THE RADIATION SAFETY AND NUCLEAR SECURITY ACT 2018

Regulations made by the Minister under section 43 of the Radiation Safety and Nuclear Security Act 2018

1. These regulations may be cited as the Radiation Safety and Nuclear Security (Radiation Protection in Medical Exposure) Regulations 2024.

2. In these regulations –

"absorbed dose" means the mean energy imparted by ionising radiation to matter in a place of interest per unit mass of matter to the place of interest;

"accident" means any unintended event, including operating errors, equipment failures and other mishaps, the consequences or potential consequences of which are not negligible from the point of view of protection and safety;

"audit" means a documented activity performed to determine by investigation, examination and evaluation of objective evidence the adequacy of, and adherence to, established procedures, instructions, specifications, codes, standards, administrative or operational programmes and other applicable documents, and the effectiveness of their implementation;

"carers and comforters" means persons who willingly and voluntarily help (other than in their occupation) in the care, support and comfort of patients undergoing radiological procedures for medical diagnosis or medical treatment;

"contamination" means radioactive substances on surfaces, or within solids, liquids or gases (including the human body), where their presence is unintended or undesirable, or the process giving rise to their presence in such places;

"dose constraint" means a source related value used in optimising the protection of carers and comforters of patients undergoing radiological procedures, and the protection of volunteers subject to exposure as part of a program of biomedical research;

"diagnostic reference level" means a level used in medical imaging to indicate whether, in routine conditions, the dose to the patient or the

amount of radiopharmaceuticals administered in a specified radiological procedure for medical imaging is unusually high or unusually low for that procedure;

"ethics committee'' means the committee established by the health authority to address ethical issues in patient care, which includes the approval of programme of biomedical research involving medical exposure and the establishment of dose constraints to be used in the optimisation of protection and safety for persons subject to exposure as part of the programme;

"health authority" means the Ministry responsible for the subject of health;

"health professional" means an individual who has been formally recognised through appropriate national procedures to practise a profession related to health (e.g. medicine, dentistry, chiropractic, podiatry, nursing, medical physics, medical radiation technology, radiopharmacy, occupational health);

"health screening programme" means a programme in which health tests or medical examinations are performed for the purpose of early detection of disease;

"medical physicist" means a health professional with specialist education and training in the concepts and techniques of applying physics in medicine and competent to practise independently in one or more of the subfields (specialties) of medical physics;

"medical radiation facility" means a medical facility in which radiological procedures are performed;

"medical radiation technologist" means a health professional with specialist education and training in medical radiation technology, competent to perform radiological procedures, on delegation from the radiological medical practitioner, in one or more of the specialties of medical radiation technology;

"medical radiological equipment" means radiological equipment us-ed in medical radiation facilities to perform radiological procedures that either delivers an exposure to an individual or directly controls or influences the extent of such exposure. The term applies to

(a) radiation generators, such as X ray machines or medical linear accelerators;
(b) devices containing sealed sources, such as ^{60}Co teletherapy units;

(c) devices used in a medical imaging procedure involving ionizing radiation to capture images, such as gamma cameras, image intensifiers or flat panel detectors; and
(d) hybrid systems such as positron emission tomography-computed tomography scanners;

"planning target volume" means a geometrical concept used in radiation therapy for planning medical treatment with consideration of the net effect of movements of the patient and of the tissues to be irradiated, variations in size and shape of the tissues, and variations in beam geometry such as beam size and beam direction;

"radiological medical practitioner" means a health professional with specialist education and training in the medical uses of radiation, who is competent to perform independently or to oversee radiological procedures in a given specialty;

"radiological procedure" means a medical imaging procedure or therapeutic procedure that involves ionising radiation - such as a procedure in diagnostic radiology, nuclear medicine or radiation therapy, or a planning procedure, image guided interventional procedure or other interventional procedure involving
(a) radiation delivered by a radiation generator,
(b) a device containing a sealed source or an unsealed source, or
(c) by means of a radiopharmaceutical administered to a patient;

"radiopharmacist" means a health professional, with specialist education and training in radiopharmacy, who is competent to prepare and dispense radiopharmaceuticals used for the purposes of medical diagnosis and radionuclide therapy;

"referring medical practitioner" means a health professional who, in accordance with national requirements, may refer individuals to a radiological medical practitioner for medical exposure;

"standards dosimetry laboratory" means a laboratory that possesses certification or accreditation necessary for the purpose of developing, maintaining or improving primary or secondary standards for radiation dosimetry;

"supplier (of a source)" means any person or organisation to whom a licensee assigns duties, totally or partially, in relation to the design, manufacture, production or construction of a source.

Responsibilities specific to medical exposure

3. The licensee shall ensure that no patient, whether symptomatic or asymptomatic, undergoes a medical exposure unless –

(a) it is a radiological procedure that has been requested by a referring medical practitioner and information on the clinical context has been provided, or it is part of an approved health screening programme;

(b) the medical exposure has been justified by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, or it is part of an approved health screening programme; and

(c) a radiological medical practitioner has assumed responsibility for protection and safety in the planning and delivery of the medical exposure as specified in regulation 6(a).

(d) the patient or the patient's legal authorised representative has been informed as appropriate of the expected diagnostic or therapeutic benefits of the radiological procedure as well as the radiation risks.

4. The licensee shall ensure that no individual incurs a medical exposure as part of a programme of biomedical research unless the exposure has been approved by the ethics committee and a radiological medical practitioner has assumed responsibility of the exposure.

5. The licensee shall ensure that no individual incurs a medical exposure as a carer or comforter unless he or she has received, and has indicated an understanding of, relevant information on radiation protection and information on the radiation risks prior to providing care and comfort to an individual undergoing a radiological procedure, and consent is given and documented.

6. The licensee shall ensure that -

(a) the radiological medical practitioner performing or overseeing the radiological procedure has assumed responsibility for ensuring overall protection and safety for patients in the planning and delivery of the medical exposure and the optimisation of protection and safety, in cooperation with the medical physicist and the medical radiation technologist, as appropriate;

(b) radiological medical practitioners, medical physicists, medical radiation technologists and other health professionals with

specific duties in relation to protection and safety for patients in a given radiological procedure are specialised in the appropriate area and meet the requirements for education, training and competence in radiation protection as specified by the Authority;

(c) sufficient medical personnel and paramedical personnel are available in the medical radiation facility, as specified by the health authority;

(d) any delegation of responsibilities by the licensee for protection and safety for patients is documented;

(e) for therapeutic radiological procedures, the requirements of these regulations for calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in regulations 22, 23(c), 26 and 27, are fulfilled by or under the supervision of a medical physicist; and

(f) for diagnostic radiological procedures and image guided interventional procedures, the requirements of these regulations for medical imaging, calibration, dosimetry and quality assurance, including the acceptance and commissioning of medical radiological equipment, as specified in regulations 22, 23(a) and (b), 24, 26 and 27 are fulfilled by or under the supervision of or with the documented advice of a medical physicist, whose degree of involvement is determined by the Authority and by the complexity of the radiological procedures and the associated radiation risks.

7. Health professionals such as radiological medical practitioners, referring medical practitioners, medical physicists and medical radiation technologists shall have the necessary authorisation to assume their roles and responsibilities, and shall be notified of their duties in relation to protection and safety for individuals undergoing medical exposures.

8. (1) The Authority shall ensure that the authorisation for medical exposures to be performed at a particular medical radiation facility allows personnel (radiological medical practitioners, referring medical practitioners, medical physicists and medical radiation technologists and other health professionals with specific duties in relation to the radiation protection of patients) to assume the responsibilities specified in these regulations only if they -

(a) specialised in the appropriate area; and

(b) meet the respective requirements for education, training and competence in radiation protection.

(2) For the purpose to fulfil the requirements for education, training and competence in radiation protection referred to paragraph (1), the health professionals with responsibilities for medical exposure shall -

(a) have basic knowledge in radiation protection and thereafter have training and periodic training in radiation protection at least every two years by an approved service provider. The level of training shall be commensurate with the level of responsibility for medical exposure; and

(b) be able to demonstrate competence on radiation protection.

(3) A formal assessment of the competence of medical physicists specialised in one or more of the subfields of medical physics (e.g. diagnostic radiology, radiation therapy, nuclear medicine) to practice independently shall be in place.

Justification of medical exposures

9. Medical exposures shall be justified by weighing the diagnostic or therapeutic benefits that they are expected to yield against the radiation detriment that they might cause, with account taken of the benefits and the risks of available alternative techniques that do not involve medical exposure.

10. Generic justification of a radiological procedure shall be carried out by the health authority in conjunction with appropriate professional bodies, and shall be reviewed from time to time, with account taken of advances in knowledge and technical developments.

11. The justification of medical exposure for an individual patient shall be carried out by means of consultation between the radiological medical practitioner and the referring medical practitioner, as appropriate, with account taken, in particular for patients who are pregnant or breast-feeding or are paediatric, of: -

(a) the appropriateness of the request;

(b) the urgency of the radiological procedure;

(c) the characteristics of the medical exposure;

(d) the characteristics of the individual patient; and

(e) relevant information from the patient's previous radiological procedures.

12. Relevant national or international referral guidelines shall be taken into account for the justification of the medical exposure of an individual patient in a radiological procedure.

13. The licensee shall ensure that no radiological procedure is performed as part of a health screening programme for asymptomatic populations, unless the procedure has been justified by the health authority in conjunction with relevant professional bodies and approved by the Authority.

14. Any radiological procedure on an asymptomatic individual that is intended to be performed for the early detection of disease, but not as part of an approved health screening programme, shall require specific justification by the radiological medical practitioner and the referring medical practitioner, in accordance with the guidelines of relevant professional bodies or the health authority. As part of this process, the individual shall be informed in advance of the expected benefits, risks and limitations of the radiological procedure.

15. (1) No person shall undertake a programme of biomedical research involving medical exposure without the approval of the Authority.

(2) The Authority may authorised the programme of biomedical research involving medical exposure only if the programme of biomedical research is justified.

(3) The programme of biomedical research involving medical exposure is deemed not justified unless -

(a) it is in accordance with the provisions of the World Medical Association Declaration of Helsinki, *Ethical Principles for Medical Research Involving Human Subjects* and takes into account the guidelines published by the Council for International Organisations of Medical Sciences, together with the recommendations of the International Commission on Radiological Protection; and

(b) it is subject to approval by the ethics committee, including to any dose constraint that may be specified by the ethics committee referred to in regulation 30, and subject to applicable national or local regulations.

Optimisation of protection and safety

16. (1) The licensee shall ensure that protection and safety is optimised for each medical exposure.

(2) The radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist, shall assist the licensee to ensure optimisation of protection and safety for each medical exposure.

Design considerations

17. The licensee shall ensure that medical radiological equipment and software that could influence the delivery of medical exposure are used only if they conform to the applicable standards of the International Electrotechnical Commission and the International Organisation for Standardisation or to any national standard adopted by the Authority.

Operational considerations

18. For diagnostic radiological procedures and image guided interventional procedures, the licensee shall ensure that the radiological medical practitioner, in cooperation with the medical radiation technologist and the medical physicist, and if appropriate with the radiopharmacist or radiochemist, use the following –

(a) appropriate medical radiological equipment and software;

(b) appropriate radiopharmaceuticals for nuclear medicine; and

(c) appropriate techniques and parameters to deliver a medical exposure of the patient that is the minimum necessary to fulfil the clinical purpose of the radiological procedure, with account taken of relevant norms of acceptable image quality established by relevant professionals and of relevant diagnostic reference levels established in accordance with regulation 24.

19. For therapeutical radiological procedures, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, shall ensure that for each patient the exposure of volumes other than the planning target volume is kept as low as reasonably achievable consistent with delivery of the prescribed dose to the planning target volume within the required tolerances.

20. For therapeutical radiological procedures in which radiopharmaceuticals are administered, the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist, and if appropriate with the radiopharmacist or radiochemist, shall ensure that for each patient the appropriate radiopharmaceutical with the appropriate activity is selected and administered, so that the radioactivity is primarily localised in the organ(s) of interest, while the radioactivity in the rest of the body is kept as low as reasonably achievable.

21. The licensee shall ensure that the particular aspects of medical exposure are considered by the radiological medical practitioner, in cooperation with the medical physicist and the medical radiation technologist in the optimisation process for –

(a) paediatric patients subject to medical exposure;

(b) individuals subject to medical exposure as part of an approved health screening programme;

(c) volunteers subject to medical exposure as part of a programme of biomedical research;

(d) relatively high doses to the patient;

(e) exposure of the embryo or foetus, in particular for radiological procedures in which the abdomen or pelvis of the pregnant female patient is exposed to the useful radiation beam or could otherwise receive a significant dose; and

(f) exposure of a breastfed infant as a result of a female patient having undergone a radiological procedure with radiopharmaceuticals.

Calibration

22. The licensee with the assistance of the medical physicist, specialised in appropriate subfields of medical physics (e.g. diagnostic radiology, radiation therapy, nuclear medicine) shall ensure that –

(a) all sources giving rise to medical exposure are calibrated in terms of appropriate quantities using internationally accepted or nationally accepted protocols endorsed by the Authority and professional bodies;

(b) calibrations are carried out at the time of commissioning a unit prior to clinical use, after any maintenance procedure that could affect the dosimetry and at intervals approved by the Authority;

(c) calibrations of radiation therapy units are subject to independent verification prior to clinical use; and

(d) calibration of all dosimeters used for the dosimetry of patients and for the calibration of sources is traceable to a standards dosimetry laboratory and is undertaken at intervals approved by the Authority.

Dosimetry of patients

23. The licensee shall ensure that dosimetry of patients is performed and documented by or under the supervision of a medical physicist, using calibrated dosimeters and applying internationally accepted or nationally accepted protocols, including dosimetry to determine the following –

(a) typical doses to patients, for common diagnostic radiological procedures;

(b) typical doses to patients, for image guided interventional procedures;

(c) absorbed doses to the planning target volume for each patient treated with external beam therapy and/or brachytherapy and absorbed doses to specific tissues or organs that have been identified as being at risk by the radiological medical practitioner, for therapeutic radiological procedures; and

(d) typical absorbed doses to patients, for therapeutic radiological procedures with unsealed sources.

Diagnostic reference levels

24. The licensee shall ensure that local assessments, on the basis of the measurements required in regulation 23, are made at intervals determined by the Authority for those radiological procedures for which diagnostic reference levels have been established by the Authority, through consultation with the health authority and relevant professional bodies.

25. The licensee shall ensure that a review is conducted to determine whether the optimisation of protection and safety for patients is adequate, or whether corrective action is required, if, for a given radiological procedure –

(a) typical doses or activities exceed the relevant diagnostic reference level; and

(b) typical doses or activities fall substantially below the relevant diagnostic reference level and the exposures do not provide useful diagnostic information or do not yield the expected medical benefit of the patient.

Quality assurance for medical exposures

26. The licensee shall ensure that a comprehensive programme of quality assurance for medical exposures is established, performed, maintained and regular reviewed, with the active participation of the medical physicist, radiological medical practitioner, medical radiation technologist and, for complex nuclear medicine facilities, the radiopharmacist and radiochemist, and in conjunction with other health professionals as appropriate.

27. The licensee shall ensure that programmes of quality assurance for medical exposure include, as appropriate to the medical radiation facility:

(a) measurements of the physical parameters of medical radiological equipment made by, or under the supervision of, a medical physicist;

(i) at the time of acceptance and commissioning of the equipment prior to its clinical use on patients;

(ii) periodically thereafter;

(iii) after any major maintenance procedure that could affect protection and safety of patients; and

(iv) after any installation of new software or modification of existing software that could affect protection and safety of patients;

(b) implementation of corrective actions if measured values of the physical parameters mentioned in paragraph (a) above are outside established tolerance limits;

(c) verification of the appropriate physical parameters and clinical protocols used in radiological procedures;

(d) maintaining records of relevant procedures and results; and

(e) periodic checks of the calibration and conditions of operation of dosimetry equipment and monitoring equipment.

28. (1) The licensee shall ensure that regular and independent audits are made of the programme of quality assurance for medical exposures and that their frequencies are in accordance with the complexity of the radiological procedures being performed and the associated risks.

(2) The licensee shall maintain the results of the audits referred to in paragraph (1).

Dose constraints

29. The licensee shall ensure that relevant dose constraints are used in the optimisation of protection and safety in any radiological procedure in which an individual acts as a carer or comforter. As a result of consultation between the health authority, relevant professional bodies and the regulatory body, dose constraints for exposures of carers and comforters shall be established.

30. The licensee shall ensure that dose constraints specified or approved by the ethics committee on a case-by-case basis as part of the programme for biomedical research are used in the optimisation of protection and safety for persons subject to exposure as part of a programme of biomedical research.

Pregnant or breast-feeding female patients

31. (1) The licensee shall, for the purpose of knowing the pregnancy or breast-feeding status of patients, ensure that -

(a) signs in appropriate languages are placed in public places within the medical radiation facility, waiting rooms for patients, cubicles and other appropriate places, and

(b) other means of communication are also used as appropriate.

(2) The signs and other means of communication referred to in paragraph (1) shall request any female patient who is to undergo a radiological

procedure to notify the radiological medical practitioner, medical radiation technologist or other personnel in the event that -

(a) she is or might be pregnant; and

(b) she is breastfeeding and the scheduled radiological procedure includes the administration of a radiopharmaceutical.

32. The licensee shall ensure that there are procedures in place for ascertaining the pregnancy status of a female patient of reproductive capacity before the performance of any radiological procedure that could result in a significant dose to the embryo or foetus.

33. The licensee shall ensure that there are arrangements in place for establishing that a female patient is not currently breast-feeding before the performance of any radiological procedure involving the administration of a radiopharmaceutical that could result in a significant dose to a breastfed infant.

Release of patients after radionuclide therapy

34. The licensee shall ensure that there are arrangements in place to ensure appropriate radiation protection for members of the public and for family members before a patient is released following radionuclide therapy.

35. The radiological medical practitioner shall ensure that no patient who has undergone a therapeutic radiological procedure with a sealed source or an unsealed source is discharged from a medical radiation facility until it has been established by either a medical physicist or the radiation protection officer that –

(a) the activity of radionuclides in the patient is such that doses that could be received by members of the public would not exceed relevant dose limits for public exposure as specified in the First Schedule of the Act, and would be unlikely to exceed the relevant dose constraints for both members of the public and family members; and

(b) the patient or the legal guardian of the patient is provided with –

(i) written instructions for keeping doses to persons in contact with or in the vicinity of the patient as low as reasonably achievable and for avoiding the spread of contamination; and

(ii) information on the radiation risks.

Unintended and accidental medical exposures

36. The licensee shall ensure that all practicable measures are taken to minimise the likelihood of unintended or accidental medical exposures arising from flaws in design and operational failures of medical radiological equipment, from failures of and errors of software, or as a result of human error.

37. The licensee shall promptly investigate any of the following unintended or accidental medical exposures -

(a) any medical treatment delivered to the wrong individual or to the wrong tissue or organ of the patient, or using the wrong radiopharmaceutical, or with an activity, a dose or dose fractionation differing substantially from (over or under) the values prescribed by the radiological medical practitioner, or that could lead to unduly severe secondary effects;

(b) any diagnostic radiological procedure or image guided interventional procedure in which the wrong individual or the wrong tissue or organ of the patient is subject to exposure;

(c) any exposure for diagnostic purposes that is substantially greater than was intended;

(d) any exposure arising from an image guided interventional procedure that is substantially greater than was intended;

(e) any inadvertent exposure of the embryo or foetus in the course of performing a radiological procedure; and

(f) any failure of medical radiological equipment, failure of software or system failure, or accident, error, mishap or other unusual occurrence with the potential for subjecting the patient to a medical exposure that is substantially different from what was intended.

38. The licensee shall, with regard to any unintended or accidental medical exposures investigated as required in regulation 37 –

(a) calculate or estimate the doses received and the dose distribution within the patient;

(b) indicate the corrective actions required to prevent the recurrence of such an unintended or accidental medical exposure;

(c) implement all the corrective actions that are under their own responsibility;

(d) produce and keep, as soon as possible after the investigation or as otherwise required by the Authority, a written record of the investigation that states the cause of the unintended or accidental medical exposure and includes the information specified in subparagraph (a) - (c), as relevant, and any other information as required by the Authority; and for significant unintended or accidental medical exposures or as otherwise required by the Authority, submit this written record, as soon as possible, to the Authority; and

(e) ensure that the appropriate radiological medical practitioner informs the referring medical practitioner and the patient or the patient's legal authorised representative of the unintended or accidental medical exposure.

Radiological reviews

39. The licensee, in cooperation with the medical radiation technologists and the medical physicists, shall ensure that radiological reviews are performed periodically by the radiological medical practitioners at the medical radiation facility which shall include an investigation and critical review of the current practical application of the radiation protection principles of justification and optimisation for the radiological procedures that are performed in the medical radiation facility.

Records related to medical exposure

40. The licensee shall keep sufficient evidence to be able to demonstrate, at any time, that -

(a) justification of each medical exposure has been carried out; and

(b) optimisation of protection and safety for each medical exposure has been carried out.

41. The licensee shall maintain for a period as specified by the Authority and shall make available, as required, the following personnel records -

(a) details of any allocation of responsibilities by the licensee, as required in regulation 6(d);

(b) training of personnel in radiation protection, as required in regulation 6(b); and

(c) an up-to-date list of medical personnel and paramedical personnel.

42. The licensee shall maintain for a period as specified by the Authority and shall make available, as required, the following records of calibration, dosimetry and quality assurance -

(a) results of the calibrations and periodic checks of the relevant physical and clinical parameters selected during treatment of patients;

(b) dosimetry of patients, as required in regulation 23;

(c) local assessments and reviews made with regard to diagnostic reference levels, referred in regulations 24 and 25; and

(d) reports associated with the quality assurance programme, as required in regulation 27(d).

43. The licensee shall maintain for a period as specified by the Authority and shall make available, as required, the following records for medical exposure –

(a) for diagnostic radiology, information necessary for retrospective assessment of doses, including the number of exposures and the duration of fluoroscopic radiological procedures;

(b) for image guided interventional procedures, information necessary for retrospective assessment of doses, including the duration of fluoroscopic component and the number of images acquired;

(c) for nuclear medicine, the types of radiopharmaceutical administered and their activity;

(d) for external beam radiation therapy or brachytherapy, a description of the planning target volume, the absorbed dose to the centre of the planning target volume, and the maximum and minimum absorbed doses delivered to the planning target volume, or equivalent alternative information on absorbed doses to the planning target volume, and the absorbed doses to relevant tissues or organs as determined by the radiological medical practitioner; and in addition for external beam radiation therapy, the dose fractionation and the overall treatment time;

(e) exposure records for volunteers subject to medical exposure as part of biomedical research; and

(f) reports on investigations of unintended and accidental medical exposures, as required in regulation 38(d).

44. These regulations shall come into operation on ……..

Made by the Minister on ……..