First FRCR Examination in Clinical Radiology

Statutory Requirements and Non-Statutory Recommendations

(b) *Ionising Radiation (Medical Exposure) Regulations 2017*

IR(ME)R

Marcus Blunkett
Medical Physics Expert

2018 changes

Before 6/2/2018

(i.e. old books)

- Ionising Radiation (Medical Exposure) Regulations 2000
  - "IRMER", "IR(ME)R", "IRMER2000", etc
- Medicines (Administration of Radioactive Substances) Regulations 1978
  - "MARS78"
- IRR 1999 r.32 Equipment used for medical exposures

Now

(i.e. The Law + Part 1 exam)

- Ionising Radiation (Medical Exposure) Regulations 2017
  - "IRMER", "IR(ME)R", "IRMER17", etc.
- IRMER17 r.15,16 Equipment

IR(ME) R

- Regulations
  - GB - IR(ME)R17 http://www.legislation.gov.uk/uksi/2017/1322
    - IR(ME) (Amendment) Regulations 2018 - http://www.legislation.gov.uk/uksi/2018/121
    - IR(ME) (Amendment) Regulations 2024 - https://www.legislation.gov.uk/uksi/2024/896
  - *NI - IR(ME)R(NI)18 – SR 2018 No. 17*
- Government Guidance
  - Department of Health & Social Security (DHSC) IRMER Guidance - *https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance*
  - Administration of Radioactive Substances Advisory Committee (ARSAC) - https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee
  - Care Quality Commission (CQC) Significant accidental and unintended exposures under IR(ME)R Guidance for employers and duty-holders - https://www.cqc.org.uk/guidance-providers/ionising-radiation/definition-significant-accidental-or-unintended-exposures

- **Regulation 1**
  - Comes into force 6th February 2018
- **Regulations 2 Interpretations**
  - i.e. defines various terms used in the regulations



RCR/BIR/SCoR/IPEM/PHE 2026,

IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine

https://www.rcr.ac.uk/our-services/all-our-publications/clinical-radiology-publications/ir-me-r-implications-for-clinical-practice-in-diagnostic-imaging-interventional-radiology-and-diagnostic-nuclear-medicine-second-edition/

Basic Principles

- Justification
- Optimisation

- Roles & Responsibilities (*employers, referrers, practitioners, operators, MP experts)*
- Procedures & Protocols
- Adequate training & Audit .

Reg 3 Application

Apply to *"medical exposure"*, which means

". . . exposure to ionising radiation . . .

(a) to patients as part of their own medical diagnosis or treatment;

(b) to individuals as part of health screening programmes;

(c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) to carers and comforters; *(pop up)*

(e) to asymptomatic individuals;

(f) to individuals undergoing non-medical imaging using medical radiological equipment. "

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(c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) to carers and comforters;

"**carers and comforters**" means individuals **knowingly and willingly** incurring an exposure to ionising radiation by helping, **other than as part of their occupation**, in the support and comfort of individuals undergoing or having undergone an exposure;

(Note, this used to be covered by IRR99 not IRMER2000)

Reg 3 Application

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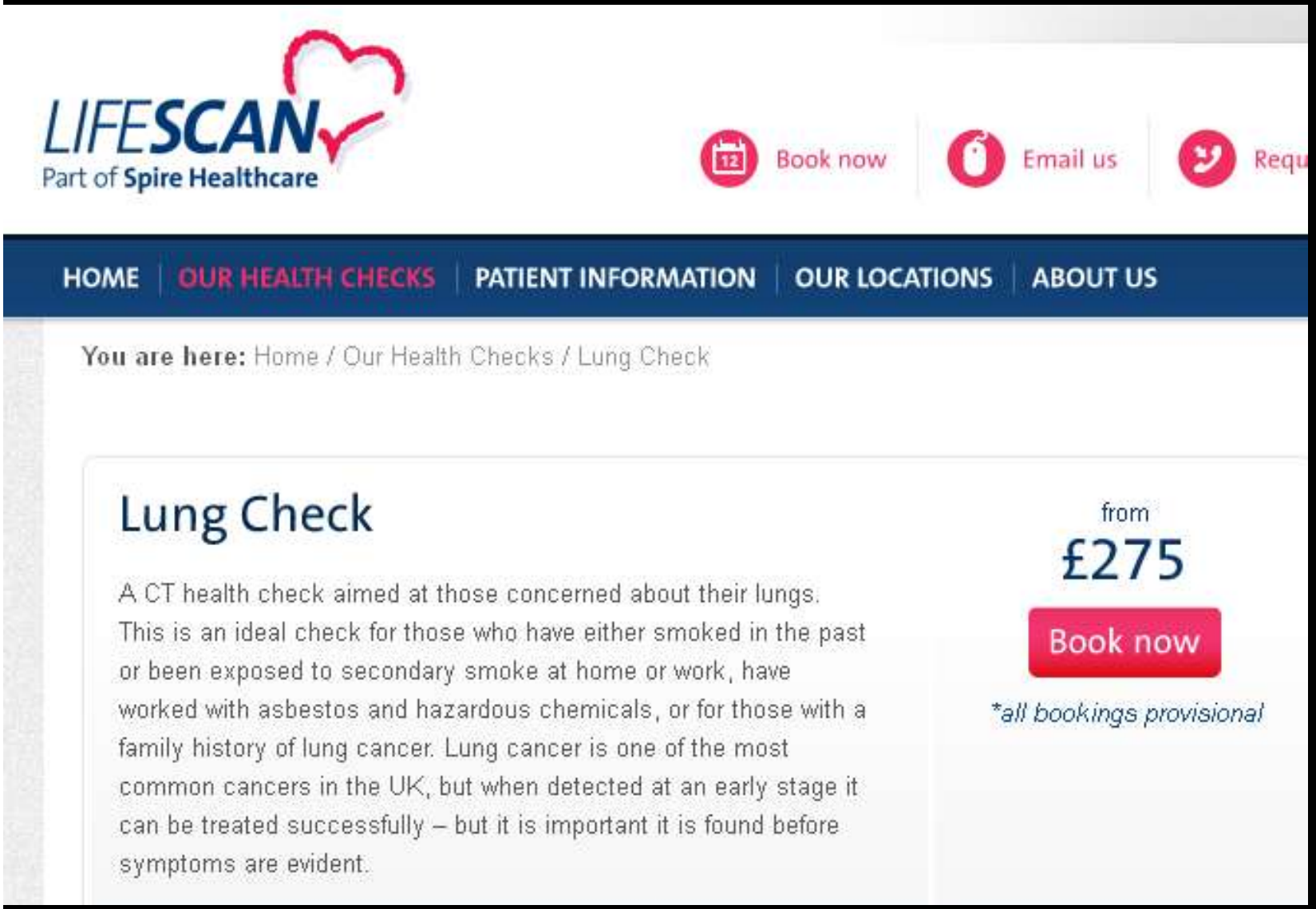
(c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) to carers and comforters;

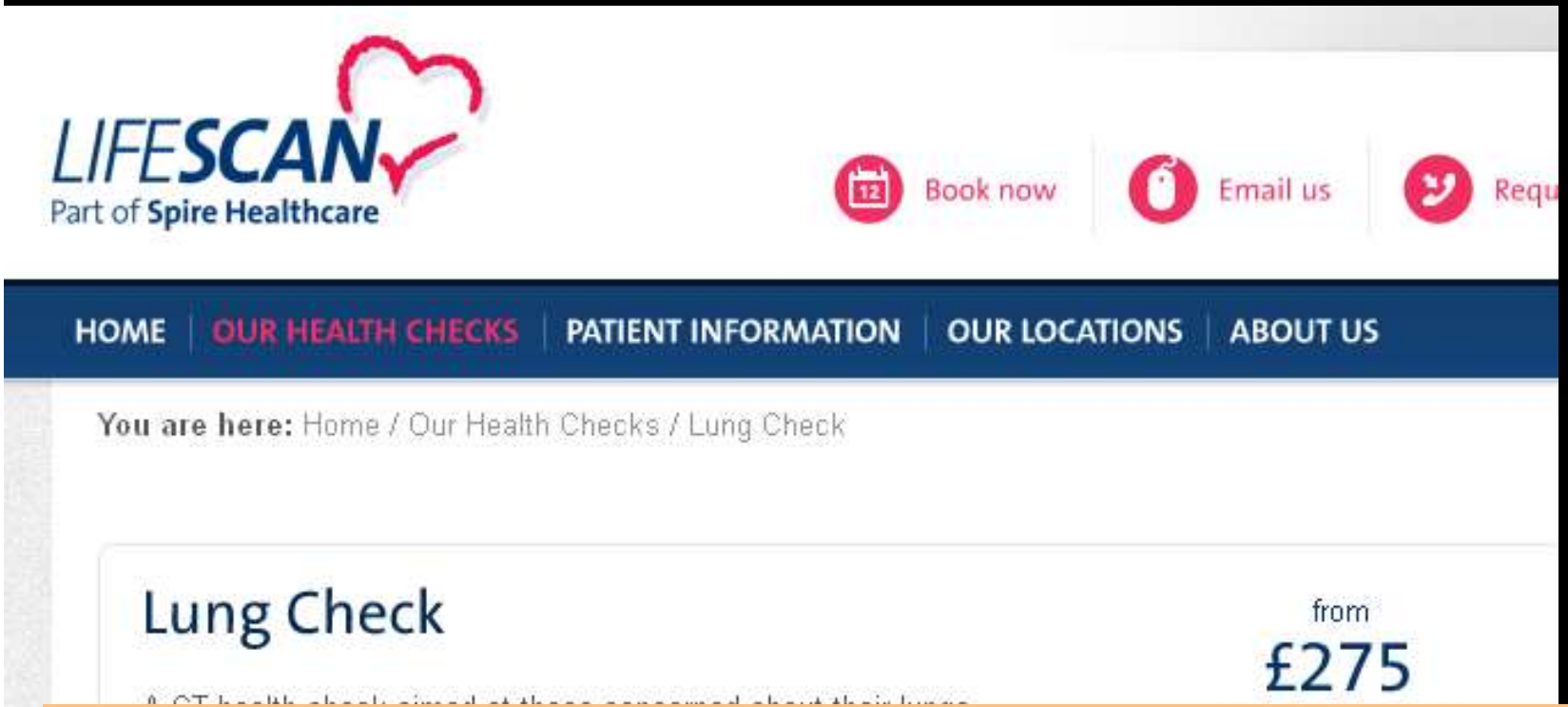
(e) to asymptomatic individuals; *(pop up)*

(f) to individuals undergoing a non-medical imaging using medical radiological equipment."

"…exposure of an asymptomatic individual"

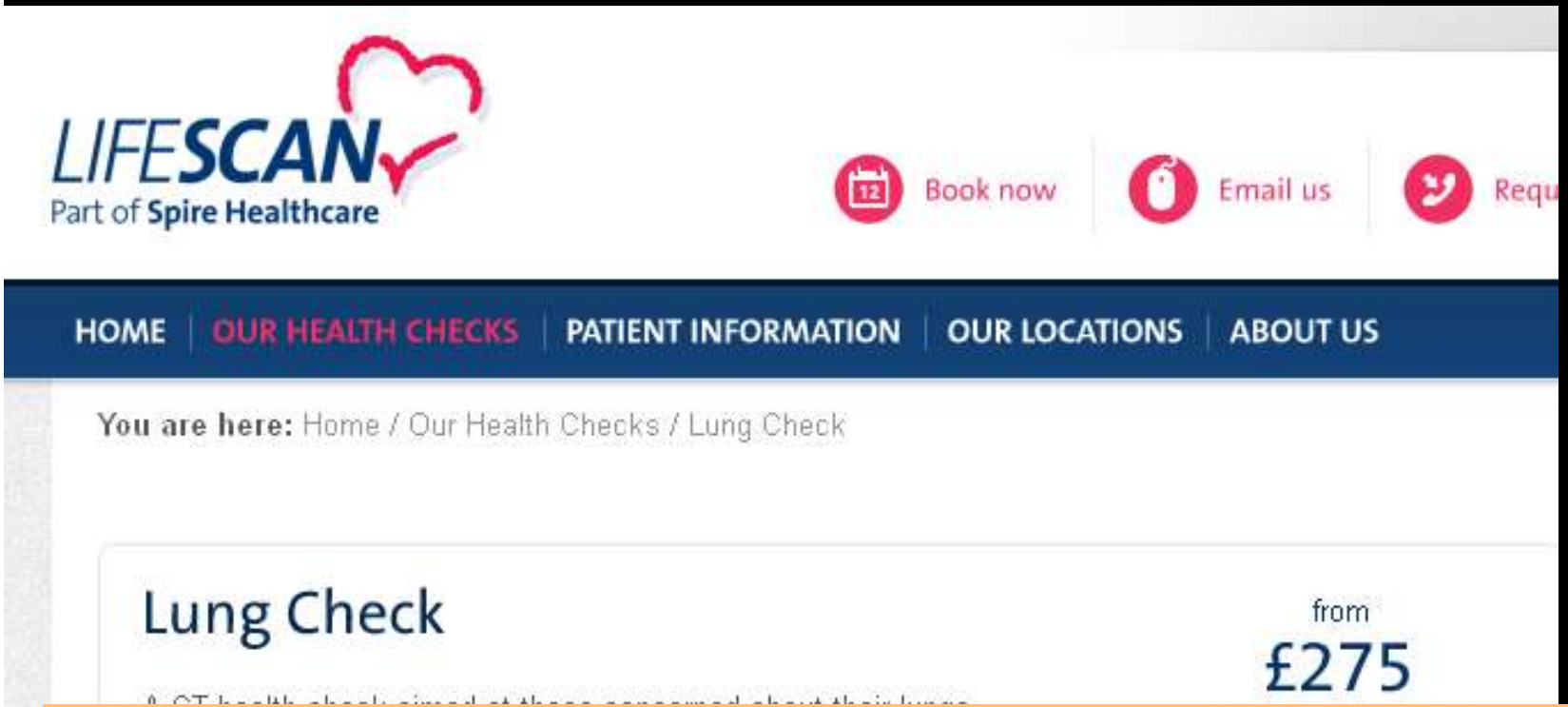


"…exposure of an asymptomatic individual"



Committee on Medical Aspects of Radiation in the Environment (COMARE) (2007) . *Twelfth Report*. ***The impact of personally initiated X-ray computed tomography scanning for the health assessment of asymptomatic individuals.***
Health Protection Agency, December 2007.
https://www.gov.uk/government/publications/comare-12th-report

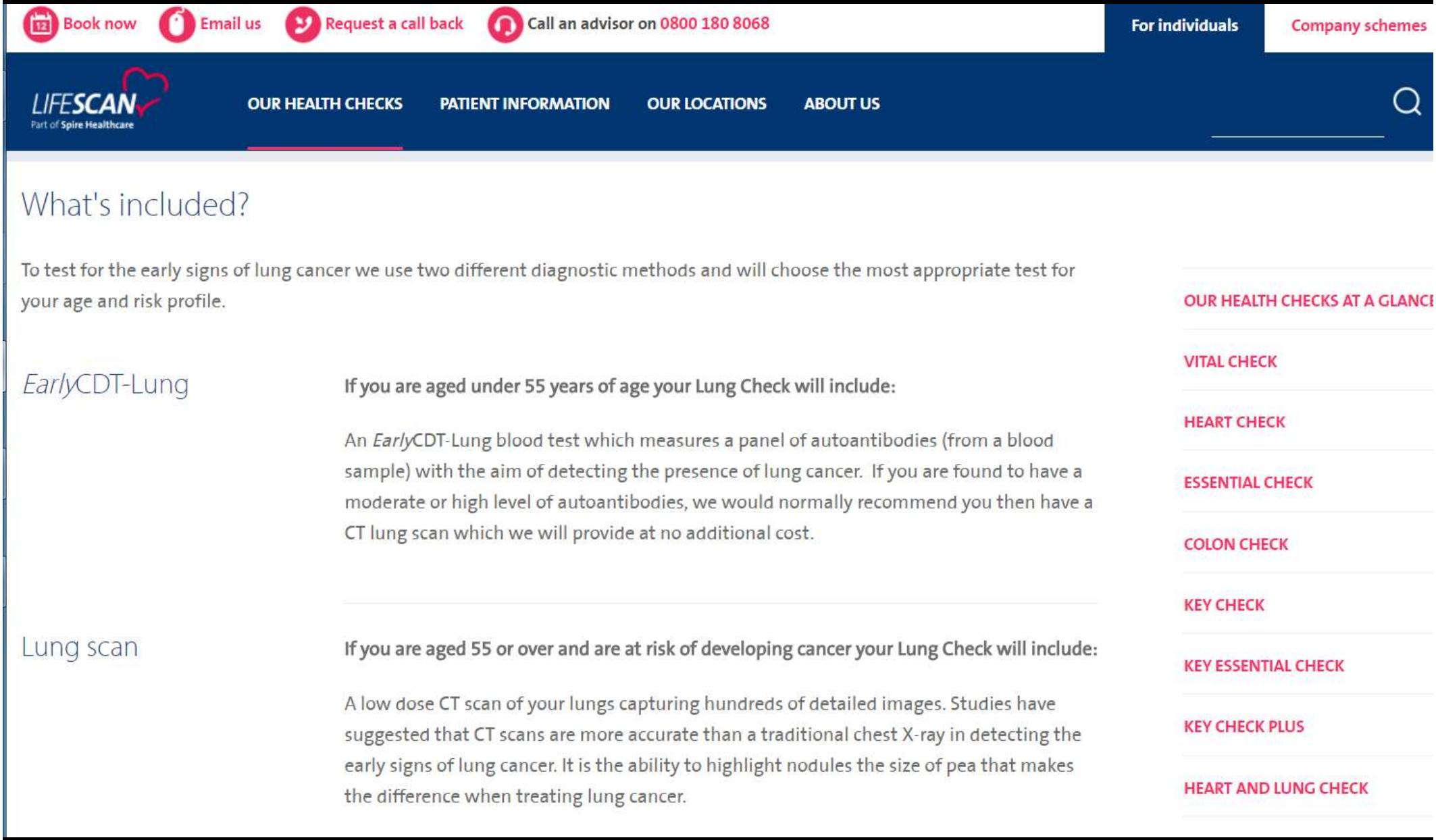
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Committee on Medical Aspects of Radiation in the Environment (COMARE) (2007) . *Twelfth Report*. ***Th***
computed tomography
asymptomatic individu
Health Protection Agency, L
https://www.gov.uk/governm

Recommendation 7 Current evidence suggests that there is **no benefit to be derived from CT scanning of the lung in asymptomatic individuals**. Further research is required in this area but, until this is available, CT scanning of the asymptomatic individual cannot be justified for the lung and should not be made available.

. . . As of Nov 2016 . . .



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Part of Spire Healthcare

OUR HEALTH CHECKS | PATIENT INFORMATION | OUR LOCATIONS | ABOUT US

What's included?

To test for the early signs of lung cancer we use two different diagnostic methods and will choose the most appropriate test for your age and risk profile.

*Early*CDT-Lung

If you are aged under 55 years of age your Lung Check will include:

An *Early*CDT-Lung blood test which measures a panel of autoantibodies (from a blood sample) with the aim of detecting the presence of lung cancer. If you are found to have a moderate or high level of autoantibodies, we would normally recommend you then have a CT lung scan which we will provide at no additional cost.

Lung scan

If you are aged 55 or over and are at risk of developing cancer your Lung Check will include:

A low dose CT scan of your lungs capturing hundreds of detailed images. Studies have suggested that CT scans are more accurate than a traditional chest X-ray in detecting the early signs of lung cancer. It is the ability to highlight nodules the size of pea that makes the difference when treating lung cancer.

OUR HEALTH CHECKS AT A GLANCE
VITAL CHECK
HEART CHECK
ESSENTIAL CHECK
COLON CHECK
KEY CHECK
KEY ESSENTIAL CHECK
KEY CHECK PLUS
HEART AND LUNG CHECK

Reg 3 Application

Apply to *"**medical exposure**"*, which means

". . . exposure to ionising radiation . . .

(a) to patients as part of their own medical diagnosis or treatment;

(b) to individuals as part of health screening programmes;

(c) to patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(d) to carers and comforters;

(e) to asymptomatic individuals;

(f) to individuals undergoing a non-medical imaging using medical radiological equipment.

"non-medical imaging exposure" means any deliberate exposure of humans for imaging purposes using medical radiological equipment,where the primary intention of the exposure is not to bring a health benefit to the individual being exposed;

Reg 4 Licensing / Reg 5 Requirement to hold a licence

Nuclear Medicine & Brachytherapy "ARSAC Licenses"

- Employers must be licensed for each radiological installation where radioactive substances are administered *(i.e. nuclear medicine, brachytherapy)*
  - In England from Secretary of State for Health and Social Care
  - In Northern Ireland the Department of Health (NI)
  - In Scotland from Scottish Ministers
  - In Wales from Welsh Ministers



- Practitioners must have license in order to justify an exposure involving the administration of radioactive substances *(fee £0)*
  - In GB from Secretary of State for Health and Social Care
  - In NI from the Department of Health



- But the *Administration of Radioactive Substances Advisory Committee* (ARSAC) /PHE advise all Licensing Authorities and process applications
- Replaces MARS78 regulations
- Comprehensive ARSAC guidance - https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee

Change from old regs

(Note, details are decided by ARSAC, not written in regulations. ARSAC can change these in future.)

MARS78

- Doctor/dentist had a certificate for each site naming
  - Doctor/dentist
  - Site *(e.g. Castle Hill Hospital)*
  - All procedures that doctor/dentist may administer *(e.g. Tc-99m bone scan, FDG tumour imaging, etc.)*
- A separate certificate for research procedures
- Granted for 5 year
- No fee

IRMER17

- Employer has a license for each radiological installation naming
  - Employer *(e.g. Hull University Teaching Hospitals)*
  - Installation *(e.g. Castle Hill Hospital)*
  - All procedures permitted at that installation for diagnosis, treatment& research *(e.g. Tc-99m bone scan, FDG tumour imaging, Ra-223 for treatment of bone metastases in breast cancer, etc.)*
- *(£250 fee for installations)*
- The practitioner has a license naming
  - Practitioner
  - All procedures that practitioner may justify

  (£0 fee for practitioners)
- Both types granted for 5 year

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Written Procedures

r. 6(1) The employer must ensure that written procedures are in place in respect of—

(a) those matters described in Schedule 2; and

(b) any other matter in relation to which these Regulations mandate the establishment of procedures.





Schedule 2. Employer's Procedures

1. The employer's written procedures for exposures must include procedures—

(a) to identify correctly the individual to be exposed to ionising radiation;

(b) to identify individuals entitled to act as referrer or practitioner or operator within a specified scope of practice;

(c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be pregnant or breastfeeding;

(d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;

(e) for the assessment of patient dose and administered activity;

(f) for the use and review of such diagnostic reference levels and dose reference levels as the employer may have established under regulation 6(5)© and 6(5)(ca);

(g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(1)(c) where no direct medical benefit for the individual is expected from the exposure;

(h) for the giving of information and written instructions as referred to in regulation 12(6) ;

(i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is provided with adequate information relating to the benefits and risks associated with the radiation dose from the exposure;

(j) for the carrying out and recording of an clinical evaluation for each exposure including, where appropriate, factors relevant to patient dose;

(k) to ensure that the probability and magnitude of accidental or unintended exposure to individuals from radiological practices are reduced so far as reasonably practicable;

(l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant clinically significant accidental or unintended exposure, and of the outcome of the analysis of this exposure;

(m) to be observed in the case of non-medical imaging exposures;

(n) to establish appropriate dose constraints and guidance for the exposure of carers and comforters.

(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.

We'll come back to this

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Written Procedures – compliance by staff

"(2) The employer must take steps to ensure that any written procedures are complied with by

- the referrer,
- practitioner and
- operator."

Roughly speaking . . .

- IRMER Referrer – requests a radiological opinion.
- IRMER Practitioner – decides there will be net benefit to patient (or society).
- IRMER Operator – does anything else effecting patient dose and diagnosis.

IRMER referrer, practitioner, operator
Regulation 2 definitions

"**referrer**" means

- a registered health care professional
- who is entitled in accordance with the employer's procedures
- to refer individuals for exposure to a practitioner;



IRMER referrer, practitioner, operator

Regulation 2 definitions

"referrer" means a registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

"**practitioner**" means

- a registered health care professional
- who is entitled in accordance with the employer's procedures
- to take responsibility for the justification of an individual exposure;

r.10(2) "(2) The **practitioner** is **responsible for** the **justification** of an exposure and such other aspects of an exposure as is provided for in these Regulations."



IRMER referrer, practitioner, operator

"referrer" means a registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

"practitioner" means a registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual exposure;

"**operator**" means

- any person
- who is entitled, in accordance with the employer's procedures,
- to carry out **practical aspects** including those to whom practical aspects have been allocated, medical physics experts and,
- **except** where they do so **under the direct supervision** of a person who is adequately trained, persons participating in practical aspects **as part of practical training**;

IRMER referrer, practitioner, operator

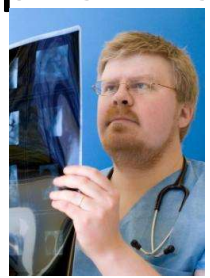
"referrer" means a registered health care professional who is entitled in accordance with the employer's procedures to refer individuals for exposure to a practitioner;

"practitioner" means a registered health care professional who is entitled in accordance with the employer's procedures to take responsibility for an individual exposure;

"operator" means any person who is entitled, in accordance with the employer's procedures, to carry out practical aspects including those to whom practical aspects have been allocated, medical physics experts and, except where they do so under the direct supervision of a person who is adequately trained, persons participating in practical aspects as part of practical training;

"**practical aspect**" 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 radio-pharmaceuticals,
  - clinical evaluation and
  - image processing;



Case Study 1



- A GP sends a patient to the HRI for chest X ray
- The radiographer checks the request form against justification guidelines written by a consultant radiologist and x rays the patient
- A radiology registrar views the images and issues a report

Who is the:

- Employer?
- HUTH Hospitals
- Referrer?
- GP
- Operator?
- Radiographer
- Reporting radiologist
- Practitioner?
- Consultant radiologist who writes the written guidelines

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Training & CPD/CME

(3) The employer must take steps to ensure that every **practitioner** or **operator**

(a) is **adequately trained**; and

(b) undertakes **continuing education and training** after qualification including, in the case of clinical use of **new techniques**, training related to those techniques and the relevant radiation protection requirements.

r.2 - "adequate training" means training which satisfies the requirements of Schedule 3 and the expression "adequately trained" is to be construed accordingly;

r.17(3) a person can participate in practical aspects as part of practical training if this is done under the supervision of a person who is adequately trained.

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Written Protocols

(4) The employer must ensure, where appropriate, that **written protocols** are in place **for every type of standard radiological practice** coming within these Regulations, including practices involving non-medical imaging.

e.g. for X-ray room 5, PA chest: 80-85 kV, 2-2.5 mAs.

For pre-programmed units i.e. with a chest button, a record should be kept of what the programmed values are. For nuclear medicine, document amount administered for each routine examination and treatment

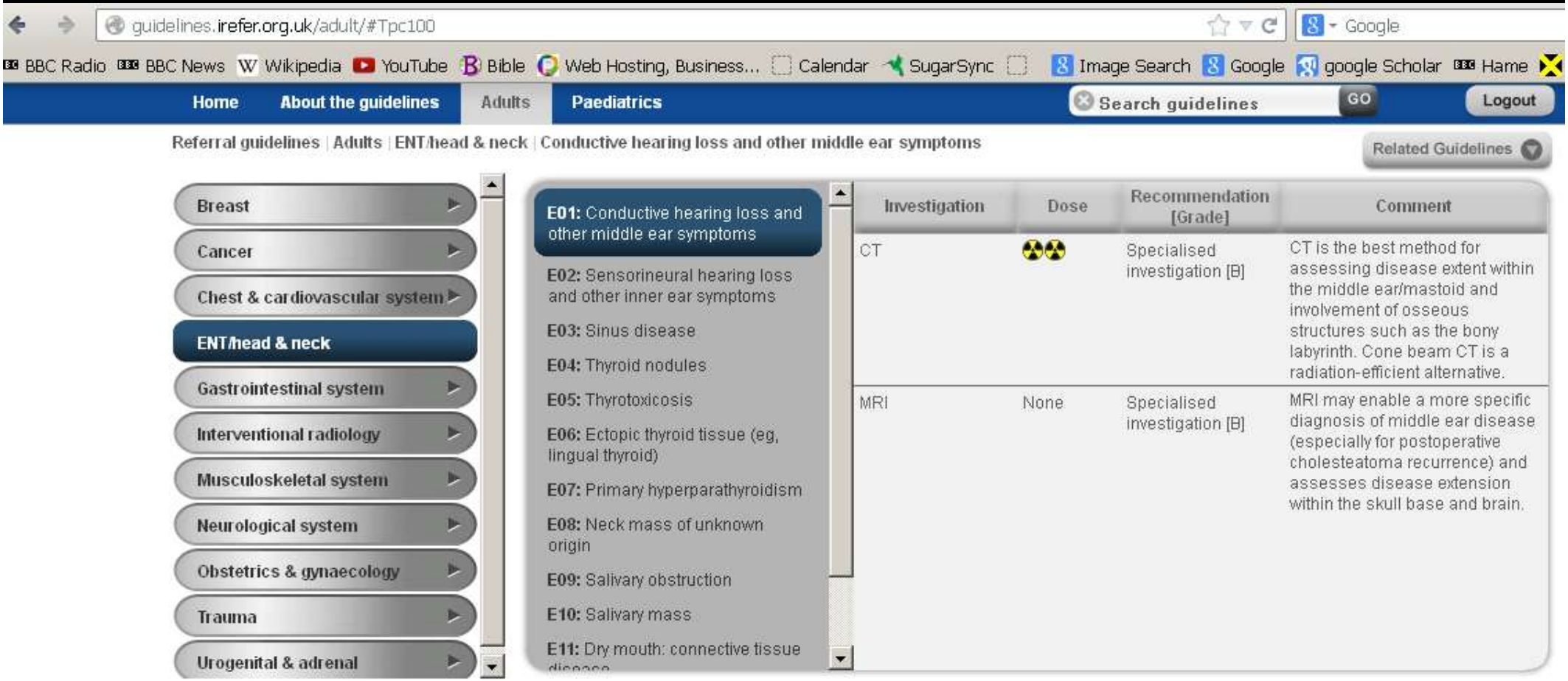
Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Referral Criteria

"(5)(a) establish recommendations concerning referral guidelines for medical exposures, including radiation doses, and ensure that these are available to the referrer"

RCR Making the best use of clinical radiology - *iRefer*

https://www.irefer.org.uk/



Local HUTH Hospitals

https://www.hey.nhs.uk/radiology/information-for-gps-and-referrers/

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Quality Assurance programme – written procedures and protocols

"(5)(b) establish quality assurance programmes for written procedures and written protocols;"

(Also r.7 must carry out clinical audit)

DHSC guidance – procedures and protocols should include
who is responsible for authorising the document, on behalf of the employer

- **who is responsible** to the authorising person for the accuracy of the document content, for document review, and for ensuring the document is up to date
- a formal **process for making changes**
- the **version number**
- the **date** of the last and **next scheduled review**
- page numbering.

Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Diagnostic Reference Levels (DRL)

"(5)(c) regularly review and make available to an operator, diagnostic reference levels in respect of an exposure falling within"

- Interventional radiology procedures where appropriate
- Diagnostic procedures including health screening, with regards to international and national DRLs
- Non-medical imaging where practicable
- Radiotherapy localisation and verification imaging.

National Diagnostic Reference Levels (NDRLs)
https://www.gov.uk/government/publications/diagnostic-radiology-national-diagnostic-reference-levels-ndrls

Reg 6 Employer's duties: establi ,
protocols and quality ass

Diagnostic Referer

"(5)(c) regularly review and ma
diagnostic reference levels in re
within"

- Interventional radiology proc
- Diagnostic procedures includ
  regards to European and nati
- Non-medical imaging where

(7) Must be reviewed when DRL
corrective action taken where a

National Diagnostic Reference Levels (NDRLs)
https://www.gov.uk/government/publications
diagnostic-reference-levels-ndrls

3. National DRLs for general radiography and fluoroscopy

3a. Individual radiographs on adult patients

Radiograph	ESD per radiograph (mGy)	DAP per radiograph (Gy cm^2)	Year NDRL adopted
Abdomen AP	4	2.5	2016
Chest AP	0.2	0.15	2016
Chest LAT	0.5		2016
Chest PA	0.15	0.1	2016
Cervical spine AP		0.15	2016
Cervical spine LAT		0.15	2016
Knee AP	0.3		2016
Knee LAT	0.3		2016
Lumbar spine AP	5.7	1.5	2016
Lumbar spine LAT	10	2.5	2016
Pelvis AP	4	2.2	2016
Shoulder AP	0.5		2016
Skull AP/PA	1.8		2016
Skull LAT	1.1		2016
Thoracic spine AP	3.5	1.0	2016
Thoracic spine LAT	7	1.5	2016

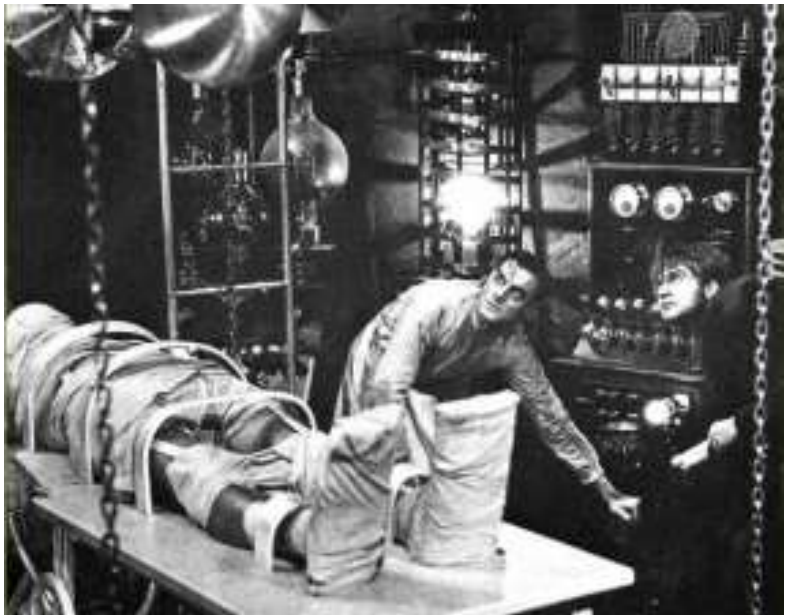
Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Dose constraints

"(5)(d) establish dose constraints"

- For research exposures where no benefit to individual
- For carers and comforters

(6) as individual effective or equivalent dose





Reg 6 Employer's duties: establishment of general procedures, protocols and quality assurance programmes

Potentially pregnant or breastfeeding patients

(8) The employer must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding."

Note

- *Where pelvic area irradiated we need to consider whether patient may be pregnant (more in future lecture or see https://www.gov.uk/government/publications/ionising-radiation-protecting-pregnant-patients-during-diagnostic-medical-exposures*
- *Breastfeeding only relevant for nuclear medicine procedures*

DHSC Guidance

- should not be restricted to enquiries by operators prior to exposure
- might include measures such as
  - signs in waiting rooms or
  - inclusion of relevant information in appointment letters, where appropriate.

Reg 6 Emp eneral procedures,
p rammes

Potentia ding patients

(8) The er se awareness of
the effects ividuals capable
of childbe



DHSC Guidanc

- should not l exposure
- might inclu
  - signs in
  - inclusio rs, where appropriate.

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

Where more than one employer carry out, or engage others to carry out, a medical exposure they must co-operate by exchange of information, etc.



Reg 7 Clinical audit

The employer's procedures must include

- provision for the carrying out of clinical audit, and
- for the taking of any appropriate action in relation to the results of such audit, as appropriate.

r.2 "clinical audit" means a systematic examination or review of medical radiological procedures which seeks to improve the quality and outcome of patient care through structured review, whereby medical radiological practices, procedures and results are examined against agreed standards for good medical radiological procedures, with modification of practices, where indicated, and the application of new standards if necessary;

Here on 07/08/2026

- **IR(ME)R 2017** applies to "**medical exposures**"
- **CQC** regulate in England
- For nuclear medicine, **ARSAC licence** for the practitioner and hospital.
- Employer must have written procedures and staff must follow them *("IRMER procedures*)
- **Referrer** – registered HCP – must be entitled by employer's procedures
- **Practitioner** – registered HCP – "**justifies**" exposure (net benefit) – must be entitled by employer's procedures
- **Operator** – any "**practical aspect**" – must be entitled by employer's procedures
- Training, written protocols, referral criteria, QA of procedures, DRL, dose constraints for C&C, info for expectant mothers, co-operation between employers, clinical audit,

Clinically Significant Accidental or Unintended Exposures

r.8(1) "The employer's procedures must provide that

the referrer, the practitioner, and the individual exposed or their representative (if there is one)

are informed of the occurrence of a clinically significant unintended or accidental exposure

and of the outcome of the analysis of this exposure."

Accidental or Unintended Exposures

r.2

- "**accidental exposure**" means an exposure of an individual in error when no exposure was intended;
- "**unintended exposure**" means any exposure to ionising radiation which is significantly different from the exposure intended for a given purpose.

Clinically Significant Accidental or Unintended Exposures

DHSC Guidance 2024

Clinically significant exposures have been defined by medical professional bodies at the request of the health departments.

RCR/BIR/SCoR/IPEM/PHE 2020, IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine

Clinically significant - either

a) > 1 in 1,000 lifetime radiation-induced cancer risk *(depends on age, sex, and life expectancy but on average 20 mSv)*, or

b) 0.5 Gy to eye, 0.5 Gy to brain, 5 Gy to skin, or 50 mGy to thyroid

c) Psychological harm requiring intervention or treatment

d) Not applicable if potential harm has been justified by practitioner

[redacted]

Accidental or Unintended Exposures
- Radiotherapy -

r.8(2) "The employer's quality assurance programme must, in respect of radiotherapeutic practices, include a study of the risk of accidental or unintended exposures."

CQC wish to know where multiple similar incidents occur to a number of patients

Accidental or Unintended Exposures

r.8(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."

Accidental or Unintended Exposures which need to be reported to CQC

Regulators call these
"SAUE" = Significant Accidental of Unintended Exposure

r.8(4) if

a) exposure "significantly greater", or

b) Radiotherapy exposure "significantly lower"

"than those generally considered proportionate in the circumstances",

Employer must

Accidental or Unintended Exposures which need to be reported to CQC

r.8(4) if

a) exposure "significantly greater", or

b) Radiotherapy exposure "significantly lower"

"than those generally considered proportionate in the circumstances",

Employer must

i. Immediately investigate

ii. Immediately report to CQC (*unless investigation showed false alarm)*

iii. Undertake detailed investigation and assess dose

iv. Provide CQC with report on investigation and actions taken within their time scale

“Significantly Greater”?

- CQC August 2024 guidance https://www.cqc.org.uk/guidance-providers/ionising-radiation/ionising-radiation-medical-exposure-regulations-irmer

Accidental Exposures

e.g.

- Wrong patient referred
- Wrong patient called from waiting room

Notification code	Exposure category	Criteria for notification [a, b]
Accidental exposure		
1 (England only)	All modalities including therapy	3 mSv effective dose or above (adult) 1 mSv effective dose or above (child) [c]
1 (Northern Ireland, Scotland & Wales)	All modalities including therapy	All, regardless of dose

Unintended exposures

Diagnostic and Interventional

- **Unintended exposures**

Code	Exposure category	Criteria for notification
2.1	Intended dose less than 0.3mSv	3mSv or above (adult) 1mSv or above (child)
2.2	Intended dose between 0.3mSv and 2.5mSv	10 or more times than intended
2.3	Intended dose between 2.5mSv and 10mSv	25mSv or above
2.4	Intended dose more than 10mSv	2.5 or more times than intended.
3	Interventional/cardiology	Any unintended exposure resulting in observable tissue reactions, including but not limited to procedural failures or equipment malfunctions.

Unintended exposures

Code	Exposure category	Criteria for notification
5	Foetal All modalities	Where there is an unintended foetal exposure **AND** the resultant foetal dose is **10mGy** or more.
6	Breast feeding infant Nuclear medicine only	Where there has been a failure in procedure **AND** the resultant infant effective dose is 1 mSv or more.

e.g. for in utero exposure, following above 10 mGy

- CT pelvis, or abdo-pelvis, or chest-abdo-pelvis
- Myocardial SPECT rest-exercise protocol
- Whole body PET/CT

For breast feeding, I-131 and I-123 scans

Unintended exposures – Nucl Med

Code	Exposure category	Criteria for notification
7	Incorrect radiopharmaceutical	Any administration of the incorrect radiopharmaceutical to a patient, regardless of dose.
10.1	Selective internal radiation therapy	Delivered activity is outside +/- 20% of the prescribed activity.
10.2	All other nuclear medicine therapies	Delivered activity is outside +/- 10% of the prescribed activity.

Unintended exposures - Radiotherapy

4.1	Radiotherapy planning scans	If a planning scan needs to be repeated twice to obtain an appropriate dataset (3 scans in total, including the intended scan).
4.2a	Radiotherapy treatment verification images	Set-up error leads to 3 or more imaging exposures in a single fraction (including the intended image, 3 images in total). **This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).**
4.2b	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **protocol failure**. **This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).**
4.2c	Radiotherapy treatment verification images	When the number of additional imaging exposures is 50% greater than intended over the course of treatment as a result of **thematic hardware or software failure.** **This applies to all radiotherapy treatment regimes, including radical short course fractionation (defined as 10 fractions or less).**

8.1	Therapy over-exposure	Delivered dose to the planned treatment volume or organs at risk is 1.1 or more times (whole course) or 1.2 or more times (any fraction) the intended dose.
8.2	Therapy under-exposure	Delivered dose to the planned treatment volume is 0.9 or less times the intended dose (whole course). **This excludes where the under-exposure to the target volume is a result of a geographical miss, which is reportable under either 9.1 or 9.2.**

9.1	Total	All total geographical misses, even for a single fraction or significant part thereof.
9.2	Partial	Where the miss exceeds 2.5 times the locally defined error margin AND the guideline dose factors (codes 8.1 and 8.2) for the planning target volume or organs at risk are exceeded. **A surrogate for the locally defined error margin might be a displacement of 2.5 times the local imaging action level for specific anatomical site and treatment intent.**

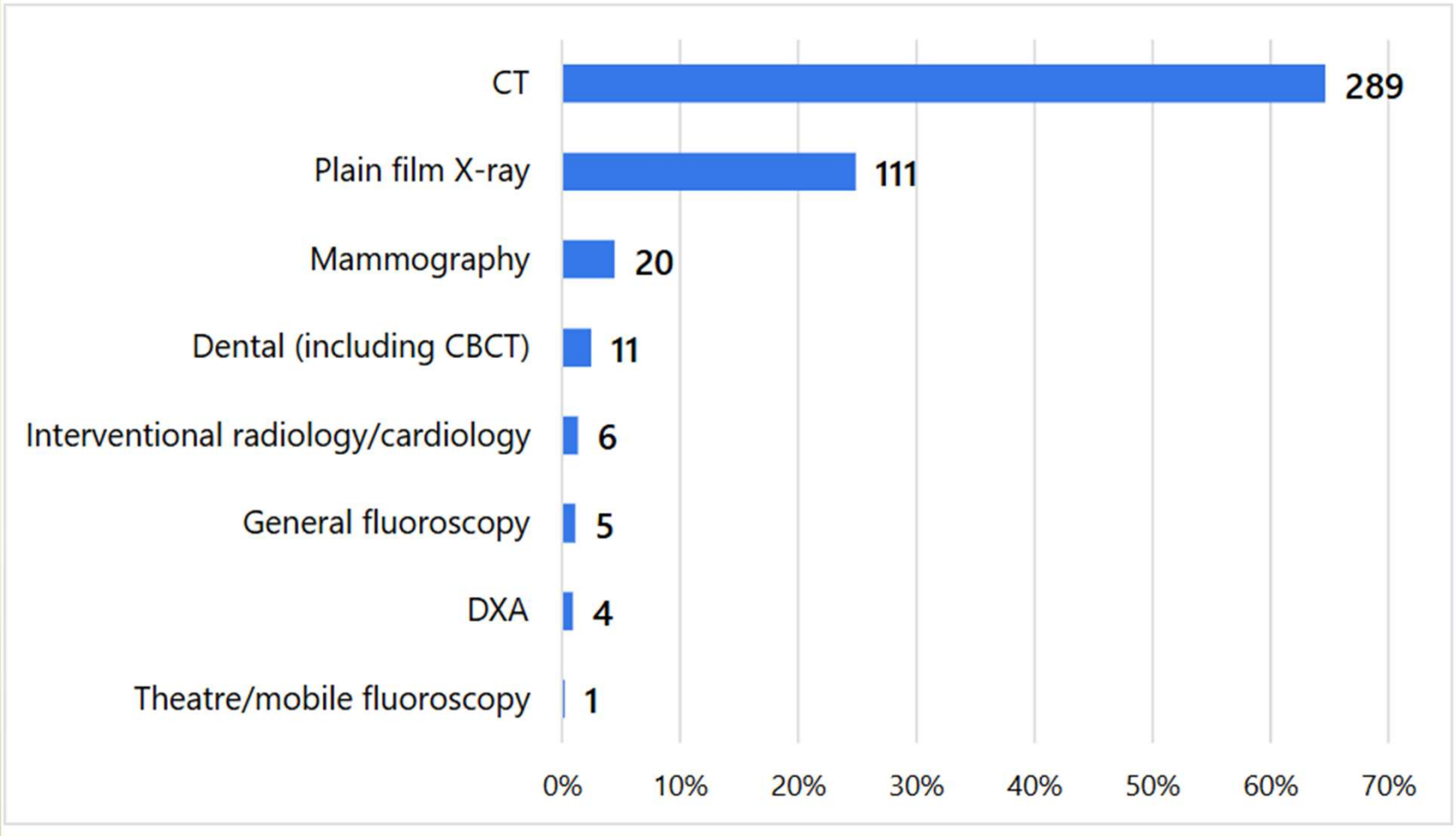
MSAUE
(Multiple SAUE)

- A theme has been identified over a number of incidents.
- A single incident has involved multiple individuals.
- A separate, but similar incident has been identified that affects more than one individual.

CQC 2023/24 IRMER Report

https://www.cqc.org.uk/publications/irmer-annual-report/2023-2024

Figure 2: Notifications from diagnostic imaging received by sub-modality, 1 April 2023 to 31 March 2024



Approximately 1 in every 25,000 exposures

Break

Type	Number	Breakdown
EMPLOYER	**2**	
Employer's responsibility		Equipment not fit for purpose (1) Inadequate training/supervision (1)
REFERRER	**146**	
Incorrect referral		Wrong patient (88) Wrong timing (10) Wrong requested modality (2)
Incorrect information		Failure to cancel (17) Duplicate/no check of previous imaging (14) Inaccurate clinical information (15)
PRACTITIONER	**10**	
Justification		Incorrect justification (8)
Safety checks		Imaging history check failure (1)
Protocol		Illegible/unclear protocol (1)
OPERATOR	**183**	

Type	Number	Breakdown
EMPLOYER	**2**	
REFERRER	**146**	
PRACTITIONER	**10**	
OPERATOR	**183**	
Pre-exposure checks		Wrong patient position/setup/protocol (90) Wrong use of equipment (17)
Patient checks		Patient ID error (27) Failure to check pregnancy/breastfeeding (2)
Clinical history		Failure to check history/details (23)
Post Examination		Failure to upload images (16) Reporting failure (2)
Authorisation		Incorrect authorisation (5)
Pharmaceutical contras		Preparation (1)
EQUIPMENT	**67**	Hardware (40) Equipment related (1) Software (16) IT failure (7) Ancillary failure (3)

Reg 10 Duties of the practitioner, operator and referrer

- **Practitioner**, **Operator** and Referrer must comply with Employer's Procedures
- **Practitioner** is responsible for justification of the medical exposure
- Practical Aspects can be allocated in accordance with Employer's Procedures
- **Operator** is responsible for the Practical Aspects they carry out
- If **Operator** can "Authorise" exposure then they are responsible for that
- The **Referrer** must supply the **Practitioner** with sufficient medical data to enable Practitioner to decide whether net benefit.
- **Practitioner** and **Operator** must cooperate, regarding Practical Aspects, with other specialists and staff involved in an exposure, as appropriate
- *(r.17 **Practitioner** and **Operator** must not carry out any practical aspect unless "adequately trained")* .

Reg 11 Justification of individual exposure

A person must not carry out a medical exposure unless

- For administration of radioactive substances, the installation and practitioner are licensed
- A practitioner has justified the exposure,

Reg 11 Justification of individual exposure

The practitioner must give appropriate weight to

- the specific **objectives** of the exposure and the characteristics of **the individual** involved;
- the total potential diagnostic or therapeutic **benefits**, including the direct health benefits **to the individual** and the benefits **to society**, of the exposure;
- the **individual detriment** that the exposure may cause; and
- the efficacy, benefits and risk of available **alternative techniques** having the same objective but involving no or less exposure to ionising radiation
- For **health screening** recommendations from appropriate medical scientific societies, etc.
- For **carer or comforters**, the **benefit to patient**, benefit **to C&C**, **detriment** to C&C
- For **asymptomatic** individuals for early detection of disease, health screening – any **guidance from medical scientific societies**, etc.
- For **pregnancy** cannot be excluded, the **urgency** of the exposure
- **Data from the referrer** .

Reg 11 Justification of individual exposure

A person must not carry out a medical exposure unless

- For administration of radioactive substances the installation and practitioner are licensed
- A practitioner has justified the exposure
- It has been authorised by the practitioner, or where not practical, by an operator in accordance with guidelines issued by the practitioner
- For research exposures, it has been approved by an Ethics Committee
- For non-medical imaging it complies with employer's procedures for these
- in the case of an individual of childbearing potential, the person has enquired whether that individual is pregnant or breastfeeding, if relevant .

Reg 12 Optimisation

- Apart from radiotherapy, **Practitioner** and **Operator** must keep doses **A**s **L**ow **A**s **R**easonably **P**racticable.
- For radiotherapy, practitioner must ensure individual target volumes are planned and verified and doses to non-target volumes as ALARP
- **Operator** must select equipment to ensure ALARP, with particular regard to
  - QA
  - Patient dose assessment
  - Adherence to DRL established by the employer.

Reg 12 Optimisation

- For research exposures
  - **Volunteers** only
  - Participants **informed** of radiation risks
  - **Dose constraints** where **no direct medical benefit** adhered to
  - **Individual target levels of dose** planned by **Practitioner** where there is **direct medical benefit**

- For carers and comforters, appropriate guidance is established

- For administration of radioactive substances (nuclear medicine & brachytherapy), written instruction and information for the patient/child/appropriate person
  - How to restrict dose to others
  - Risks from ionising radiation

Reg 12 Optimisation

- **Practitioner** and **Operator** must pay **particular attention** to medical exposure of
  - **Children**
  - For **health screening**
  - individual and **unborn child** of potentially pregnant patients, particularly if abdomen or pelvis exposed
  - individual and child if **breastfeeding** where radioactive substances administered

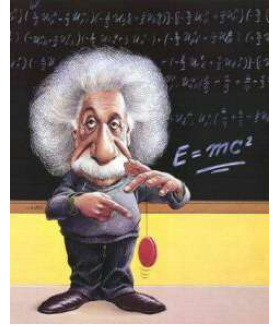
- The employer must take steps to ensure that a **clinical evaluation** of the outcome of each exposure, other than where the person subject to the exposure is a carer or a comforter, is recorded in accordance with the employer's procedures **including, where appropriate, factors relevant to patient dose**.

Reg 13 Estimates of population doses

- The employer must **collect dose estimates** from medical exposures **for radiodiagnostic and interventional procedures**, taking into consideration the distribution by age and gender of the exposed population and, **when** so **requested**, must **provide it to the Secretary of State**

UKHSA have collected this data on a voluntary basis for over 20 years, but will have the right to demand it in future.

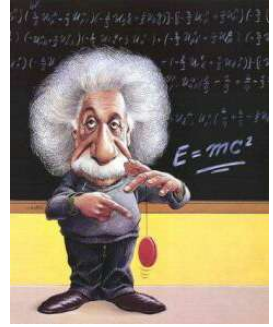
Reg 14 Expert Advice *(MPE)*



r.2 "**medical physics expert**" means an individual or a group of individuals, having the knowledge, training and experience to act or give advice on matters relating to radiation physics applied to exposure, whose competence in this respect is recognised by the Secretary of State;

- A suitable MPE must be appointed and involved in medical exposures and
  - Closely involved in radiotherapy
  - Be involved in nuclear medicine, high dose interventional radiology and high dose CT
  - Involved as appropriate in optimisation for all other radiological practices
  - Give advice on
    - dosimetry and quality assurance matters relating to radiation protection concerning exposures;
    - physical measurements for the evaluation of dose delivered;
    - medical radiological equipment.

Reg 14 Expert Advice *(MPE)*



An MPE must also contribute to

a) **optimisation** of the radiation protection of patients and other individuals subject to exposures, including the application and use of **diagnostic reference levels**;

b) the definition and performance of **quality assurance of the equipment**;

c) **acceptance testing** of equipment;

d) the preparation of **technical specifications** for equipment and installation design;

e) the **surveillance** of the medical radiological installations;

f) the **analysis of events** involving, or potentially involving, accidental or unintended exposures;

g) the **selection of equipment** required to perform radiation protection **measurements;**

h) the **training of practitioners, operators and other staff** in relevant aspects of **radiation protection**;

i) the provision of **advice** to an employer relating **to compliance with these Regulations**;

the medical physics expert is, where appropriate, to **liaise with the RPA and RWA**.

Reg 15 Equipment: general duties of the employer

- **QA programme**, including assessment of patient dose and administered activity
- **Inventory** of
  - equipment and
  - software controls or influences the exposure or directly assists an operator in carrying out a clinical evaluation *(new)*;
- **Test** before first use, regular testing, and after significant maintenance or repair
- Fluoroscopy equipment must have AEC
- At end of exposure, CT and IR equipment must be able to inform operator of relevant parameters for assessing patient dose
- Employer must take steps to improve inadequate or defective equipment, and specify what to do if steps fail

Reg 16 Equipment installed after 6/2/2018

- EBRT > 1 MV must have a device, or other feature, the purpose of which is, to verify key treatment parameters
- IR equipment must display amount of radiation to operator
- Equipment used for planning, guiding and verification purposes, must have a device or other feature capable of informing the practitioner, at the end of an exposure, of relevant parameters for assessing the dose.
- CT and IR equipment must be able to transfer dose data to patient record
- Equipment producing ionising radiation must have device or feature capable of informing practitioner of parameters for assessing dose and where appropriate capable of transferring to patient record

Reg 17 Training

- **Practitioner** and **Operator** must not carry out any practical aspect unless “adequately trained”
- Unless a person is undergoing practical training if this is done under the supervision of a person who is adequately trained
- The employer must have **available for inspection** by CQC up-to-date **record of all relevant training** undertaken by all **Practitioners** and **Operators** engaged by the employer to carry out any exposures or any practical aspect of such exposures **showing the date or dates on which training qualifying as adequate training was completed and the nature of the training**.
- Where the employer (“employer A”) enters into a contract with another employer (“employer B”) to engage a practitioner or operator otherwise employed by that employer B, employer B is responsible for keeping the records and must supply such records to employer A immediately upon request.

Schedules

1. Licensing *(i.e. nuclear medicine & brachytherapy)*
2. **Employer's Procedures**
3. Adequate Training
4. Consequential amendments

Reg 6 Employer's Procedures (a) to (n)

(a)to **identify** correctly the **individual to be exposed** to ionising radiation

(b)to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;



Reg 6 Employer's Procedures

(a)to **identify** correctly the **individual to be exposed** to ionising radiation

(b)to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;

(c)for making enquiries of individuals of childbearing potential to establish whether the individual is or may be **pregnant or breastfeeding;**



Reg 6 Employer's Procedures

(a)to **identify** correctly the **individual to be exposed** to ionising radiation

(b)to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;

(c)for making enquiries of individuals of childbearing potential to establish whether the individual is or may be **pregnant or breastfeeding;**

(d)to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;



Reg 6 Employer's Procedures

(a)to **identify** correctly the **individual to be exposed** to ionising radiation

(b)to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;

(c)for making enquiries of individuals of childbearing potential to establish whether the individual is or may be **pregnant or breastfeeding;**

(d)to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;

(e) for the assessment of patient dose and administered activity

(f) for the use and review of such diagnostic reference levels and dose reference levels as the employer may have established for radiodiagnostic examinations *(except research and carers & comforters) ;*

Reg 6 Employer's Procedures

(a) to **identify** correctly the **individual to be exposed** to ionising radiation

(b) to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;

(c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be **pregnant or breastfeeding;**

(d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;

(e) for the assessment of patient dose and administered activity

(f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations *(except research and carers & comforters) ;*

(g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of **dose constraints** established by the employer **for biomedical and medical research programmes** falling within regulation 3(1)(c) **where no direct medical benefit** for the individual is expected from the exposure;

Reg 6 Employer's Procedures

(a) to **identify** correctly the **individual to be exposed** to ionising radiation

(b) to **identify** individuals entitled to act as **referrer** or **practitioner** or **operator** within a specified **scope of practice**;

(c) for making enquiries of individuals of childbearing potential to establish whether the individual is or may be **pregnant or breastfeeding;**

(d) to ensure that quality assurance programmes in respect of written procedures, written protocols, and equipment are followed;

(e) for the assessment of patient dose and administered activity

(f) for the use and review of such diagnostic reference levels as the employer may have established for radiodiagnostic examinations *(except research and carers & comforters) ;*

(g) for determining whether the practitioner or operator is required to effect one or more of the matters set out in regulation 12(4) including criteria on how to effect those matters and in particular procedures for the use of dose constraints established by the employer for biomedical and medical research programmes falling within regulation 3(c) where no direct medical benefit for the individual is expected from the exposure;

(h) for the giving of information and written instructions *to nuclear medicine patients to protect others*;

Reg 6 Employer's Procedures

(i) providing that wherever practicable, and prior to an exposure taking place, the individual to be exposed or their representative is **provided** with **adequate information** relating to the **benefits and risks** associated with the radiation dose from the exposure;

DHSC Guidance 2018

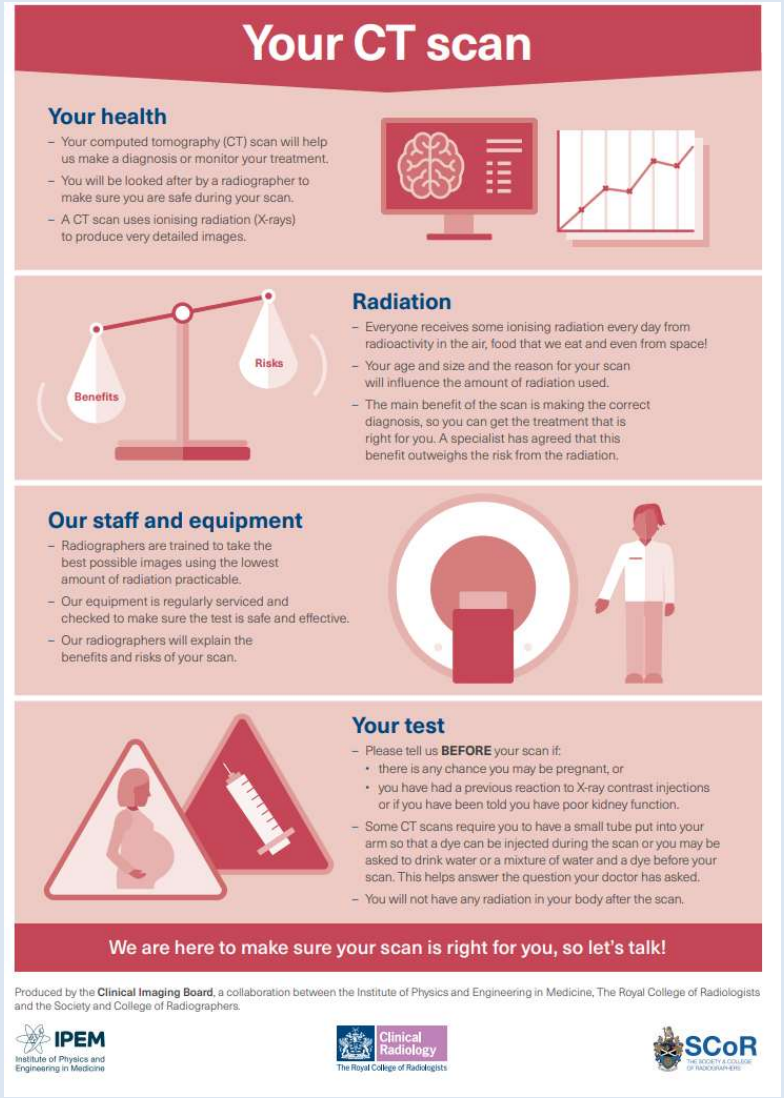
The amount of information and the methods of conveying information should be commensurate with the associated risk. Posters, leaflets and information provided directly by a professional can all be useful in fulfilling this requirement. . . . .

For example, "**we believe the risks of the procedure are small and the procedure will help us to address your suspected clinical condition through diagnosis and treatment, where appropriate**".

Clinical Imaging Board

https://www.rcr.ac.uk/clinical-radiology/service-delivery/clinical-imaging-board/clinical-imaging-board-projects Posters produced so far for

- Nuclear Medicine
- CT
- Dental X-ray
- X-rays
- Fluoroscopy
- Symptomatic mammography



Reg 6 Employer's Procedures

- (j) for the carrying out and recording of a **clinical evaluation for each exposure** including, where appropriate, factors relevant to patient dose;

Reg 6 Employer's Procedures

- (k) to ensure that the probability and magnitude of **accidental or unintended exposure** to individuals from radiological practices are reduced so far as **reasonably practicable**;

Reg 6 Employer's Procedures

- (l) to ensure that the referrer, the practitioner, and the individual exposed or their representative are informed of the occurrence of any relevant **clinically significant accidental or unintended exposure**, and of the outcome of the analysis of this exposure;

Reg 6 Employer's Procedures

- (m) to be observed in the case of **non-medical imaging exposures**;

- (n) to establish appropriate **dose constraints** and guidance for the exposure of **carers and comforters**.

Reg 6 Employer's Procedures

- (o) or the carrying out of **clinical audit**, and for any appropriate action to be taken in accordance with regulation 7 (clinical audit); and
- (p) for making, amending and **cancelling any referrals for exposure**.

IRMER

Ionising Radiation (Medical Exposure) Regulations



First FRCR Examination in Clinical Radiology

Statutory Requirements and Non-Statutory Recommendations

(c) *Other relevant legislation*

Marcus Blunkett
Principal Medical Physicist

Other relevant legislation

Environmental Permitting Regulations 2016

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009.

Only apply to use of radioactive substance (e.g. nuclear medicine)

Environmental Permitting Regulations 2016 “EPR16”

Unless exempt, must have PERMIT to

- keep or use radioactive material
- dispose of radioactive waste
- accumulate radioactive waste

Permits are issued by the Environment Agency.

Source Registration

- Limits activity and number of sources
- Requires
  - supervision
  - labelling
  - security
  - report losses to Police & EA
  - Records .

Waste Authorisation

- Limits activities, disposal routes, accumulation times
- Requires
  - security
  - report losses to Police & EA
  - Records & annual summaries to EA
- Disposal routes may be
  - aqueous to drain
  - incinerate solid
  - transfer solid to others
  - gaseous discharge.

Part Exemptions

- e.g. < 10,000 MBq Tc-99m in human excreta to drains per year
- Approximately equivalent to 166 bone scans a year.



The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

"It does what it says on the packet"

- Controls transport of radioactive materials *(and other dangerous goods)*
  - driver training
  - packaging

Typical packages



FIGURE 6 General-purpose Type B package



FIGURE 3 Type A packaging for a liquid source



FIGURE 1 Excepted package, with no external label

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009

Controls transport of radioactive materials by road

- driver training
- Packaging
- labelling - packages and vehicles



- consignment notes
- QA.


END

Here on 07/09/2025