Practice section.

- many different industries use FRGs from individual family-businesses right up to multi-national corporations. As such, there is a lack of homogeneity across the 'industry' and this could lead to a lack of consistent safety advice thereby creating confusion and uncertainty as to appropriate safe practices; and
- equipment suppliers could provide safety advice with their equipment but the consistency of the advice might vary considerably with each manufacturer.

51 As a result, workers' expectations are unlikely to be met with self-regulation. Occupationally exposed persons have preferred, in the past, dose limits to be well defined and enforced by regulators. Regulators are viewed as independent and impartial. Self-regulation would not satisfy concerns of occupationally exposed persons that their health and safety has been adequately addressed by their employers. While codes and standards are not directly enforceable documents, Governments have incorporated them into their legislation (either directly or indirectly through conditions of registration and/or licence) resulting in the dose limitation and safety practices prescribed within them being legally enforceable.

52 Equipment standards would need to be set by industry in a self-regulation model. The setting of these standards could be affected by commercial interests and could be subject to change without a rigorous process. This could result in Australia becoming a 'dumping ground' for defective or sub-standard devices from overseas.

53 These factors combined, lead to a conclusion that radiation exposure is likely to increase under self-regulation thus resulting in a cost to workers, the general public, and the potential for an increased number and severity of incidents involving FRGs.

Cost to workers

54 As was discussed earlier, the average annual effective dose for workers is 0.24 mSv per year. Assuming that self-regulation resulted in an increase in the effective dose of 1 per cent — this is consistent with the approach adopted by New South Wales in a recent regulatory impact statement[14] — then a move to self-regulation would result in a cost to workers of around $4 000 per year. This is based on:

- a population of workers of 20 000 — this assumes that there is at least one radiation safety officer per premises that has a FRG and that there is on average around 40 workers who are potentially exposed to FRG indirectly while at work; and
- an estimate of the cost per person sievert of $80 000 — which is an inflation adjusted and exchange rate converted estimated cost per person sievert.[15]

Given the average effective annual dose is already low, a 1 per cent increase results in an almost negligible cost.

55 This result though, is sensitive to the absolute size of the impact. If it is assumed, for illustrative purposes, that self regulation resulted in the average annual effective dose increasing by 50 per cent — that is, increasing from 0.24 mSv to 0.36 mSv — then the cost would be $173 000 per year. If self–regulation were to result in the average annual effective dose increasing by 100 per cent — that is, it increased to 0.5 mSv, which is still 40 times lower than the proposed exposure limits — the cost would be around $350 000 per year.

[14] New South Wales 2003, *Radiation Control Regulations 2003*: *Regulatory Impact Statement*, *Appendix C*, Sydney p. 53.

[15] Taken from United Kingdom National Radiological Protection Board 1986, *Board advice on cost-benefit analysis*, Chilton, UK, p10.

56 This sensitivity analysis highlights that while the current occupational average annual effective dose is low, it would only take a small absolute increase in the effective dose to result in a significant costs for workers.

Cost to the community

57 On its own, self-regulation for FRGs would be inconsistent with the approach taken in other radiation protection regulations. Promoting an exemption for one area of radiation protection while at the same time promoting the benefits of coordination and national uniformity of radiation protection in other areas is likely to undermine the broader radiation protection regulatory system and lead to reduced benefits due to less rigorous application of the ALARA principle[16].

58 Keeping this in mind and by taking the same approach as 'cost for workers' as well as drawing on an estimate of the average annual effective dose received by the public — as estimated by UNSCEAR and measured as the world wide average annual effective dose from exposure from diagnostic and medical X-ray examinations[17] — the estimated cost to the broader community (rather than just workers) of moving to self-regulation is likely to be around $800 000 per year based on:

- an estimated population of 20 million;
- an estimated cost per person sievert of $23 664 — which is an inflation adjusted and exchange rate converted estimate taken from the NRPB 1986 study;
- UNSCEAR's estimate that the world wide average annual effective dose from diagnostic and medical X-ray examination is 1.2 mSv per year[18]; and
- an assumption that self regulation will lead to an increase in the medical average annual effective dose of 0.14 per cent. In New South Wales' regulatory impact statement it was assumed that self-regulation (considered by them as a 'no regulation' case) resulted in an annual increase in the effective dose of 1 per cent per year every year. However, FRGs do not represent all radiation sources in Australia
- in fact, the proportion of people who directly or indirectly use FRGs being 14 per cent of the total who use radiation. The assumption of an increase of 0.14 per cent is taken as the proportional impact of 14 per cent of the 1 per cent increase (i.e. 0.14 per cent) assumed by New South Wales rather than the full 1 per cent increase.

59 As with 'cost to workers', this estimate is sensitive to the absolute change in effective dose, and again the analysis shows that if self-regulation results in a higher effective dose — for example, anything greater than 1 per cent — then the cost to the community will be extremely high and may range in the hundreds of millions of dollars per year.

Cost of incidents

60 While it is always difficult to predict when incidents will occur, it is possible to consider their impact should they occur. If a FRG is lost or inappropriately disposed of then there is the potential for that 'orphaned' source to result in radiation contamination of other industrial materials. The cost associated with contamination will depend on where and how contamination occurs. While in Australia, no significant costs have been incurred due to

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16 It is acknowledged that this is an assertion for which there is no supporting research.

17 United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2000, *Sources and Effects of Ionising Radiation: UNSCEAR 2000 Report to the General Assembly, with Scientific Annexes*, United Nations, New York.

18 UNSCEAR 2000, op. cit., p. 7

incidents involving FRGs, in the United States it has been estimated that if an orphaned source became mixed with recycled metal and contaminated a large steel mill then the cost could be as high as $US100 million.[19]

61 Overall the number of incidents has been low but their cost is potentially significant. Under self-regulation there is a greater chance that the number of incidents will increase, hence increasing the likelihood that the community could incur the significant cost of contamination involving orphaned FRGs.

Security of sources

62 In an environment increasingly concerned about terrorism, self-regulation is likely to increase worries about the security of FRGs and radiation sources more generally. Self-regulation may lessen:

- the scope for monitoring gauges;
- the ability to ensure that FRGs are maintained to appropriate standards; and
- the ability to satisfy government, regulatory agencies, policing and security agencies, and the broader public that FRGs are secure and inaccessible to terrorists or other nefarious intentions.

Benefits

Compliance

63 For many firms, self-regulation would mean that they would have, and would also exercise, the opportunity to reduce their expenditure on health and safety related to FRGs.

64 However, as noted above, the existence of a range of other duties and OH&S requirements means that compliance costs are unlikely to fall as significantly as would otherwise be expected (at least in larger firms with more clearly enunciated safety systems).

Administration

65 With no code to administer, regulators across Australia would have the opportunity to reduce their expenditure on FRG-related monitoring and enforcement. In practice, however, this benefit is likely to be slight as the expenditure would most likely be diverted to litigation and enforcement of other OH&S standards related to FRG operations.

Proposed Code of Practice

66 The third option involves the revision of the 1982 Code to bring it into line with current radiation protection philosophies and practices. Any revision of the existing 1982 Code would be published as part of the ARPANSA Radiation Protection Series (RPS).

67 A revised ARPANSA Code of Practice would differ from the 1982 Code of Practice in the following ways:

- the requirement for stakeholders to develop, document, implement and regularly review a radiation management plan. A radiation management plan is designed to formalise, in writing, the working rules, emergency procedures and disposal requirements of the Code of Practice. It is considered that preparation of a radiation management plan would

[19] United States Nuclear Regulatory Commission 2001, *Regulatory Analysis: Requirements for the Possession of Industrial Devices containing By-product Material*, Rockville, MD, USA.

engender an improved safety culture within the organisation by raising the awareness of radiation hazards thus reducing the likelihood of radiation incidents. An improved safety culture would also contribute to lowering occupational doses. It should be noted that most Australian jurisdictions are currently moving toward this outcome based form of regulation;

- the introduction of specific requirements for service technicians ensuring consistent and effective safety requirements across Australia for this occupational category of gauge users;
- by bringing the requirements for the safe transport of radioactive materials into line with the Code of Practice for the Safe Transport of Radioactive Material 2001 (the Transport Code). While compliance with the Transport Code is already mandated under the legislation of each jurisdiction, alignment of the requirements of the proposed Code and the existing Transport Code would avoid confusion where potential conflicts in the information exist;
- a change in the radiation protection policy that incorporates the dose limitation and protection philosophies in ICRP Publication 60 [1991]. The 1982 Code, while also adopting ICRP recommendations and dose limits, relied on ICRP Publication 26 [1977]. The latest radiation protection measures as specified in ICRP 60 are now incorporated into the Australian radiation protection scene through Radiation Protection Series Publication No. 1. This therefore means that the 1982 Code of Practice is inconsistent with current Australian and international radiation safety practices;
- a change to the maximum dose rates around a gauge. The proposal in the draft Code is for a factor of two decrease in the maximum surface dose rates. While very few gauges will be affected by this change, ; and
- FRGs incorporating X-ray tubes or neutron generator tubes will be included in a national code for the first time.

Costs

Compliance

68 Businesses that use gauges may be affected in a number of ways:

- additional shielding costs — the proposed Code would lower the dose rate limit by a factor of two (from 500 μSv/h to 250 μSv/h at 0.05 metres from the surface of a radiation gauge). This change could involve costs to some gauge users due to the need to increase the shielding around the gauge to meet the new requirement. This is only expected to affect a very small number of gauges, if any, and the total cost should therefore be small. The 1982 Code was written at a time when ICRP stipulated annual dose limits of 50 mSv for workers and 5 mSv for members of the public. The annual dose limits have since been reduced to 20 mSv and 1 mSv respectively (ICRP 1991). It was felt that the dose rate limits on the gauge should be lowered accordingly to reflect the lower annual dose limits. As already noted, the Queensland regulator has advised that:

  > In Queensland, the radiation safety standards for gauges requires that the radiation levels around a gauge must not exceed 300 μSv/h at any point 0.05 m from the gauge surface. No gauge currently in use in Queensland has failed this requirement.

- preparation of a radiation management plan — any business that uses FRGs is required to prepare a radiation management plan. It is believed that only major companies (e.g. large construction and fabrication companies, manufacturing plants, etc) would have had formal, written safe working rules in the past, usually as part of their OH&S requirements. Smaller companies are unlikely to have had formal, written safety procedures. The radiation management plan would require consideration to be given to all aspects of safety, including defined emergency procedures, and would necessitate a person to draft such a plan. The nature of these costs varies according to the size of the business and the likelihood that they will actually prepare a radiation management plan:

– larger companies — for a larger company owning many devices, preparation time has been estimated at twenty-four person hours, which includes training of operators by the Radiation Safety Officer. This latter figure includes the time required to brief relevant personnel at the company. Using an average figure of $25 per hour for a radiation safety officer and associated staff in industry and an on-cost multiplication factor of 2.2, the preparation cost would therefore be $1320.[20]

– smaller companies — it has been estimated though that the time to prepare the Radiation management plan by a small company would be about eight person-hours. Using an average figure of $20 per hour for a safety officer and an on-cost multiplication factor of 2.2, the preparation cost would therefore be $352.[18]

69 However, estimating the costs on a company-by-company basis is not necessarily appropriate because a plan needs to be prepared by each ‘Responsible Person’. While this requirement implies that a plan only needs to be prepared for each company, the statement ‘in all applicable dealings with the fixed radiation gauge’ in the requirement indicates that it needs to apply to each premises at which a gauge is used.

70 Thus, it is possibly more appropriate to look at a per premises cost. Before doing so however, it should be noted that Queensland licensees in possession of radioactive substances have had radiation safety plans since well before 1990. Although these are called “radiation safety and protection plans”, the Queensland regulator has advised that they are essentially what will be required by the proposed Code. With 82 premises in Queensland with FRGs, and 497 premises (total) nationally that have FRGs, assuming that the preparation cost per premises is $352 (the preparation cost per small firm), the initial Australia-wide compliance costs without the Queensland component would be in the order of $146 000.

71 Additionally, there will be some ongoing plan-related costs as new FRGs are installed and as operational circumstances change.

72 Of course, these costs could be reduced in part by regulators preparing a template radiation management plan (see below). This would involve the users to ‘fill-in-the-gaps’ to suit their own situation but the total time to prepare the final document would be reduced.

73 Introducing FRGs with X-ray gauges and neutron generator tube gauges in the proposed Code could involve some cost to the key stakeholder groups (i.e. suppliers, users, service providers). The number of these types of gauges is small though and represents less than 2 per cent of all FRGs currently in use in Australia. Their potential hazard however, is relatively high and there remains the need to control them. For that reason, all jurisdictions currently license and/or register this equipment so the regulatory impact on the key stakeholders groups would be small. There might however, be some compliance costs, particularly for suppliers, although these costs are also expected to be small as the safety requirements incorporated into the proposed Code are based on international guidelines for this equipment.

74 Compliance costs would also be incurred by service technicians who, for the first time, are explicitly obliged to comply with safety aspects of the proposed Code. It is unlikely however,

[20] Estimations of costs and preparation time provided by the Victorian regulator.

that the compliance costs would be significant as the general provisions of the 1982 Code are applied to all groups that use FRGs, including service technicians, as a requirement of current State/Territory licensing arrangements.

Administration

75 With the introduction of any new code, the regulators themselves require some retraining and familiarisation with the proposed Code, which incorporates the 1990 ICRP radiation protection philosophy and includes reference to the 2001 Transport Code. As these documents have been utilised in the Australian radiation protection environment for some time now, it is expected that the cost to Governments to retrain or familiarise regulators would be small. It should be noted that the proposed Code is not an entirely new code and essentially revises the older version. Retraining and familiarisation of regulators with the proposed Code should therefore not be as extensive as would be the case with a completely new code.

76 The Victorian regulator has estimated that the cost of familiarisation with a new code and briefing/training the remainder of staff within the regulatory unit would be of the order of forty person-hours. Using an average figure of approximately $25 to $30 per hour per staff member and an on-cost multiplication factor of 2.2, the cost to the regulatory body for retraining/familiarisation would be between $2200 and $2640. This equates to around $25 000 in national costs (assuming that costs in each jurisdiction are proportional to the number of FRGs).

77 As noted above, the industry compliance costs associated with the preparation of a radiation management plan could be reduced if regulators prepare a template radiation management plan so that users can 'fill-in-the-gaps' to suit their own situation. Preparation of such a template would, of course, transfer part of the preparation costs to the Government agencies. The time taken by Government agencies to prepare and maintain such a template would be expected to be less, however, than the collective time of all the individual users to prepare their own individual radiation management plan without the guidance of a template.

78 The introduction of a new code would likely mean that each jurisdiction would need to amend an Act and/or Regulations. Changing legislation or regulations governing these issues will require resources and costs on behalf of government. While somewhat stylised, the process will involve:

- policy approval:
  - policy officer time;
  - departmental approval;
  - cabinet approval;
- drafting:
  - policy officer time;
  - parliamentary Counsel's drafting time;
- legislative approval:
  - the Bill to be read, debated, and approved by legislative assembly or house of representatives;
  - the Bill to be reviewed by upper house;
  - the Act to be given Royal Assent by Governor or Governor General;

- promulgation:
  - printing; and
  - information and promotional material about changes.

79 These costs will be one-off and will have no further impact on the way in which jurisdictions regulate radiation protection issues nor will they have any impact on industry, consumers of products that use radioactive substances, nor the public more generally. Hence such administrative costs are rarely costed, although it should be recognised that even machinery of government legislative changes will impose government costs. By way of example of what this might costs:

- in Western Australia, the average cost of legislative amendments that was directly attributable to a department was estimated to be around $45 000 — although it was acknowledged that this was an underestimate of the costs;[21] and
- in the United Kingdom it was estimated that to implement regulatory changes relating to European Works Councils would involve an administrative cost of amending legislation of approximately $400 000.[22]

80 Using these estimates as a guide to the administrative cost of implementing the proposed Code, then the total administrative cost of amending legislation in all jurisdictions could range from $400 000 and $3.6 million. This assumes that all jurisdictions need to pass some legislative amendments. The actual cost however, is expected to be at the lower end of this range, as amendments are relatively non-controversial, they have been subject to considerable debate between the jurisdictions, and the impacts have been open to public comment and review for some time — hence should not consume significant parliamentary or departmental resources.

Benefits

Health and safety

81 The core benefit ascribed to the proposed Code is to create improved health outcomes by aligning requirements for FRG safety with current radiation protection philosophy.

82 Improved health outcomes should result from at least three factors:

- Improving radiation protection awareness and safety culture throughout the industry by the formal requirement for a radiation management plan;
- the broadening of the range of sources addressed by the proposed Code (i.e. the inclusion of FRGs with X-ray tubes or neutron generator tubes); and
- the tightening of the annual radiation dose limits from 50 mSv per year to 20mSv per year averaged over five years.

83 The implementation of a radiation management plan will set up a more structured regime of testing and accountability of gauges than previously required, thus lowering the risk of an incident occurring. Further, the radiation management plan will result in the documenting of more efficient strategies for better dealing with incidents should they occur, thus reducing the consequences of an incident. It will not take many avoided radiation incidents to generate significant benefits. For example, as a rough guide, a human capital model of workplace

21 Department of Local Government and Regional Development 2003, *Annual Report 2002-2003*, Perth, p. 21.

22 Department of Trade and Industry (UK) 1998, ‘Implementation of the Regulations on European Works Councils — Regulatory Impact Assessment, London, p. 10.

costs suggests that the major categories of indirect costs associated with workplace-related disease-induced death — i.e. consequential overtime, loss of productivity, staff turnover costs, retraining costs; lost future earnings, legal costs, pain and suffering, loss of income, health and medical costs, loss of gross domestic product (i.e. human capital), and loss of tax and revenue — are worth in excess of $500 000 per work-place related death.[23]

84 The proposed requirement for a formal written radiation management plan will increase safety awareness in the industry in general and FRG users in particular. Better safety awareness and improved safety culture should lead to a reduction in the potential for incidents or abnormal radiation exposures. These benefits would flow to the community as a whole from reduced incident investigation or compliance activity costs. The public (including employees) could also be assured of a lower risk of exposure to radiation, a greater confidence in the level of safety in the industry and a lower likelihood of incidents leading to less potential for harm to the environment.

85 Overall these benefits can be considered in terms of:

- Benefits to workers who directly or indirectly use FRGs — it is estimated this will be at least $3 000 to $4 000 per year;[24]
- Benefits to the community — it is estimated that this is likely to be at least $800 000 per year;[25]
- Reduced number of incidents — while it is not possible to quantify this impact, reduced number and severity of incidents could result in savings in the order of millions of dollars in avoided costs.

Caveat on health and safety benefits

86 While this analysis has assessed costs and benefits, at least in part, in terms of changes to average annual effective dose it is important to at least acknowledge that there is some academic debate about the effects of low doses of radiation on humans.[26]

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23 Derived from Industry Commission 1995, *Work, Health and Safety*, AGPS, Canberra. Collins and Lapsley note that 'The human capital approach is necessarily always adopted in benefit-cost analysis (BCA) where the nature of the task is to compare, on a common basis, time streams of costs and benefits.' — D. Collins and H. Lapsley 2002, *Counting the Cost: Estimates of the Social Costs of Drug Abuse in Australia in 1998-99*, Monograph Series No. 49, Commonwealth Department of Health and Ageing, Canberra, p. 14. It is noted that the observation that the human capital approach "is used most often" in cost-benefit and cost-effectiveness analyses is due to the availability of reliable statistics, the relative simplicity of calculations and the consistency of results, which permit comparison between diagnostic categories or with other cost-of-illness studies using this approach. For further information please see http://www.phac-aspc.gc.ca/publicat/ebic-femc93/burd2_e.html.

24 This is based on the same approach used earlier when considering the impact of self-regulation — see paragraph 54 — although the analysis considers the implications for a reduction in average annual effective does rather than an increase. This analysis assumes that the introduction of the proposed Code will reduce occupational average annual effective dose by 1 per cent for the population of workers who use FRGs directly or indirectly. This is consistent with the approach adopted for the cost benefit analysis for the National Directory Edition 1.0 and it is consistent with advice from ARPANSA on the expected benefits of the FRG Code.

25 This is based on the same assumptions in paragraph 58, although it is assumed here that instead of an increase in medical average annual effective dose there will be a decrease of the equal but opposite magnitude. Again, this is consistent with the approach adopted for the cost benefit analysis for the proposed National Directory Edition 1.0 and it is consistent with advice from ARPANSA on the expected benefits of the FRG Code.

26 This issue was most recently raised in an article in the *Australian Financial Review* (see D. Taverne 2004, *Exposed: some facts about radiation*, *Australian Financial Review*, Review, 13 August, p. 3). For a full discussion and further background on this debate see OECD Nuclear Energy Agency 1998, *Developments in Radiation Health Science and their Impact on Radiation Protection Committee on Radiation Protection and Public Health*, Report of the Working Group on Science and Technology Affecting Radiation Protection Sub-

87 Some scientists believe that at doses below about 100 mSv, the evidence of radiological harm is not clear-cut. While some studies indicate evidence of radiation-induced effects, epidemiological research has been unable to establish unequivocally that there are effects of statistical significance at doses below a few tens of millisieverts. That is, in questioning the veracity of the linear non-threshold relationship, some scientists are challenging whether current exposure standards are set too restrictively.

88 It is noted however, that the United Nations Scientific Committee on the Effects of Atomic Radiation has supported the linear non-threshold and the basic assumptions that underpin the ICRP 60 and hence exposure limits set in the proposed Code.[27] It is also noted that there is no alternative regulatory approach adopted elsewhere in relation to radiation protection standards and exposure limits. In the absence of any demonstrated or agreed alternative it is believed that the assessment of health and safety benefits in this report is reasonable.

Compliance

89 While there are costs associated with complying with the proposed Code, there are also some compliance benefits. In particular:

- the proposed Code would give clear up-to-date guidance and provide advice on safety obligations to all users, manufacturers, suppliers and service technicians who deal with FRGs;
- a single ARPANSA Code would also enable a uniform approach to radiation protection for FRG use across Australia. This would ensure that all stakeholders would be aware of their obligations even when operating in another jurisdiction; and
- the public would also have access to the safety requirements that operators need to comply with.

90 In particular, compliance costs are likely to be reduced for firms that have cross-jurisdictional operations (i.e. they will be able to have a single standardised operational approach) in respect of two particular activities:

- for the first time for FRG use in Australia, requirements for service technicians are proposed. The benefit of including safety requirements for this occupational category in the proposed Code is to achieve a consistent approach to regulating them across Australia. While individual licensing within each jurisdiction would remain, specifying safety requirements would ensure a uniform approach to safe working practices by service technicians across the country; and
- by including X-ray gauges and neutron generator tube gauges into a code for the first time, suppliers, users and those who service this type of equipment will have a clear idea of the safety obligations that they must meet uniformly across Australia. This will reduce costs to those stakeholders as they will no longer need to determine what they need to do to comply in each separate jurisdiction.

91 The fiscal cost of an incident involving a FRG can be quite high. If, for example, a FRG is disposed of to a scrap metal dealer along with an abandoned process line, an investigation by the regulatory authority could take several person-days, including report writing. Further costs would be incurred in recovering the damaged device, in packaging and returning the device to the supplier (if possible), and in replacing the gauge (if required). In some

Group on Radiation Health Sciences (WGST-RHS), pp. 11-17. Also see OECD Nuclear Energy Agency 2000, *A Critical Review of the System of Radiation Protection: First Reflections of the OECD Nuclear Energy Agency's Committee on Radiation Protection and Public Health (CRPPH).*

27 UNSCEAR 2000, op. cit., p. 14.

circumstances it may not be possible to recover the gauge, particularly if it is damaged or destroyed, but costs will still be incurred in recovering the source material (if possible) and in decontamination for plant and equipment. These costs could feasibly be in the order of thousands to tens of thousands of dollars. Hence, any reduction of the risk of an incident would represent a benefit to the government, the industry as a whole and to the public.

Dynamic efficiency

92 Another advantage of redrafting the 1982 Code as an ARPANSA Code is that all jurisdictions would be able to collectively ensure that the Code remains current through regular updates by the Radiation Health Committee to reflect changes in international dose limits or device design.[28] This would also involve additional implementation costs but the advantage of using the most recent dose and risk data at all times would be considered to outweigh the cost.

International standing and consistency

93 The proposed Code would refer to Australia's most recent radiation protection standards that, in turn, incorporate current international radiation protection guidelines using dose limits in ICRP Publication 60 (1991). It would also:

- incorporate current international best practice for the safe design and operation of FRGs, particularly those that incorporate X-ray or neutron generator tubes; and
- refer to the ARPANSA Code of Practice for the Safe Transport of Radioactive Material (2001), which would ensure international best practice for the transport of FRGs that contain radioactive sources.

Summary of identified costs and benefits

94 A list of the costs and benefits provided by each of the three identified options (with the *status quo* options used as the base comparator) is shown in table 3.

95 The costs and benefits identified in table 3 are not necessarily spread evenly among the community. Relative to the *status quo*, the major distributional impacts associated with:

- self-regulation include:
  - the increased flexibility and reduced compliance costs will likely be most readily captured by smaller firms. Larger firms are more likely to have systemised safety processes that will otherwise address safety issues related to FRGs;
  - government regulators will save administrative costs associated with the 1982 Code, those savings are likely to be redirected into the administration and enforcement activities under more general radiation protection regulations and broader OH&S regulatory arrangements;
  - there will be a greater onus on workers to protect themselves by being knowledgeable of risks, and enforcing their rights under other regulatory obligations — given that employees and the general public are not usually in the best position to protect

[28] The Radiation Health Committee has stipulated a 10-year review cycle for all of its Codes and Standards or sooner where there are significant international changes. At the time of writing, the ICRP were proposing changes to their radiation protection philosophy in 2005 and the IAEA Transport Regulations could be updated within the next few years. RHC would then need to evaluate any international changes and their impact on its Radiation Protection Series of publications before determining the need for reviews of individual Codes.

themselves, largely because of information asymmetries, they will likely bear the burdens associated with reduced health and safety outcomes;

- there will be a cost of between $4 000 and $350 000 per year for workers resulting from an assumed increase in the doses received of between 1-100% by moving to self regulation. The cost to the community could be of the order of $800 000 per year. These costs could be significantly higher if self-regulation resulted in a less rigorous application of the ALARA principle — ranging into the tens of millions rather than the hundreds of thousands;
- security of FRG sources may be reduced and hence raises a concern about national security and terrorism;

- the introduction of the proposed Code include:
  - users of FRGs that incorporate X-ray tubes or neutron generator tubes will incur additional costs as they will be included in a code of practice for the first time, although this only affects 2 per cent of all FRGs. It is unlikely that this will affect the market for the production of FRGs;
  - there will be increased costs for regulators as they come up to speed on the proposed Code. Such costs are not considered significant; and
  - standardisation of the regulation of all FRGs across Australia should provide relatively greater benefits for firms that operate in more than one jurisdiction.
  - reduced average annual effective dose levels should result in a benefit for workers in the order of $3 000 to $4 000 per year and a benefit to the community more broadly in the order of $800 000 per year.

96 In summary:

- the *status quo* has the benefit of familiarity (and hence attendant low compliance and administrative costs), but will promote an inconsistent approach to radiation protection more broadly and is likely to result in health and safety outcomes which are inconsistent with international best practice;
- self-regulation, the second option, is constrained by the fact that to be successful:
  - there must be sufficient power and commonality of interest within an industry to deter non–compliance; or
  - the cost of non–compliance must be small.

  Neither of these threshold problems is satisfied with respect to the use of FRGs. Additionally, self-regulation is likely to lead to greater exposure levels and hence reduced health and safety outcomes — overall a net negative is expected by moving to self-regulation; and
- the third option entails higher administrative and compliance costs than the *status quo* (in the order of at least $200 000 in the first year, and significantly less thereafter). Against these costs, the principle benefits relate to:
  - a slight reduction in compliance costs for firms that operate across jurisdictions because of national standardisation;
  - a reduction in ambiguities that have arisen in the 1982 Code and more recent radiation-related codes; and

- improved health and safety benefits by a tightening of exposure standards — which could result in benefits in excess of $800 000 per year. While this benefit is not all that large, given current low average annual effective dose levels and the relatively small number of FRG-related radiation incidents, the proposed Code brings Australia into line with international standards and ensures a consistent regulatory approach to radiation protection across Australia. The key to acknowledge here is that while effective dose levels are low the cost of even a small absolute increase is high and that while the incidence of incidents may be low, the potential severity for any incident is also high — the proposed Code would need to make only a small difference to justify the increased compliance costs.

97 The challenge in assessing these options is that the costs are readily observable, the benefits are somewhat more nebulous. While the *status quo* is clearly preferable to self-regulation, the difference between the *status quo* and option 3 (i.e. a new standardised code) is marginal but still positive — particularly when you consider that most of the costs are establishment costs (i.e. incurred in the first year) whereas the benefits are ongoing.

TABLE 3 – NATURE OF IMPACTS COMPARED TO THE *STATUS QUO*

Date	Self-Regulation	Proposed Code
Cost		
Compliance	*Slight decrease in costs* As regulatory obligations are reduced (but not eliminated, due to remaining occupational health and safety standards) compliance costs will fall for some (probably smaller) firms Employees and tradespeople may faced increased compliance costs because they cannot necessarily rely on firms adhering to acceptable standards	*Increase in costs* The initial generation of Radiation management plans is estimated to cost FRG users about $0.146 million as a one-off cost. There will be significantly smaller annual costs for Radiation management plans as new FRGs are installed and/or circumstances change National harmonisation reduces cross-jurisdictional information asymmetries and therefore compliance costs for larger national firms.
Administration		*Significant one-off cost* The need to amend legislation to accommodate a new Code may incur one-off administrative costs in the vicinity of $0.4 million. Approximately $25 000 in one-off staff training costs for regulators. Ongoing additional costs are not considered significant.
Health and safety	*Increase in costs* Self-regulation is likely to lead to higher exposure levels — as measured in terms of average annual effective dose — and differential standards across firms means that informational asymmetries will make attainment of positive health and safety outcomes more difficult. The cost to workers is likely to be from $4 000 to $350 000 per year while the cost to the community could be of the order of $800 000 per year.	
Dynamic efficiency	*Increase in costs* Firms have the ability to adopt least cost safety approaches, and to adapt as standards (e.g. set through judicial interpretation of general duties) and technologies change	
International standing and consistency	*Significant reduction in consistency* Self-regulation would move our regulatory approach away from internationally agreed	
Security of FRG sources	*Potential for extremely high costs* In the event that self-regulation resulted in reduced security of FRG sources and that this is a contributing factor in a terrorist attack involving a FRG, then the potential cost — personally and financially — would be extremely high.	

Date	Self-Regulation	Proposed Code
Benefit		
Compliance	*Reduction costs (i.e. a benefit)* Significantly reduced compliance costs for smaller firms, but less so for larger firms (as other OH&S obligations remain)	*Slight benefit* Will promote greater uniformity and consistency in radiation protection across Australia in the area of FRG.
Administration	*Slight reduction in costs (i.e. a benefit)* Significantly reduced administrative costs specifically associated with FRGs, but costs likely transferred to related OH&S enforcement	
Health and safety		*Increased benefit* Will result in lower average annual effective dose levels and should result in benefits in excess of $800 000 per year. Should also promote better regulation to ensure that the number and severity of incidents is reduced, thus resulting in an avoided cost.
Dynamic efficiency		*Increased benefit* By incorporating the ability to adjust standards on a more frequent basis the new code provides greater scope to remain appropriate over time
TOTAL	***Net cost***	***A potential net cost (or at least very small benefit) in the first year, with subsequent net benefits thereafter***

Consultation

98 The proposed Code of Practice, and associated Safety Guide, was developed by a working group of the Radiation Health Committee. The working group included representation from the legislator in Victoria, a supplier of radiation gauges from the private sector, and ARPANSA. The Radiation Health Committee includes representatives from all Commonwealth, State and Territory radiation protection regulators.

99 The draft Code of Practice has been made available from the ARPANSA web site at www.arpansa.gov.au for a period of public comment until 14 October 2005. The following organisations have been advised of the availability of the proposed ARPANSA Code and this Regulatory Impact Statement and their comments have been requested:

(a) Australian Council of Trade Unions
(b) Community and Public Sector Union
(c) Australian Radiation Services Pty Ltd
(d) Radiation Safety Services
(e) Dr K W Terry — Radiation Wise
(f) All registered gauge owners in New South Wales
(g) Registered gauge users in Victoria (list supplied)
(h) Registered gauge users in South Australia (list supplied)
(i) Registered gauge users in Queensland (list supplied)
(j) CSIRO, Division of Minerals
(k) Queensland Alumina Limited
(l) CSIRO, Division of Minerals
(m) Queensland Alumina Limited
(n) Tasmanian Chamber of Commerce & Industry
(o) Tasmanian Department of Economic Development
(p) Workplace Standards Tasmania
(q) Mineral Resources Tasmania
(r) The Institution of Engineers Australia
(s) Australasian Radiation Protection Society (ARPS)

Please note, additional organisations will be advised once contact details from Regulatory Authorities have been finalised.

Conclusion and Recommendation

100 Option 1 does not meet the objectives as NHMRC has decided to discontinue its RHS publications. The 1982 Code has not been revised since it was promulgated and the NHMRC will not review or update it in future. Hence, it is out-of-date with changes to international guidelines and new scientific findings and will increasingly be so. It does not incorporate gauges that use X-ray tubes or neutron generator tubes which, although small in number, should have uniform safety requirements placed upon them. It should also be noted that some jurisdictions have already opted to introduce their own requirements for gauges as evidenced by the quote from the Queensland regulator given in paragraph 68. Consequently, the continued use of the 1982 Code is unlikely to protect persons, property and the environment from the adverse effects of radiation in the most cost-effective manner.

101 Option 2 is not preferred for the following reasons:

(a) There is little evidence that the industry has the structure to organise itself for self regulation and keep up with international guidelines or scientific findings.

(b) Self-regulation does not satisfy concerns of occupationally exposed persons that their health and safety has been adequately addressed by their employers.

(c) There is no evidence that self-regulation would meet governments' objective as the industry would need to draft its own equipment standards, and could be overly influenced by commercial interests. This could result in sub-standard equipment being purchased from overseas by Australian companies.

102 On balance, Option 3 is preferred as it provides greater nett benefit than Options 1 and 2 for the following reasons:

(a) Although there is no short-term benefit, the proposed ARPANSA Code will ensure that there is increased safety awareness throughout the industry through preparation of a radiation management plan by all users.

(b) Option 3 ensures that the most recent international developments in radiation protection philosophy and equipment standards are utilised in the Australian situation.

(c) Service technicians would have a clear and uniform set of guidelines to cover their profession that would, in turn, engender an increased safety awareness and culture.

(d) The inclusion of X-ray gauges and neutron generator tube gauges for the first time in an Australian Code of Practice will lead to uniform regulation of these types of gauges

(e) An ARPANSA Code of Practice would mean that Governments would maintain control over radiation protection and the standards of the gauges used. A uniform approach to radiation protection across each sector of the industry would therefore be ensured.

(f) Unless practical measures for compliance are prepared to supplement the proposed Code, persons owning/using FRGs will find it difficult to comply. As such, a Safety Guide has been produced detailing practical and cost-effective means of complying with the Code. The proposed Safety Guide will be published together with the proposed ARPANSA Code.

Stakeholders are encouraged to provide their views on the adequacy of the Safety Guide attached to the proposed ARPANSA Code of Practice.

103 Jurisdictions will incur costs to implement, monitor and enforce compliance with the Code although these costs are unlikely to be substantially higher than current costs. Jurisdictions will, however, retain control over the cost of implementation and enforcement as these matters are not prescribed in the proposed ARPANSA Code and it is up to regulators to determine the most cost-effective implementation and enforcement mechanism.

104 The key issue is whether the costs of implementing the Code outweigh the benefits. It is believed that the cost of implementation is relatively small but the benefits from introducing a new ARPANSA Code could be significant. By requiring compliance with up-to-date dose limits and transport requirements, the industry as a whole will benefit from an improved safety culture. The costs are relatively small because the Code is essentially a re-write of an existing Code and many of the safety requirements should have been employed since the early 1980s.

Stakeholders, particularly users, manufacturers, suppliers and service technicians who disagree with the conclusion above are urged to substantiate their view with a description and quantification of costs to apply, implement, administer or enforce the proposed ARPANSA Code of Practice.

Implementation and Review

105 The proposed Code will be published by ARPANSA under its Radiation Protection Series. ARPANSA's Radiation Health Committee will review the Code within 10 years of its commencement to ensure it is still relevant to radiation protection needs. Earlier review would be undertaken if there are problems in the implementation of the Code, if international or national radiation protection objectives change or if there is new information from international research.

106 After publication, the Code will be proposed for incorporation into the National Directory for Radiation Protection, which is now being prepared by ARPANSA. In August 1999, the Australian Health Ministers' Conference endorsed the National Directory as the mechanism for implementing national standards and codes of practice in radiation protection. When the Code is incorporated into the National Directory, all States and Territories must adopt it into their regulatory frameworks.

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