IRR, IRMER, etc.

What's changed for RT?

John Saunderson

Consultant Physicist /RPA/RWA/MPE

Chair of working party to revise the Medical & Dental Guidance Notes

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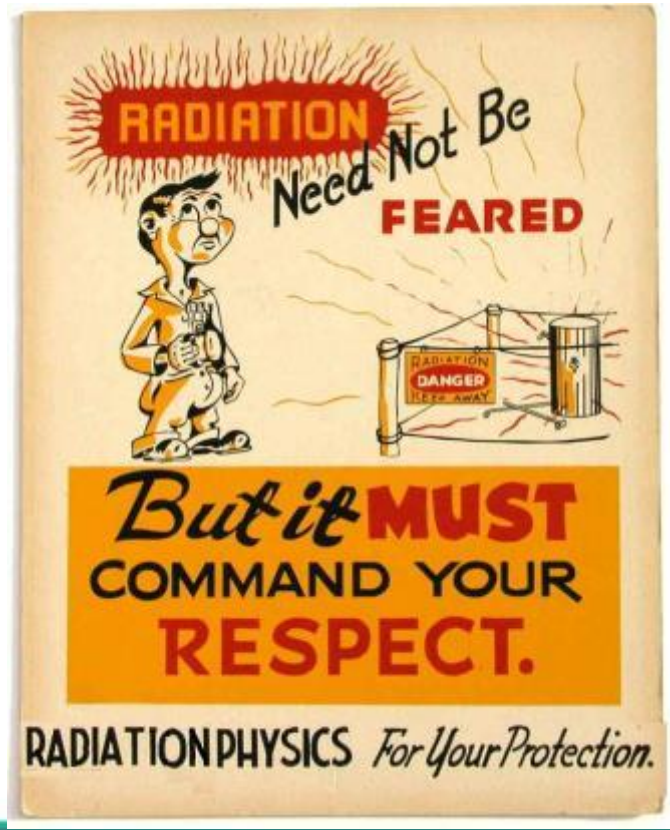


Change in Regulations

1st January 2018

Ionising Radiations Regulations

- ~~IRR99~~
- ~~IRR(NI)2000~~
- ~~etc.~~
- **IRR17**
- **IRR(NI)17**

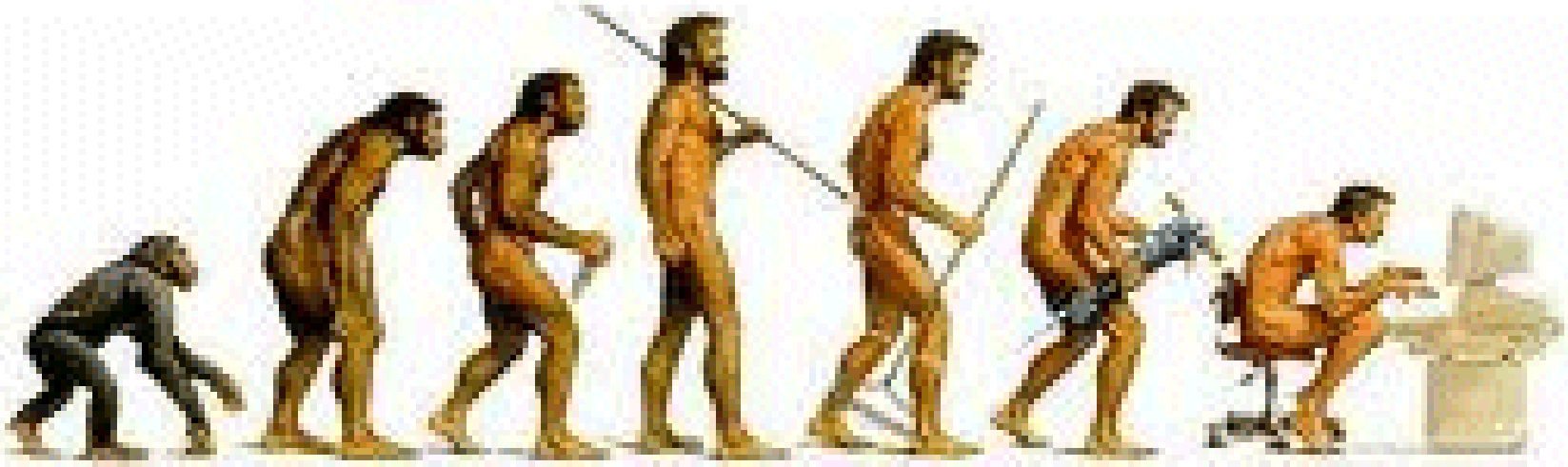
6th February 2018

Ionising Radiation (Medical Exposure) Regulations

- ~~IR(ME)R2000~~
- ~~IR(ME)R(NI)2000~~
- ~~MARS78~~
- ~~*IRR99 (33)*~~
- ~~*IRR(NI)17 (33)*~~
- **IR(ME)R17**
- **IR(ME)R(NI)18**

By end of March 2018 amended EPR & JoPiIR for England.
Work underway for Scotland, Wales and Northern Ireland regulations.

"Evolution not revolution"



Ionising Radiations Regulations 2017 (IRR17)

- Regulations
  - GB http://**www.legislation.gov.uk**/uksi/2017/1075/contents/made
  - NI http://www.legislation.gov.uk/nisr/2017/229/contents/made

- Draft L121 Regs + Approved Code of Practice + HSE guidance
  - http://**www.hse.gov.uk/radiation**/ionising/index.htm
  - *(linked from both HSE and HSENI web sites – 3/1/18 draft)*

- **Regulation 1**
  - Came into force 1st January 2018

So, what's changed?

Regulation 2. Interpretation

- "**OUTSIDE WORKER**" now includes both classified and non-classified workers of another employee working in your Controlled Area
- New definitions for
  - "**CLASSIFIED OUTSIDE WORKER**"
  - "**NON-CLASSIFIED OUTSIDE WORKER**"

Your must ensure outside workers receive training, information, PPE, etc. before entering your Controlled Area.

Outside workers must act responsibly, report PPE defects , etc.

Regulation 2. Interpretation

"**MEDICAL EXPOSURE**"- clearer definition

a) **patients and asymptomatic individuals as part of their own medical diagnosis or treatment;**

b) individuals as part of health screening programmes;

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

d) individuals undergoing non-medical imaging using medical radiological equipment;

6/2/2017 IR(ME)R17 will add

e) Carers and comforters

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medical radiological equipme

6/2/2017 IR(ME)R17 will add

e) Carers and comforters

IRR and IR(ME)R will have *(virtually)* the same definition.

C&C become medical exposures.

Regulation 3. Application *(continued)*

- Apply to any "**PRACTICE**", but excluding to person undergoing **MEDICAL EXPOSURES** for the following
  - 8.Radiation risk assessments;
  - 9.Restriction of exposure;
  - 12. Dose limitation
  - 17-18.Controlled areas;
  - 24.Dosimetry for accidents etc;
  - 26.Investigation & notification of overexposures;
  - 2(1) Duties of manufacturers to restrict exposure;
  - 35(1)Employees duty not to expose anyone

Changes to IRR

IRR99

- **Reg 5 Authorisation of specific practices**
  - HSE issued generic authorisations; e.g. one for "X-rays" and one "accelerators
- **Reg 6 Notification of specific work**
  - Employer notified HSE 28 days before first using radiation, and before any material change

IRR17

- **Reg 5 Notification of certain work**
- **Reg 6 Registration of specific practices**
- **Reg 7 Consent to carry out specific practices**
- *The "graded approach"*

- No longer needed 28 days in advance of first work.
- Apply to an employer for all sites.
- HSE guidance at https://webcommunities.hse.gov.uk/connect.ti/radiationcom

Reg 5 Notification of certain work

Covers

a) Work with ionising radiation which is
   i. Not exempt (*below schedule 1 limits, e.g. very small amounts of radioactive material*)
   ii. Not registerable
   iii. Not requiring consent

b) i.e. work with under 1,000kg of artificial or naturally occurring radionuclides that is:
   a) between the low and medium end of specific concentration levels
   b) above specific quantity levels

c) And work in a radon atmosphere above an annual average of 300Bq.m^{-3}

d) Free.

Only applies to piffling amounts of radioactive materials

Reg 7 Consent to carry out specific practices

Covers nine types of practice

a) Administration of radioactive substances to persons or animals for diagnosis, treatment or research
   - *e.g. brachytherapy, unsealed source therapy*

b) Uranium mines

c) Deliberately adding radioactive substances to products
   - *e.g. radiopharmacy (?LDR brachy moulds, etc.?)*

d) Operation of an accelerator > 1MeV
   - *e.g. linacs, cyclotron for positron therapy*

e) Industrial radiography

f) Industrial irradiation
   - *e.g. cyclotron for PET tracer production (?)*

g) Use of high-activity sealed source (HASS)
   - *e.g. Gamma Knife, HDR brachytherapy*

h) Long-term storage or disposal of radioactive waste

i) Discharging significant amounts of radioactive effluent
   - *e.g., from HSE guidance > 10 GBq I-131 in a single discharge.*

Consent Yes/No Question

- Appropriate programme of **monitoring of arrangements**
- **Person(s) of appropriate authority** identified as responsible for radiological protection for this practice
- **Risk assessment** including foreseeable accidents, engineering controls, planned systems of work, estimated radiation dose rates and the action to keep doses as low as reasonably practicable.
- Management will ensure exposures **ALARP** for any **radiation source no longer used** and **radioactive waste**
- **Engineering controls**, etc. will restrict exposure to ALARP, be properly **maintained** and, where appropriate, thorough **tested** at suitable intervals
- **Contingency plans** for all reasonably foreseeable radiation
- Suitable **RPA** appointed and consulted
- Employees engaged in this practice **training, informed, instructed** in radiation safety and precautions necessary and will receive **updates/refresher training in radiological protection at appropriate intervals**.
- **Other employees** likely to be affected suitably trained/informed/instructed and this repeated at appropriate intervals

Reg 7 Consent to carry out specific practices

- Consent for one of the nine practices covers all such practices by that employer at all sites
- GB - Online service (https://services.hse.gov.uk/bssd/) - *£25 per practice*
- NI - downloadable form (https://www.hseni.gov.uk/articles/ionising-radiation) – *no fee*

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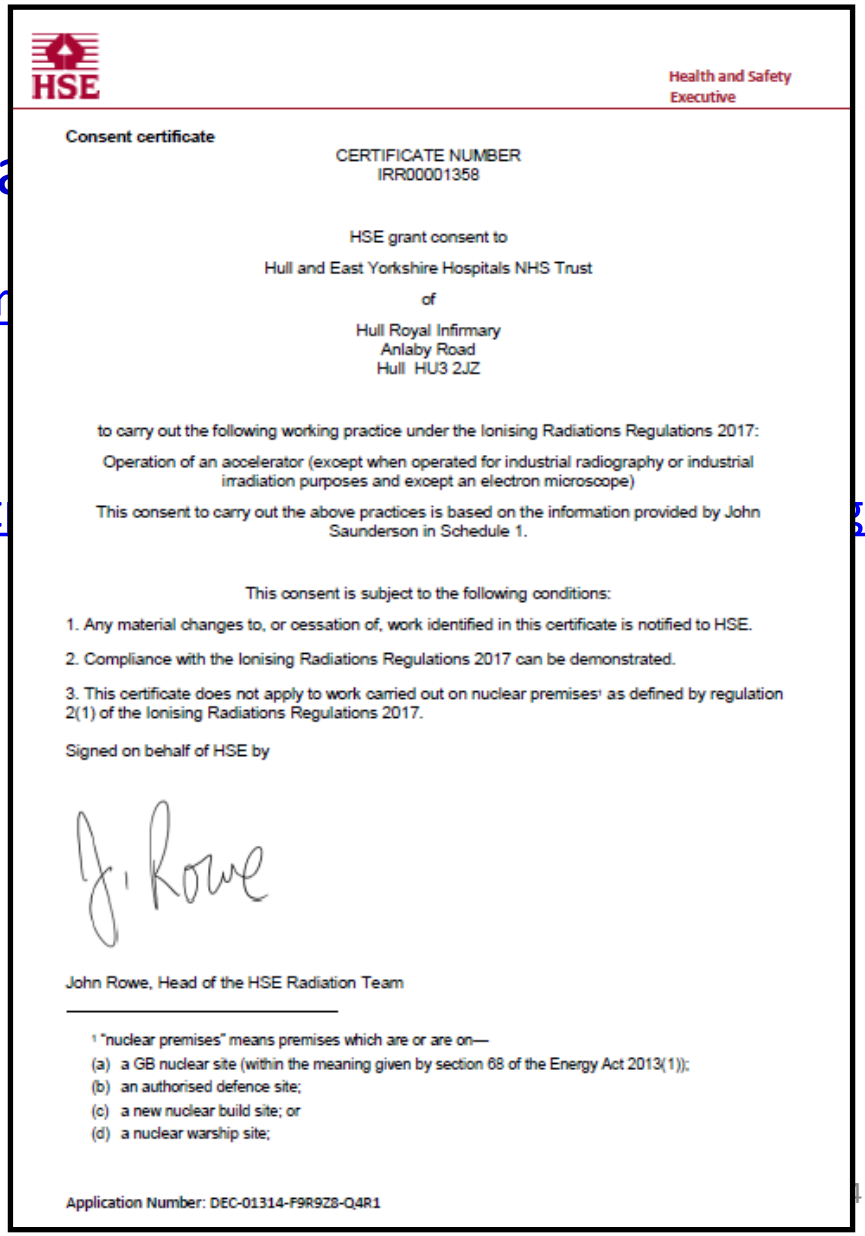


HSE

Health and Safety Executive

Consent certificate

CERTIFICATE NUMBER
IRR00001358

HSE grant consent to

Hull and East Yorkshire Hospitals NHS Trust

of

Hull Royal Infirmary
Anlaby Road
Hull HU3 2JZ

to carry out the following working practice under the Ionising Radiations Regulations 2017:

Operation of an accelerator (except when operated for industrial radiography or industrial irradiation purposes and except an electron microscope)

This consent to carry out the above practices is based on the information provided by John Saunderson in Schedule 1.

This consent is subject to the following conditions:

1. Any material changes to, or cessation of, work identified in this certificate is notified to HSE.

2. Compliance with the Ionising Radiations Regulations 2017 can be demonstrated.

3. This certificate does not apply to work carried out on nuclear premises[1] as defined by regulation 2(1) of the Ionising Radiations Regulations 2017.

Signed on behalf of HSE by

J. Rowe

John Rowe, Head of the HSE Radiation Team

[1] "nuclear premises" means premises which are or are on—
(a) a GB nuclear site (within the meaning given by section 68 of the Energy Act 2013(1));
(b) an authorised defence site;
(c) a new nuclear build site; or
(d) a nuclear warship site;

Application Number: DEC-01314-F9R9Z8-Q4R1

Reg 6 Registration of specific practices

Covers all PRACTICES that don't fit into other categories

a) radiation generators, such as X-ray devices, that are not a specific practice requiring consent, e.g.
   i. *diagnostic X-ray,*
   ii. *superficial X-ray therapy,*
   iii. *CT scanners*

b) ≥ 1 tonne radionuclides that are above the low end of specific concentration levels

c) < 1 tonne of radionuclides that are above the medium end of specific concentration levels, e.g.
   i. *Sr-90 consistency check source > 1 MBq*
   ii. *for I-125 >1 kBq/g or >1 MBq.*

Reg 6 Registration of specific practices

- A single registration from an employer covers all their registrable practices at all their sites
- GB - Online service (https://services.hse.gov.uk/bssd/) - £25 per employer
- NI - downloadable form (https://www.hseni.gov.uk/articles/ionising-radiation) – no fee
- Must notify immediately HSE/HSENI if employer ceases to carry out the practice or material change
- HSE anticipate around 28,000 employers registering.

Must REGISTER all PRACTICES *(unless consent applies)*

PRACTICES means work involving

(a) the production, processing, handling, disposal, use, storage, holding or transport of **radioactive substances**; or

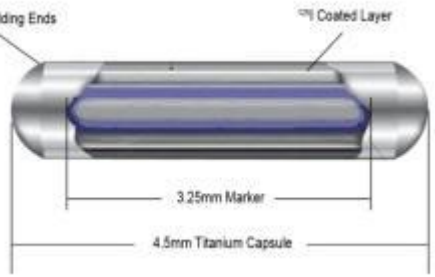
(b) the operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5kV, ***(e.g. x-ray tubes, linacs, etc.)***

which can increase the exposure of individuals to ionising radiation;

e.g. CT scanning, orthovoltage or superficial X-ray therapy, etc.

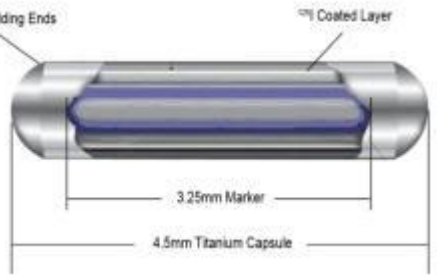
"RADIOACTIVE SUBSTANCE" means any substance which contains one or more radionuclides whose activity cannot be disregarded for the purposes of radiation protection

The following may be "PRACTICES" which may need to REGISTER if *"activity cannot be disregarded for the purposes of radiation protection"*



- I-125 prostate seed patients (< 1MBq)
  - Hospital undertaking prostate surgery (e.g. TURPs), where not part of a Trust which has registered as working with radioactive substances
  - Mortuary - post mortem involving prostate
  - Crematorium
  - Transport of retrieved prostate
- I-131 patient returning to nursing home
- Ra-223 patient undergoing hip surgery

The following may be "PRACTICES" which may need to REGISTER if *"activity cannot be disregarded for the purposes of radiation protection"*



- I-125 prostate seed patients (< 1MBq)
  - Hospital undertaking prostate surgery (e.g. TURPs), where not part of a Trust which has registered as working with radioactive

Reg 37 Defence from contravention

If an employer did not know that they needed to register it is a defence to notify immediately they discover that they do *(unless it's a radiation generator)*.

Registration Yes/No Question

You must be able to confirm, on behalf of the employer, the following:

- A **risk assessment** has been completed including foreseeable accidents
- **Estimates of employees' exposure** and appropriate action taken
- **Actions** to keep exposure as low as reasonably practicable
- **Contingency pla**ns
- **RPA** has been appointed and consulted
- Appropriate **training, information and instruction** is provided
- *Where required* ***controlled and/or supervised areas***
- *Where required* ***local rules, radiation protection supervisor***

Material Changes - Registration

- Change of employers address
- Number of
  - classified radiation employees (0)(1-5)(6-10)(11-25)(26+)
  - Fixed sites (1)(2-5)(6-10)(11-25)(26+)
- Starting or ceasing to
  - Undertake use of radiation generators or use radioactive sources (*not previously registered)*
  - transport radioactive substances
  - Use portable radiation sources *(e.g. mammo vans)*
- Cessation of radiation work

Material Changes - Consent

- As for registration, plus
  - Maximum effective doses in mSv to radiation worker
    - *(0-1) (1.1-5.9) (6-9.9) (10-14.9) (15-20) mSv*
  - Max radiation worker eye dose
  - Max radiation worker skin dose
  - Ditto for other employees
  - Ditto for public
  - Change in whether REPPIR applies

Number shuffle

Regulation	IRR 1999	IRR 2017
5	~~Authorisation of practices~~	Notification of certain work
6	Notification of specific work	**Registration of certain practices**
7	Prior risk assessments	**Consent to carry out specified practices**
8	Restriction of exposure	Risk assessments
9	*Personal protective equipment*	Restriction of exposure
	etc. up to reg 38	
		etc. up to reg 39

Reg 9. Restriction of exposure

NEW

- Dose constraints must be in terms of individual effective or equivalent dose
- **Dose to foetus** of pregnant worker must be
  - < 1 mSv during declared term, **and**

–A.L.A.R.P.

Reg 12 Dose limitation

Change

- Lens of **eye** dose limit for employees reduced from 150 mSv to **20 mSv a year**

- Removal of 13 mSv in 3 months to abdomen of woman of reproductive capacity limit

- All other dose limits the same

Reg 12 Dose limitation

Change

- Lens of eye dose limit for employees reduced from 150 mSv to 20 mSv a year
- Removal of 13 mSv in 3 months to abdomen of woman of reproductive capacity limit
- Employers (with registration or consent) must **estimate doses to members of the public** from the relevant practice. Guidance says
  - Identify highest dose and dose rate groups
  - Estimate highest annual effective dose

Reg 13 Contingency plans

Same

Any reasonably foreseeable radiation accident needs a contingency plan.

Train staff. Rehearse at suitable intervals.

Does apply to medical exposures.

NEW

(2)(d) if contingency plans triggered then:

(i) Analyse what happened and determine reasonable measures to prevent it happening again;

(ii) Record the analysis and kept for at least 2 years, and,

(iii) Note on dose record of affected persons if they received extra dose.

e.g. from CHH linac Local Rules

CONTINGENCY PLANS & ACCIDENTAL OVEREXPOSURE

1) **If the beam fails to terminate** after the treatment time is completed, the red emergency stop button should be pressed. All incidents should be reported through the standard incident reporting process. It must not be used again until an investigation has resulted in a satisfactory explanation, and remedial work has been carried out.

2) **If the area of patient being treated/exposed is disturbed (e.g. patient moves, treatment head moves) the treatment should be stopped.**

3) **When the beam interlock button in the room is pressed** a warning sound is activated which stops shortly after the second button is pressed. If unknown to the person activating the interlock**, another person is still in the room** then the person still in the room should press an emergency stop button immediately to prevent beam on.

4) **If** as a result of malfunction or defect, a **patient undergoing a medical exposure** may have been exposed to ionising radiation to an extent **much greater than intended**, the incident must be investigated immediately. Unless this demonstrates beyond reasonable doubt that no such incident occurred, it must be notified to your Radiation Protection Supervisor in the first instance, and then the Radiation Protection Adviser.

e.g. from CHH linac Local Rules

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3) If as a result of malfunction or defect, a patient undergoing a medical exposure may have been exposed to ionising radiation to an extent very much greater than intended, the incident must be investigated immediately. Unless this demonstrates beyond reasonable doubt that no such incident occurred, it must be notified to your Radiation Protection Supervisor in the first instance, and then the Radiation Protection Adviser.

Reg 15 Education, training and provision of information

NEW

- 1(d) training specific to the controlled area they work in

- 1(e) **repeated training at suitable intervals and document**

- (2) If **HASS** used training in **specific requirement**

Reg 15 & HASS training

15(2) In addition to the requirements in paragraph (1), every employer who is engaged in work with ionising radiation involving a **high-activity sealed source** must ensure that the **information and training** given to employees involved in such work **includes**—

(a) specific requirements for **the safe management and control** of high-activity sealed sources for the purpose of preparing such employees for any events which may affect their radiation protection;

(b) particular emphasis on the necessary **safety requirements** in connection with high-activity sealed sources; and

(c) specific information on the possible **consequences of the loss of adequate control** of high-activity sealed sources.

Controlled Areas

IRR99 Reg 16 Designation of controlled or supervised areas

CONTROLLED AREAS

(a) … necessary … to follow special procedures … ; or

(b) … likely to receive

- *> 6 mSv a year effective dose, or*
- *> 3/10th other dose limit*

SUPERVISED AREAS

(a) … necessary … to keep … under review … ; or

(b) … likely to receive

- *> 1 mSv a year effective dose, or*
- *> 1/10th other dose limit*

IRR17 Reg 17 Designation of controlled or supervised areas

CONTROLLED AREAS

a) … necessary … to follow special procedures … ; or

b) … likely to receive

- *> 6 mSv a year effective dose,*
- ***> 15 mSv a year lens of eye**, or*
- *> 150 mSv a year skin or extremity*

SUPERVISED AREAS

(a) … necessary … to keep … under review … ; or

(b) … likely to receive

- > 1 mSv a year effective dose, or
- **> 5 mSv lens of eye**
- > 50 mSv skin or extremity

Change to ACOP re. Controlled Areas

L121 2000 - ACOP

248) …Employers must designate controlled areas, in cases where:

a) external dose rate > 7.5 µSv/h averaged over working day;

b) Hand dose rate > 75 µSv/h averaged over working day;

c) Contamination risk

d) Need to restrict access by non-radiation employees

e) > 6 mSv/year liable

249) In addition if **> 7.5 µSv/h averaged over a minute**, and either

a) Site radiography

b) Untrained employees may enter and none of the above apply

L121 3/1/2018 draft - ACOP

307) …Employers must designate controlled areas, in cases where:

a) external dose rate > 7.5 µSv/h averaged over working day or instantaneous > 100µSv/h;

b) Hand dose rate > 75 µSv/h averaged over working day;

c) Contamination risk

d) Need to restrict access by non-radiation employees

e) > 6 mSv/year liable

f) Untrained employees may enter, unless only radioactive patient and (a)-(e) don't apply

- HSE Guidance

- Also likely if > 100 µSv/h instantaneous
- Also if > 7.5 µSv/h averaged over a minute and site radiography

Reg 19 Additional requirements for designated areas

NEW

- Requirements for PPE, restrictions on eating, etc. apply to outside workers as well as employees.
- Where risk of spread of contamination, must be able to monitor where appropriate in adjacent areas as well as controlled area.

Designation of classified persons

IRR99

Reg 20 Designation of classified persons

If likely to receive

> 6 mSv effective dose

> $^{3}/_{10}^{th}$ other dose limit

IRR17

Reg 21 Designation of classified persons

If likely to receive

> 6 mSv effective dose

> 15 mSv lens of eye dose limit

> 150 mSv extremity or skin limit

SAME

- > 18 years
- Signed as fit by relevant doctor

Keeping of certain records

IRR99	IRR17
Reg 21 Dose assessment & recording *(classified person)*	Reg 22 Dose assessment & recording (classified person)
Reg 23 Dosimetry for accidents etc	Reg 24 Dosimetry for accidents etc
Reg 24 Medical surveillance	Reg 25 Medical surveillance
Reg 25 Investigation and notification of overexposure	Reg 26 Investigation and notification of overexposure
Keep **records** until person would have been 75 years old, and at least **50 years**	Keep records until person would have been 75 years old, and at least **30 years**

Manufacturers' duties

IRR99

Reg 31 Duties of manufacturers etc of articles for use in work with ionising radiation

"… where appropriate, undertake a critical examination …"

IRR17

Reg 32 Duties of manufacturers etc of articles for use in work with ionising radiation

"… undertake a critical examination …"

SAME

- articles must be designed to keep doses ALARP
- Installer must provide adequate info to user

Imminent Changes to IRR

IRR99

Reg 32 Equipment used for medical exposure

IRR17

Reg 33 Equipment used for medical exposure

Same, but only applies until midnight tonight!

This will be revoked by IR(ME)R17 and new requirements included in IR(ME)R17 from 6th February 2018

IRMER

Ionising Radiation (Medical Exposure) Regulations

Change in Regulations

- 6th February 2018
  - IR(ME)R2000, IR(ME)R(NI)2000, MARS78 *& IRR17(33) will be repealed*
  - Replaced by **IR(ME)R17** & **IR(ME)R(NE)18**[a]

Not yet published as of 31/1/2018, but referred to in new ARSAC guidance notes

New IR(ME)R

- Regulations
  - GB - IR(ME)R17 http://www.legislation.gov.uk/uksi/2017/1322/contents/made
  - IR(ME)(Amendment) Regulations 2018 - http://www.legislation.gov.uk/uksi/2018/121/contents/made
  - *NI - IR(ME)R(NI)18 – SR 2018 No. 17*
- Guidance
  - ARSAC 30/1/2018 – UK wide - https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee
  - *DH, CQC, etc. plan guidance out on 6th February (?)*

- **Regulation 1**
  - Comes into force 6th February 2018

Reg 3 Application

i.e. what is a "medical exposure"

2000

(a)the exposure of patients as part of their own medical diagnosis or treatment including any exposure of an asymptomatic individual;

(b) the exposure of individuals as part of occupational health surveillance;

(c) the exposure of individuals as part of health screening programmes;

(d) the exposure of patients or other persons voluntarily participating in medical or biomedical, diagnostic or therapeutic, research programmes;

(e) the exposure of individuals as part of medico-legal procedures

2018

(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 non-medical imaging using medical radiological equipment.

IR(ME)R 2018
Reg 4 Licensing / Reg 5 Requirement to hold a licence

For the administration of radioactive substances *(i.e. nuclear medicine and brachytherapy)*

- Replaces MARS78 regulations
- Reg 4 – *NEW* ARSAC can now charge a fee
- Reg 5 – *NEW* Employers must be license for each installation where radioactive substances are administered
  - 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
  - *Fees apply, e.g. £250 for new license payable to the Secretary of State*

- Reg 5 – Practitioners must have license, but *NEW* will no longer specify site *(fee £0)*
  - In GB from Secretary of State for Health and Social Care
  - In NI from the Department of Health
- But ARSAC /PHE advise all Licensing Authorities and process applications

Employer licenses; when do we need to apply?

(3) Any certificate issued to a person under the MARS which is valid on 6th Feb 2018 is deemed—

(a) to be a licence issued under these Regulations for as long as that certificate remains valid; and

(b) to license the employer responsible for the medical radiological installation for the matters specified in that certificate.

(4) Nothing in paragraph (3) prevents a person from applying for a licence under these Regulations on or after the date that they come into force.

Application

- Download from https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee
- Fill in and email to ARSAC

Application

- Name and details of
  - installation, employer, chief executive, medical director, lead MPE,
  - all the licensed practitioners, radiopharmaceutical service provider
- Codes for all diagnostic procedures on that site
- For sealed and unsealed source therapy
  - Procedure codes
  - Number performed in last 12 months (if applicable)
  - Predicted number on next 12 months
- For sealed source therapy
  - Radionuclides (sealed only)
  - Appliance/Device (sealed only)
  - Indication (sealed only)
- Research exposures? Paediatrics?
- Summary of IR(ME)R procedures, details of local and national audit
- Number of MPEs
- etc, etc.

- **ARSAC must be notified if any changes to the above .**

Reg 6 Duties of Employers (2017 Employer's duties: establishment of general procedures, protocols and quality assurance programmes)

- IRMER Procedures – new ones in Schedule 2
  - (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;

IPEM news December 2017

“Explaining radiation risk to patients

… the Clinical Imaging Board … are working on a project to produce leaflets for patients about the balance of risks and benefits involved in modern imaging techniques.

Members Jim Thurston and Mark McDade, and Public Engagement Panel members Helen King and Howard Widdall, will be contributing for IPEM”

Reg 6 Duties of Employers (2017 Employer's duties: establishment of general procedures, protocols and quality assurance programmes)

- IRMER Procedures – new ones in Schedule 2
  - (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;
  - (l) to ensure that the **referrer, the practitioner, and the individual exposed** or their representative are i**nformed of** the occurrence of any relevant **clinically significant unintended or accidental exposure**, and of the **outcome** of the analysis of this exposure.
  - (n) to establish appropriate **dose constraints** and guidance for the exposure of **carers and comforters**.
  - (m) to be observed in the case of **non-medical imaging exposures** (*replaces procedures to be observed in the case of medico-legal exposures)*

Reg 6 Duties of Employers - note

- Schedule 2(b) "*to identify individuals entitled to act as referrer or practitioner or operator* ***within a specified scope of practice***;"
- Need to take steps to ensure **referrer** complies as well as practitioner and operator
- dose constraints must be in E or H_{tissue}
- (8) The employer must take measures to raise awareness of the effects of ionising radiation amongst individuals capable of childbearing or breastfeeding.

2018 Regulation 8: Employer's duties: **accidental or unintended exposure**

- Replaces "*much greater than intended*" provisions in both IRR99 and IRMER 2000
- QA programme for radiotherapeutic exposures must include study of the risk of accidental or unintended exposures
- Must have system of recording and analysis of incidents proportional to risk .
- "clinically significant" and "significant" events

2018 Regulation 8: Employer's duties: accidental or untended exposure

- "**clinically significant**" unintended or accidental exposure
  - Inform referrer, practitioner, and individual exposed of occurrence and outcome of analysis
  - *DH will work with professional bodies on what is "clinically significant"*

- "**significantly greater**" unintended or accidental exposure, or <u>for radiotherapy "**significantly lower**"</u>
  - Replaces "*much greater than intended*"
  - CQC to be tasked with defining "significant event"
  - Investigate immediately, and if real report immediately to CQC
  - Detailed investigation – report to CQC results and actions

Reg 14 Expert Advice

Change from 2000 Reg 9 for Medical Physics Experts

- Employer must ensure suitable MPE **appointed** and involved
- Must meet criteria of competence set by DH
  - Closely involved in every radiotherapy practice
  - Involved in nuclear medicine and **interventional radiology** and **high dose CT** *(?CT sim, 4DCT?)*
  - Involved as appropriate for others
- MPE give advice on dosimetry, QA, measurements of dose, medical radiological equipment
- MPE must contribute to *(PTO)*

Reg 14(3) Medical Physics Experts

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 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 2 Interpretation

- "**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

2017 Reg 15 Equipment: general duties of the employer

Reg 15 & 16 take over IRR99(32) / IRR17(33)

- **QA programme**, including assessment of patient dose and administered activity (*IRR99)*
- **Inventory** of equipment (*IRMER 2000)*
- **Test** before first use, regular testing, and after significant maintenance or repair (*IRR99)*
- Fluoroscopy equipment must have AEC (*IRMER 2000)*
- At end of exposure, CT and IR equipment must be able to inform practitioner 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

Links (2/2/18)

- IRR17, IRR(NI)17, IR(ME)R17, IR(ME)(A)R18
  - www.legislation.gov.uk
- Ionising Radiations Regulations 2017 - Guidance for Notifications, Registrations and Consents
  - https://webcommunities.hse.gov.uk/connect.ti/radiationcom
- Work with ionising radiation: Approved Code of Practice and guidance (d*raft 3/1/2018)*
  - http://www.hse.gov.uk/pubns/books/l121.htm
- ARSAC guidance and forms
  - https://www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee