

Annual Report

Ionising Radiation (Medical Exposures) Regulations (IR(ME)R) 2017-2018



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Healthcare Inspectorate Wales (HIW) is the independent inspectorate and regulator of healthcare in Wales

Our purpose

To check that people in Wales receive good quality care.

Our values

We place patients at the heart of what we do. We are:

- Independent
- Objective
- Collaborative
- Authoritative
- Caring

Our priorities

Through our work we aim to:

Provide assurance:

Provide an independent view on the quality of care.

Promote improvement:

Encourage improvement through reporting and sharing of good practice.

Influence policy and standards:

Use what we find to influence policy, standards and practice.

1. Foreword

Healthcare Inspectorate Wales (HIW) is responsible for monitoring compliance with the Ionising Radiation (Medical Exposure) Regulations IR(ME)R 2000 and its subsequent amendments in 2006 and 2011. A new set of regulations, The Ionising Radiation (Medical Exposure) Regulations 2017, were introduced on 6 February 2018, however, all IR(ME)R compliance inspections carried out as part of our 2017-18 inspection programme took place before this date. The regulations are intended to protect patients from hazards associated with ionising radiation.

Whilst HIW is responsible for monitoring compliance with IR(ME)R, individuals working within healthcare organisations have both professional and legal obligations to ensure that patients undergoing medical exposures receive safe and effective care.

This report brings together our findings across NHS radiotherapy, radiology (including Cardiology) departments and NHS and private dental practices in Wales. It aims to identify common strengths and areas for improvements, and makes recommendations for organisations providing relevant services. It also highlights good practice to support improvement in the services provided to patients.

Individual reports have been published for all inspections and can be found on HIW's website www.hiw.org.uk

2. Summary

Whilst areas for improvement were identified across the radiotherapy, radiology departments and dental practices HIW inspected, overall these services had arrangements in place to provide safe and effective care to patients in relation to IR(ME)R.

During 2017-18 HIW completed a range of activities to monitor compliance with the Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2000. This included a programme of IR(ME)R compliance inspections of radiotherapy and radiology (including Cardiology) departments within NHS organisations, inspections of NHS and private dental practices and review of incidents notified to HIW involving 'exposures much greater than intended'¹.

During the course of our inspections of radiotherapy and radiology departments, we invited patients to provide feedback about their experiences of using these services. Positive comments were made, with patients telling us that they were happy with the service they had received. Overall, we saw that departments offered suitable areas for patients to wait and be seen. Where we identified improvement was needed, this was in relation to developing environments to further promote patients' privacy. Our inspections of dental practices were broader in scope but for the purposes of this report, only our findings specific to IR(ME)R are included.

HIW inspection teams found that radiotherapy and radiology departments provided safe and effective care and that staff made efforts to comply with IR(ME)R. We found dental teams were mostly compliant with the regulations for those areas of IR(ME)R we considered.

From our inspections of radiotherapy and radiology departments, we identified that improvement was needed around the level of detail within some written procedures and protocols, the arrangements for the entitlement of duty holders, the completeness of training records, privacy and dignity for patients and the replacement of ageing radiotherapy equipment.

In dental practices we identified improvement was needed around:

- Dentists recording the justification for and clinical evaluation of radiographs.
- Audit activity.
- Training in Ionising Radiation or record keeping to demonstrate that staff had received the necessary training.
- Completeness of radiation protection documentation.

¹ When a person undergoing medical exposure is exposed to ionising radiation to an extent much greater than intended, this should be investigated by the health care organisation and reported to HIW. Revised guidance on investigation and notification of medical exposures much greater than intended was published in January 2017. www.gov.uk/government/publications/the-ionising-radiation-medical-exposure-regulations-2000

Where incidents occur in which a person, whilst undergoing a medical exposure, has been exposed to ionising radiation to an extent 'much greater than intended', this should be investigated by the healthcare organisation and reported to HIW. From our evaluation of incidents involving exposures 'much greater than intended' we found that there was variation in the numbers of notifications received from healthcare organisations. The main reasons for patients receiving an exposure 'much greater than intended' was due to incorrect addressographs (labels with patient identification details) being used, a failure to correctly confirm a patient's identity and staff not checking previous imaging or treatment history. Investigation reports submitted by healthcare organisations demonstrated that action had been taken to reduce the likelihood of similar incidents happening again.

3. What we did

Prior to 6 February 2017, HIW was responsible for monitoring compliance with IR(ME)R 2000 (and its subsequent amendments 2006, 2011). From 6 February 2017 these regulations were revoked and replaced. As a result, HIW now monitors compliance against IR(ME)R 2017.

During 2017-18 we carried out our role through:

- A programme of IR(ME)R compliance inspections of NHS radiotherapy and radiology (including cardiology) departments.
- A programme of inspections of NHS and private dental practices.
- Reviewing incidents reported to us where patients had received exposures 'much greater than intended'.

IR(ME)R compliance inspections of NHS hospitals and screening services

HIW conducted IR(ME)R compliance inspections of the following:

- Radiotherapy Department, South West Wales Cancer Centre, Singleton Hospital (Abertawe Bro Morgannwg University Health Board).
- Radiography (diagnostic imaging) Departments, Brecon War Memorial Hospital and Llandrindod Wells Hospital (Powys Teaching Health Board).
- Diagnostic Imaging, Cardiac Department, Morriston Hospital (Abertawe Bro Morgannwg University Health Board).
- Diagnostic Imaging, Cardiac Department, University Hospital of Wales (Cardiff and Vale University Health Board).

Inspections of NHS and private dental practices

During 2017-18, HIW conducted a total of 104 inspections of dental practices. These included 79 practices providing both NHS and private dental services and 19 practices providing private only dental services. 6 follow up inspections were carried out at practices providing mixed NHS and private dental care.

Inspection methodology

Each of our IR(ME)R compliance inspections of NHS radiotherapy and radiology departments were announced. Each was given advance notice and required to complete and return a self-assessment to HIW prior to the inspection. This information allowed inspection teams to plan their approach and prioritise the areas to focus on. We were accompanied by senior clinical officers from Public Health England, acting in an advisory capacity. During our inspections we looked at documentation and information specifically to establish how departments were complying with IR(ME)R.

Inspections of dental practices were also announced. Each inspection was conducted by at least two members of HIW staff; a HIW inspector and a HIW dental peer reviewer. Dental peer reviewers were all currently practising general dental practitioners, or were recently retired from general dental practice. We considered how practices met the Health and Care Standards and, where private dentistry was provided, the Private Dentistry (Wales) Regulations 2008 and the Private Dentistry (Wales) (Amendment) Regulations 2011. HIW considered how each practice met these regulations, as well as IR(ME)R and any other relevant professional standards and guidance.

We provided an overview of our main findings to representatives of services at the feedback meeting held at the end of each of our inspections. Where we identified immediate risks to the safety and welfare of patients, these were brought to the attention of senior representatives within services at the time. We also followed these up in writing in accordance with our immediate assurance process.

Where we identify any serious regulatory breaches or concerns about the safety and wellbeing of patients, the organisation providing the service will be notified via a non-compliance notice. The issuing of a non-compliance notice is a serious matter and is the first step in a process which may lead to civil or criminal proceedings.

Following each inspection, the service was sent a draft report of our findings and (where necessary) an improvement plan to complete. The completed improvement plan informed HIW of the actions being taken to address the improvement(s) needed. All improvement plans were evaluated by HIW to determine whether the service had taken, or proposed to take sufficient action.

We published our findings within our inspection reports under three themes:

- Quality of the patient experience.
- Delivery of safe and effective care.
- Quality of management and leadership.

Once agreed, the improvement plan was also published alongside the final inspection report for each department or dental practice.

Individual reports for all our inspections and can be found on HIW's website www.hiw.org.uk

Notifications of exposures 'much greater than intended'

During 2017-18, HIW received 21 notifications of incidents where patients had been exposed to ionising radiation 'much greater than intended'.

The following shows the number of incidents within each health board locality:

Organisation	Number of incidents
Abertawe Bro Morgannwg University Health Board	3
Aneurin Bevan University Health Board	3
Betsi Cadwaladr University Health Board	2
Cardiff and Vale University Health Board	7
Cwm Taf University Health Board	3
Hywel Dda University Health Board	2
Powys Teaching University Health Board	0
Velindre NHS Trust	2

We required healthcare services to provide HIW with details of their investigation findings and the action taken as a result. We evaluated this information to determine whether the service had taken sufficient action to reduce the likelihood of similar incidents happening again. Incidents were only closed when HIW was content with the action taken by the service.

4. What we found

Quality of patient experience

We spoke with patients, their relatives, representatives and/or advocates (where appropriate) to ensure that the patients' perspective is at the centre of our approach to inspection.

Patients told us they were happy with the care they had received and we received many positive comments from patients via completed HIW questionnaires, in writing and through face to face conversations.

Patients felt that they had been given enough information about their care.

We found that environments provided safe and clean areas for patients to wait and be seen. However, improvements were identified relating to aspects of patients' dignity and privacy.

IR(ME)R compliance inspections of NHS hospitals and screening services

We sought patients' views about their experiences of using departments by inviting them to complete a HIW questionnaire. We also spoke to patients and their families who were visiting departments on the days of our inspections.

In total, 111 completed questionnaires were returned to us during the course of our IR(ME)R compliance inspections.

Patients told us that they were happy with the services they had received and praised the approach and attitude of the staff. Comments we received included:

"Great service offered to me. All staff are friendly and super efficient"

"Excellent service"

"This is the second time I have been... and both occasions have been pleasant as they could make things"

"Staff are a credit"

"All the staff from the cardiac day unit along with all operation theatre staff were warm, welcoming and kept me informed of all going on. The atmosphere was relaxed and easy going"

"Excellent service on arrival and throughout the day. Can't fault anyone"

"High quality service, very satisfied"

"The atmosphere generated by all in this department is second to none"

We also saw staff treating patients with respect and kindness during the course of our inspections.

Patients told us that they had been given enough information about their care and treatment.

Overall, we found that departments provided suitable environments for patients to wait and receive care. Within the diagnostic imaging and radiotherapy departments we saw that thought had been given to make waiting rooms pleasant areas in which patients could wait. For example, pictures were displayed and reading material was available.

We also saw that waiting areas and treatment rooms were clean and tidy, although further efforts could be made to protect patients' privacy and dignity. Whilst staff promoted patients' privacy and dignity as far as possible, environmental issues provided some challenges in this regard. For example, we identified improvements could be made to patient changing rooms by relocating them away from the main waiting area and adding dedicated private areas for patients to speak with staff when sensitive information needed to be shared.

When asked to provide comments about whether they had experienced any delays, patients told us that generally they had received timely care. Where delays had been experienced, this was due to patients being collected from their homes by the ambulance service much earlier than their treatment time (but were unable to receive their treatment any earlier) or delays in having their procedure performed. However, we were unable to determine whether these delays were due to clinical reasons or service pressures.

Delivery of safe and effective care

We considered the extent to which services provide high quality, safe and reliable care centred on individual patients.

Whilst we identified areas for improvement during our inspections, overall services had arrangements in place to provide safe and effective care to patients in relation to IR(ME)R.

The number of notifications of exposures 'much greater than intended' received varied across healthcare services. The main reason for patients receiving unnecessary over exposures was due to patient identification incidents.

IR(ME)R compliance inspections of NHS hospitals and screening services

Duties of employer

Each organisation had identified an employer in accordance with the regulations. This was the Chief Executive of the NHS Health Board or Trust and is in keeping with national guidance on implementing IR(ME)R.

Duties of the employer were set out in policy documents within all departments we inspected. We identified that these duties could sometimes be described more clearly and in practical terms for staff. Where they were not included, we required that this be addressed.

Procedures and protocols

It was evident that patient safety was a priority and this was reflected in the written procedures and policies in place. Whilst those procedures and policies required by IR(ME)R were available, we identified that some of these needed to be more detailed, could have been written more clearly for staff teams and better reflect current practice requirements. We found that improvement was needed within three of the four departments we inspected.

Incident notifications

We found that all departments had arrangements in place for the reporting, recording, investigation and learning from patient safety incidents. These arrangements included reporting incidents to HIW in accordance with IR(ME)R and Welsh Government as required through the Serious Untoward Incident/Never Events reporting system.

Diagnostic reference levels

We found that, where required, all departments had established diagnostic reference levels² (DRLs) and there were arrangements in place to monitor these. All departments also had local DRLs as well as national DRLs that had been determined taking into account the local population and equipment used. We identified this as noteworthy practice.

Staff were aware of the local procedure to follow should a DRL be consistently exceeded.

Entitlement

Senior staff within all departments we inspected were able to identify and describe the arrangements for the entitlement of duty holders, namely referrer, practitioner and operator.

Written procedures for entitlement accurately reflected those staff groups/individuals who were performing duty holder functions in practice in three of the four inspections undertaken. The procedures also set out the expected level of training for each entitled staff group together with their scope of practice.

We looked at a sample of training and competency records for different grades of staff working within each of the departments we inspected. The completeness of such records varied. We saw examples where comprehensive training records had been maintained, whilst others we saw were incomplete.

Referral criteria

We found that all departments had procedures and referral criteria for referring patients for medical exposures.

Justification

We found that all departments had procedures in place for justifying medical exposures of patients.

Identification

We found that all departments had procedures in place for the positive identification of patients with the intention of ensuring the correct patient underwent the correct medical exposure. Staff working in departments, and with responsibility for correctly identifying patients, were able to describe the procedure to follow.

Whilst procedures were in place, one of the main reasons for patients receiving an exposure 'much greater than intended' was due to patient identification errors (see section *Notifications of exposures 'much greater than intended'*). Organisations need to ensure that they adhere to their procedures and act according to them to minimise incidents.

² The objective of diagnostic reference levels is to help avoid excessive radiation doses to patients. DRLs are used as a guide to help promote improvements in radiation protection practice.

Females of childbearing age

We found that all departments had procedures in place to identify potentially pregnant women and also those who may be breastfeeding. Staff we spoke to were able to describe the correct procedure to follow.

As an additional safety system, we saw signs were displayed advising female patients to let staff know if they were or could be pregnant and/or were breast feeding.

Medico legal exposures

Where departments performed exposures for medico legal reasons, we found that procedures were in place.

Optimisation

We found that all departments had arrangements for keeping doses of diagnostic medical exposures As Low As Reasonably Practicable (known as ALARP). However, one of the departments did not have a specific procedure in place to demonstrate how this was done.

Paediatrics

Where departments provided services to children, we found that procedures were in place for medical exposures of children.

Clinical evaluation

All departments had arrangements for the clinical evaluation of medical exposures.

Medical and research programmes

Where departments were involved in medical and research programmes we found that procedures were in place setting out the arrangements for these. However, two departments needed to review and revise their procedures to accurately reflect current practice.

Clinical audits

We saw evidence that audit activity had been conducted within all the departments we inspected. The aim of these audits is to identify possible areas where service improvements could be made. However, in one department we did not have sight of the department's annual audit plan at the time of the inspection.

Expert advice

We were able to confirm that Medical Physics Experts (MPEs) were available to provide advice on medical exposures to staff teams within each of the departments.

Equipment

Each department was able to provide an up to date written inventory of equipment being used. These contained all the information required under IR(ME)R.

In the South West Wales Cancer Centre (radiotherapy department) we identified that the department had aging Radiotherapy equipment. Action should be taken to replace this equipment which would result in the department being able to deliver a wider range of procedures and increase the numbers of timely, higher-dose radiotherapy treatments.

IR(ME)R compliance inspections – Immediate assurance

We did not identify any imminent risk of harm to patients; therefore it was not necessary for HIW to issue improvement notices to any of the departments we inspected in accordance with HIW's immediate assurance process.

We did not identify any serious or regulatory breaches or concerns; therefore HIW did not issue any non-compliance notices to any of the departments.

Inspections of NHS and private dental practices

The number of issues identified through HIW's inspection of dental practices has reduced, but the areas for improvement remain the same. In the majority of cases practices had good arrangements in place for the safe use of radiography equipment and to ensure the highest possible image quality. In a small number of dental inspections (around 15%) we found that practices needed to review and make improvements in some areas. Where practices were good, we found that they had well organised radiation protection files, evidence of up to date training for all relevant staff and suitable practical arrangements to ensure that each x-ray was taken as safely as possible. Whilst the majority of patient dental records showed evidence of the justification for taking the x-ray and a note of the findings, in around 20% of the practices inspected we found instances where radiographs had not been justified.

Aside from justification, the other recurring issues we found were:

- Maintenance certificates for the x-ray equipment were in need of renewal.
- Insufficient training in Ionising Radiation or a lack of evidence available at inspection to demonstrate that staff had received the necessary training.
- In some practices we found image quality audits had not been completed, or found that audits were only being completed on an ad hoc basis. We also found poor quality audits which had identified issues but lacked follow up actions to resolve the problems identified. Image quality audits should be carried out regularly to ensure that x-ray quality is as good as possible for the most effective use of this as a diagnostic tool.
- Incomplete Radiation Protection Files.

We did not issue any non compliance letters to dental practices in relation to IR(ME)R.

Notifications of exposures ‘much greater than intended’

During 2017-18, HIW received 21 notifications of exposures ‘much greater than intended’. This is a decrease from 65 in the previous year.

Of the notifications received, 19 occurred in diagnostic imaging departments, one occurred within a radiotherapy department and one occurred within a nuclear medicine department. Each notification affected a single patient receiving a given exposure and so did not result in harm or affect the outcome of any treatment.

The following table shows the number of notifications received annually by HIW between 2012 and 2018, as part of our IR(ME)R enforcement responsibilities in Wales.

Year notifications received						
	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18
Number of notifications	32	47	46	45	65	21

The main reasons for patients receiving an exposure ‘much greater than intended’ within diagnostic imaging and nuclear medicine departments were due to incorrect addressographs (labels with patient identification details) being used, a failure to correctly confirm a patient’s identification, or the failure to check previous imaging or treatment history. These resulted in patients receiving unnecessary or repeat procedures. In the notification relating to the radiotherapy department, the incident was caused by a failure to adjust the treatment couch to the planned position prior to treatment.

Quality of management and leadership

We considered how services are managed and led and whether the workplace and organisational culture supports the provision of safe and effective care.

Overall, we found effective leadership and management arrangements around IR(ME)R with clear lines of accountability and reporting.

IR(ME)R compliance inspections of NHS hospitals

Overall, we found arrangements to support the effective management and leadership of the radiotherapy and radiology departments with clear lines of reporting and accountability in place. Staff at all levels engaged well with HIW inspection teams and showed that they were committed to providing a safe service to patients.

We found examples of effective management arrangements during the course of our inspections, provided by both senior managers and team leaders within departments.

Senior management staff demonstrated a commitment to making improvements as a result of our inspection findings.

Where we identified regulatory breaches or areas for improvement, organisations were required to provide HIW with improvement plans. Overall, plans were comprehensive and submitted within agreed timescales. Where necessary HIW requested further information until we were assured that suitable action had been taken or was being taken to address the improvement needed.

5. Conclusions

Whilst areas for improvement were identified across the services and dental practices we inspected, overall these services had arrangements in place to provide safe and effective care to patients in relation to IR(ME)R.

We found that some employers' written procedures and protocols would benefit from being more detailed to help guide staff teams involved in medical exposures. Employers also need to ensure that all individuals with responsibility for medical exposures and/or operating associated equipment are trained and entitled to perform these functions.

In relation to IR(ME)R within dentistry, practices need to ensure that dental professionals involved in taking exposures have attended the required training. In addition, dentists must always record the justification for medical exposures and their evaluation. Also, audit activity must demonstrate what improvement action, if required, has been taken.

During 2017-18 the number of notifications to HIW from healthcare organisations varied by health board/trust. Higher numbers of notifications from particular organisations may be due to an open and positive reporting culture, rather than indicating failures in procedures or safety issues. Another reason for this variation may be due to how organisations interpreted 'much greater than intended'. We saw a decrease in the overall number of notifications notified to HIW this year. This may be due to the revised arrangements for reporting IR(ME)R incidents together with the updated guidance on incidents which was issued in January 2017.

This is HIW's 4th annual report regarding compliance with IRMER and once again the main reason for patients receiving an exposure much greater than intended is due to patient identification errors. We would encourage all services conducting medical exposures to review their procedures and training to and identify meaningful action to tackle this issue.

6. What next?

HIW's operational plan³ for 2018-19 sets out our commitment in relation to IR(ME)R. During this period, we aim to conduct approximately five IR(ME)R compliance inspections and 70 dental practice inspections. In addition HIW will continue to evaluate notifications involving exposures 'much greater than intended' from healthcare organisations. We will publish reports from our inspection activity in accordance with our performance standards.

HIW will continue to work closely with our stakeholder groups and the Medical Exposures Group of Public Health England to develop our approach to these inspections and update HIW's IR(ME)R self-assessment and inspection tools. In line with IR(ME)R 2017, HIW is working with Public Health England (PHE) to update our inspection methodology so that it aligns with the requirements under the IR(ME)R 2017.

HIW will also continue to build in-house expertise to lead and support its IR(ME)R work activity through a training programme for HIW staff.

³ HIW Operational Plan 2017-18 www.hiw.org.uk/docs/hiw/publications/170330opplanen.pdf

Appendix A – Recommendations

As a result of the findings from our four inspections in date, we have made the following overarching recommendations which all services should consider as part of providing a safe and effective service.

Recommendations	Regulation/Standard
Patient Experience	
Organisations must maintain a focus on promoting patient privacy and dignity.	Health and Care Standards – Standard 4.1
Delivery of safe and effective care	
Written procedures and protocols should be sufficiently detailed and clear for staff to understand and reflect current practice requirements.	IR(ME)R – Regulation 4(1) and Schedule 1
Dentists (who may be practitioners and operators) must record the justification and authorisation for taking exposures and their clinical evaluation.	IR(ME)R – Regulation 6(1)(a), (b) and 7(8)
Quality of management and leadership	
Organisations must maintain a focus on ensuring the positive and correct identification of patients to reduce the risk of patients receiving unnecessary or repeat medical exposures.	IR(ME)R – Regulation 4(1)(a) and Schedule 1(a)

Appendix B – Glossary

Term	Definition
Duty Holder	Duty holders include the following: <ul style="list-style-type: none"> • Employer • Referrer • Practitioner • Operator.
Employer	Any natural or legal person who carries out or engages others to carry out, medical exposures or practical aspects, at a given radiological installation.
Referrer	A registered healthcare professional who is entitled, in accordance with the employers procedures, to refer individuals for medical exposures.
Practitioner	A registered healthcare professional who is entitled, in accordance with the employers procedures, to take responsibility for an individual medical exposure. The primary role of the practitioner is to justify medical exposures.
Operator	Any person who is entitled, in accordance with the employers procedures, to carry out the practical aspects of a medical exposure.
Entitlement	The process of defining the duty holder roles and tasks that individuals are allowed to undertake.
Justification	The intellectual process of weighing up the potential benefit of a medical exposure against the detriment for that individual from the ionising radiation risk.
Medico Legal Exposure	Procedure performed for insurance or legal purposes without a medical indication.
Optimisation	The process by which individual doses are kept as low as reasonably practicable.
ALARP	As Low as Reasonably Practicable.
Medical Physics Expert	A person who holds a science degree or its equivalent and who is experienced in the application of physics to diagnostic and therapeutic uses of ionising radiation.