

BIR publishes guidance on patient contact shielding

The British Institute of Radiology has recently published its guidance on the use of patient contact shielding in diagnostic radiology. The guidance represents the outcome of a BIR working party which was tasked with investigating the effectiveness of placing protective material directly onto the surface of the patient during radiodiagnostic procedures to help reduce the dose to critical organs. Lack of an evidence base for such practices has led to large inconsistencies in use of patient contact shielding between imaging departments in the UK. These inconsistencies can in turn lead to friction between patients who demand shielding and healthcare professionals advising that it is unnecessary or counterproductive.

Despite comprising a total of 87 pages, the authors simply conclude the following:

- The evidence shows that patient contact shielding is not generally required in diagnostic and interventional radiology.
- Patient contact shielding can lead to an increase in patient dose due to the need to repeat an examination or interference with automatic exposure control (AEC) systems
- Exceptions may occasionally occur where a particular patient care

pathway requires a number of repeat examinations where patient contact shielding may be applied, particularly in the case of paediatric patients.

The authors propose that healthcare professionals should concentrate on other areas of radiation protection to improve patient care. They conclude that cessation of the widespread practice of using patient contact shielding will require a major cultural change and that adoption of these guidelines will also require a suitable education programme.

RPC's advice sheets on patient shielding during imaging procedures have been updated in line with the guidance and are available for free download at <http://www.sghrpc.co.uk/Advice.htm>. A 3-page summary of the BIR guidance is also available via our website at the same link. Our summary provides a brief synopsis of how the BIR advice applies to each of the main imaging modalities.

We advise our clients to adopt the advice from the BIR guidance with immediate effect. This may be achieved by distributing our summary of the document to operators (see above), as well as adopting the advice in the form of a short addendum to the department's basic imaging protocols. The full guidance document is available for download at https://www.bir.org.uk/media/416143/final_patient_shielding_guidance.r1.pdf

Online radiation protection training extended

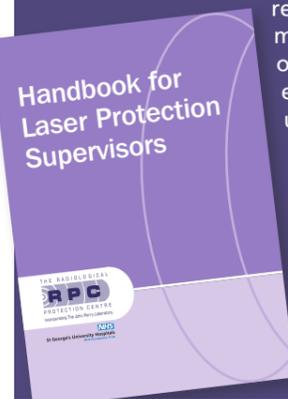
We have recently extended the scope of our online radiation protection training to include safety instruction for porters, cleaners and administrative staff. The training is freely available via our website at <http://www.sghrpc.co.uk/Online%20Training.htm> (no log in required) and aims to provide a basic level of safety training to those persons who may visit the imaging department without having a direct involvement with radiology. Such persons are often overlooked in an organisation's radiation safety programme, although the Ionising Radiation Regulations 2017 impose an explicit requirement for training to be provided which is appropriate to the role. The training is split into three parts and covers the hazards presented by Magnetic Resonance Imaging, nuclear medicine and diagnostic radiology areas. It provides background information on the respective imaging modalities, details of their potential risks, information on controlled areas and gives clear information about access arrangements. Information about working during pregnancy is also provided. The training materials are interactive and involve a series of questions to ensure that the course content has been understood. Each module is designed to last around 20 minutes and a certificate of attendance is available for download and completion by the delegate.

RPC will shortly be launching a similar course aimed primarily at theatre staff who work around a mobile image intensifier, as well as other healthcare staff who may be present during mobile X-ray procedures. Please check our website for access to the training materials.

New Laser Protection Supervisor's handbook available

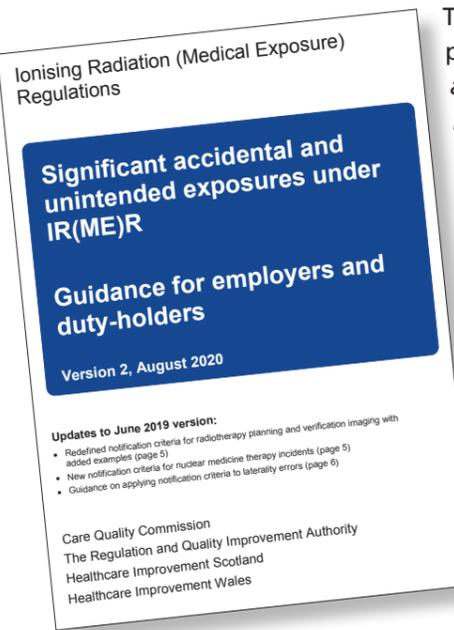
Clients using medical lasers and intense pulsed light sources will be pleased to know that we have completely overhauled our Laser Protection Supervisor's handbook. The new handbook has a significantly improved design and layout which should make it easier to use and navigate. The advice in the handbook has been updated to reflect the current regulatory framework. There is an improved operator authorisation process and an updated risk assessment proforma, which should satisfy the requirements of the Health and Safety Executive's specialist inspectors. There is also a comprehensive self-audit checklist which is designed to help the user ensure that laser/IPL hazards are kept under regular review and action taken to mitigate risks where appropriate. The handbook provides an improved pre-use checklist to help ensure that safety measures are in place before commencing laser/IPL use, as well as forms for recording eyewear checks, maintenance records, etc. The list of specialist suppliers of laser safety equipment has been comprehensively updated.

Clients with whom we have a contract as Laser Protection Adviser may request a copy of the new handbook by emailing info@sghrpc.co.uk. The handbook will also be provided directly to clients at their next laser safety audit, where the LPA will also explain how it should be used.



RPC News

CQC Guidance on Reporting Radiation Incidents



The Care Quality Commission (CQC) first published their guidance on "Significant accidental and unintended exposures under IR(ME)R" in June 2019. The guidance has recently been updated and is available from their website at https://www.cqc.org.uk/sites/default/files/20200826_sau_e_guidance_updated_aug20.pdf.

The document gives clear guidance about what constitutes a reportable radiation incident and the process for notifying the Care Quality Commission (or the Medicines and Healthcare Products Regulatory Authority for certain systemic device-related incidents).

This supersedes the previous "Much greater than intended (MGTI)" guidance and is expected to result in far fewer incidents being reported to the regulators.

Reportable incidents are described as those resulting in significant accidental or unintended exposures (SAUE). These terms are defined as:

- **Accidental:** where an individual has been exposed to ionising radiation when no exposure was intended.
- **Unintended:** where an exposure to ionising radiation was intended, but the exposure was delivered incorrectly. This includes use of the incorrect modality or technique, anatomical misses, radiopharmaceutical administration errors and timing errors. These can be due to procedural, systematic or human errors. Equipment malfunction (including ancillary equipment and software systems) resulting in the reporting criteria being met should now also be reported to the CQC.

The employer is responsible for informing the enforcing body of any significant accidental or unintended exposure after taking advice from the RPA or MPE. On discovering a

(Continued on page 2)

Contents

Page 1 - 2

CQC Guidance on Reporting Radiation Incidents

Page 2

Online incident reporting available

Page 3

Guidance on IR(ME)R 2017 published by the Royal College of Radiologists

Sentinel Node Localisation RPS handbook updated

Royal College of Radiologists provides definition of a "Clinically Significant" radiation incident

Page 4

BIR publishes guidance on patient contact shielding

Online radiation protection training extended

New Laser Protection Supervisor's handbook available



St George's University Hospitals NHS NHS Foundation Trust

Welcome to the latest edition of RPC News

I hope that all of our readers are keeping safe and well during this difficult and unprecedented time.

Despite some of the difficulties posed by the lockdown, RPC staff have used the time as an opportunity to improve many of our products and services. You will see from this newsletter that most of our handbooks have been comprehensively updated, there has been an expansion to our online training, we have updated our DRL software and made significant improvements to our templates for risk assessments and local rules. As a result we hope that you will receive a better service from RPC to facilitate your compliance with the current regulatory framework for radiation protection. This is set to come increasingly into focus as the Health & Safety Executive

and Care Quality Commission intensify their efforts to provide more proactive inspections of imaging services (details to follow in the next edition of RPC News).

We thank our clients for their patience over survey and audit visits that have inevitably been delayed during this period. We are in the process of fully resuming routine commitments and clients are welcome to get in touch directly to arrange their visit. We hope to run our normal training course programme next year as far as practicable, although this will depend on prevailing government guidance. Please check the website to see the current status of our training courses. Best wishes to you all. Stay safe!

The Radiological Protection Centre

(Continued from previous page)

SAUE may have occurred, a preliminary investigation must be carried out as soon as possible.

If this investigation shows that a significant exposure did occur, the enforcing body must be notified within two weeks of the exposure. Following this, a full report detailing the SAUE must be submitted within 12 weeks of the incident.

This report should include details including:

- what happened, including estimates of dose(s) to the exposed person(s)
- an account of how this occurred and whether this is a systematic failing
- whether local procedure has been followed
- whether duty of candour requirements have been met
- any lessons learned from this incident and how this knowledge has been shared
- how measures have been taken to prevent similar incidents happening again.

The guidance provides codes categorising reportable incidents, which are reproduced below. This guidance introduces age-bracketed dose thresholds for accidental exposures in England, where only adult doses > 3 mSv and child doses > 1 mSv are required to be reported to the CQC. In Northern Ireland, Scotland and Wales, all accidental exposures should be reported to the relevant authority.

Notification codes, categories and criteria

NOTIFICATION CODE	EXPOSURE CATEGORY	CRITERIA FOR NOTIFICATION
ACCIDENTAL EXPOSURE		
1	All modalities	≥ 3 mSv effective dose (adult) ≥ 1 mSv effective dose (child) England only
1	All modalities	All, regardless of dose Northern Ireland, Scotland and Wales
UNINTENDED EXPOSURE (ALL RADIOLOGY MODALITIES)		
2.1	Intended dose < 0.3 mSv	≥ 3 mSv (adult) ≥ 1 mSv (child)
2.2	Intended dose between 0.3 mSv and 2.5 mSv	10 or more times than the intended dose
2.3	Intended dose between 2.5 mSv and 10 mSv	≥ 25 mSv
2.4	Intended dose ≥ 10 mSv	2.5 or more times than the intended dose
3	Interventional/cardiology	Where no procedural failure has occurred and the dose is ≥ 10 times the local DRL and/or observable deterministic effects occur (excluding transient erythema)
5	Foetal exposure	Where departmental procedure for making pregnancy enquiries has not been met and the resultant dose to the foetus is ≥ 1 mGy
6	Breastfeeding infant (nuclear medicine only)	Where there has been a failing in departmental procedure and foetal dose is ≥ 1 mSv
7.1	Therapy over-exposure (including nuclear medicine)	Delivered dose to treatment volume or activity is ≤ 0.9 times that intended over the whole course
7.2	Therapy under-exposure (including nuclear medicine)	Delivered dose to treatment volume or activity is ≤ 0.9 times that intended over the whole course
8.1	Therapy total geographical miss (including nuclear medicine)	All total geographical misses, including for a single fraction or part of fraction
8.2	Therapy partial geographical miss (including nuclear medicine)	Where the miss exceeds 2.5 times the locally defined error margin and the guideline dose limit factors (see 7.1 & 7.2) are exceeded

In addition, complementary notification codes are supplied by the CQC to help identify specific types of incident. These should be used alongside a notification code from the table above. The complementary codes are as follows:

COMPLEMENTARY NOTIFICATION CODES	
M	Incidents where a theme has emerged after involving multiple individuals, or a single exposure incident has involved multiple people All cases, regardless of dose Plus suffix with appropriate code 1 – 8.2
E	Exposures where equipment fault or failure is the direct cause Plus suffix with appropriate code 1 – 8.2
V	Incidents where the criteria for statutory notification are not met, but for other unusual or significant circumstances may be valuable for wider learning Plus suffix with appropriate code 1 – 8.2
C	An event involving a clinically significant exposure—the definition of clinically significant is not included in the report, and instead refers the reader to guidelines published by “professional bodies” Plus suffix with appropriate code 1 – 8.2

Please continue to notify RPC of all radiation incidents in the normal way, even where you are aware that they do not meet the reporting criteria. RPC will normally respond in the form of a letter advising further action to be taken, including advice on the mechanism for reporting to the CQC (or other relevant authority outside England), where relevant.

Online incident reporting available

RPC has recently provided an online system to allow clients to report radiation incidents to us directly via our website. The system is available via our homepage (www.sghrpc.co.uk) by clicking the “Incident Reporting” tab at the top of the page. The online system is designed to streamline the reporting process for clients and ensure that we obtain all the information we need

to advise on the incident appropriately. Supporting documents can be emailed to info@sghrpc.co.uk.

Clients are welcome to continue reporting radiation incidents to us on paper or via email. We aim to provide a formal response to all radiation incidents within five days.

Guidance on IR(ME)R 2017 published by the Royal College of Radiologists

The Royal College of Radiologists (RCR) has recently published guidance on the implications of IR(ME)R 2017. The document, entitled *IR(ME)R: Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine*, aims to explain how the requirements of the regulations should be interpreted and used in practice. It explains the principles and requirements of IR(ME)R 2017 and provides clinical scenarios to help with the understanding of the practical interpretation of the regulations. The RCR advice effectively supersedes the Department of Health and Social Care guidance published in June 2018.

The practical consequences for RPC’s clients are deemed to be very small. Customers who are using the current version our Employer’s Procedure template (first issued Feb. 2018) should be substantially compliant with the advice given by the RCR and it is unlikely many changes will be needed. RPC have made some minor updates to our IR(ME)R 2017 procedures template since the RCR guidance was published. These include the definition of a “Clinically Significant Accidental or Unintended Exposure” (see separate article for details) and incorporation of the guidance for dealing with potential pregnancy in transgender individuals. These updates are available via our Dropbox link.

Please see the separate article on clinically significant radiation incidents for full details of how to access the RCR guidance.

Sentinel Node Localisation RPS handbook updated

Sites performing sentinel lymph node biopsies using Tc-99m nanocolloid will be pleased to know that we have updated our Radiation Protection Supervisor’s handbook for the procedure. The handbook is aimed primarily at sites who receive a radioactive patient for surgery following injection by a third party and has been significantly reformatted to improve its appearance and ease of use. The references have been updated to include the requirements of the EPR 2016, IRR 2017 and IR(ME)R 2017 legislation and use of the new handbook should help our customers ensure that they remain

compliant with the current regulatory framework. The handbook is now supplied with an Excel spreadsheet which can be used to record and analyse the data from the probe quality assurance checks. The spreadsheet is designed to automatically change the baseline and remedial levels as the Co-57 source used for the probe testing decays and will automatically highlight any probe readings that are out of tolerance. The revised handbook has detailed instructions on how to perform the probe quality assurance and links to videos demonstrating the QA being performed.

The handbook is also supplied with editable forms for recording contamination and waste, an improved radiation risk assessment template and an information sheet on the radiation risks for staff. Clients with whom we have a contract as Radiation Protection Adviser/ Radioactive Waste Adviser for the SLNB procedure may request a copy of the updated handbook and associated documents by emailing info@sghrpc.co.uk. RPC will also be pleased to support the SLNB procedure via telephone and email advice.

Royal College of Radiologists provides definition of a “Clinically Significant” radiation incident

In June this year, the Royal College of Radiologists published new guidance on IR(ME)R 2017 – ‘Implications for clinical practice in diagnostic imaging, interventional radiology and diagnostic nuclear medicine’.

Since the introduction of IR(ME)R 2017 it has been necessary to consider whether a radiation incident is clinically significant, in addition to whether it is a significant accidental or unintended exposure (SAUE). The guidance has provided clarification on the definition of clinically significant accidental or unintended exposures (CSAUE).

A CSAUE is defined for stochastic effects as an accidental or unintended exposure to ionising radiation that results in a 0.1% (1 in 1,000) or greater lifetime cancer risk or 0.1% or greater risk of childhood cancer in the case of fetal exposures.

For deterministic effects, a CSAUE is defined as an unjustified exposure resulting in greater than:

- 0.5 Gy to the lens of the eye
- 0.5 Gy to the heart or brain
- 5 Gy dose to skin including backscatter for skin reactions
- 50 mGy to the thyroid following the administration of a radiopharmaceutical

where there has been a failure in the thyroid blocking procedure

In rare circumstances, an accidental or unintended exposure may be considered a CSAUE regardless of the dose received by the patient if it affects the individual’s quality of life to a level that requires intervention or treatment.

Where it is determined that the radiation incident is clinically significant, IR(ME)R 2017 requires the referrer, IR(ME)R practitioner and patient (or their guardian) to be informed and advised of the outcome of the incident investigation. All incidents determined to be clinically significant should also be notified to the CQC, even where it does not meet the normal CQC reporting thresholds. RPC will advise on an individual basis whether a radiation incident meets the CSAUE criteria.

The full guidance document is available at: <https://www.rcr.ac.uk/publication/irmer-implications-diagnostic-imaging-interventional-radiology-diagnostic-nuclear-medicine>