IRMER 2017 – what your IRMER inspector will be looking for…

Sarah Peters - Clinical Specialist Inspector

Disclaimer

Nothing to disclose

The IRMER team at CQC

Who are we?

- **Rachael Ward** (Radiographer) – IRMER inspection manager
- **Cliff Double** (Clinical Scientist) – Diagnostics, south and central west
- **Sarah Peters** (Radiographer) – Diagnostics, London, southeast and East Anglia
- **Holly Warriner** (Radiographer) – Diagnostics, central midlands
- **Sean Duignan** (Radiographer) – Diagnostics, the north
- **Malcolm Ramsdale** (Clinical Scientist) – Nuc Med and Radiotherapy

Contact us at IRMER@cqc.org.uk Tel 020 7448 9025

The IRMER team at CQC

Primarily:

IR(ME)R regulators for England

- Have authority under the HSWA 1974 (like HSE)
- Investigate significant accidental or unintended exposures (SAUE)
- Inspect organisations to assure compliance
- Publish our findings to improve understanding

Other roles:

- Engage with stakeholder groups professions and partner enforcement authorities
- Support CQC ‘comprehensive inspections’ of radiology services
- Clinical specialist advice to policy makers and hospital inspectors

IRMER 2017

- IRMER 2017 came into force 6th February 2018
- More or less the same as IRMER 2000 but with some important changes:
    - Equipment (once it has been brought into clinical use) now falls under IRMER
    - Reportable incidents are now called accidental or unintended exposures as they now include under-doses in radiotherapy etc
    - Site and practitioner licences if NM examinations are being performed
    - Justification of exposures to carers and comforters (separate to justification of exposure to patient)
    - Communication of risk prior to the exposure

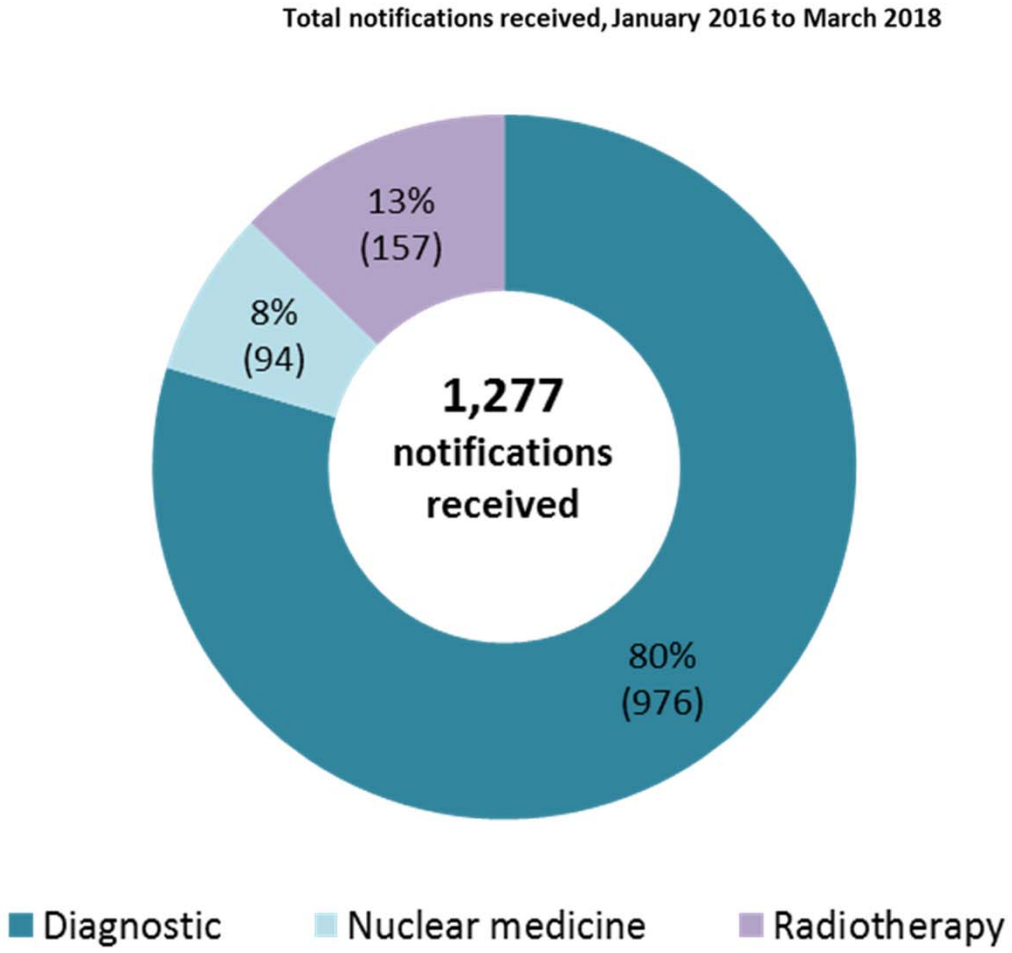
IR(ME)R 2017 – Myth, legend or reality?

Contrary it some beliefs ***IR(ME)R 2017 is not optional*** in the absence of guidance

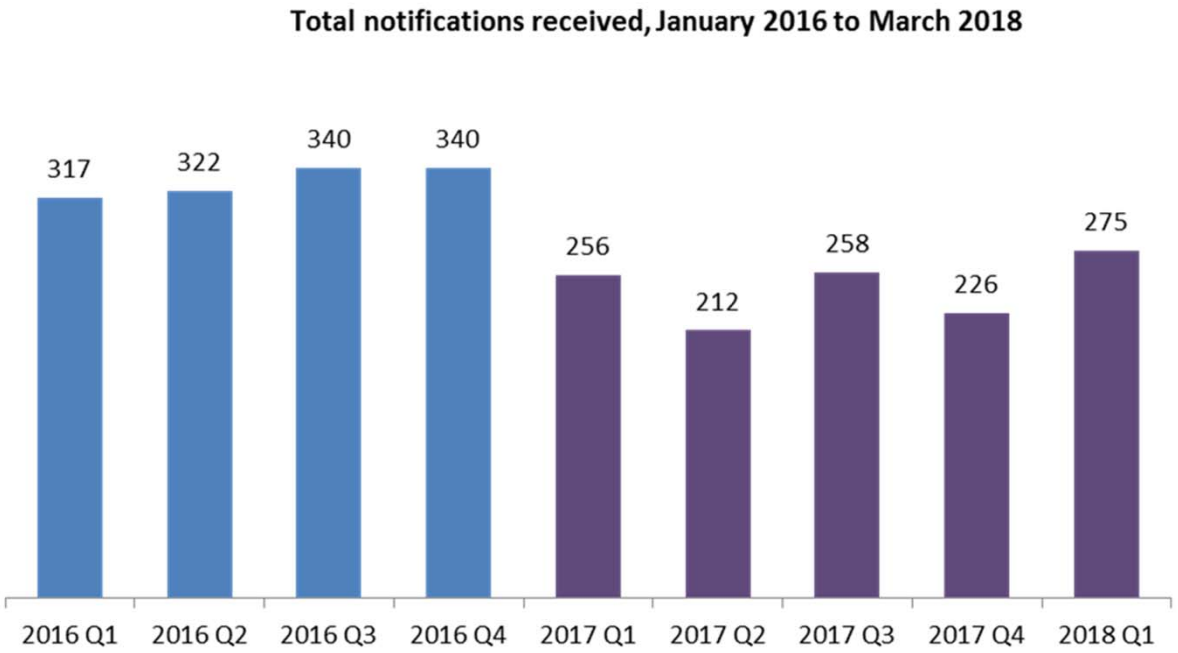
We require all departments bound by the regulations to have suitable and appropriate procedures in place for all provisions within IR(ME)R

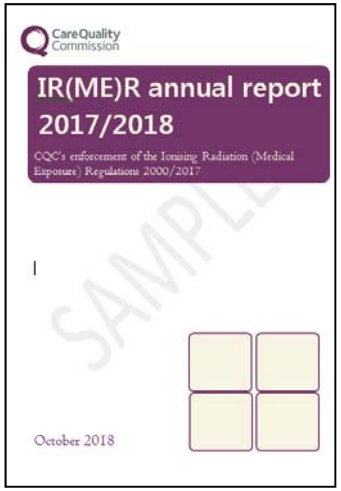
Reality!

Notifications received Jan 16 - March 18



IR(ME)R notifications





'Much Greater Than Intended' (IR(ME)R2000) changed to 'Significant Accidental or Unintended Exposure' (IR(ME)R2017)

Why it needs to change

‘SIGNIFICANT’

What is the risk to patients?

- Age – increased risks by a factor of 2-3 in early age compared to a reduction of 5-10 in later life.
- Dose – heavily weighted on low dose, low risk examinations (plain film and diagnostics)

Mean unintended dose (mSv)

Submodality	2016	2017	2018 Q1
CT	9.9	9.0	11.2
Plain film X-rays	1.2	0.8	1.3

‘GOVERNANCE’

More time inspecting and looking at general compliance

What changes are being made
(provisional)

Introduction of threshold criteria based on ages

Under age 16	16- 60	Over 60

Keeping multiplication factors – but clearly defining them by dose

Intended Dose category	Factor to be applied (intended + accidental) / intended
> 5mSv	1.5 or 2.5
RT planning/ verification	2.5
0.5-5 mSv	10
< 0.5 mSv	20

Clearer definitions of what constitutes an unintended or accidental exposure to allow for more consistency

Provider Information Returns (reg 8(3)) to ensure we do not lose intelligence

What will the impact be – on CQC

- New error coding and notification platform (more in depth analysis of errors)
- A significant reduction in diagnostic imaging notifications
- New collation of intelligence through an IR(ME)R specific data tool which will allow CQC have a greater overview of all radiation incidents not just ones that are notifiable. This will span across NHS and independent health organisations
- All of the changes will give a greater view of incident management and IR(ME)R compliance
- Increased inspection activity by the IR(ME)R team = more enforcement

IRMER notifications to CQC

Our process for notifications:

- Receive web-form notifications
- We conduct an initial risk triage, (to determine whether ‘immediate’ action required) and acknowledge receipt
- Internal system to alert colleagues in CQC
- Look for a *report* comprising risk assessment, evidence of review and escalation, shared learning locally, measures to prevent a recurrence
- Once we are happy that notification has been managed appropriately we will close it with an email to trust chief executive
- Publish some ‘highlights’ in our annual report (to meet Reg 9 requirement)

How we determine where to inspect

Proactive

Inspection Programmes

- Children's Hospitals (finishing soon)
- Low/high numbers of notifications vs activity
- Non Medical Imaging facilities (football clubs, gyms etc.)
- Independent providers (single specialties)

Reactive

- Concerns raised at a comprehensive inspection
- Risk based SAUE notifications
- Repeated notifications with no learning
- Whistle-blowers

What happens at an inspection?

Announced or Unannounced usually takes 4-6 hours

Morning

- Q&A with management, MPE, governance, superintendents
- Review documentation
    - Employer's procedures, radiation incidents, training records, protocols, authorisation guidelines

Afternoon

- Observe practice
- Talk to radiographers
- Review patients records on RIS

IRMER inspections

After the inspection we will produce a letter/report that is sent to your chief executive.

This report will:

- Outline our main findings
- List our requirements and recommendations
- Request an action plan from the site for addressing the requirements and recommendations

We will follow up on the action plan

Where breaches of IRMER are highlighted we may take enforcement action by issuing improvement or prohibition notices

Findings from recent inspections

We publish annual reports on our activities under IRMER on our website http://www.cqc.org.uk/content/key-findings-and-reports

Recent themes have included:

- Poor document control and QA of procedures and protocols
- Equipment quality assurance not routinely/consistency undertaken
- Capital replacement of aging equipment
- ARSAC Licences not renewed in timely manner
- All Schedule 2 procedures not being in place
- Procedures not matching clinical practice
- Poor oversight of equipment and staff outside of radiology (MINI C-ARMS!)

Increased inspection activity

Less notifications = more inspections

Employed new inspector which has already had an impact

2014 = 9 inspections, 2 INs

2015 = 5 inspections, 1 IN

2016 = 16 inspections, 4 INs

2017 = 13 inspections, 2 INs

2018 = 11 inspections, 3 INs *so far*

Will be following CQC methodology more with risk based approach to inspection driven by IR(ME)R and now incorporating wider CQC intelligence

Review of Core Service Framework for DI now greater emphasis on high level questioning with specific trigger points for escalation to IR(ME)R team

Examples of improvement notices

Enforcement register on CQC IR(ME)R website

- Poor governance surrounding the mini C-arm x2
- Inadequate training of a radiographer to undertake NAI skeletal surveys and not optimising paediatric x-ray unit
- Inadequate training of CT agency radiographer and not entitling agency radiographers
- Poor document control and procedure QA
- Incomplete training records x2
- Absence of clinical audit programme x2
- Absence of up to date employer's procedures x4
- Poor MPE support
- Equipment not routinely tested

DRLs for interventional procedures

IRMER Reg 6 (5)(c)(i)(bb) requires the employer to regularly review and make available DRLs for interventional radiology procedures, where appropriate.

- If you undertake interventional or cardiology procedures we would expect to see DRLs for commonly performed examinations
- A limited selection of national DRLs for interventional procedures are available on .GOV.uk website
- Might be more appropriate to set local DRLs for your depts. If your typical doses are much lower that the national ones

Interventional radiology national DRLs

3.3 Interventional procedures on adult patients

Interventional procedure	DAP per exam (Gy cm^2)	Fluoroscopy time per exam [3] (minutes)
Biliary intervention	43	14
Facet joint injection	6	1.4
Hickman line insertion	3	1.5
Nephrostomy	13	6.7
Oesophageal stent	13	5
Pacemaker (permanent)	7	6
Percutaneous transluminal coronary angioplasty (PTCA) (single stent) [4]	40	11.3

Medical Physics Experts

- MPEs now need to be formally appointed (much as RPAs are under IRR)
- The areas that MPEs should be involved in are now outlined e.g
  - Optimisation of the radiation protection of patients inc DRLs
  - Equipment QA and performance
  - Acceptance testing of equipment
  - Preparation of technical specifications of equipment and installation design
  - Advice to the employer on IRMER
- MPE recognition scheme is being operated by RPA2000

Carers and Comforters

- Carers and comforters are now under IRMER and not IRR
- The exposure of a carer/comforter must be justified separately from the justification of the patient
- The employer must establish dose constraints for carers and comforters
- There must be an employer's procedure for carers and comforters

Essentially, do what you were doing under IRR99 e.g. document who held, what PPE they were given, some indication that someone checked whether they were pregnant etc and get the individual to sign something

Information on the risks

- Schedule 2 (i) is a new required employer's procedure relating to information on the risks of the exposure
- The information should be provided to the patient, where appropriate, prior to the exposure
- Information should include the risks of not having the exposure (the aim of this requirement is to inform patients and not scare them into not having the examination)
- Could include this information in patient examination leaflets if they're being sent out with appointment letters
- Could also be included as part of a written consent procedure for interventional/cardiology procedures
- Some working parties are looking at producing possible resources but this may take quite a while

Publication of IRMER Inspection Reports and other resources

To date we have published:

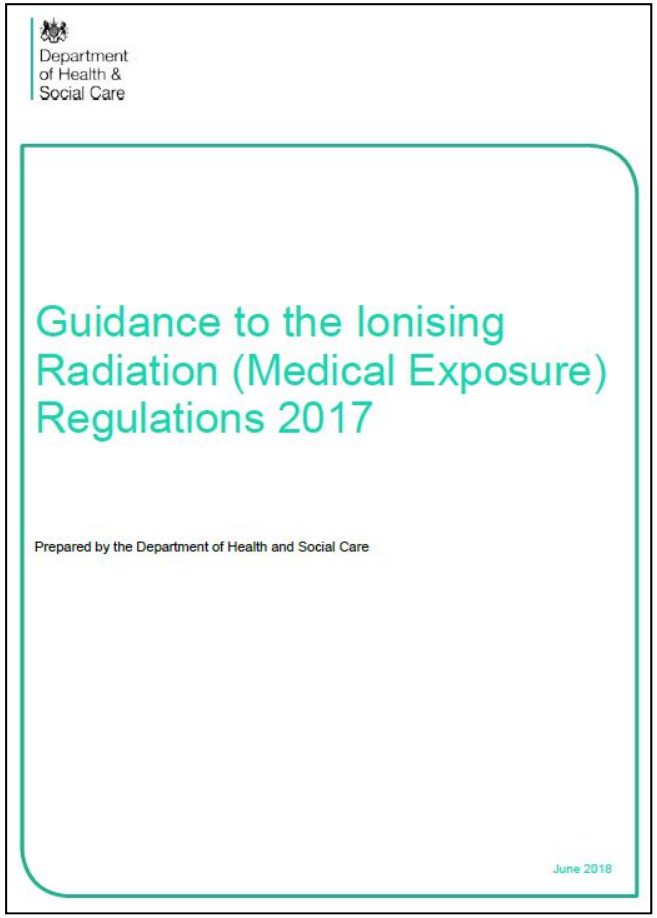
- 10 annual reports describing activities (2006-7, annually to 2016)
- 4 ‘quarterly’ reports (to 2008-9 – no longer published)
- 33 radiotherapy ‘organisation-specific’ inspection reports
- 1 summary ‘retrospective’ radiotherapy compliance report
- 1 summary ‘early findings’ radiology compliance report
- 8 cardiology inspection reports
- 1 review of radiology reporting backlogs

We have also published:

- Our enforcement policy
- Register of enforcement actions (IN, PN)

IRMER Guidance

- DHSC published guidance on IRMER 2017 on 27th June
- https://www.gov.uk/government/publications/ionising-radiation-medical-exposure-regulations-2017-guidance



What good looks like

- Clear radiation protection governance frameworks showing escalations and overview by employer
- Radiation protection committee incorporating a wide range of specialties and representatives outside of radiology department
- Evidence based procedures owned and used by clinical staff
- CPD of staff encouraging radiation protection at heart of practise
- Self assessment and audit of practice against IR(ME)R procedures and protocols
- Robust overview of local equipment QA
- Training records incorporating equipment and protocol training subject to regular review for **ALL** practitioner and operators
- LDRLs and staff dose knowledge
- Clear closing of the feedback loop for incidents