Regulatory control of medical research involving the use of radiation

Suppose a team of medical researchers wants to investigate the efficacy of a new treatment compared either with current treatment, or with a placebo for a particular medical condition. Part of the evaluation of the treatment involves radiation.

The use of radiation may be a DEXA bone scan to measure bone mineral density at various stages of the trial, or it may be a CT scan to provide radiological evaluation, or it may be radioactive materials to assess organ function. The radiation is not for the direct benefit of the individual patient, but typically is just one of several measures for establishing the effectiveness of the new treatment. This situation, with many variations, occurs quite frequently in New Zealand.

What regulatory controls are applied to this radiation use?

Every medical procedure that uses radiation must be prescribed or authorised by someone licensed under the *Radiation Protection Act* to do this. It is a fundamental principle of radiation protection that any exposure to radiation must produce a net benefit (the principle of *justification*), and every licensee is required by a *Code of safe practice* to take this into account. How can this be assured in the case of a research subject – that the radiation risk to the individual is outweighed by the benefit to the community from the research?

The role of the ethics committee and NRL

Radiation risk is not the only possible hazard for research volunteers. They are typically also at risk from reactions to medicines, infections, etc. The task of measuring up the risks against the benefits belongs to one of the medical ethics committees, of which there are 20, in New Zealand. The committee will consider all aspects of the proposal prior to any consent being given. It is vital that the risks from exposure of volunteers to radiation are correctly estimated and described in a way that will allow the committee to reach a balanced appraisal. For this reason the relevant *Codes of safe practice* require every research proposal to be submitted to NRL to check the radiation risk assessment prior to going to the ethics committee. The project proposal must state clearly what radiation is intended to be used, age and gender details of those who will be involved in the trial, and dose and radiation risk estimates. If these estimates are correctly presented in the proposal, a formal ratification to that effect is issued by the National Radiation Laboratory. The ratification is then included in the proposal submitted to the ethics committee.

Note that NRL does *not* give the approval for the research itself. This is solely the responsibility of the ethics committee. However, with the assurance that the radiation risks are fairly assessed, and with the judgement of the ethics committee that the value of the research justifies all of the risks, including those from radiation, a licensee who has research subjects referred for a particular radiation procedure can be confident that the justification principle has been satisfied.

For further information contact John Le Heron (John_Le_Heron@nrl.moh.govt.nz) for research proposals involving the use of x-rays or Vere Smyth (Vere_Smyth@nrl.moh.govt.nz) for those using of radioactive materials.

Smoke detector discovery provokes emergency response in Wellington

A casual evening walk in a Wellington park recently caused a full-scale radiation emergency response. A man walking his dog noticed a small metal canister embedded in the ground. The canister was also prominently labelled with a trefoil and radiation warning statement. The concerned citizen notified local authorities and within minutes several fire tenders and ambulances were in attendance, as well as the local Health Protection Officer.

NRL was then contacted, and after discussions with various emergency response staff it was ascertained that the canister was the ionisation chamber from a domestic smoke detector. Measurements confirmed that there was no evidence of radiation associated with the canister and it was removed from the ground. It was then apparent that the canister was empty and the emergency response teams were stood down.

While the incident was generally well managed and there were no attendant radiation risks, it was an expensive call-out for the response teams. Furthermore, it seems consideration was given by emergency services to evacuating residents from a wide area around the park, a move that would have been inconvenient and a cause of concern to people.

This incident should serve to reinforce to owners and users of radioactive materials the levels of concern that exist in society with respect to ionising radiation, and indeed radiation in all forms. Owners and users of radioactive sources have obligations under the law regarding their use, safe handling, storage and transportation. Incidents such as this are a reminder of the potential consequences that can occur if these responsibilities are not adequately discharged. Licensees are reminded of the legal requirement to obliterate any 'radioactive' markings when disposing of empty packaging.

An information sheet IS 8: *Domestic smoke alarms*, is available on the NRL web site. The recommended method of disposal of obsolete alarms is through conventional refuse collection and subsequent landfill.

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ReSources

Two new information sheets are now available (from our web page, or contact Ursula Ryan, Ursula_Ryan@nrl.moh.govt.nz):

IS 25 is entitled *General guidance on shielding requirements for medical x-ray diagnostic rooms*. It has been written in response to queries from architects and gives general information on shielding requirements in diagnostic rooms, CT and mammography rooms. It deals with both primary and secondary barriers especially across transitional areas, ie, walls to doors, or walls to windows, and preferred type of doors. For more specific requirements, advice should be sought from a Qualified Health Physicist.

In response to interest in the item on radiopharmaceuticals and cremation in the September issue of *The Source*, IS 26 is now available. *Death of a patient treated with radioactive material* examines the risks and precautions advised in this situation. In all cases, conventional burial, either of the ashes after cremation or of the body, is the recommended course of action.

NRL Codes of safe practice update

The drafts of 2 new *Codes of safe practice* and complementary *Guidance notes* will shortly be released for public consultation. The Codes:

- *Code of safe practice for the use of x-ray security and inspection systems*, NRL C16,
- *Code of safe practice for x-ray analytical equipment*, NRL C17,

will be sent out to interested parties for comment, and will also be available on the NRL web page. Visit our *What's new* page for more information.

Non-ionising news

Power frequency fields & cancer risk

A report issued by the National Radiological Protection Board's Advisory Group on Non-Ionising Radiation has concluded that the low frequency electromagnetic fields that exist in the vast majority of houses in the UK are not a cause of cancer in general. Although they noted that exposures to unusually high levels of power frequency electromagnetic fields have been associated in some epidemiological studies with a very small increase in childhood leukemia, there was no evidence for an effect on cancer in laboratory studies and no clear evidence for an effect in adults.

The report is consistent with a NZ study carried out by the University of Otago Medical School. None of the subjects in this study, which examined all cases of childhood leukemia reported over a four-year period, were exposed to high levels of power frequency electromagnetic fields.

Further information is available at: www.nrpb.org.uk/Pressr.htm

Radiofrequency transmitter guidelines

The *National guidelines for managing the effects of radiofrequency transmitters* were published in December 2000. The result of a partnership between the Environment and Health ministries, the National guidelines aim to:

- Increase public understanding of how radiofrequency transmission facilities operate and how international exposure standards are developed
- Provide the Ministry of Health's advice on health effects
- Encourage a consistent approach by territorial authorities in managing the effects of radiofrequency transmission facilities
- Encourage industry to reduce community concern through non-regulatory approaches
- Ensure people are aware of the implications of the Environment Court decisions.

The entire 94 page document is available at the Ministry for the Environment's website (www.mfe.govt.nz/new/index.htm). An information booklet on *Cellsites* is available from the NRL web page.

Cellphones & brain tumours

Three studies reported over the past few months do not support an association between cellphone use and risk of brain tumours. The authors of two of the studies, carried out in the USA, caution that although they see no evidence for an association, the exposures occurred comparatively recently and if there is a long latency between use of the phone and appearance of a tumour, this may not have shown up. The third, more comprehensive, study encompassed all cellphone users in Denmark between 1982 and 1995 and linked subscriber lists with the Danish Cancer registry. Even with this longer follow-up time, there were no associations between brain tumours and phone use.

Several similar studies (including one at the Wellington Medical School), forming part of an International Agency for Research on Cancer project, are still in progress and will be reported over the coming years.

IS 21 *Safety of cellphones* has been revised. It has been rewritten to incorporate the most recent information and includes references to other reports on cellphone safety.

IAEA assistance to developing countries

The International Atomic Energy Agency (IAEA) provides assistance in the form of equipment, training courses and visits of technical experts to developing country Member States. Under the Regional Cooperative Agreement (RCA) which involves 17 countries in the east Asia and Pacific region a range of projects are being conducted. Over 19-21 February a group of national project coordinators from 5 of the countries met at NRL to assess the effectiveness of the regional programme in radiation protection and to plan for or revise plans for future activities.

The IAEA has made some changes in emphasis in its radiation protection support programmes. It is now providing assistance in two 'umbrella' project areas; one relates to regulatory infrastructure and occupational exposure control, and the other to medical and public exposure control and emergency planning.

A significant undertaking by the IAEA during 2000 was a series of peer review missions to developing countries among the 17 Member States. The missions were designed to assess the level of development and effectiveness of radiation protection infrastructures and to identify needs for the establishment and enhancement of effective regulation and radiation protection programmes.

The RCA radiation protection coordination group reviewed the effectiveness of activities conducted in 2000 and reassessed future planned activities to ensure consistency with the umbrella projects and avoid overlaps. Greater attention was given at the meeting to more clearly defining the types of person who should be nominated for participation in planned workshops and training courses. NRL is to be involved with a further personal dosimetry intercomparison study which is to commence during 2001.

Dental drill: doses to patients

Dose is a term that tends to be used very loosely, but in practice requires careful definition. In most situations dose is used to characterise how much radiation there is or was. From a radiation protection perspective dose is the quantity that is assumed to correlate with radiation harm and hence dose is a measure of risk. When a dose is quoted for a given examination it is almost certainly being used as an indicator of radiation harm.

However dose comes in various guises. This and two further articles will introduce various forms of dose and discuss these in the context of dental radiography.

Absorbed dose

In its simplest interpretation, dose is a measure of the amount of radiation absorbed by whatever has been placed in the radiation beam. More precisely, dose (often called absorbed dose) is the energy absorbed per mass of the material at the point of interest.

The SI unit of dose is joules per kilogram, given the special name of the gray (Gy) in honour of an English physicist. A gray of radiation is quite a large dose, and an exposure of a few grays of radiation would have quite serious consequences. Dental (and medical) x-ray exposures are at much lower levels and the submultiples of milli- or even micro-grays (mGy and µGy) are usually used.

Entrance surface dose

In dental radiography the amount of radiation arriving at the patient's skin is often used to characterise how well (or not) the examination is being performed from a radiation protection perspective. This is mainly because dose at this position is relatively easy to measure.

Entrance surface dose is the name often given to the dose that the region of skin in the incident primary beam receives in the course of an x-ray exposure. Most of the entrance surface dose in dental radiography is directly due to the incident primary beam, but about 20 – 30% is due to energy absorbed from x-rays scattered back from the head as the primary beam travels through the head.

Typical values of entrance surface dose for a single intra-oral bitewing exposure are in the range 1 to 5 mGy, but can be as high as 10 mGy. Future articles will discuss the many factors that can influence the size of the entrance surface dose.

How do dental entrance surface doses compare with those in medical radiography?

Perhaps surprisingly the entrance surface dose for a single bitewing is significantly higher than for a chest x-ray (PA projection) where the entrance surface dose is usually less than 0.3 mGy. There are many factors involved, but the key factor is the relatively short distance between the x-ray tube and the patient's skin in intra-oral dental radiography.

The simple comparison of the entrance surface doses of a bitewing x-ray and a chest x-ray should alert the reader to the fact that there is more involved. Such a comparison does not take into account the size of the respective x-ray beams, nor what tissues were being irradiated. The next two articles will introduce equivalent dose and effective dose as means of more fully describing the doses involved.

For more information contact John Le Heron (John_Le_Heron@nrl.moh.govt.nz)

In the news and on the web

There has been media interest in the possibility of illness caused by the use of depleted uranium in weapons. Information on what depleted uranium is and why it is used in weapons is available on the NRL *FAQs and information sheets* web page. Also included are links to several reports on the topic and a WHO fact sheet.

Protest boats set out on 18 February to sail close to the 2 ships carrying the latest shipment of MOX (mixed-oxide) fuel from France to Japan. Information on the method of transport, risks and precautions was prepared at the time of an earlier shipment and can be found on the NRL *Press releases and topical issues* web page.

Following interest in radioactivity levels in phosphate rock imported into New Zealand, (see Issue 4 of *The Source*), a short report on analyses of 7 different phosphate rock samples, including samples from Chatham Rise and Hokianga, has been released. *The natural radioactivity of a selection of phosphate rocks* has been printed as a Supplement to NRL report 1986/1.

If you do not have internet access and wish to obtain any of the items above, please contact Ursula Ryan (Ursula_Ryan@nrl.moh.govt.nz)

Changes to regulations on transport of radioactive material

All transport of radioactive material into and within New Zealand must comply with the Regulations for the safe transport of radioactive material *of the International Atomic Energy Agency (IAEA). The version of the IAEA* Regulations *currently in effect is the 1985 edition. In 1996 the IAEA issued a new revision for adoption by international transport organisations (principally the International Air Transport Association (IATA), and the International Maritime Organisation (IMO)) and national governments.*

Transport by air and sea

In effect both internationally and within most countries, air and sea freight of radioactive materials is governed by the IATA *Dangerous goods regulations* and the IMO *Dangerous goods code* respectively. The radioactive materials provisions of both documents are derived from the IAEA *Regulations*. Compliance with them ensures compliance with the IAEA *Regulations*. From 1 July 2001 both documents will adopt the 1996 revision. For acceptance for air or sea freight after that date, all consignments of radioactive material must comply with the new revision.

Transport within New Zealand

It is expected that the 1996 edition of the IAEA *Regulations* will be formally adopted in New Zealand with effect from 1 July 2001. Once this is confirmed an *NRL Matters* information sheet will be sent to all affected parties.

Practical implications of the changes

There are new requirements for the marking of packages. The shipper's declaration will still be required for TYPE A and TYPE B packages and there will be some changes to some of the *proper shipping names* and the corresponding *United Nations (UN) numbers*. A full list of these changes will be available from NRL. In practice, although most of the new names and numbers are unlikely to be used in New Zealand, many packages will be affected.

Any *Shipper's declaration for dangerous goods* form, either the IATA form for air freight or the road/rail/marine form (available from NRL) filled out after 30 June 2001 should use these new names and UN numbers.

Apart from this, no other significant changes are anticipated in the transport of radioactive material in New Zealand.

Compliance with *Code of safe practice for the use of nuclear density meters*

In the last quarter of 2000, NRL performed random compliance monitoring visits at facilities with nuclear density meters. Compliance with the Code of safe practice for the use of nuclear density meters, *NRL C15 was inadequate. If non-compliance is found and the corrective actions detailed in the monitoring report are not addressed as requested, then the licensee is in breach of an important licence condition. Continued non-compliance is likely to result in a cancellation of licence, and other enforcement actions.*

Requirements for safe transport

The most frequent area of non-compliance relates to requirements for the safe transport of radioactive materials. Regulation 3 of the *Radiation Protection Regulations 1982* requires full compliance with the *Regulations for the safe transport of radioactive material* published by the International Atomic Energy Agency (IAEA). Those parts that are relevant to the transport of nuclear density meters can be found in pages 17-21 of *Guidance Notes: Safe practice for the use of nuclear density meters* issued with NRL C15 and sent to all relevant licensees. The *Radiation Protection Regulations*, and consequently the IAEA *Regulations*, are administered by NRL. The *Land Transport Rule: dangerous goods 1999*, including the subordinate document *Transport of dangerous goods on land NZS 5433:1999* is administered by the Land Transport Safety Authority.

Specific areas of non-compliance

- Labels: Labels required for transport purposes are described in full on pages 18-20 of the *Guidance notes*. In addition, section 3.3.2 of NRL C15 requires the nuclear density meter and the transport case to be labelled with licensee or owner identification and contact details.
- Documents: A *Shipper's Declaration for Dangerous Goods* and when necessary a current *Special Form Certificate* must be carried in the vehicle (see p 20 of the *Guidance notes*.)
- Placards: Placards required are described on p 20 & 21 of the *Guidance notes*.

Please note that changes to the UN numbers and wording required for transport of radioactive materials as published on p19 of the *Guidance notes* did not take place as anticipated on 1/1/2001. It is now expected that the change will occur on 1 July 2001 (see item above). Until then, please continue to use the 'before 1/1/2001' numbers.

Additional transport information, related to the impact of the *Land Transport Rule*, can be found in *NRL Matters* no. 3, April 1999. For further information contact Murray Robertson (Murray_Robertson@nrl.moh.govt.nz)

Prosecution for failure to hold a licence

The Ministry of Health recently prosecuted 2 dentists under the *Radiation Protection Act 1965* after they refused to renew their licences, despite repeated requests. At the time of prosecution one of the defendants was still unlicensed while the other had obtained a licence. The Court found the charges laid by the Ministry were proven and both were then discharged without conviction.

The prosecution and Court decision that the charges were proven are a reminder to anyone using irradiating apparatus that they must hold a current licence. The licensing regime is necessary to verify that irradiating apparatus is operating correctly and is being used properly. Although the risks from dental x-ray equipment are small, they do exist and excessive or improper exposure through faulty equipment is a public health issue.