Latest Care Quality Commission IR(ME)R Report Published

The latest IR(ME)R report from the CQC has been published and is available via their website at https://www.cqc.org.uk/sites/default/files/20181115-IRMER-annual-report-2017-18-FINAL.pdf. The report provides an analysis of notifications of unintended exposures between January 2017 and March 2018.
It covers an additional 3 months into 2018 in order to move to a schedule of analysing findings for the financial year rather than calendar year in the future.

Two key changes occurred since the last CQC report. In January 2017, the Department of Health and Social Care (DHSC) published new guidance on what constituted a dose 'much greater than intended' (MGTI). And in January 2018, new regulations IR(ME)R 2017 were enacted, which included significant changes in wording and definitions relating to radiation incidents. The definition of MGTI has been replaced with 'significant accidental or unintended exposure' (SAUE). Professional bodies expect to publish guidance and definitions relating to SAUE in 2019.

For the first time, the number of notifications decreased from the previous year

For the first time, the number of notifications decreased from the previous year (952 total notifications in 2017 vs. 1319 in 2016). This is likely a direct result of the DHSC 2017 guidance.

For the 15 month period of analysis, a total of 1226 notifications were made, of which 80% were from diagnostic radiology (no change from 2016). However the total number of diagnostic radiology notifications decreased by 30% between 2016 and 2017. This decrease in notifications can mainly be attributed to a decrease in notifications from CT exams (46% decrease) as the notification level for high dose CT exams increased from a multiplication factor of 1.5 to 2.5, thereby eliminating repeat exposures from needing to be reported to the CQC. Where there were no changes to the guidance, the numbers of notifications remained comparable with previous years. The majority of root causes for notifications in diagnostic radiology were from operator errors (57%) and referrer errors (41%). There was an unexpected increase in operator errors for plain X-rays, where staff have not checked a patient's identity before the X-ray (33% increase) or not checked the exposure factors before carrying out the examination (33% increase). Operators in these types of incidents cited time pressure as being a contributing factor leading to their error.

Several key themes were identified from notifications received for diagnostic imaging. The majority of diagnostic imaging departments have adopted the 'pause and check' initiative; however the CQC continue to receive many notifications where a simple 'stop' moment could have prevented an unintended or over-exposure. Employers should continue to reinforce this initiative to staff and remind them not to become complacent about checking the identity of patients or to be distracted by other pressures when carrying out these vital safety checks. The total number of errors by referrers when requesting examinations of the wrong patient increased slightly since the last report. In July 2017, the Society and College of Radiographers launched a referrer 'pause and check', which follows a similar concept to the one used by operators. More than 50 notifications were received where an examination had been carried out despite being cancelled. There were a range of causes for these incidents, such as confusion over who was responsible for the cancellation and poor communication between referrers and diagnostic imaging departments. Failures with interfacing between IT systems are also common, where cancellation messages are not communicated between e-referral systems and RIS.

This report highlights the importance of honest and open discussion surrounding errors in radiation

For Nuclear Medicine, notifications increased by 26% (77 in 2017 vs 61 in 2016). The increase can be directly attributed to the new 2017 guidance, which now includes reporting all incidents involving the administration of the incorrect radiopharmaceutical. The overall magnitude and risk profile of incidents remains relatively low and the CQC does not attribute the increase to deterioration in practice. The categories of error were comparable to previous years in terms of operator/administration and referrer errors.

For Radiotherapy, a decrease in notifications of 35% was seen compared to the previous year (123 in 2017 vs 189 in 2016). This is due to a decrease in notifications from planning and verification imaging of 53%, while the number of brachytherapy and beam therapy notifications remained largely comparable with previous years. This is again due to the change in the definition of notifiable incidents for CT examinations in the new 2017 DHSC guidance.

This report highlights the importance of honest and open discussion surrounding errors in radiation exposures within and between trusts in order to better instil a culture of radiation protection and to share good practice in order to prevent future incidents. RPC's customers should continue to report radiation incidents to us and we will advise when notification to the CQC is necessary, as well as give advice on the reporting process.

RPC News

The new IRR2017 and its impact on diagnostic radiology

The Ionising Radiation Regulations 2017 (IRR17) came into force on 1st January 2018, replacing the previous regulations, IRR99. Whilst the majority of the regulatory requirements remain the same, there are some key changes to be aware of.

Registration/Consent Process

One major change was the process for obtaining registration/consent with the Health and Safety Executive for carrying out work with ionising radiation. For further information, see the previous RPC newsletter (Spring/Summer 2018).

Risk Assessments

We have created an updated and improved risk assessment template that facilitates compliance with IRR2017. The new risk assessments include detailed dose estimates for various scenarios involving unintended exposures to both staff and patients. These are currently being rolled out across all sites.

Local Rules

It will also be necessary to update all local rules to facilitate compliance with IRR17. We have created an updated and more comprehensive local rules template which is currently being provided to our clients. The new local rules comprise a general section on the requirements of IRR 2017, with separate appendices giving systems for safe working for each modality. The most significant changes in the new local rules are as follows:

Outside workers

Outside workers are those who enter a controlled area who are not employees or directly contracted to work in the department. The definition of 'outside workers' now includes non-classified persons (compared to IRR99 which only referred to classified outside workers). The intention is that they will have the same level of protection as other employees in relation to training, instruction, protective equipment, dose monitoring and entry to controlled and supervised areas.

- Engineers are not considered outside workers as the controlled area is handed over to them.
- Student radiographers are not considered outside workers although local training should be provided as deemed necessary.
- Medical physics and technicians are considered outside workers. However they are trained in radiation safety so local safety instruction does not need to be provided.
- Agency staff are considered outside workers. They are expected to have a basic knowledge of radiation safety. However, the RPS should establish any further training needs with individual agency staff and local radiation safety instruction should be provided on an individual basis as necessary.
- The training for other outside workers should be considered on an ad hoc basis and the RPA may be consulted as necessary.

Reduced eye dose limit

The dose limit for exposure to the lens of the eye has been reduced from 150 mSv to 20 mSv per annum. It is therefore usually mandatory that staff close to the patient during interventional radiology wear protective eyewear (0.75 mm lead glasses). The requirement for eye dose monitoring should be determined by the risk assessment. Where lead glasses are worn, the dose should ideally be measured on the inside of the glasses to get a realistic estimate of eye dose. Alternatively headband or collar dose badges can be used to estimate eye dose. These are usually issued to staff whose eye dose is expected to exceed 5 mSv per year.

Contents

Welcome to the latest edition of RPC News

This newsletter focuses exclusively on the impact of the new regulations and gives you the key changes you need to be aware of.

We hope you find the information useful and if you need further clarity please don't hesitate to contact us by e-mail **info@sghrpc.co.uk** or by telephone on **020 8725 1050.**

Best wishes

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THE RADIOLOGICAL PROTECTION CENTRE
Incorporating The John Perry Laboratory

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Cooperation between employers

IRR99 required dose information to be shared between employers. However, IRR17 is more specific and the associated Approved Code of Practice states that it should be possible to determine where a dose was received in the event that a person exceeds a dose limit. This means that it may be necessary for staff working with different employers to have separate dose badges. However, the decision whether to provide workers with a single or separate radiation monitors will be based on whether they are expected to receive a significant dose at each site.

- Where a worker is employed in radiation work at your site which is likely to result in an annual dose exceeding 10% of any relevant dose limit and they also engage in such work with other employers, separate radiation monitors should be provided. Your organisation should then cooperate with the other employers to assess the worker's total occupational exposure and take action as appropriate.
- Where staff at your site are not likely to receive greater than 10% of any relevant dose limit, then the personal dose monitor issued by your site may also be worn for work with other employers. This will allow a total occupational exposure to be assessed using a single monitor. It would not be suitable to use separate dose monitors in this scenario as the dose detection thresholds of current dose monitors may be too high to detect the low doses expected at each site.
- If a radiation worker at your site has a different main employer and they are not expected to receive more than 10% of any relevant dose limit from work with any employer, then that employer's badge may be used for dose monitoring at your organisation.

For reference, the annual dose limits for employees and trainees of 18 years of age or above are 20mSv for whole body, 20 mSv for eye/collar and 500mSv for extremities.

Staff holding patients/carers and comforters

Comforters and carers are now under the remit of IRMER 2017, further information can be found in the new IRMER procedures being rolled out to all sites this year. In cases where it is not practical for a carer or comforter to hold a patient, a member of staff may carry out this function. Where this is deemed essential the following applies:

- The person holding the patient should not be pregnant and must be 18 years of age or over.
- They must wear appropriate protective clothing and must follow the instructions of the radiographer as to where to stand. This will ensure that any radiation dose received is as low as reasonably practicable.
- A record of the name of the employed person holding the patient should be kept. Holding duties should be shared between colleagues as far as practicable. The advice of the RPA should be sought where a single person is required to hold a patient more than five times in a year for high dose procedures e.g. CT or fluoroscopy.

RPS Handbook

We are aiming to provide a new RPS Handbook by the end of 2019 which will help you to comply with the new regulations. However, we are still waiting for the publication of the new Medical and Dental Guidance Notes before we can complete the new handbook.

RPC NEWS • SPRING/SUMMER 2019

IR(ME)R 2017: What Do You Need to Know?

The Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R 2017) came into force on 6th February 2018, replacing the previous regulations, IR(ME)R 2000 and its 2006 and 2011 amendments. Some of the significant changes are described here. These are reflected in RPC's new IRMER procedures template, which is available to all our clients. Further advice on the new ARSAC requirements under IR(ME)R 2017 will be provided in a future newsletter.

For further information, the Department of Health has produced a guidance document: **https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance.**

Employers Procedures

Schedule 2 of IR(ME)R 2017 sets out the requirement for employers to produce specific written procedures relating to protection of the patient. There are requirements for new employer's procedures under IR(ME)R 2017, as well as requiring amendments to existing ones.

Benefit and risk information for patients

It is now a requirement under IRMER to provide patients with information about the benefits and risks of the exposure they are about to receive. At present it is not necessary for the operator to proactively give this specific advice to the patient and it may be provided in the form of posters or leaflets in the department. Alternatively, the patient can be directed to suitable information via the RPC or www.gov.uk websites. However, where the patient specifically requests information on the radiation dose and risk from the procedure, the operator should attempt to provide information on the dose in terms of the time that would be required to receive the same exposure from sources of natural background radiation. Where relevant, the practitioner and/or operator should reference the justification process for medical exposures to the patient and make it clear that the examination will only take place because it has been deemed that the benefit from the examination outweighs any radiation risks, which are considered low. Further advice is expected to be provided by the Department of Health and RPC will keep customers informed of any changes to the process.

Clinically significant accidental or unintended exposures

'Clinically significant' incidents are currently undefined by the regulations. These are likely to be where the IRMER referrer or practitioner feels that the incident may have a significant adverse impact on the patient's care/clinical management. It is unlikely that incidents or accidents arising from diagnostic radiology or nuclear medicine would be considered clinically significant based on the radiation dose alone and RPC will advise on an ad hoc basis. Where it is determined that the radiation incident is clinically significant, the patient (or their guardian), referrer and practitioner should be informed of the incident, as well as provided with details of the incident investigation and its outcome. A formal definition of the term is likely to be provided by the Department of Health in due course and RPC will update its advice accordingly.

Carers and comforters

The role of carers and comforters is now included in IRMER (it previously came under IRR99). "Carers and Comforters" are individuals who knowingly and willingly incur an exposure to ionising radiation by helping, other than as part of their occupation, in the support and comfort of individuals undergoing or having undergone an exposure. The following actions should be applied for the exposure of carers and comforters:

- Justify the need for them to remain in the room during the exposure
- If the person is or may be pregnant, an alternative carer/comforter should be sought
- It is not recommended that persons under the age of 18 take on the role
- The risks should be discussed with them
- They should wear appropriate PPE and stand in an appropriate place
- The form provided in the employers procedures should be completed

Appropriate dose constraints are provided in the new employers procedures from RPC, which also contain a form to record that an exposure of a carer and comforter has taken place and capture details that the IR(ME)R requirements have been considered.

Non-medical exposures

The regulation for medico-legal exposures has been expanded to a more general definition of 'Non-Medical Exposures'. Non-medical imaging exposures are any deliberate exposure of humans for imaging purposes where the primary intention of the exposure is not to bring a health benefit to the individual being exposed; such as those required for court cases, immigration or other medico-legal purposes. The procedure to follow in such cases includes: Written request from a referrer, consent from the patient, justification from a practitioner, and a written clinical evaluation of the exposure including factors relevant to patient dose. Please consult RPC's new procedures template for further details.

Operator training

There is an increased emphasis on operator training. Schedule 3 of IR(ME)R 2017 sets out details of the training which operators (and practitioners) must have successfully completed. The subjects of Schedule 3 that would need to be covered will depend on the range of exposures the operator intends on carrying out. Evidence of competence to act as operator must be documented in that person's training file (or other suitable place) and a scope of practice document. Training records should demonstrate theoretical training, equipment-specific competence and adequate qualifications. For operators who are not employees, for example agency staff, the employer must seek assurance that they are adequately trained.

Patient Doses, DRLs and Optimisation

It is a legal requirement for patient doses to be recorded for all examinations. The term patient dose means any easily recorded value that is representative of patient exposure such as DAP for plain radiography/fluoroscopy or DLP for CT. Patient doses do not need to be recorded manually where they are captured electronically (i.e. on RIS/PACS) and the information is easily accessible. A more detailed explanation of the patient dose recording and audit process is included in the updated employer's procedure, including worked examples of calculations. This will allow departments to set local Diagnostic Reference Levels (DRL) which can be used to ensure doses are optimised. There may also be a need for increased involvement from an MPE in the optimisation of high dose CT and interventional radiology. We are awaiting further guidance of the level of MPE involvement required for such procedures.