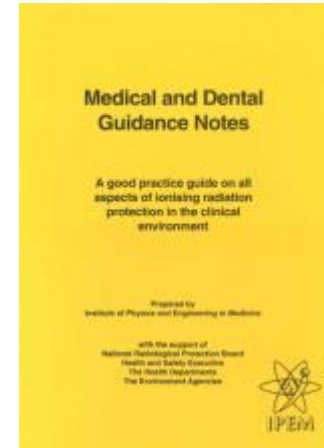


New Ionising Radiation Regulations: What does it mean for me?

26 September 2017



The new Medical and Dental Guidance Notes (MDGN): role and content



Mr John Sanderson,

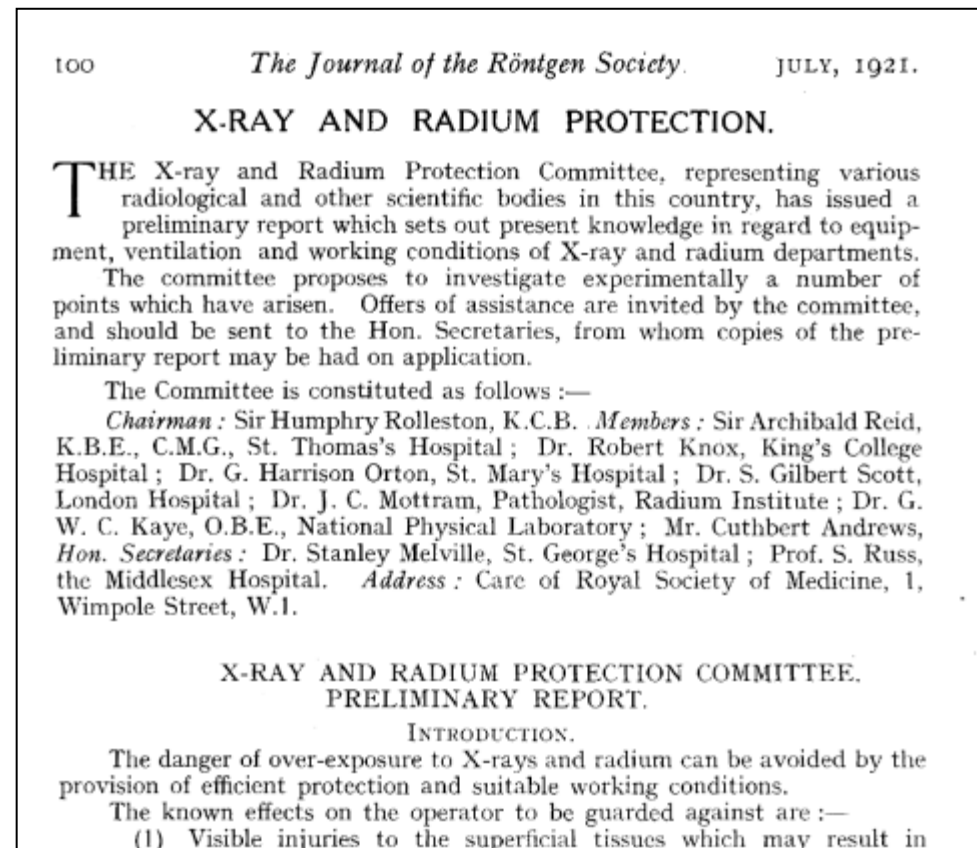
Consultant Physicist/Radiation Protection Adviser,

Hull and East Yorkshire Hospitals NHS Trust

Chair of MDGN Working Party

UK “Medical & Dental Guidance Notes”

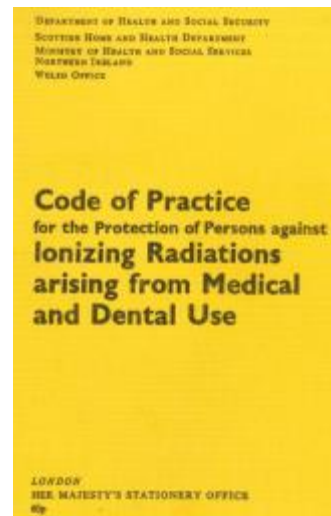
- 1921 – 1948, British X-Ray & Radium Committee
– 7 editions of *Report of the British X-ray and Radium Protection Committee*



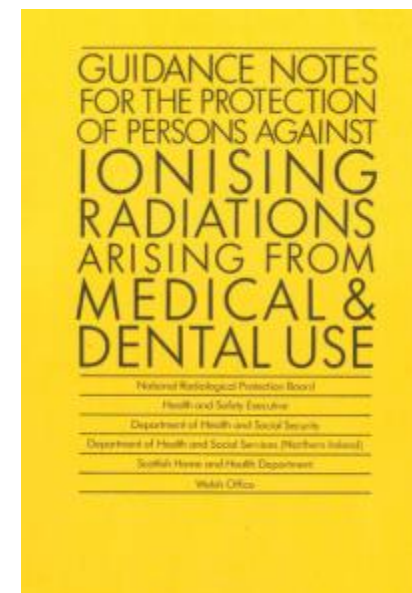
UK “Medical & Dental Guidance Notes”

- 1948 – 1988, UK Government - Radioactive Substances Advisory Committee / National Radiological Protection Board (NRPB)
 - *Code of practice for the protection of persons exposed to ionizing radiations*, HMSO, 1957
 - *Code of Practice for the Protection of Persons against Ionizing Radiations arising from Medical and Dental Use*, HMSO, 1964, 1972
 - *Guidance notes for the protection of persons against ionising radiations arising from medical and dental use*, NRPB, 1988

1921



1972



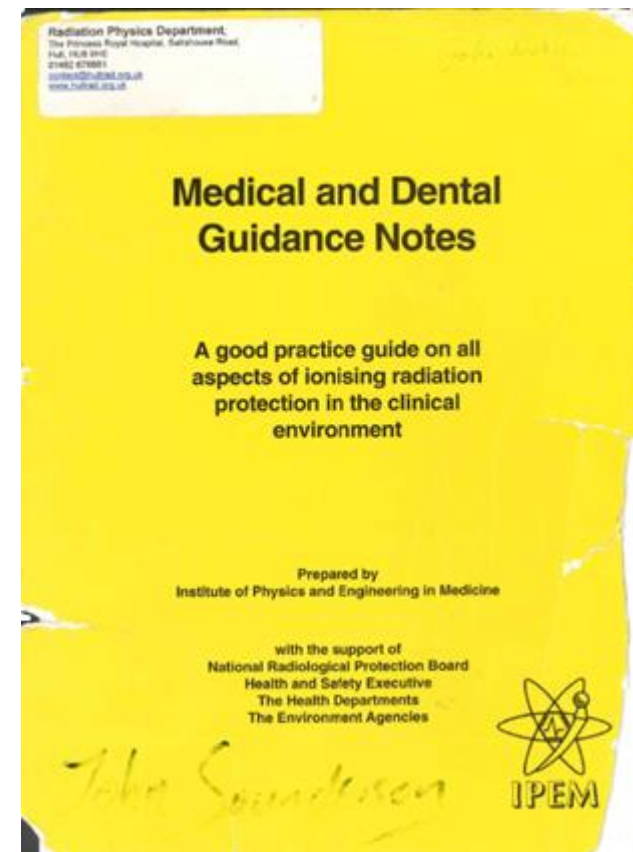
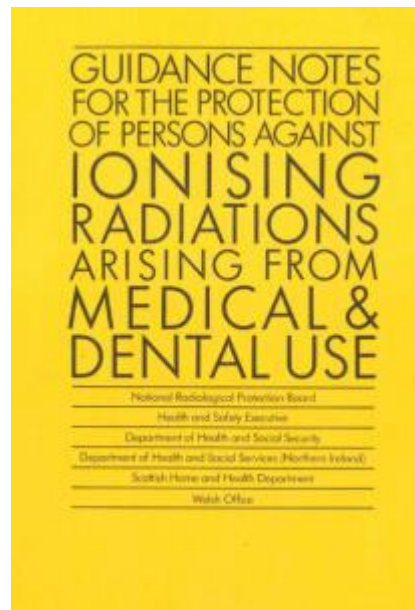
1988

UK “Medical & Dental Guidance Notes”

- 2002, Institute of Physics & Engineering in Medicine (IPEM)
 - *Medical & Dental Guidance Notes: A good practice guide on all aspects of ionising radiation protection in the clinical environment, IPEM, 2002*

1988

1921



Medical and Dental Guidance Notes

A good practice guide on all
aspects of ionising radiation
protection in the clinical
environment

Prepared by
Institute of Physics and Engineering in Medicine

with the support of
National Radiological Protection Board
Health and Safety Executive
The Health Departments
The Environment Agencies



These notes provide general guidance on good practice:

- they are not an attempt to repeat or interpret the legal requirements and advice contained in the legislation.
- Following the guidance is not compulsory but should suffice operationally to comply with the law;
- other actions may be equally valid.
- Individuals who carry responsibilities under the legislation are advised to acquaint themselves appropriately with the legal requirements.

e.g. Radioiodine patient dies. Can their body be cremated?

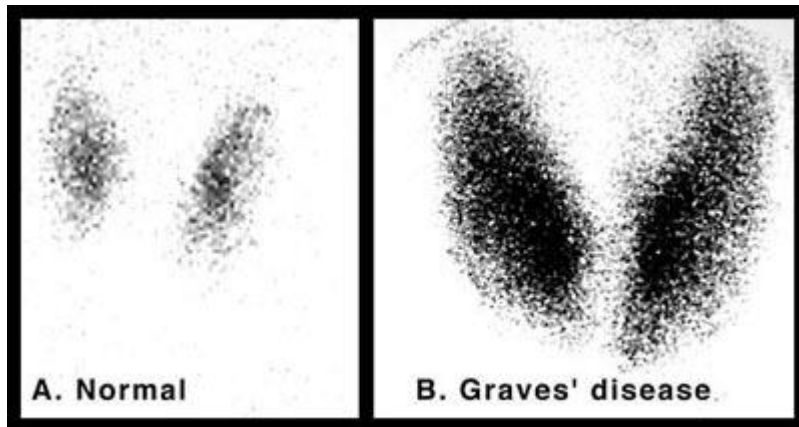


Table 16.1 Maximum activities of radionuclides for disposal of corpses without special precautions (activities in MBq)

Radionuclide	Burial	Cremation
^{131}I	400 ^a	400 ^a
^{125}I seeds	4000 ^b	see paragraphs 16.29 to 16.31
^{103}Pd seeds	15000 ^a	see paragraphs 16.29 to 16.31
^{90}Y colloid	2000 ^b	70 ^c
^{198}Au seeds	4000 ^a	see paragraphs 16.29 to 16.31
^{198}Au colloid	400 ^a	100 ^c
^{32}P	2000 ^b	30 ^c
^{89}Sr	2000 ^b	200 ^{c, d}

GUIDANCE NOTES FOR THE PROTECTION OF PERSONS AGAINST IONISING RADIATIONS ARISING FROM MEDICAL & DENTAL USE

National Radiological Protection Board

Health and Safety Executive

Department of Health and Social Security

Department of Health and Social Services (Northern Ireland)

Scottish Home and Health Department

Welsh Office

1988

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2002

2002 Content

(19 chapters, 21 appendices)

1. General measures for radiation protection

- Mostly IRR99 requirements – employer's duties, RPA, risk assessments, controlled areas, local rules, personal monitoring, incidents, emergencies, etc.

2. Radiation protection of persons undergoing medical exposures

- Mostly IRMER requirements – employer, referrer, practitioner, operator, MPE, DRL, incidents, training

. . . . 2002 Content

- 3. Diagnostic (other than dental) and interventional radiology**
- 4. Diagnostic X-ray equipment excluding equipment for dental radiography
- 5. Dental radiology**
- 6. Equipment for dental radiography

. . . . 2002 Content

7. Radiotherapy

8. Radiotherapy and brachytherapy equipment

9. Brachytherapy sources

. . . . 2002 Content

- 10. Diagnostic uses of unsealed radioactive substances**
- 11. Preparation of radiopharmaceuticals
- 12. Therapeutic uses of unsealed radioactive substances**
- 13. Ionising radiation in general laboratories
- 14. Diagnostic uses of sealed radioactive sources**
- 15. Patients leaving hospital after administration of radioactive substances
- 16. Precautions after the death of a patient to whom radioactive substances have been administered**
- 17. Keeping, accounting for and moving radioactive substances (including transport)
- 18. Disposal of radioactive waste**
- 19. Contingency planning and emergency procedures

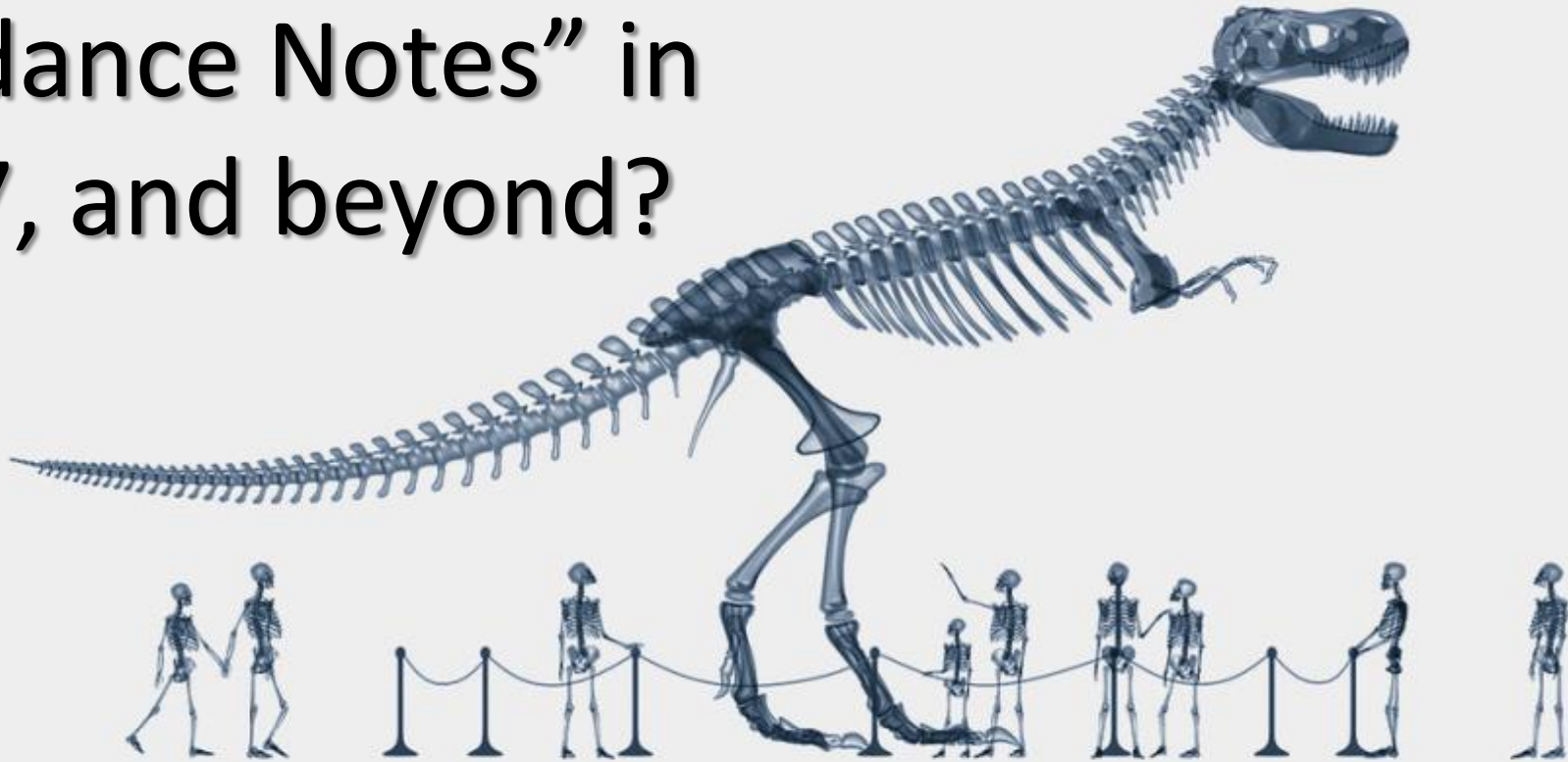
. . . . 2002 Content (*appendices*). . . .

- 1. Roles & responsibilities of the employer**
2. Example of radiation safety policy for NHS Trusts
- 3. Role of the radiation protection supervisor**
4. Role of the radiation protection adviser
- 5. Role of the medical physics expert**
6. E.g. of a pro-forma risk assessment for the IRR99
- 7. E.g. of radiation incident report**
8. Ionising Radiation Incident Database
- 9. Record keeping**
10. Guidance on medical research exposures

. . . . 2002 Content (*appendices*).

- 11. Designation of controlled and supervised areas**
12. Warning signs and notices
- 13. British Standards for radiotherapy equipment**
14. United Kingdom radiotherapy dosimetry protocols
- 15. Procedures for the definitive calibration of radiotherapy equipment**
16. Addresses of authorities and organisations
- 17. Environment Agency internal handbook – guidance for inspectors**
18. Generic authorisations under the Ionising Radiations Regulations 1999
- 19. List of acronyms**
20. Acts and regulations in the United Kingdom
- 21. References.**

Is there still a role for
“Guidance Notes” in
2017, and beyond?



UK Radiation Legislation



- 1921
 - None
- 1948
 - Radioactive Substances Act 1948
- 2017
 - Ionising Radiations Regulations 1999, etc.
 - Ionising Radiation (Medical Exposure) Regulations 2000, etc.
 - Environment Permitting Regulations 2016/Radioactive Substances Act 1993, etc.
 - Medicines (Administration of Radioactive Substances) Regulations 1978, etc.
 - The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, etc.
 - REPPIR, JoPIIRR, etc.



Regulator Guidance



Health and Safety
Executive



- IRR Approved Code of Practice (ACOP)
- HSE Working with ionising radiation guidance L121
- Guidance Note PM77 Equipment used in connection with medical exposures
- www.hse.gov.uk/radiation/ionising/
- www.hse.gov.uk/articles/ionising-radiation

Regulator Guidance



Department
of Health

- Departments of Health
 - IRMER Notes on Good Practice
 - ARSAC Notes for Guidance
 - Guidance on investigation and notification of medical exposures much greater than intended
 - National Diagnostic Reference Levels (NDRLs)
 - www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000
 - www.gov.uk/government/organisations/administration-of-radioactive-substances-advisory-committee

agc
hiw

Arolygiaeth Gofal Iechyd Cymru
Healthcare Inspectorate Wales

Regulator Guidance



- www.gov.uk/government/collections/radioactive-substances-regulation-for-non-nuclear-sites
- www.sepa.org.uk/regulations/radioactive-substances/
- www.daera-ni.gov.uk/articles/radiation-overview
- naturalresources.wales/permits-and-permissions/non-nuclear-radioactive-substance-sites/?lang=en

www.onr.org.uk/transport/guidance.htm

- Summary of changes to ADR regulations regarding the carriage of Class 7 dangerous goods
- Transporting radioactive material - Guidance on radiation and contamination monitoring requirements, and determining a Transport Index
- Guidance for Consignors and Carriers of Class 7 Dangerous Goods Who Wish to Transport Such Goods into and within GB via Road and Rail
- Guidance on special arrangement approvals
- Transporting radioactive material - Security Guidance on the carriage of Class 7 radioactive material
- Transporting radioactive material - Guidance on emergency arrangements (principally for non-nuclear sector dutyholders)
- Guidance for Applications for UK Competent Authority Approval
- Guidance Note - Regulation Change relating to Shielding Design in Packaging Safety Reports
- Technical Guide - European Package Design Safety Reports for the Transport of Radioactive Material
- Seals Guide: radioactive materials
- Freight Containers Guide: radioactive materials
- UK guidance on radiation protection programmes
- Guidance note - Application of Climate Study to Class 7 Dangerous Goods Package Design
- Met Office - Range of environmental temperature conditions in the United Kingdom

[Home](#)

Guidance

Regulatory Controls for Radiation Protection in the UK

From: [Department for Business, Energy & Industrial Strategy, Health and Safety Executive, and Office for Nuclear Regulation](#)
Part of: [Radioactive and nuclear substances and waste and Energy industry and infrastructure licensing and regulation](#)
Published: 10 October 2016

Exemption, Notification, Registering & Licensing of Radioactive Substances and radiation generators in the UK.

Contents

- [UK-wide regulation](#)
- [GB-Wide Regulation](#)
- [Regulation in England](#)
- [Regulation in Northern Ireland](#)
- [Regulation in Scotland](#)
- [Regulation in Wales](#)

This guide brings together webpages from the various bodies across the UK who regulate the use of radioactive substances and radiation generators:

- Department of Health;
- Health & Safety Executive (HSE) and the Health and Safety Executive for Northern Ireland (HSENI);
- Office for Nuclear Regulation (ONR); and
- UK Environment Agencies.

Is there still a role for “Guidance Notes” in 2017, and beyond?

Or are regulations and regulator guidance sufficient?



e.g. Staff working in fluoroscopy



e.g. Staff working in fluoroscopy

- **Ionising Radiations Regulations 1999**
 - Regulation 8(1) – keep exposures as low as reasonably practicable
 - Regulation 11(1) – keep doses below dose limits
 - +
- **IRR99 Approved Code of Practice, HSE 2000**
 - 59 - Don't use dose sharing as primary means, rather engineering controls, methods of work, etc.
 - 181 – use radiation and tissue weighting factors from Euratom BSS to calculate dose
 - +
- **IRR99 Guidance, HSE, 2000**
 - Valuable feedback from reviewing previous monitoring
 - +

Medical & Dental Guidance Notes

Protection against scattered radiation for fixed fluoroscopy installations

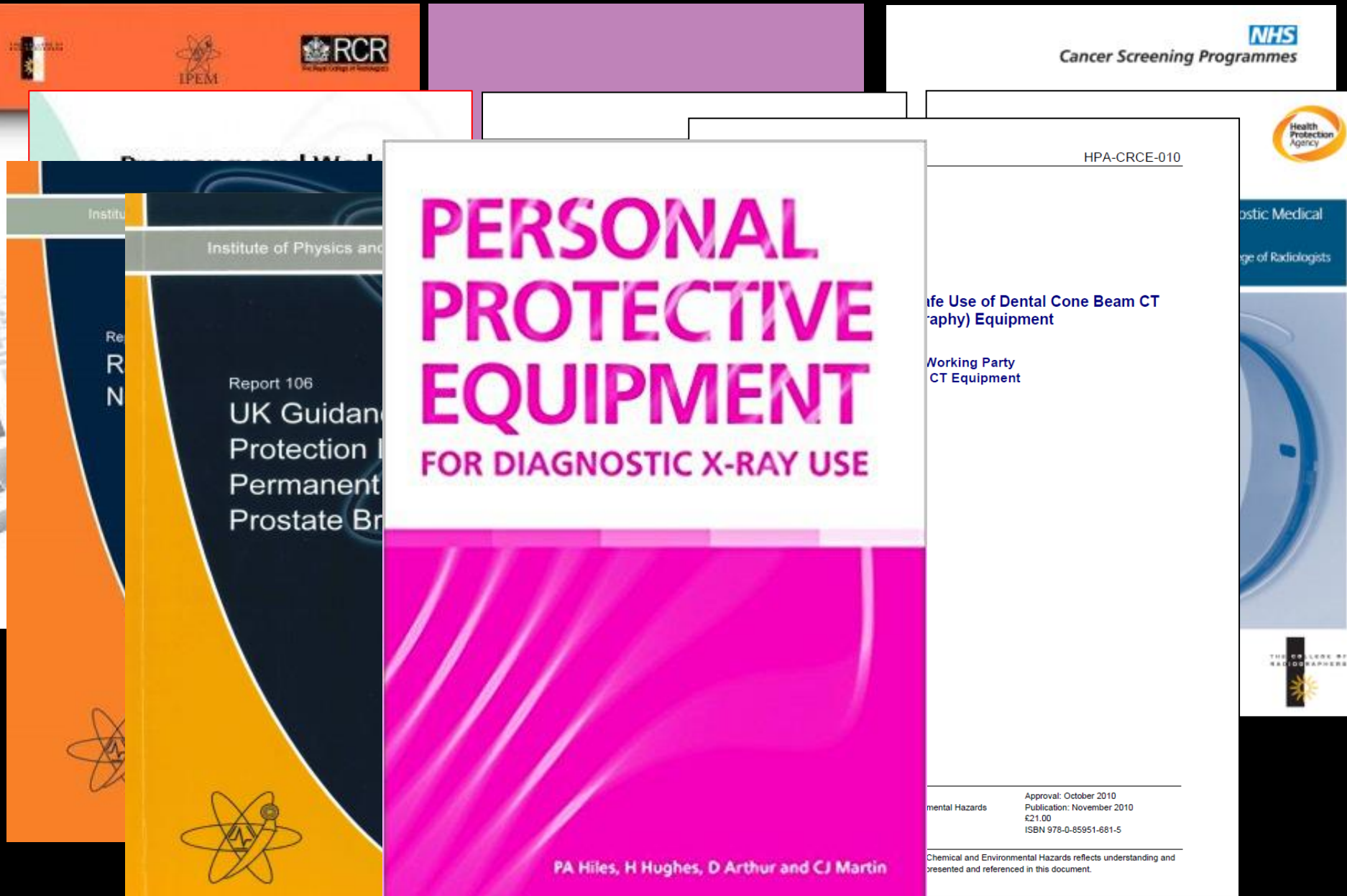
- 4.43 All equipment used for fluoroscopy should be provided with adequate protection for staff against scattered radiation arising from the patient and from materials between the X-ray tube and the patient. Protective materials should be equivalent to not less than 0.5 mm lead at 100 kVp.
- 4.44 Over-table and C-arm tubes should be operated remotely where possible, with operators protected by a fixed lead glass screen installed between them and the X-ray equipment. When remote operation is not feasible, alternative screens and aprons should be provided for protection against scattered radiation. These may be:
- (a) ceiling suspended screens to protect the operator's head and upper body
 - (b) attached to the sides of the table and configured to reduce back and side scatter from the patient
 - (c) suspended from the X-ray tube and extending down to the patient to provide local protection, or
 - (d) floor standing mobile screens to provide general protection.
- 4.45 Equipment with an enclosed under-table tube and over-table intensifier should provide adequate protection in the side of the table, including bucky slots and openings. Above the tabletop, the operator should be protected, normally by a lead rubber apron suspended from the intensifier support. The apron should be large enough to provide adequate shielding (not normally less than 45 cm wide and 40 cm long) and be adjustable in position so that the operator protection is maintained when the table is tilted. Special attention should be paid to the mechanical robustness of the drapes when switching between vertical and horizontal table positions.

- 3.88 During fluoroscopy, palpation with the hand should be reduced to a minimum. It should only be undertaken on the image receptor side of the patient and therefore should not be carried out at all with an overcouch tube; in the latter case, automatic compression devices should be available. A protective glove with a lead equivalent thickness of at least 0.25 mm for up to 150 kV should always be worn during palpation. The need to wear a fingertip dosimeter should be considered (see paragraph 1.94). The presence of the glove used for palpation can cause a significant increase in absorbed dose rate when an automatic dose rate system is used. Care should be taken to minimise this effect by keeping the glove outside the sensing area of the automatic system (which is normally close to the centre of the field of view) and/or by locking the fluoroscopic factors before palpation begins.

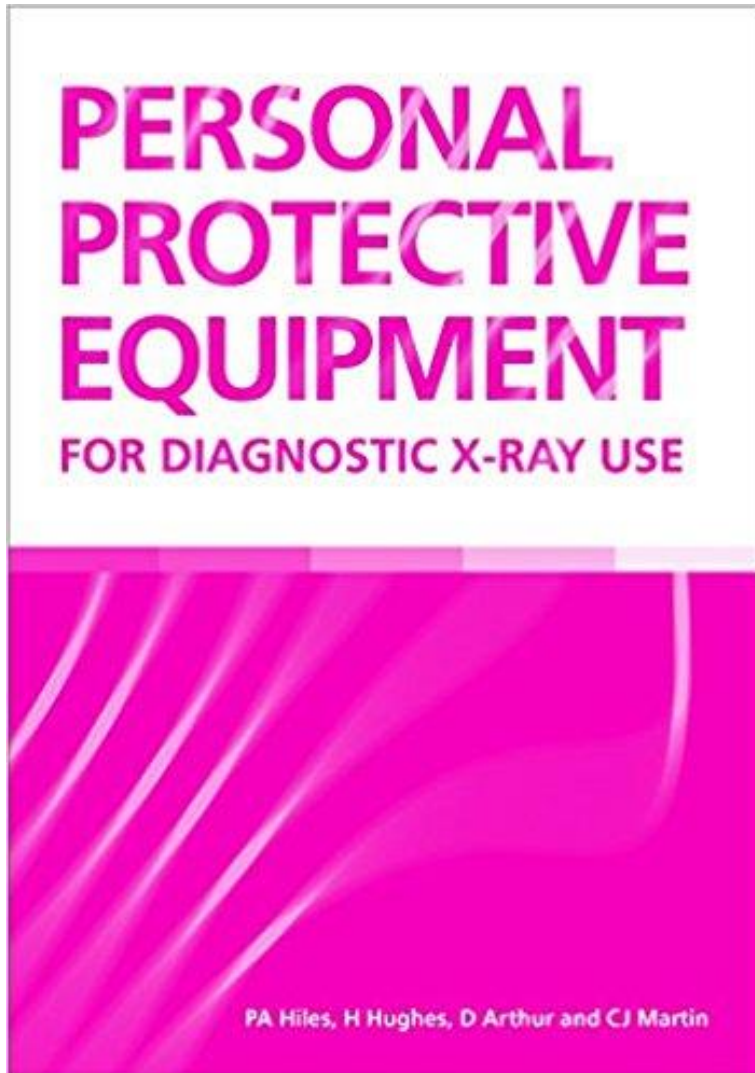
Protective clothing

- 3.117 Gloves, aprons and eye protectors are designed to protect the wearer only from primary radiation transmitted through the patient, and from scatter. They will not provide adequate protection from the unattenuated primary beam.
- 3.118 Gloves should be available with a protection equivalent throughout both front and back (including fingers and wrist) to not less than 0.25 mm lead for X-rays up to 150 kV. They should be labelled with a CE mark and an indication of their lead-equivalence. They may comply with BS EN 61331-3:1999 *Protective Devices Against Diagnostic Medical X-Radiation* [42].
- 3.119 Body aprons should be available with a protective equivalent of not less than 0.25 mm lead for use with X-rays up to 100 kV and not less than 0.35 mm lead for use with X-rays over 100 kV. They should be labelled with a CE mark and indication of their lead equivalence. They may comply with BS EN 61331-3:1999 [42]. Where extra protection is required, the addition of a thyroid shield is generally more useful to reduce effective dose than moving to thicker body aprons. Half body aprons should not be used except for specific applications for which the RPA has advised they will offer sufficient protection.
- 3.120 A range of PPE should be provided in all X-ray rooms and for use with mobile X-ray equipment. PPE should be used and stored properly, and employees should be aware of their duties relating to PPE (see L121 paragraph 163 [2]).

Healthcare Radiation Guidance



Other Guidance, e.g.



Thorough guidance on lead aprons, eyewear, thyroid shields, gloves, etc.

Include logic behind why 0.35 mm above 100 kV, etc.

Needed on every RPA's (*DR RPS's?*) shelf?

Medical & Dental Guidance Notes often where you start, and then refers to other document if you (or your RPA) need to look any deeper.

**Is there still a role for
“Medical & Dental Guidance Notes”
in 2017, and beyond?**



Medical & Dental Guidance Notes

Need for a new edition?

- New regulations since 2002
 - e.g. EPR2016, CDG2009
- New techniques
 - e.g. PET/CT
- New guidance
 - e.g. BIR PPE for Diagnostic X-Ray Use
- New Euratom BSS
 - New IRR/IRMER/MARS by 6th February 2018

IPEM Project 552

IPEM Working Party on the Revision of the Medical & Dental Guidance Notes

- Chair
 - John Sanderson, Hull, johnsaunderson@nhs.net
- Radiation Protection chapter editor
 - Will Mairs, Manchester, william.mairs@christie.nhs.uk
- Diagnostic Radiology chapter editor –
 - Mark Worrell, Dundee, markworrall@nhs.net
- Radiotherapy chapter editor
 - Philip Mayles, Clatterbridge, philip.mayles@nhs.net
- Nuclear Medicine chapter editor
 - Lisa Rowley, Leicester, lisa.rowley@uhl-tr.nhs.uk



NEW CONTENT

General radiation protection

Will Mairs, Manchester, william.mairs@christie.nhs.uk

- Culture
- Co-operation between employers
- Radon
- PPE
- *+Registration & Licensing*
- Information, Instruction and Training
- *Equipment QA, etc expanded*
- Area monitoring
- Performing an investigation
- Employers procedures
- Written protocols
- Authorisation
- Optimisation
- Pregnant patients
- Duty of candour
- Clinical audit
- Medical legal procedures
- Consent & having that dose vs risk conversion

Diagnostic & Dental Radiology

Mark Worrell, Dundee, markworrall@nhs.net

- Dental hand-helds, CBCT, detector technologies
- Use of equipment outside main department
- Additional precautions by modality
- More on interventional radiology
- Specific IRMER section
- Equipment testing
- Facility design
- PPE



Radiotherapy

Philip Mayles, Clatterbridge, philip.mayles@nhs.net

- Licensing accelerators
- FFF (Flattening Filter Free) – shielding & IDR
- Intraoperative radiotherapy?
- Tomotherapy
- Cyberknife
- Gammaknife



Radioactive Substances

Lisa Rowley, Leicester, lisa.rowley@uhl-tr.nhs.uk

- New PET chapter (inc. cyclotrons and mobiles)
- Radium-223, Lu-177, Y-90
- Hybrid imaging – PET/CT, etc.
- Management systems for radioactive substances (RS)
- Receipt and collection of RS.
- Much more on transport of RS, inc. packaging etc.
- Methods for calculating excreted activities
- Updated therapy advice
- Staff eye doses
- Extremity monitoring
- Laundry
- Ward advice
- Therapy dosimetry



New Ionising Radiation Regulations: What does it mean for me?

26 September 2017



Medical and Dental Guidance Notes

A good practice guide on all
aspects of ionising radiation
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environment

Second Edition
2018

with whatever endorsement we can
agree with the regulators

