The Radiation Protection Slot

BSS, IRR17, IDR, ETC.

John Saunderson

Consultant Physicist /RPA/RWA/MPE

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

01482 461329

john.saunderson@hey.nhs.uk

Head of Radiotherapy Physics Departments meeting

Sheffield, 19/5/2017

(This PPT at www.hullrad.org.uk/share)

Changes to regs

- 2013/59/EURATOM - Basic Safety Standards for protection against the dangers arising from exposure to ionising radiation
- Must be UK law by 6th February 2018 (even though UK is leaving Euratom)
- IRR/HSE, IRMER/DH, EPR/EA, CDG/ONR, etc.
- HSE required by Government to minimise changes (but . . .)

Ionising Radiations Regulations 2017

- Consultation on regs and ACOP closed 2nd April 2017 (http://consultations.hse.gov.uk/consult.ti/cd282/consultationHome)
- Same structure with as little changed as possible *(mostly)*
- The following were proposed by the consultation document

HSE

Health and Safety Executive

Consultation on the implementation of Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation – Occupational health and safety

This consultative document is issued by the Health and Safety Executive in compliance with its duty to consult under sections 16 and 50 of the Health and Safety at Work etc Act 1974.

Comments should be sent to:

The Radiation Policy Team,
Health and Safety Executive,
2.1 Redgrave Court,
Merton Rd,
Bootle,
Merseyside,
L20 7HS

Email: basdconsultation@hse.gov.uk

To reach there no later than 2nd April 2017

The Executive tries to make its consultation procedure as thorough and open as possible. Responses to this consultation document will be lodged in the Health and Safety Executive's Knowledge Centre after the close of the consultation period where they can be inspected by members of the public.

Information provided in response to this consultation, including personal information, may be subject to publication or disclosure in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004 (EIR)). Statutory Codes of Practice under the FOIA and EIR also deal with confidentiality obligations, among other things.

If you would like us to treat any of the information you provide, including personal information, as confidential, please explain your reasons for this in your response. If we receive a request under FOIA or EIR for the information you have provided, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will be disregarded for these purposes. Requests for confidentiality should be made explicit within the body of the response.

HSE will process all personal data in accordance with the DPA. This means that personal data will not normally be disclosed to third parties and any such disclosures will only be made in accordance with the Act.

CD282
Consultative Document

1

Proposals:

- Most regulations to apply from 1/1/2018
  - Makes more sense for new annual dose limit to the lens of the eye
- Move “medical exposures” bits to IRMER/DH, i.e.
  - Comforters and carers
  - Reg 32 Equipment used for medical exposure
    - Restriction of exposure to patients
    - Exposures much greater than intended due to equipment
    - QA programme, etc.
    - *Note, testing of safety features for staff and public still in with HSE IRR*

Number shuffle

Regulation	IRR 1999	Draft IRR 2017
5	~~Authorisation of practices~~	Notification of specific work
6	Notification of specific work	**Registration of specific practices**
7	Prior risk assessments	**Licensing of specific practices**
8	Restriction of exposure	Prior risk assessments
9	etc. up to reg 31	Restriction of exposure
		etc. up to reg 32

The “graded approach”

Notification, Registration, Licensing

A. Exempt

B. Notification

   i. Notify HSE before 6th Feb 2018 *(even if registerable or licensable practice)*

   ii. Probably online from October, and free

C. Registration

   i. Complete registration process before 6th Feb 2018

   ii. Probably online from October, and small fee

D. Licensing

   i. Complete online application, small fee

   ii. Receive license from HSE before 6th Feb 2018.

"Practice"

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 radiation from a radiation source;

Licensable Practice (Reg 7)

- Administration of radioactive substance for medical or veterinary exposures
  - e.g. nuclear medicine, brachytherapy
- Manufacturing products with added radioactive substances
  - e.g. radiopharmacy
- Use of High Activity Sealed Source (HASS)
  - e.g. HDR brachytherapy, Gammaknife, MRIdian
- Operation of an accelerators (> 1 MeV)
  - e.g. linacs, cyclotrons (PET isotopes, protons therapy)
  - *(Not in BSS, but HSE say as dangerous as HASS so propose licensing)*
- Industrial radiography, industrial irradiation, long-term storage & disposal of radioactive substances, discharging significant amounts of gaseous or liquid radioactive waste to the environment

(Note, examples are John's interpretation)

Probable **Licensing Process**

- Online system *(so you need to decide who for you Trust fills this in)*
- 1st Jan or 6th Feb deadline?
- Available from late 2017
- License each "practice" not each source
  - e.g. license linacs for radiotherapy once, not every individual linac separately
  - May even be one license for "Operation of an accelerators" to cover RT linacs, RT cyclotrons and PET cyclotrons, etc.
- There will be a list of online questions

Licensing - Indicative online questions (from James Taylor, HSE, Nov 2016)

(Some of these required by Schedule 2 of draft regulations)

GENERAL	
Has the overall management, planning, organising, controlling and reviewing of this radiation risk been considered?	Yes / No
Has RPA been appointed and consulted?	Yes / No
Are the design features; engineering controls; and safety features of the facility and the radiation sources such that exposures to radiation will be as low as reasonably practicable (ALARP)?	Yes / No

Licensing - Indicative online questions

TRAINING	
Have staff working with radiation received appropriate radiation protection training?	Yes / No
Have those staff been informed of the radiological risks and the precautions that should be taken?	Yes / No
Will those staff receive regular updates/refresher training in radiological protection?	Yes / No
Have staff not engaged in work with ionising radiation but who are likely to be affected by it received appropriate training in radiological protection?	Yes / No

Licensing - Indicative online questions

DOSES	
Maximum annual effective dose to staff working with practice?	___ mSv
Maximum annual equivalent dose to lens of eye?	___ mSv
Maximum annual equivalent dose to extremities?	___ mSv
Maximum annual equivalent dose to other tissues/organs?	___ mSv
Maximum annual effective dose to other staff?	___ mSv
Maximum effective dose to member of public?	___ mSv

Licensing - Indicative online questions

Has a PRIOR RISK ASSESSMENT been completed that has identified:	
Ways in which potential exposures or accidental and unintended medical exposures could occur?	Yes / No
The probabilities and magnitude of potential exposures to the extent practicable?	Yes / No
The quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures required to all exposures ALARP?	Yes / No
The operational limits and conditions of operation?	Yes / No

Licensing - Indicative online questions

THIS 'N' THAT	
Have you drawn up **contingency plans** for all reasonably foreseeable radiation accident and **rehearsed** them at suitable intervals?	Yes / No
Have you considered **REPPIR** and acted as necessary?	Yes / No
Have you a suitable **maintenance, testing, inspection and servicing regime**?	Yes / No
Will the management of any **radioactive waste** ensure that exposures to employees will be ALARP?	Yes / No
Will the management of any **disused source** or radiation generators ensure that exposures to employees will be ALARP?	Yes / No
Where appropriate are suitable and sufficient **quality assurance regimes** in place?	Yes / No

HASS licensing

Draft Regs say must also include information on

a) responsibilities;

b) minimum staff competencies, including information and training;

c) minimum performance criteria for the high-activity sealed source, its container and any additional equipment;

d) requirements for emergency procedures and communication links;

e) work procedures that must be followed;

f) maintenance of equipment, high-activity sealed sources and containers;

g) adequate management of disused high-activity sealed sources, including agreements regarding the transfer, if appropriate, of such sources to a manufacturer, supplier, another licensed employer or a waste disposal or storage facility.

Probable **Licensing Process**

- Fee to recover costs *(a few tens of £ per practice)*
- License each "practice" not each source
  - e.g. license linacs for radiotherapy once, not every individual linac separately
  - May even be one license for "Operation of an accelerators" to cover RT linacs, RT cyclotrons and PET cyclotrons, etc.
- HSE can ask for more detailed information
- Must have a license from HSE to continue these practices after 6/2/2017
- License can include additional conditions from HSE (e.g. time limit for renewal)

Registration of specified practices (reg 6)

- "REGISTRABLE PRACTICE" = operating a radiation generator or a radioactive source, which is not "LICENSABLE"
- Work with radioactive source not registerable if activity concentration < Schedule 7, part 1, column 4 values
  - e.g. for Sr-90 < 100 Bq/g
- e.g.
  - Diagnostic or interventional X-ray imaging
  - Orthovoltage, superficial, contact radiotherapy
  - RT CBCT, CT
- Online system, 6th Feb deadline, available from late 2017, fee to recover costs *(a few tens of £ per practice)*
- HSE can ask for more information, and can add conditions (e.g. time limit).

Registration - Indicative online questions (from James Taylor, HSE, Nov 2016)

- Have you done **risk assessments**?
- Have you taken action to keep doses **ALARP**?
- Have you contingency plans for **foreseeable accidents**?
- Have you adequately **trained** those undertaking work with radiation?
- Have you **designated controlled/supervised areas** where necessary?
- Have/will you **measure/estimate staff doses**?
- Have you **appointed RPS** and written **local rules** where necessary?
- Have you **consulted an RPA**?

Online Registration

- If all ticked “yes” then (probably) you are registered.
- Must inform HSE where things change
- HSE will probably require re-registration at regular intervals so their records are up to date.

Notification of specific work (reg 5)

- Must notify HSE of all licensable and registerable practices
- Any other work with ionising radiation not exempt by Schedule 1
- Online by 6th Feb; free; simple (who, what where).

Schedule 1 exempt from notification

i. Working small concentrations or quantities of radioactive substances (< Schedule 7, part 1, columns 2 or 3 values)
ii. VDUs with cathode ray tubes
iii. X-rays < 30 kV and < 1 μSv/h @ 10 cm
iv. Out of scope disposals *(e.g. decayed iodine seeds)*
v. Anything else the HSE allows

Other changes . . . .

Notification and recording of significant events:

- If “contingency plans” in Local Rules are carried out
  - Analyse cause
  - Take reasonable measures to prevent reoccurrence
  - Record analysis and keep for at least 2 years
  - Record any accidental exposures on dose record
- *So if something is fairly routine, consider whether it should be in “contingency plan” section of local rules or normal “system of work”.*
- Notification to HSE - trigger levels will not change from IRR99.

Outside workers :

- IRR99 - only applies to Classified Person working in another employer's Controlled Area
- IRR17
  - "classified outside worker" means a classified person who carries out services in the controlled or supervised areas of any employer (other than the controlled or supervised areas of their own employer);
  - "non-classified outside worker" means a person who is not a classified person who carries out services in the supervised or controlled areas of any employer (other than the supervised or controlled areas of his own employer);
  - "outside worker" - both
- Extra duties related to non-classified OW include
  - Reg 15(2) – specific training in characteristics and activities in your controlled area, including use of PPE
  - Reg 19(2)(c) – ensure they don't go above classified worker trigger because of exposure in your controlled area
  - Reg 19(8)(c) – If contamination risk, no eating, smoking, etc.

Public dose estimation:

- Procedures are required that estimate the does to members of the public. Although environmental regulations cover most practices, IRR will be amended to cover those that do not. Guidance on methodology will be provided.

Lens of Eye Dose Limit

- Employees > 18y limit
  - Changed from 150 mSv to 20 mSv in a year
- Trigger for classified person
  - Changed from 45 mSv to 15 mSv in a year
- Authorisation of 5 year averaging for dose limit to lens of the eye:
  - Dutyholders can make use of this flexibility but this will be subject to conditions specified by HSE

Other dose limit changes

- Removal of Subsidiary Dose Limit for the Abdomen of a Woman of Reproductive Capacity
  - IRR99 – maximum of 13 mSv in 3 months

- Authorisation of the whole body dose limit in special cases:
  - HSE will authorise the application of an effective dose limit of 100 mSv over five years (with no more than 50 mSv in a single year) rather than dutyholders only giving prior notification

Move to IRMER2018 and DH

- Comforters and carers
- Reg 32 Equipment used for medical exposure
  - *Note, testing of safety features for staff and public still in with HSE IRR*

Less interesting changes *(please call out if you disagree)*

- Distinction between "radiation employer" and "employer" scrapped
- Weighting factors for dosimetry
  - w_T & w_R values changed from 1990 to 2007 values
- Record retention
  - changed from 50 to 30 years after last day of work
- Appointed doctor:
  - removed requirement to be appointed 'in writing'
- Radon trigger levels
- Dosimetry services:
  - HSE will "recognise" dosimetry services rather than "approve" them

Approved Code of Practice - 7.5 μSv/h issue

- IRR85 schedule 6 used IDR, TADR
  - "1. Subject to paragraphs 2 & 3, the employer shall designate as a **controlled area** any area in which the **instantaneous dose rate** exceeds or is likely to exceed **7.5 μSvh^{-1}**"
- 50 mSv x $^{3}/_{10}^{th}$ ÷ 50 wk/y ÷ 40 h/wk = 7.5 μSv/h
- IRR99 – removed from regulations, but reproduced in APPROVED CODE OF PRACTICE 248, 249
  - *"Approved Codes of Practice have a special legal status. If employers are prosecuted for a breach of health and safety law, and it is proved that they have not followed the relevant provisions of the Approved Code of Practice, a court can find them at fault unless they can show that they have complied with the law in some other way."*

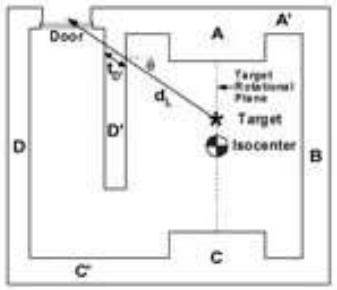
ACOP(IRR99) 249

"In addition, an area should be designated as a controlled area if the **dose rate (averaged over a minute) exceeds 7.5 microsieverts per hour** and:

(a) the work being undertaken is site radiography; or

(b) **employees untrained in radiation protection are likely to enter that area**, unless the only work with ionising radiation involves a radioactive substance dispersed in a human body and none of the conditions in the previous paragraph apply."

Example of a problem



- Linac IDR at isocentre
  a) Flattened beam circa 1999 ~ 4 Gy/min
  b) Flattened beam circa 2017 ~ 6 Gy/min
  c) FFF ~ 30 Gy/min

- IDR to surrounding area higher for FFF
  – But if same isocentre dose per day, dose to surrounding area not much higher

e.g. *(courtesy of Philip Mayles)* - 5 patients/h, 3Gy/#, 2.5 m concrete wall primary barrier to office (10% occupancy)

a) Flattened beam circa 1999 ~ 4 Gy/min
   - Annual dose = 0.3 mSv
   - IDR = 4.9 μSv/h
   - OK ☺

b) Flattened beam circa 2017 ~ 6 Gy/min
   - Annual dose = 0.3 mSv
   - IDR = 7.3 μSv/h
   - Oooh – just OK 😐

c) FFF ~ 30 Gy/min
   - Annual dose = 0.3 mSv
   - IDR = 36 μSv/h
   - **CONTROLLED AREA ☹.**
   - *"Fake risk"?*

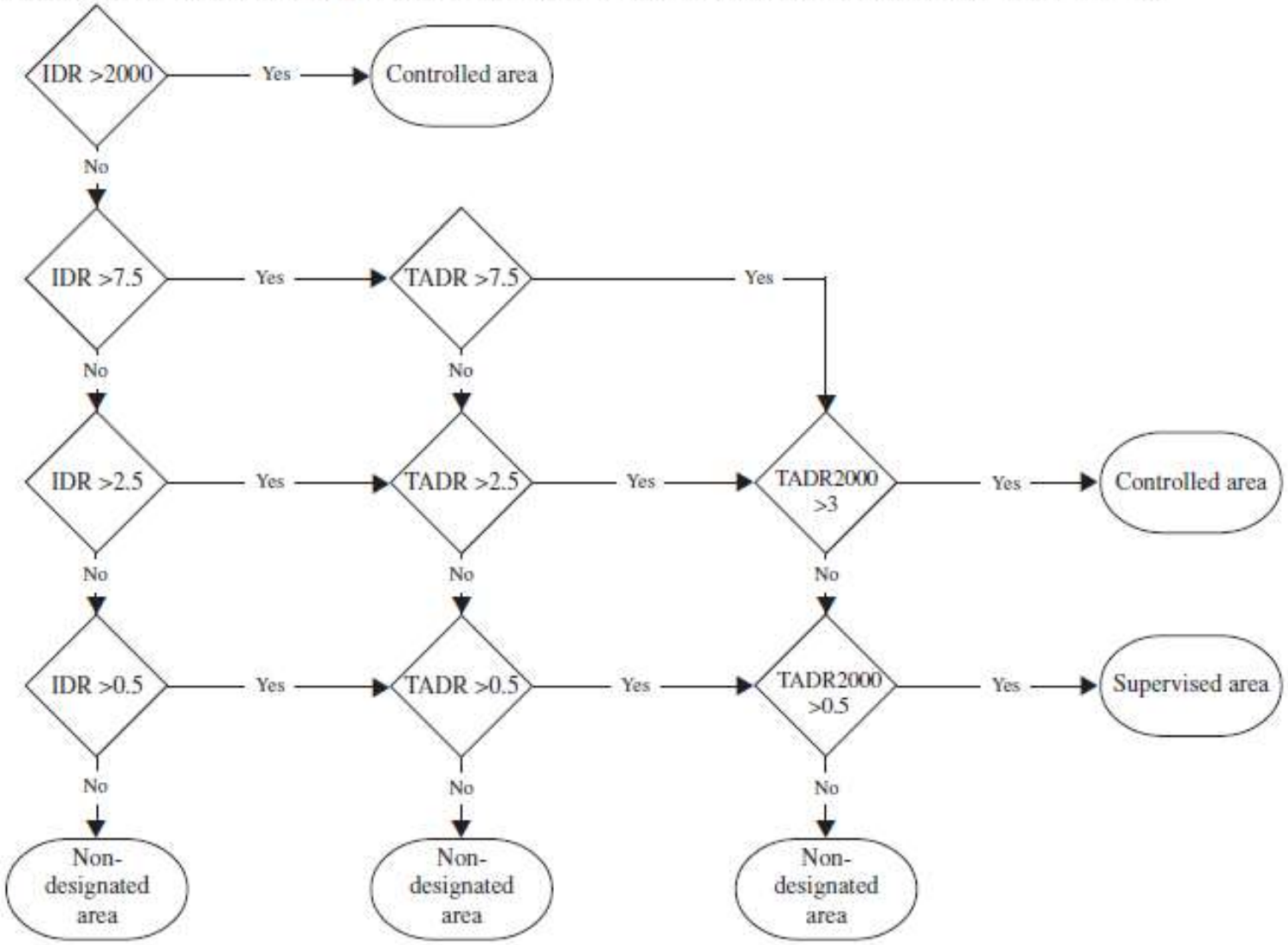
Same scenario, but car park

- Assume 10% occupancy
- 2.06 m concrete wall needed for 0.3 mSv constraint
  a) Flattened beam circa 1999; IDR = 49 μSv/h
  b) Flattened beam circa 2017; IDR = 73 μSv/h
  c) FFF; IDR = 365 μSv/h

- To achieve 7.5 need 2.75 m concrete @ approximately £76,000 per barrier

Medical & Dental Guidance Notes, IPEM, 2002

Figure A11.1 Designation of controlled and supervised areas (numbers in μSv h^{-1}): non-public areas



ACOP 248 draft in consultation

"Employers must designate controlled areas, in cases where:

(a) the external dose rate in the area exceeds 7.5 microsieverts per hour;

. . . ."

(Note dose rate is defined as averaged over 1 minute in regulation 2)

- Justification given
- "The text supports the Articles of the Directive – however the 7.5 μSv rate is not specified in the Directive. Specialists advise that it would be a major change for industry if this were to be removed and it gives limits for dutyholders to aid designation."

Some further reasons 7.5 μSv/h limit is ~~silly~~ inappropriate

- Not in new BSS (not in old BSS or the BSS before that)
- No scientific basis
  - Not in ICRP, UNSCEAR, PHE, etc.
  - Risk is from dose, not dose rate unless high dose rate and ICRP, etc. class low dose rate as < 0.1 mGy/min (6,000 μSv/h)
- Extremes
  - 1 minute in a year at 7.5 μSv/h → 0.000125 mSv
  - 24/7 at 7.5 μSv/h → 66 mSv

IPEM response

- RPSIG (Phil Orr) objected to 7.5 μSv/h in consultation response
- HSE have asked for a meeting of their Policy Team and inspector David Orr with IPEM
- Heads of RT, NM, DR, RP SIGs been asked for delegate to meeting, and any suggestions of any others key people.

IRR17 Guidance

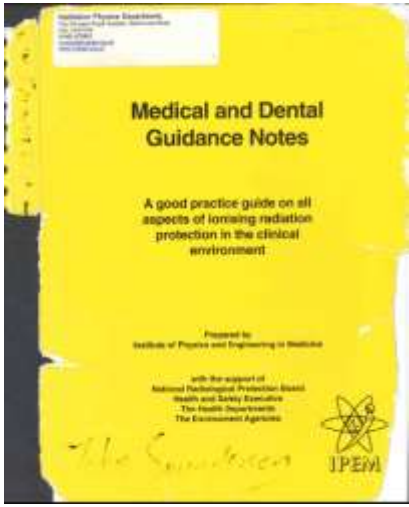
- In production
- Some bits run past SRP BSS2013 Working Group *(but not IPEM?)*

IRMER

- Steve Edbon-Jackson at PHE leading for DH
- “a limited consultation exercise” after the general election
- Basic IRMER structure the same, with add-ons
- Medical exposures bits from IRR99 move to IRMER + non-medical exposures using “medical radiological equipment”
- MARS/ARSAC also moving to IRMER
  - Site licenses will be required
  - Doctor’s license won’t be site specific
- MPE accreditation and role change

Medical & Dental Guidance Notes Working Party

- Chair
  - John Saunderson, Hull, john.saunderson@hey.nhs.uk
- Nuclear Medicine chapter editor
  - Lisa Rowley, Oxford, lisa.rowley@ouh.nhs.uk
- Diagnostic Radiology chapter editor –
  - Mark Worrell, Dundee, markworrall@nhs.net
- Radiotherapy chapter editor
  - Philip Mayles, Clatterbridge, philip.mayles@nhs.net
- Radiation Protection chapter editor
  - Will Mairs, Manchester, william.mairs@christie.nhs.uk



See for yourself?

- IRR17 consultation document - http://consultations.hse.gov.uk/consult.ti/cd282/consultationHome

- This PPT at www.hullrad.org.uk/share