Legislative changes for patient radiation protection in Ireland

With a new European Directive coming into Irish law in February 2018, Janet Wynne outlines the current legislative framework for patient radiation protection and highlights the areas of practice that will be affected by the new legislation.

THIS ARTICLE OUTLINES the current legislative framework and national arrangements for patient radiation protection and aims to highlight areas of practice that will be affected by the transposition of the European Basic Safety Standard Directive 2013/591 into Irish law in February 2018.

The Department of Health is the designated competent authority, under statutory instrument (SI) 478 (2002), for regulating medical ionising radiation in Ireland and the National Radiation Safety Committee (NRSC) is the statutory committee established under this legislation. The responsibility for patient radiation protection has been delegated to the director general of the HSE who nominates relevant experts in radiation safety to become members of the NRSC and provide advice on matters pertaining to medical ionising radiation exposure.2

The HSE Medical Exposure Radiation Unit (MERU) was established to regulate patient radiation protection practices in both public and private radiological facilities, and is the executive, administrative and advisory unit for the NRSC. MERU has an important national role in monitoring and trending patient radiation safety incidents, commissioning audits, producing guidance documents and representing the Department of Health at international forums.

Under the current legislation, MERU does not have the authority to compel radiological facilities to accept and implement patient safety guidelines or recommendations. However, the unit does have the authority to publish its findings.

The current legislative framework for medical ionising radiation practices in Ireland is outlined in Figure 1.

The International Atomic Energy Agency / Integrated Regulatory Review Service Mission4

In 2015, at the request of the Irish government, the International Atomic Energy Agency convened an international team of senior safety experts to conduct a review of the Irish regulatory framework for radiation safety. This review was largely positive and identified the following areas relevant to patient radiation protection that are in need of urgent attention:

• The requirement for an effective legal framework to facilitate inspection and enforcement by the regulator to ensure patient protection
• The requirement for an independent regulatory body for patient protection which does not have responsibilities for, or interests in, providing medical ionising radiation to patients

• The requirement to ensure effective coordination between the Office of Radiation Protection and Environmental Monitoring (ORPEM) and the regulatory body for patient protection
• The requirement to establish policies and the processes regarding development and updating of guidance documents and a code of practice for radiation safety.

These gaps in practice were accepted by the Department of Health and it is proposed that the forthcoming legislative changes offer a unique opportunity to address the issues raised.
The European Basic Safety Standard Directive 2013/59

In February 2018, the Medical Exposure Directive 97/43/EURATOM and the Basic Safety Standard Directive 96/26/EURATOM will be replaced by the revised European Basic Safety Standard (BSS) Directive 2013/59. This will necessitate the enactment of new Irish legislation for radiation safety. The transposition process is being led by the Department of Environment, Community and Local Government, with assistance from the Department of Health on the patient safety aspect, and is being supported by various stakeholders including MERU, the ORPEM and the Health Information and Quality Authority (HIQA).

Figure 2 details the five priorities for patient radiation protection that will be affected by the BSS Directive.

Governance of patient radiation safety

Currently, the competent authority for medical ionising radiation is the Department of Health, and the HSE acts as both provider and regulator of patient radiation safety. Agreements have been put in place between the Department of Health, the HSE and HIQA to transfer the competent authority and regulatory functions to HIQA in February 2018. This will ensure an independent regulator for patient radiation protection and it is anticipated that the new statutory instrument will give the regulator inspection and enforcement powers.

The principle of justification

Justification requires that the benefit of each procedure outweighs the possible risk caused by radiation exposure. Under current legislation, the referrer (a medical specialist, dentist or appropriately trained nurse specialist) making the referral, the practitioner accepting the referral (typically a radiologist) and the professional (usually a radiographer) undertaking the procedure have a role in the justification process.

The Medical and Dental Councils are responsible for regulating the justification process. Although the Dental Council reviews justification, the Medical Council Ionising Radiation Committee, established in 2004, is not active. Consequently, there is no formal governance structure to review generic justification, no process to assess new practices involving medical ionising radiation and no specific requirements for justifying procedures for asymptomatic individuals.

For example, the increased justification of radiological imaging procedures such as computed tomography for diagnosing medical conditions has not been formally reviewed by the Medical Council since 2004. Additionally, the Medical Council approved the use of ionising radiation in medical specialties, such as interventional cardiology, where patients routinely undergo high dose radiation procedures, but there has been no formal assessment of new practices since 2004.

Robust governance and clear lines of accountability are required to enforce a culture of patient radiation safety. It is anticipated that the new legislation will require the roles and responsibilities assigned to each practitioner involved in justification to be clearly defined and documented.

The principle of optimisation

Optimisation is where medical radiation exposures are kept as low as reasonably achievable to obtain the required diagnostic outcome for the patient. For patients requiring radiation therapy, exposures of target volumes are individually planned and maintained as low as reasonably achievable to be consistent with the intended radiotherapeutic purpose of the exposure.

Existing legislation relating to optimisation is clear on responsibilities and delegation in relation to practical aspects. The radiation protection adviser and/or medical physics expert have a responsibility for developing and implementing a quality assurance programme. The practitioner in charge is responsible for ensuring that the radiation dose delivered is at the lowest practicable level while achieving the optimum outcome for the patient.

However, there is no mandatory requirement for the practitioner in charge to make or retain written records to demonstrate that advice received had been considered, approved and implemented. This is expected to be addressed in the new legislation, together with a requirement to develop specific optimisation protocols and to maintain documented records of medical exposures to patients, comforters and carers for a specified period of time.

In addition, it is anticipated that the forthcoming legislation will make it mandatory for the principle of optimisation to be considered in the procurement of new radiological equipment and dose monitoring software, or the upgrade of existing equipment and software. For example, the least expensive piece of equipment or software package may not offer the safest optimisation process for the patient and so may not be the best option to purchase.

Education and training in patient radiation safety

It is best practice, but not mandatory, that all staff working with medical ionising radiation are appropriately trained and competent in patient radiation protection.
This includes staff making a referral, those responsible for maintaining radiological equipment, those who administer the radiation dose and those who assess the patient outcomes. However, there is no system to determine what an appropriate patient radiation safety training programme entails.

Currently, patient radiation protection training for medical and dental practitioners is mandatory but it does not require oversight from professional bodies or governance from employers. There is no requirement for continuous professional development for medical specialists in relation to patient radiation safety. There is no recognised patient radiation safety training programme for non-radiographers operating equipment, and chiropractors and sports scientists administer ionising radiation without being recognised under SI 478 (2002). Radiographers and nurse specialists must register with their respective professional bodies in order to practise and they must demonstrate continuous professional development. Medical physics experts can voluntarily register with a professional body, which includes a framework for continuous professional development, but this register is not recognised by the competent authority.

In the BSS Directive, there is a requirement for ongoing training and development in radiation protection. It is expected that the chief executive officer at each radiological facility will be delegated responsibility for ensuring that all staff involved in the use of medical ionising radiation are appropriately trained and competent. Documented evidence of training records may be required by the regulator.

Evidence based training programmes on patient radiation safety may need to be agreed and developed nationally by the relevant professional bodies, in consultation with the competent authority.

**Accidental exposures and incident reporting**

Currently, all public and private radiological facilities report and manage patient radiation safety incidents locally and report to MERU, where appropriate. This is self-regulated and MERU has no inspection or enforcement authority. The MERU Patient Radiation Protection Manual offers guidance but is not mandatory.

Under the BSS Directive, it is mandatory to report, analyse and record unintended radiation exposures in radiology, nuclear medicine and radiotherapy. The new legislation will transfer regulation to HIQA and is expected to give inspection and enforcement powers. Thus, all locations that administer medical ionising radiation to patients will be required to demonstrate compliance.

**Going forward post transposition**

Following the transposition of the BSS Directive into Irish law in February 2018, the role of the competent authority for patient radiation protection will transfer from the Department of Health to HIQA and the NRSC and MERU will be stood down. It is possible that the HSE may maintain a national unit to monitor patient radiation protection practices in public facilities but this has yet to be confirmed. Almost half of all radiological locations that engage with MERU are privately managed and not associated with the HSE. These locations currently fall under the remit of the NRSC but post transposition, this will change.

The promotion of best practice in relation to patient radiation safety and maintaining the continued delivery of a safe and effective service during this transition period, and thereafter, is essential. Engagement between the HSE, ORPEM, HIQA and the Department of Health is ongoing and will continue post transposition to ensure a smooth transition and the best outcomes for patients and those who work with medical ionising radiation.

**References**


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