This Statutory Instrument has been made in consequence of a defect in SI 2018/121 and is being issued free of charge to all known recipients of that Statutory Instrument.

STATUTORY INSTRUMENTS

2024 No. 896

HEALTH AND SAFETY

The Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024

Made - - - -	*2nd September 2024*
Laid before Parliament	*3rd September 2024*
Coming into force - -	*1st October 2024*

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 15(1), (2) and 82(3)(a) of, and paragraph 13(2) and 20 of Schedule 3 to, the Health and Safety at Work etc. Act 1974(**1**) and paragraph 7 of Schedule 4 and paragraph 21 of Schedule 7 to the European Union (Withdrawal) Act 2018(**2**).

In accordance with section 50(1AA)(**3**) of the Health and Safety at Work etc. Act 1974, the Secretary of State has consulted the Health and Safety Executive and the Office for Nuclear Regulation.

In accordance with paragraph 10 of Schedule 4 to the European Union (Withdrawal) Act 2018, the Treasury consent to the making of these Regulations.

Citation, commencement, extent and interpretation

1.—(1) These Regulations may be cited as the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2024.

(2) These Regulations come into force on 1st October 2024.

(3) These Regulations extend to England and Wales and Scotland.

(**1**) 1974 c. 37. Section 15(1) was substituted by paragraph 6 of Schedule 15 to the Employment Protection Act 1975 (c. 71) and amended by S.I. 2002/794. Section 15(2) was amended by paragraph 5(3) of Schedule 12 to the Energy Act 2013 (c. 32).

(**2**) 2018 c. 16. Paragraph 7 of Schedule 4 was amended by paragraph 8 Schedule 2 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28). Paragraph 21(a)(i) of Schedule 7 was amended by paragraph 53(2)(a) of Schedule 2 to the European Union (Withdrawal Agreement) Act 2020 (c. 1) and by paragraph 8(14)(b) of Schedule 2 to the Retained EU Law (Revocation and Reform) Act 2023 (c. 28). The term "appropriate authority" is defined in paragraph 8 of Schedule 4 to the European Union (Withdrawal) Act 2018.

(**3**) Subsection (1AA) was inserted by S.I. 2008/960 and amended by paragraph 11(2) of Schedule 12 to the Energy Act 2013 (c. 32).

(4) In these Regulations, "the 2017 Regulations" means the Ionising Radiation (Medical Exposure) Regulations 2017(**4**).

Amendments to regulation 2 of the 2017 Regulations (interpretation)

2.—(1) Regulation 2(1) of the 2017 Regulations (interpretation) is amended as follows.

(2) In the definition of "accidental exposure", for "as a result of an accident" substitute "in error when no exposure was intended".

(3) After the definition of "clinical audit", insert—

""clinical evaluation" means interpretation of the information resulting from an exposure, including the outcome and implications;".

(4) After the definition of "diagnostic reference levels", insert—

""dose reference levels" means dose levels in radiotherapeutic practices for typical localisation or verification exposures for groups of standard-sized individuals or standard phantoms for broadly defined types of equipment;".

(5) In the definition of "employer", for "regulation 3" substitute "regulation 3(1)";

(6) In the definition of "equipment"—

(a) after "means equipment", insert "(including any software)";

(b) omit the "or" after paragraph (a);

(c) in paragraph (b), omit "which";

(d) after paragraph (b), insert—

"; or

(c) directly assists an operator in carrying out a clinical evaluation;".

(7) After the definition of "equipment", insert—

""ethics committee" means—

(a) an ethics committee established or recognised in accordance with Part 2 of the Medicines for Human Use (Clinical Trials) Regulations 2004(**5**);

(b) the Ethics Committee constituted by regulations made by the Scottish Ministers under section 51(6) of the Adults with Incapacity (Scotland) Act 2000(**6**); or

(c) any other committee established to advise on the ethics of research investigations in human beings, and recognised for that purpose by or on behalf of the Secretary of State, the Scottish Ministers or the Welsh Ministers;".

(8) Omit the definition of "evaluation".

(9) After the definition of "health screening", insert—

""individual detriment" means clinically observable deleterious effects in individuals or their descendants, the appearance of which is either immediate or delayed and, in the latter case, implies a probability rather than a certainty of appearance;".

(10) In the definition of "medical exposure", for "regulation 3" substitute 3(1)";

(11) In the definition of "non-medical imaging exposure", after "purposes", insert "using medical radiological equipment,".

(12) In the definition of "practical aspect"—

(**4**) S.I. 2017/1322, as amended by S.I. 2018/121.
(**5**) S.I. 2004/1031.
(**6**) 2000 asp 4.

(a) for "a medical exposure" substitute "an exposure to which these Regulations apply";

(b) for "medical radiological equipment" substitute "equipment";

(c) omit "and maintenance".

(13) In the definition of "practitioner", after "for", insert "the justification of".

(14) After the definition of "quality control", insert—

""radiation protection adviser" means an individual who, or a body which is competent to advise on radiation protection in relation to occupational and public exposures;".

(15) After the definition of "radioactive substance", insert—

""radioactive waste adviser" means an individual who, or a body which is competent to provide expert advice on radioactive waste management and environmental radiation protection;".

Amendments to regulation 3 of the 2017 Regulations (application)

3. In regulation 3 of the 2017 Regulations (application)(**7**), in paragraph (1), in sub-paragraph (f)—

(a) after "individuals undergoing", insert "a";

(b) for "using medical radiological equipment" substitute "a non-medical imaging exposure".

Amendments to regulation 6 of the 2017 Regulations (employer's duties: establishment of general procedures, protocols and quality assurance programmes)

4.—(1) Regulation 6 of the 2017 Regulations (employer's duties: establishment of general procedures, protocols and quality assurance programmes) is amended as follows.

(2) In paragraph (5)—

(a) in sub-paragraph (a), for "medical exposures" substitute "exposures to which these Regulations apply";

(b) in sub-paragraph (c)—

(i) in paragraph (i)—

(aa) the words before sub-paragraph (aa), for "regulation 3(a)" substitute "regulation 3(1)(a)";

(bb) in sub-paragraph (bb), for the words from "European" to "levels" substitute "international and national diagnostic reference levels and local dose surveys";

(ii) in paragraph (ii)—

(aa) for "regulation 3(b)" substitute "regulation 3(1)(b)";

(bb) for "European" substitute "international";

(cc) after "levels", insert "and local dose surveys";

(iii) in paragraph (iii)—

(aa) for "regulation 3(f)" substitute "regulation 3(1)(f)";

(bb) after "practicable", insert ", in which case regard must be had to local dose surveys where available;"

(c) after sub-paragraph (c), insert—

(**7**) Regulation 3 was amended by regulation 2(2) of the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 (S.I. 2018/121).

"(ca) regularly review and make available to an operator, dose reference levels in respect of radiotherapeutic procedures for typical localisation or verification exposures falling within regulation 3(1)(a), in which case, regard must be had to international and national dose reference levels and local dose surveys where available;";

(d) in sub-paragraph (d)—

(i) after "establish dose constraints", insert "for individual effective or equivalent doses over a defined appropriate time period — ";

(ii) in paragraph (i), for "regulation 3(c)" substitute "regulation 3(1)(c)" and omit the final "and";

(iii) in paragraph (ii), for "regulation 3(d)" substitute "regulation 3(1)(d)";

(e) after sub-paragraph (d), insert—

"and

(e) conduct local dose surveys where practicable.".

(3) Omit paragraph (6).

(4) In paragraph (7), after "diagnostic reference levels", insert "or dose reference levels".

Insertion of new regulation 6A

5. After regulation 6, insert—

"**6A Employer's duties: co-operation between employers**

6A.—(1) This regulation applies where, in respect of the same individual, two or more employers carry out or engage others to carry out in their behalf—

(a) those exposures described in regulation 3(1) or any practical aspects;

(b) a referral for any such exposures; or

(c) a justification of any such exposures.

(2) The employers concerned must co-operate with each other to the extent necessary (by the exchange of information or otherwise) to ensure that each such employer—

(a) has access to information on the exposure, or the potential exposure, of the individual to ionising radiation; and

(b) is enabled to comply with the requirements of these Regulations in so far as their ability to comply depends upon such co-operation.".

Amendment to regulation 7 of the 2017 Regulations (employer's duties: clinical audit)

6. In regulation 7 of the 2017 Regulations (employer's duties: clinical audit), after "clinical audit", insert ", and for the taking of any appropriate action in relation to the results of such audit,".

Amendment to regulation 8 of the 2017 Regulations (employer's duties: accidental or unintended exposure)

7. In regulation 8 of the 2017 Regulations (employer's duties: accidental or unintended exposure), for paragraph (3), substitute—

"(3) The employer must establish a system for—

(a) recording analyses of events involving or potentially involving accidental or unintended exposures proportionate to the radiological risk posed by the practice; and

(b) the taking of any appropriate action in relation to such analyses.".

Amendment to regulation 9 of the 2017 Regulations (relevant enforcing authority's duties: accidental or unintended exposure)

8. In regulation 9 of the 2017 Regulations (relevant enforcing authority's duties: accidental or unintended exposure), for "medical exposures" substitute "exposures to which these Regulations apply.".

Amendment to regulation 10 of the 2017 Regulations (duties of the practitioner, operator and referrer)

9. In regulation 10 of the 2017 Regulations (duties of the practitioner, operator and referrer), in paragraph (1), for "and the operator" substitute ", the operator and the referrer".

Amendments to regulation 11 of the 2017 Regulations (justification of individual exposures)

10.—(1) Regulation 11 of the 2017 Regulations (justification of individual exposures) is amended as follows.

(2) In paragraph (1)—

(a) in sub-paragraph (d), for "regulation 3(c)" substitute "regulation 3(1)(c)";

(b) in sub-paragraph (e), for "regulation 3(f)" substitute "regulation 3(1)(f)";

(3) Omit paragraph (6).

Amendments to regulation 12 of the 2017 Regulations (optimisation)

11.—(1) Regulation 12 of the 2017 Regulations (optimisation) is amended as follows.

(2) In paragraph (3)—

(a) in sub-paragraph (a), for "assurance" substitute "control";

(b) omit the "and" after sub-paragraph (b);

(c) in sub-paragraph (c)—

(i) after "radiodiagnostic examinations", insert "and interventional radiology practices";

(ii) for "regulation 3(a)" substitute "regulation 3(1)(a)".

(d) after sub-paragraph (c), insert—

"; and

(d) adherence to such dose reference levels for radiotherapeutic practices for typical localisation or verification exposures falling within regulation 3(1)(a) as the employer may have established,".

(3) In paragraph (4)—

(a) In the opening words, for "regulation 3(c)" substitute "regulation 3(1)(c)";

(b) for sub-paragraph (a), substitute—

"(a) consent to take part in the research programme is given by or, where appropriate, on behalf of, the individuals concerned;";

(c) in sub-paragraph (b), after "the individuals concerned", insert ", or their representative (if there is one) where appropriate,".

(4) In paragraph (5), for "regulation 3(d)" substitute "regulation 3(1)(d)".

(5) In paragraph (6)—

(a) in sub-paragraph (a), after "capacity", insert "or, as the case may be, competence";

(b) after sub-paragraph (a), insert—

"(aa) where the patient is in England or Wales and is a child under the age of 16 who lacks competence to consent, a person with parental responsibility for the child;

(ab) where the patient is in Scotland and is a child under the age of 16 who lacks capacity to consent, a person with parental responsibility for the child; or";

(c) for sub-paragraph (b), substitute—

"(b) where the patient is a person aged 16 or older who lacks capacity or, as the case may be competence, to consent, the person who appears to the operator to be the most appropriate person.";

(d) omit the "or" after sub-paragraph (b);

(e) omit sub-paragraph (c).

(6) In paragraph (8)—

(a) in sub-paragraphs (a) to (c), in each place it occurs omit "medical";

(b) in sub-paragraphs (d) and (e), in each place it occurs for "a medical" substitute "an".

(7) After paragraph (9), insert—

"(10) In this regulation, the references to—

(a) a person's capacity are to be read—

(i) in relation to England and Wales, in accordance with the Mental Capacity Act 2005(**8**) (in the case of a person aged 16 years or older); and

(ii) in relation to Scotland, in accordance with the Age of Legal Capacity (Scotland) Act 1991(**9**) (in the case of a person under the age of 16) and the Adults with Incapacity (Scotland) Act 2000(**10**) (in the case of a person aged 16 years or older); and

(b) "parental responsibility" are to be read—

(i) in relation to England and Wales, in accordance with the Children Act 1989(**11**); and

(ii) in relation to Scotland, in accordance with the Children (Scotland) Act 1995(**12**).".

Amendment to regulation 13 of the 2017 Regulations (estimates of population doses)

12. In regulation 13 of the 2017 Regulations (estimates of population doses), for "medical exposures for radiodiagnostic and interventional procedures" substitute "exposures to which these Regulations apply".

(**8**) 2005 c. 9.
(**9**) 1991 c. 50.
(**10**) 2000 asp 4.
(**11**) 1989 c. 41.
(**12**) 1995 c. 36.

Amendments to regulation 14 of the 2017 Regulations (expert advice)

13.—(1) Regulation 14 of the 2017 Regulations (expert advice) is amended as follows.

(2) In paragraph (2), in sub paragraph (d), in paragraph (i), for "assurance" substitute "control".

(3) In paragraph (3)—

(a) in sub-paragraph (a), after "levels", insert "and dose reference levels";

(b) in sub-paragraph (h), after "practitioners", insert ", operators".

(4) Omit paragraph (5).

Amendments to regulation 15 of the 2017 Regulations (equipment: general duties of the employer)

14.—(1) Regulation 15 of the 2017 Regulations (equipment: general duties of the employer) is amended as follows.

(2) In paragraph (2), after "information", insert "for equipment other than software".

(3) After paragraph (2), insert—

"(2A) The inventory referred to in paragraph (1)(b) must contain the following information for equipment that is software—

(a) name of software company;

(b) brand name;

(c) current software version;

(d) year of original installation; and

(e) year of current software version installation in clinical use.".

(4) In paragraph (3), in sub-paragraph (a), for "a medical radiological purpose" substitute "an exposure to which these Regulations apply".

(5) In paragraph (5), for "practitioner" substitute "operator".

Amendments to regulation 22 of the 2017 Regulations (review)

15. In regulation 22(4) of the 2017 Regulations (review), for the words from "the Articles" to the end substitute "the international obligations implemented by these Regulations are implemented in other countries which are subject to those obligations.".

Amendments to Schedule 1 to the 2017 Regulations (licensing)

16.—(1) Schedule 1 to the 2017 Regulations (licensing) is amended as follows.

(2) In paragraph 2, in sub-paragraph (g), for "testing" substitute "quality control".

(3) For Table 1, which follows paragraph 4, substitute—

"**Table 1**

Licence type (1)	*Application type (2)*	*Fee (£) (3)*
Employer	New	298
	Amendment of an existing licence	244
	Renewal of an existing licence	244

Licence type (1)	*Application type (2)*	*Fee (£) (3)*
	Notification	0
Practitioner	New	0
	Amendment of an existing licence	0
	Renewal of an existing licence	0
	Particular patient request	0".

Amendments to Schedule 2 to the 2017 Regulations (employer's procedures)

17. In Schedule 2 to the 2017 Regulations (employer's procedures), in paragraph 1—

(a) in sub-paragraph (f)—

(i) after "diagnostic reference levels", insert "and dose reference levels";

(ii) for the words "for radiodiagnostic" to the end substitute "under regulation 6(5)(c) and 6(5)(ca)";

(b) in sub-paragraph (g), for "regulation 3(c)" substitute "regulation 3(1)(c)";

(c) in sub-paragraph (j), for "an evaluation" substitute "a clinical evaluation";

(d) in sub-paragraph (l), for "unintended or accidental" substitute "accidental or unintended";

(e) after sub-paragraph (n), insert—

"(o) for the carrying out of clinical audit, and for any appropriate action to be taken in accordance with regulation 7; and

(p) for making, amending and cancelling any referrals for exposure.".

Amendments to Schedule 3 to the 2017 Regulations (adequate training)

18. In Schedule 3 to the 2017 Regulations (adequate training)—

(a) for Table 1 (radiation production, radiation protection and statutory obligations relating to ionising radiations), substitute—

"**Table 1**

Radiation production, radiation protection and statutory obligations relating to ionising radiations

Fundamental Physics of Radiation	
Properties of Radiation	Excitation and ionisation
	Attenuation of ionising radiation
	Scattering and absorption
Radiation Hazards and Dosimetry	Biological effects of radiation - stochastic and deterministic
	Risks and benefits of radiation
	Absorbed dose, equivalent dose, effective dose, other dose indicators and their units

Fundamental Physics of Radiation	
Management and Radiation Protection of the individual being exposed	
Special Attention Areas	Pregnancy and potential pregnancy
	Asymptomatic individuals
	Breastfeeding
	Infants and children
	Medical and biomedical research
	Health screening
	Non-medical imaging
	Carers and comforters
	High dose techniques
Justification and authorisation	Justification of the individual exposure
	Use of existing appropriate radiological information
	Alternative techniques
Radiation Protection	Diagnostic reference levels
	Dose reference levels
	Dose Constraints
	Dose Optimisation
	Dose reduction devices and techniques
	Dose recording and dose audit
	General radiation protection
	Quality Assurance for written procedures and written protocols
	Quality Control for the routine inspection and testing of equipment
	Risk communication
	Use of radiation protection devices
Statutory Requirements, Non-Statutory Guidance and other documents	
	Regulations
	Non-statutory guidance
	Local procedures and protocols
	Individual responsibilities relating to exposures
	Responsibility for radiation safety

Fundamental Physics of Radiation	
	Proactive use of clinical audit
	Analysis of events involving accidental or unintended exposures
	Study of risk of accidental or unintended exposures”;

(b) for Table 2 (diagnostic radiology, radiotherapy and nuclear medicine), substitute—

“**Table 2**

Diagnostic radiology, radiotherapy and nuclear medicine

All Modalities	
General	Fundamentals of radiological anatomy
	Factors affecting radiation dose
	Dosimetry
	Fundamentals of clinical evaluation
	Identification of the individual being exposed
	Equipment specification
Contrast Media	Use and preparation
	Contraindications
	Use of contrast injection systems

Diagnostic radiology	
General	Principles of radiological techniques
	Production of X-rays
Specialised Techniques	Computed Tomography
	Interventional procedures
	Hybrid imaging
Practical aspects for diagnostic radiology	Patient positioning
	Equipment selection and use
	Protocol selection
	Optimisation of image quality and radiation dose
	Dose assessment and recording
	Image acquisition, artefacts, processing, display and storage

Radiotherapy	
General	Production of ionising radiation
	Treatment of malignant disease
	Treatment of benign disease
	Principles of external beam radiotherapy
Specialised techniques	Brachytherapy
	Intra-operative radiotherapy
	Proton therapy
	Magnetic Resonance Linac therapy
	Computed Tomography: applications limited to radiotherapy
	Advanced techniques
Radiobiological Aspects for Radiotherapy	Fractionation
	Dose rate
	Radiosensitisation
	Target volumes
	Organs at risk
	The Radiobiological effect of gaps in treatment
	The Radiobiology of re-treatment
Practical Aspects for Radiotherapy	Patient positioning
	Equipment selection and use
	Principles of localisation techniques
	Principles of planning techniques
	Principles of dose calculation and verification techniques
	Principles of treatment techniques
	Principles of on-treatment imaging
	Optimisation of image quality and radiation dose
Radiation Protection Specific to Radiotherapy	Side effects—early and late
	Toxicity
	Assessment of efficacy

Nuclear Medicine	
General	Atomic structure and radioactivity

Nuclear Medicine	
Molecular Radiotherapy	Radioactive decay
	Principles of molecular imaging and non-imaging exposures
	Principles of molecular radiotherapy
	Dose rate
	Fractionation
	Radiobiology aspects
	Radiosensitisation
Specialised techniques	Quantitative imaging—advanced applications
	Hybrid imaging—advanced applications
	Selective Internal Radiation Therapy
Radiopharmaceuticals	Calibration
	Working practices in the radiopharmacy
	Preparation of individual doses
Practical aspects for nuclear medicine	Patient positioning
	Equipment selection and use
	Protocol selection
	Optimisation of image quality and radiation dose
	Dose assessment and recording
	Image acquisition, artefacts, processing, display and storage
Radiation Protection Specific to Nuclear Medicine	Conception, pregnancy and breastfeeding
	Radiation protection arrangements for radioactive individuals”.

Andrew Gwynne
Parliamentary Under-Secretary of State
Department of Health and Social Care

2nd September 2024

We consent

Jeff Smith
Vicky Foxcroft
Two of the Lords Commissioners of His Majesty's Treasury
HM Treasury

2nd September 2024

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Ionising Radiation (Medical Exposure) Regulations 2017 (S.I. 2017/1322) ("the 2017 Regulations"). These Regulations are being issued free of charge to those who purchased the Ionising Radiation (Medical Exposure) (Amendment) Regulations 2018 (S.1 2018/121) ("the 2018 Regulations"). The 2018 Regulations made amendments to the 2017 Regulations which re-numbered regulation 3 but failed to update all cross references to regulation 3. These regulations correct that defect.

Amendments in these Regulations include:

- amending a number of definitions within the 2017 Regulations including expanding the meaning of 'equipment' to include any software which directly assists the operator in carrying out a clinical evaluation;
- inserting a new regulation 6A (Employer's duties: co-operation between employers) which obliges employers to co-operate with each other by exchanging information, or otherwise;
- amending regulation 12 (Optimisation) of the 2017 Regulations to add a further factor which operators must have regard to when ensuring that each dose of ionising radiation is as low as reasonably practicable and consistent with the intended diagnostic or therapeutic purpose;
- increasing the fees charged to employers for licence applications set out in Table 1 of Schedule 1 (Licensing) to the 2017 regulations;
- amending the training requirements for practitioners and operators set out in table 2 of Schedule 3 (Adequate Training) the 2017 Regulations; and
- a number of other technical and/or minor amendments.

A full impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary sector or public sector is foreseen.