Faculty of Radiologists
RCSI

Dámh na Raideolaithe

SI 256 2018: Implications of the new patient protection law for Radiological Practice in Ireland.

Background to the new legislation

Statutory Instrument 256 2018 was signed into law by Minster Simon Harris on the 8th January 2019. The law is based on EU directive 59/13 known as the Basic Safety Standard in Radiation Protection. A Statutory Instrument is a law that only requires signature by the relevant Minister rather than Oireachtas approval and changes the law in an expedient manner. EU directive 59/13 was mandated to be transposed into Irish and European law on February 6th 2018 - the purpose of this directive was to consolidate protection of the patient, healthcare workers and public into one directive. It was also to reflect an improving standard of radiation protection both for patients and staff in the European Union including new dose limits for workers' eyes, improving access to dose and risk information for patients, reducing incidents and improving training requirements. In Ireland the implementation of the directive has been kept separate in two legislative strands: public and staff safety will continue to be regulated by the EPA under the Department of Communications, Climate Action and the Environment and patient protection will be regulated by HIQA under the Department of Health and Children. This document refers only to the patient regulation rather than staff and public legislation which is due imminently.

The manner in which each country transposed the directive is dependent on local practices and political policy of the departments involved. However the essential elements of the directives must be maintained. In Ireland there were further requirements to implement the findings of a 2015 International Atomic Energy Agency review which cited a lack of enforcement provision and lack of an independent regulator in the previous legislation. The Faculty of Radiologists proffered commentary and was consulted on key aspects of the directive including submissions via the National Radiation Safety Committee, face to face meetings with the legislative team from the Department of Health and Children, meetings with the Chief Medical Officer and several written communications. The Faculty also testified in front of the Oireachtas Health committee discussing the new legislation and chiropractors.

Although some advice of the Faculty was taken on board, the substantive issue around clinical governance, supervision and training of non-radiologist practitioners was not adopted in the new legislation. The legislation has no mention of radiologists or radiation oncologist and their

role in protection of the patient despite the key demands of the directive that practitioners have adequate medical and radiation protection training and this role is reflected in both the IAEA documents and the directive preamble. The final definitions were only seen subsequent to the new legislation being enacted; the department felt that our request for clinical governance under a radiologist/radiation oncologist-in-charge were not consistent with the *vires* of the directive so could not be implemented. Therefore, it should be highlighted that the role of practitioner-in-charge is not included in the new legislation.

The Faculty Radiation Protection Committee wrote to the Department indicating that this lack of governance may ultimately create potential for patient safety issues; clinical and financial issues for the health services and has the potential to create serious incidents such as those observed in other states particularly for CT and radiotherapy. The Department have not taken this advice and the Faculty will undertake to reiterate concerns over patient safety. It should also be stated that the extra training hours recommended in the European Directive (4-5 hours under the previous legislation, increases to 30-40 hours under the new legislation) will be very challenging to implement and enforce. Being clinically responsible for implementing such requirements could be very resource intensive and create legal exposure for the radiologists were they to continue to fulfil the role of a practitioner-in-charge type position under the new legislation. The extra training requirements of the new legislation highlight training deficits for non-radiologist physician referrers as indicated by the Faculty in its submission to the Department of Health.

Key legislative impacts for the Faculty of Radiologists in the new directive

Governance

The regulatory authority has moved from MERU/ National Radiation Safety Committee, which had no enforcement powers, to HIQA which have significant enforcement powers (€256k fine and 1 year in prison). HIQA will have a remit over both public and private facilities. The reporting criteria of radiation safety incidents are the same as those under the HSE, however will now be reported to HIQA. These include but are not limited to doses greater than intended, inadvertent dose to the foetus, 15 Gy entrance air kerma. MERU and the NRSC have ceased to exist. The HSE are setting up a new overarching radiation protection structure to advise itself as an undertaking which is the term used in the new legislation to describe an entity which carries out medical radiologic procedures (see definition below). The Faculty Radiation Protection Committee would recommend participation in such structures. The new HSE committees' remit will only apply to HSE services and not private services.

The new legislation places far more onus on the undertaking than the individual clinician or referrer similar to the U.K. approach to such legislation i.e. those businesses that carry out or engage others to carry out medical exposures. This could be interpreted as those who outsource and also those radiologists who work as private entities in third party institutions. The undertaking has responsibilities around training, optimisation, dose recording and incidents. Indeed HIQA have already asked healthcare providers for a list of persons responsible and to whom they have delegated what tasks to under the legislation.

Roles:

A referrer is entitled to refer a patient for a medical radiologist procedure to a practitioner.

The practitioner has clinical responsibility for an exposure which includes providing existing medical radiological and clinical information, providing patient information regarding risks of ionising radiation, cooperating with practical aspects of radiological procedure, justification, optimisation, clinical evaluation of the outcome.

An undertaking is a person or body who as part of trade and business carries out or engages others to carry out medical radiological procedures.

Referrers include:

1. Dentists
2. Registered nurse or midwife
3. Radiographers
4. Medical practitioners
5. A professional registered with the General Medical Council (UK) practicing in Northern Ireland

The undertaking must ensure that they meet the criterion set down by a training body with reference to European training document RP 175:

1. The Dental Council;
2. Nursing and Midwifery Board;
3. Radiographer Registration Board;
4. Training body recognised by the Medical Council.

Practitioners include:

1. Registered dentists
2. Registered medical practitioners
3. Radiographers

The details around these new practitioner and referral roles for radiographers and whether practical duties, scope of practice, training requirements or indemnity arrangements have not been established by the radiographers registration board or the medical council to date.

Referrals from persons other than those listed in the legislation

4.(2) of the new regulations state that "A person shall not carry out a medical radiological procedure on the basis of a referral from a person other than a referrer."

This means that it is not possible to accept a referral from physiotherapists and speech and language therapists. It also means that referral from chiropractors are not catered for. The previous legislation, which is no longer valid, stated that in the absence of a referrer, the practitioner could become the referrer. This clause has been replaced by 4.(2) above. However the ability for the practitioner to become the referrer is not explicitly excluded from the legislation and it was the understanding of the Faculty at the Oireachtas committee meeting on chiropractors that this would remain. It is hoped HIQA will provide guidance in time. It would be the view of the Faculty that if the radiologist takes on the role of the referrer the radiologist will need to assume all of the duties of the referrer including clinical follow up.

Practical aspects

"Practical aspects of medical radiological procedures" means the physical conduct of a medical exposure and any supporting aspects, including handling and use of medical radiological equipment, the assessment of technical and physical parameters (including radiation doses), calibration and maintenance of equipment, preparation and administration of radiopharmaceuticals, and image processing.

The persons to whom the undertaking or practitioners can delegate to are recognised by the same group above. However there are additional categories to be recognised by the minister or medical council. Records of such delegations must be held for five years and made available to HIQA upon request.

Justification of medical exposures

The wording around justification has changed to take account of lower dose techniques. An additional criterion is inserted : "Takes into account the efficacy, benefits and risks of available alternative techniques having the same objective but involving no or less exposure to ionising radiation".

Health screening must now go through HIQA, and symptomatic, early detection of disease all get a mention. Risk information to the patient is specifically mandated by the legislation:

"*The Authority shall, after consultation with the relevant professional body or bodies, carry out specific justification for medical radiological procedures to be performed as part of a health screening programme prior to the commencement of such programme."*

"An undertaking shall ensure that medical radiological procedures to be performed as part of a health screening programme are not carried out unless the specific justification has been issued by the Authority for the particular medical radiological procedure.

An undertaking shall ensure that, in the case of a medical radiological procedure on an asymptomatic individual, performed for the early detection of disease—

(a) The procedure is part of a health screening programme, or requires specific documented justification for that individual by the practitioner, in consultation with the referrer, following guidelines published by the Authority in accordance with paragraph (6), and (b) special attention is given to the provision of information to the individual, as required by paragraph (13).

The Authority shall, after consultation with the relevant professional body or bodies, publish guidelines on the specific justification of medical radiological procedure on an asymptomatic individual, performed for the early detection of disease but not as part of a health screening programme.

(7) The relevant professional body or bodies to be consulted, under paragraphs (3) and (6) shall be determined by the Authority."

In effect new types of walk-in screening e.g. low dose lung cancer or CT colonography will need a referral letter unless approved by HIQA.

Optimisation:

The practitioner or the undertaking must ensure that optimisation is performed for each radiological procedure involving the practitioner, the person carrying out the medical procedure and the medical physics expert.

Benefit risk information

The practitioner or undertaking must ensure that the patient or their representative must provide information on the benefits and risk associated with the radiation dose to the patient or their representative

Obligations on undertaking:

The age-based equipment criteria is gone with the new legislation. However strict surveillance is required and HIQA must take steps to ensure that the necessary measures are taken by an undertaking to improve inadequate or defective performance of medical radiological equipment in use, and adopt specific criteria for the acceptability of equipment in order to indicate when appropriate corrective action is necessary, including taking the equipment out of service. All equipment other than CT or fluoroscopic equipment installed after 6th February 2018 will have methods of displaying dose. CT or fluoroscopic equipment must have this ability regardless of date of install.

Dose Reference Levels now must be used, as opposed to promoted in the previous legislation, and followed up, with evidence of same. HIQA will produce national DRLs upon consultation with professional bodies. The undertaking must provide HIQA with information to help with population dose estimates.

"An undertaking shall ensure that written protocols for every type of standard medical radiological procedure are established for each type of equipment for relevant categories of patients, that information relating to patient exposure forms part of the report of the medical radiological procedure, that referral guidelines for medical imaging, are available to referrers and that clinical audits are carried out in accordance with national procedures established by the Minister. The biggest change here is that the minister decides on clinical audit and the dose has to be in the medical radiological report."

The wording around pregnancy has changed and further guidance will be needed for its interpretation;

"An undertaking shall ensure that, the referrer or a practitioner, as appropriate, shall— (a) inquire as to whether an individual subject to the medical exposure is pregnant or breastfeeding, unless it can be ruled out for obvious reasons or is not relevant for the radiological procedure concerned, and record the answer to in writing."

The undertaking must do what it can to minimise accidents and arrangements are made to inform the referrer and the practitioner, and the patient, or their representative, about clinically significant unintended or accidental exposures and the results of the analysis.

For the first time medical physics experts are registered by the minister and the minister is using the voluntary register set up by the Irish College of Physicists in Medicine (ICPM) to facilitate this. Their roles are defined under the legislation but they shall be involved in high dose interventional procedures.

Education, Information and Training

As the Faculty of Radiologists is primarily a training body the aspects in Section four of the legislation are worth examining in more detail. Note written evidence is required for all aspects of the training:

"An undertaking shall ensure that— (a) practitioners, and individuals to whom the practical aspects of medical radiological procedures are delegated pursuant have adequate education, information and theoretical and practical training for that purpose, as well as relevant competence in radiation protection, in accordance with the provisions of this Regulation.

(2) Nothing in paragraph (1) prevents a person from participating in practical aspects of a medical radiological procedure as part of a relevant training programme if such participation is supervised by a person who is adequately trained.

(3) The persons referred to in paragraph (1) must have successfully completed training, including theoretical knowledge and practical experience, in medical radiological practices and radiation protection, as prescribed by— (a) the Dental Council, (b) the Irish College of Physicists in Medicine, (c) the Nursing and Midwifery Board of Ireland, (d) the Radiographers Registration Board, or (e) a training body approved by the Medical Council having the relevant expertise in medical ionising radiation to provide such course, as appropriate, having regard to the European Commission's Guidelines on Radiation Protection Education and Training of Medical Professionals in the European Union (Radiation Protection No. 175).

(4) An undertaking shall ensure that the persons referred to in paragraph (1) undertake continuing education and training after qualification including, in the case of clinical use of new techniques, training related to these techniques and the relevant radiation protection requirements.

(5) An undertaking shall retain records evidencing compliance with this regulation for a period of five years from the date of the exposure, and shall provide such records to the Authority on request.

(6) Where an undertaking enters into a contract with another party to engage a practitioner or an individual referred to in paragraph (1) (b) employed by that other party, such other party is responsible for keeping the records required by paragraph (5) and must supply such records to the undertaking forthwith upon request."

It has been offered as an opinion that paragraph 2 allows for the cardiologist to continue under the supervision of someone who is qualified i.e. a radiographer or radiologist, if it can be

assumed that they are in training. However guidance will be needed in this regard. The Faculty may consider whether it is appropriate for them to organise formal training for these groups. Some of the radiography colleges may also offer to provide such training programs too.

Compliance and Enforcement

The legislation contains ten pages on enforcement.

Transitional Arrangements

The legislation allows for health screening programs and research projects prior to the commencement of the legislation to continue.

Conclusions

The new patient protection law addresses some of the deficits of previous legislation particularly enforcement. Legislation and procedures are only one part of a quality system for delivering good radiation protection to patients. In the absence of detailed guidance, hospitals with good governance structures, radiological protection practice and culture can comply with the majority of the stipulations in the new regulations. There are new technical, record keeping and administrative requirements that will require additional resources. The increased onus on the undertaking themselves combined with the regulatory enforcement of HIQA rather than the radiologist should make competing for resources for patient protection easier. The implications of the change or lack of clinical oversight by a radiologist/radiation oncologist will become evident when scope of practice and guidelines become available. The Faculty of Radiologists need to ensure that they have evidence that their training programs meet the requirements of RP 175 and are at the core of any training recommendations by the medical council. The role of the Faculty in training non-radiologists/radiation oncologists is something that needs to be considered.

ANNEX: ICRP 113 TABLES 3.1 AND 3.2

The ICRP 113 tables 3.1 and 3.2 are reproduced below with the kind permission of the ICRP.

Table 3.1. Recommended radiological protection training requirements for different categories of physicians and dentists.

Training area	Category							
	1DR	2NM	3CDIMDI	4MDX	5MDN	6MDA	7DT	8MD
Atomic structure, x-ray production, and interaction of radiation	m	h	l	l	l	l	l	–
Nuclear structure and radioactivity	m	h	l	–	m	–	–	–
Radiological quantities and units	m	h	m	m	m	l	l	l
Physical characteristics of x-ray machines	m	l	m	m	l	l	m	–
Fundamentals of radiation detection	m	h	l	l	m	–	l	–
Principle and process of justification	h	h	h	h	h	h	h	m
Fundamentals of radiobiology, biological effects of radiation	h	h	m	m	m	l	l	l
Risks of cancer and hereditary disease	h	h	m	m	m	l	m	m
Risk of deterministic effects	h	h	h	m	l	l	m	l
General principles of radiation protection including optimisation	h	h	h	m	m	m	m	l
Operational radiation protection	h	h	h	m	h	m	m	l
Particular patient radiation protection aspects	h	h	h	h	h	m	h	l
Particular staff radiation protection aspects	h	h	h	h	h	m	h	l
Typical doses from diagnostic procedures	h	h	m	m	m	m	m	m
Risks from foetal exposure	h	h	l	m	m	l	l	l
Quality control and quality assurance	m	h	m	l	l	–	l	–
National regulations and international standards	m	m	m	m	m	l	m	l
Suggested number of training hours	30–50	30–50	20–30	15–20	15–20	8–12	10–15	5–10

RP, radiological protection; DR, diagnostic radiology specialists; NM, nuclear medicine specialists; CDI, interventional cardiologists; MDI, interventionalists from other specialties; MDX, other medical specialists using x-ray systems; MDN, other medical specialists using nuclear medicine; MDA, other medical doctors assisting with fluoroscopy procedures such as an aesthetists and occupational health physicians; DT, dentists; MD, medical doctors referring for medical exposures and medical students; l, low level of knowledge indicating a general awareness and understanding of principles; m, medium level of knowledge indicating a basic understanding of the topic, sufficient to influence practices undertaken; h, high level of detailed knowledge and understanding, sufficient to be able to educate others.