

Radiation protection and the safe use of X-ray equipment: Laws, regulations and responsibilities

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Author's note: Since completion of this article, the licencing conditions have been changed again and, moreover, been removed from the website of the Department of Health, and are now on an independent website at <http://sites.google.com/site/radiationcontroldoh>. Revising the article in its current form to take these developments into account will lengthen it and delay its publication; but its principle message – an appeal for implementing an advisory body, as statutorily provided for – is yet further strengthened.

Background. South Africa's regulatory framework for electromagnetic medical devices has come under considerable criticism. Here it is reviewed in terms of how it has given form to protective measures against ionising radiation. The Hazardous Substances Act provides for effective protection against radiation, but has been undermined by poor administration and uncertainty about regulations and licensing conditions. The legal weight of enforcing licensing conditions through a website without proper consultation with all parties concerned is questionable and ineffective. Effective and legal radiation control is possible by activating the National Advisory Committee on Electronic Products, provided for in Regulation R326 published in 1979, but this has never been implemented. The possible impact of annual quality assurance tests currently enforced through licensing conditions on radiation dosage to the population is not cost-effective, as new training and accreditation structures have to be created.

Conclusions. That more than 80% of overexposures are generally caused by human error is a clear indication that training of the regular users of X-ray equipment should be emphasised, and not the training and accreditation of the technicians responsible for a single quality assurance test per year. Constructive engagement with the professional bodies involved in the medical use of X-rays through a National Advisory Committee on Electronic Products may be a cost-effective solution for lowering radiation dosage to the population.

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Introduction

It has been recognised since early studies on X-rays that exposure to high levels of radiation may cause tissue damage, and that chronic exposure to lower levels of radiation may result in cancer. However, the use of X-rays is part and parcel of the fight against disease and plays an indispensable role in clinical management of patients. The annual

worldwide number of X-ray procedures has been rapidly increasing, from 1.9 billion in 2000 to 3.1 billion in 2008.¹ Over the same period, the annual collective dose to the world's population increased from 2.4 MSv to 4 MSv. Today, electromagnetic radiation from medical procedures constitutes the single largest manmade means by which people encounter radiation exposure.² Protection against the medical use of radiation is therefore even more important than protection against any other source of radiation.

The innovative use of radiation, and specifically X-rays, imposes risks if inadequately controlled by suppliers, users and government. Concerns about the possible effects of exposure to radiation on the human body were raised to a high level during the 1980s and 1990s, culminating in several international studies³ that proposed basic safety standards to control and limit exposure to such radiation.⁴ The Department of Health (DoH) in South Africa has, through its Directorate: Radiation Control (DRC), adopted these standards and applied excerpts as legal requirements and guidelines. In addition, the Minister of Health, and specifically the Director-General: National Health and Population Development (DG), are mandated to administer the Hazardous Substances Act of 1973 by granting, suspending or revoking licences to importers, manufacturers and users of electromedical products (X-rays).⁵ The licence is issued if the product and usage comply with legislative and international requirements for safety and performance.

However, in November 2010, the DoH briefed the Parliamentary Health Portfolio Committee that the administration of South Africa's regulatory framework for electromagnetic medical devices was under considerable pressure as its technical and managerial competence was impugned by inadequate and insufficiently qualified personnel⁶ – fewer even than in Botswana. Accordingly, it is the aim of this review to determine whether South Africa has in place a sound legislative framework and effective regulatory infrastructure for guaranteeing the safe application of radiation and radioactive substances. This will be done by firstly looking at how the legislature has given form to protective measures against ionising radiation and, secondly, discussing the application in practice of Group III hazardous substance control and the shortcomings of the regulatory infrastructure. Lastly, recommendations and a possible future path are set out.

The legal framework for radiation control in South Africa: An historical and critical appraisal

South Africa is considered to have had a relatively 'good' system of electro-medical device regulation in place, which started in 1971.

The legislative control of electronic products was for the first time introduced by the Public Health Amendment Act of 1971⁷ that added section 133A to the Public Health Act of 1919, allowing the Minister of Health to make regulations mandating the Secretary of Health to grant, suspend and revoke licences in respect of electronic products and prescribe conditions and requirements for the categories of electronic products, premises and persons in control of the equipment.

Comprehensive regulations (Regulation R1332) concerning the use of X-ray equipment in terms of the 1971 Amendment Act were made in 1973.⁸ These regulations pertaining to Group III hazardous substances are still in force, although some uncertainty prevailed after the whole of section 133A along with the Amendment Act of 1971 (and by implication also Regulation R1332) were specifically repealed by section 32(1) of the Hazardous Substances Act, 1973. Superficially viewed, the uncertainty was reinforced when almost all of the Public Health Act of 1919 and the whole of the Public Health Amendment Act of 1971 were for a second time repealed, this time by section 63(1) of the Health Act of 1977,⁹ which in turn was abrogated partially by the National Health Act of 2003,¹⁰ omitting any reference to radiation control whatsoever. However, section 32(2) of the Hazardous Substances Act revived Regulation R1332 indirectly, deeming the latter to have been made under its own reserved capacity.

Hazardous Substances Act and Regulations

The Hazardous Substances Act (1973)¹¹ prohibits and controls the importation, manufacture, sale, use, operation, application, modification, disposal or dumping of substances and (electronic) products that may hurt or kill human beings by reason of their detrimental direct or side effects. The Act classifies such substances and products in groups according to the degree of danger. The Minister of Health, by one of only two ruling regulations issued in terms of section 29 of the Hazardous Substances Act, listed electronic products (X-rays) to be a Group III hazardous substance.¹²

The Act empowers the DG to grant, refuse, amend, suspend or revoke a licence for the use of X-ray equipment.¹³ These powers may be delegated in writing to 'any officer of the Department of Health'.¹⁴ Current practice is that these powers are executed by the Directorate of Radiation Control (DRC), but no such authority has been bestowed (by any statutory stipulation) on the DRC. In fact, the DRC is not a juristic person and has no *locus standi* or legal capacity to take decisions, issue licences, determine conditions or function on its own. The common idea that the DRC is the 'regulatory authority' is not only wrong, but also without legal foundation.

Section 3(1)c of the Act prohibits anybody to '... install or keep installed any Group III hazardous substance on any premises ... otherwise than subject to the conditions **prescribed or determined** [author's emphasis] by the Director-General'.¹⁵ The definition of 'prescribed' in Section 1 of the Act stipulates that 'prescribed' means prescribed by regulations. It is only fair and transparent if conditions are subject to a process of regulatory consultation. Such a procedure allows public and interest group scrutiny before the final notification is published in the Government Gazette. If the DG (or delegate) should 'determine' the conditions without a consultation processes, it may create uncertainty and reinforce the idea of unfair coercion. There is, however, a time-consuming and probably less effective legislative escape for the licence holder. If a person is aggrieved by the decision or condition imposed by the DG, such person may appeal to the Minister.¹⁶

Notwithstanding that there are no regulatory prescripts regarding inspections, inspectors are appointed and have powers prescribed by sections 8 and 9 of the Hazardous Substances Act. In an effort to overcome the insufficient number of inspectors (12 posts in South Africa for more than 6 500 licence holders and 16 000 X-ray machines!),¹⁷ the DRC granted permission to Inspection Bodies (IBs) to perform the required acceptance and annual quality assurance tests of equipment. Although the intention was that only South African National Accreditation System (SANAS)-accredited companies would be approved as an IB, no official reference to this policy could be found.

In general, the **control and sale** of listed electronic products are satisfactorily regulated in South Africa by Regulations R690 of 1989 and R1302 of 1991. As mentioned above, **the use** of listed electronic products is regulated by die-hard Regulation R1332 as well as additional restrictions imposed by licencing conditions.

Licensing conditions for medical X-ray equipment users

Current practice of the DRC when a licence is issued is to attach licensing conditions as an annexure to the licence, which usually refers to only two conditions directly but to more conditions indirectly. The annexure does not contain the licencing conditions, but refers the licence holder to documents containing the licensing conditions on the DoH website. These web-based documents therefore possess legal authority as licence requirements, but may change without further notice to the licence holder.

The first licensing condition, namely the *Code of Practice for Users of Medical X-ray Equipment*¹⁸ (hereinafter Code of Practice) (note that the URL on the document is wrong as it has changed since the last revision), is based on recommendations of the Australian Radiation Protection and Nuclear Safety Agency, recommendations (1991, 1996, 2000) of the International Commission on Radiological Protection (ICRP), and the Code of the National Radiation Laboratory of the New Zealand Ministry of Health.

Whether the Code of Practice was first of all subject (if at all) to comment from the medical radiation community, followed by formal public consultation and finally approved or adopted by the DG (or delegate), is unclear. What is clear, however, is that the DRC has no legal status to devise new requirements or conditions, and the fact that they had been incorporated in the Code of Practice would be of no consequence. Furthermore, within the Code of Practice it is stated that 'This Code must be read in conjunction with DOH guideline documents as listed in Annexure A of this Code.' The **guidelines** annexed to the Code of Practice are also published on the website and consequently also form part of the licensing conditions.

The second licensing condition usually attached to a licence enforces annual quality assurance according to a prescribed list, and is also listed on the website under the guidelines.

Weaknesses in the current legal framework and enforcement of the Act

Poor management, insufficient staffing levels, high vacancies, outdated data for radiation sources and installations, lack of financial resources and deficient human regulatory capacity, undermine a sound radiation protection infrastructure and put the health and safety of South Africans at risk.

The practice of publishing licensing conditions on a website as an annexure to an annexure of the licence without a proper consultation process is questionable, and leads to ambiguities and inconsistencies in the radiation protection legislature and license requirements. Potential areas of conflict include the repeal of regulations and paragraphs from Regulation R 1332 (published after a consultation process) by the Code of Practice (published without consultation). Besides the questionable legal basis of the Code of Practice, unpredictable and *ad hoc* requirements/conditions are added randomly, making license compliance uncertain and may be against basic human rights enshrined in the Constitution, namely academic freedom,¹⁹ the freedom to pursue economic activities,²⁰ and access to healthcare services.

Furthermore, the legal standing of the Inspection Body is unclear, as neither the Act nor any regulations make provision for such a body. This fact may have severe consequences in cases where the results via an IB differ from those of the company responsible for maintenance of the equipment.

Legal pathway to the future

Is it fair to say that South Africa has failed in almost every aspect of the IAEA's safety standards for radiation safety and infrastructure, apart from the relatively 'good regulations' that are in place?

The constitutional dispensation

The State has the obligation to take steps to acknowledge the socio-economic rights of all individuals so that they may be pursued to the optimum. These steps include legislative frameworks within which individuals can exercise their rights. The Constitution specifically makes provision for the right of access to healthcare services,²¹ in which area the State has been extremely active.²² Since 1994, more than 40 pieces of legislation have been promulgated under the auspices of the Minister of Health²³ – yet we still rely on the outdated regulation R1332 of 1971 to protect users and patients against the serious risk of radiation effects.

The revival or creation of a regulatory authority – currently and in the future

In view of the inability of the DoH, its division (the DRC) and the DG to administer the provisions of the Hazardous Substances Act (and regulations) effectively, it remains to be answered how the situation can be speedily turned around.

The Hazardous Substances Act provides adequate measures for ensuring public safety; but the administration of the Act leaves much to be desired. The uncertainty about Regulation R1332, lack of proper regulations, and discrepancies between existing regulations and licensing conditions may be addressed within a framework that has already been created, but not put into operation.

The National Advisory Committee in terms of the Hazardous Substances Act

Regulation R326 of 1979, published under this Act, provides for a statutory legal entity, known as the National Advisory Committee on Electronic Products,²⁴ but nothing has been realised. The Committee was to function as, firstly, an advisory body to the DG and, secondly, as a research facility to engage with international institutions in an effort to combat the dangers associated with electronic products.²⁵ By not instituting an informed, independent and statutory body, the

valuable opportunity was lost to promote safety standards and proactive management performance. The creation of the Committee, though, is still latent and remains captured in the 1979 regulation for urgent implementation. This National Advisory Committee on Electronic Products could and should play a pivotal role in all future radiation control requirements.

The contemplated South African Health Products Regulatory Authority in terms of the Medicines and Related Substances Amendment Act, 2008

After a relatively long, shaky and controversial beginning, the Medicines and Related Substances Amendment Act of 2008 was assented to on 19 April 2009.²⁶ Although the Act has yet to come into operation, the new regulator (the South African Health Products Regulatory Authority (SAHPRA)) was expected to have started functioning in April 2012 and is destined to replace the Medicines Control Council (MCC).²⁷ The main aim of the Act (2008) is to register medicines, products, medical devices, certain foodstuffs and cosmetics. Although the definition of 'product'²⁸ in the 2008 Act is too narrow to involve radiation equipment and sources, the definition of 'medical device',²⁹ however, is broad enough to do so. In this way, the SAHPRA may become the regulatory authority for X-ray equipment and radioactive substances as well. Recent indications are that this is precisely what is contemplated as a panacea. The radiation inspectorate is bound for absorption in some way or another into the designated SAHPRA under the Medicines and Related Substances Act of 1965 (as amended in 2008³⁰).

This possible accommodation will involve a second act without any current regulations controlling the use of X-ray equipment. In view of the administrative inability of the DRC to function under a single act, it is hard to foresee that the new amendment will relieve any of the problems encountered, *inter alia* lack of regulations, lack of a consultative process, and lack of a management system referred to above. The solution may very well lie on another level.

Responsible use of radiation equipment

The strong enforcement of licensing conditions that were set without public consultation, and the lack of communication between the 'regulator' and users of radiation equipment, have created a confrontational culture. The strong enforcement of conditions may also lead to a false sense of security on the side of users, as enforcement of the restrictions of the licensing conditions is regarded as sufficient radiation control. This is counter-productive as the unfortunate reality is that approximately 80% of overexposures in radiology are caused by human error.^{11,31} The 20% of overexposures caused by faulty equipment are mostly caused by intermittent AEC failure or breakdown of equipment during complex radiological procedures.

If we are really concerned about exposure levels to staff, patients and the public, the problem should be addressed at source, i.e. human incompetency.

The use of medical X-ray equipment should be restricted by regulation (not licensing conditions) to professionals registered with the HPCSA and appropriately trained in those aspects of imaging or therapy and safety relevant to their clinical role in order to limit overexposures caused by human error. This will bring us in line with other countries (e.g. Australia,³² Canada,³³ the European Community³⁴) as well as recent recommendations by the radiological community of the United States³⁵

that acknowledge the importance of human competency in radiation protection and where each user of a machine must be certified to do so. Constructive engagement with the HPCSA and professional bodies may set the required standards and ensure that current and potential future users (surgeons, cardiologists, urologists etc.) will have the necessary skills and knowledge to perform their duties with minimal risk to patients, the public and personnel.

By engaging with the professional bodies, high-risk areas can be identified. In 2008, for example, CT examinations accounted for 80% of the total Norwegian population's medical radiation exposure.³⁶ Similar trends were observed in the USA.³⁷ By concentrating on high-risk areas, manpower can be utilised more effectively (and no increase in cost) with a marked impact on the population's cumulative radiation dosage.

The unwillingness to engage with existing professional bodies about including radiation protection as a prerequisite for registration/certification is in sharp contrast to the very active engagement with SANAS for setting standards and creating a previously non-existing accreditation body that will accredit IBs. An irony is that the impact of the financial burden concentrating on quality assurance of equipment once per year may be insignificant to the radiation dose of the population at large, as equipment-related over-exposures will not be prevented nor reduced by the annual quality assurance imposed by the licensing conditions.

Conclusion

As pointed out above, the Hazardous Substances Act provides adequately for regulatory measures to ensure public safety, but the administration of the Act leaves much to be desired.

The National Advisory Committee on Electronic Products Committee should be constituted by the Minister as soon as possible to investigate and rectify the uncertainties and discrepancies pointed out above. The committee should include radiologists, medical physicists, radiation biologists, radiographers, the HPCSA and equipment suppliers. The constructive engagement between the DRC, the HPCSA, the radiological community of South Africa and other roleplayers will ensure appropriate regulations with correct terminology and unambiguous interpretation that will conform to legal requirements.

By the appropriate sharing of the responsibility for radiation protection with professionals registered with the HPCSA, the burden on the understaffed directorate will also be alleviated by concentrating on high-risk areas identified and agreed upon within a properly constituted National Advisory Committee on Radiation Equipment. Until that time, the danger will remain that the current situation may be legally challenged by an affected party.

One might summarise the situation by saying that inadequate personnel (in numbers as well as competency) are using obsolete legislation and control measures to protect the public against the most important source of radiation. The situation will be rectified by actively engaging the trained professionals primarily and routinely responsible for radiation, under the auspices of the HPCSA, and to use their professional expertise within a National Advisory Committee on Radiation Equipment to identify the highest risk areas to be addressed by appropriate legislation and other measures.

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