# Post-Implementation Review of Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017

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| **Title:** Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) 2017 | Post Implementation Review |
| **PIR No:** 9606 | **Date: 10/11/2023** |
| **Original IA/RPC No:** Click here to enter text. | **Type of regulation:** Domestic |
| **Lead department or agency:** DHSC | **Type of review:** Statutory |
| **Other departments or agencies:** Click here to enter text. | **Date measure came into force:** 06/02/2018 |
| | **Recommendation:** Amend |
| Contact for enquiries: Priya Iype (Priya.iype@dhsc.gov.uk) | **RPC Opinion:** Choose an item. |

**1. What were the policy objectives of the measure?** (Maximum 5 lines)

The Ionising Radiation (Medical Exposure) Regulations (IR(ME)R) implement the medical exposure aspects of the European Council Directive 2013/59/Euratom, which establishes uniform basic safety standards to protect the health of patients, workers and the general public against the dangers arising from ionising radiation.

The amendments revoke and replace the Ionising Radiation (Medical Exposure) Regulations 2000, The Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS), and The Medicines (Radioactive Substances) Order 1978 (MARO) regulations. The high level policy objectives of the regulations are to:

- Implement the medical exposure aspects of the European Council Directive 2013/59/Euratom
- Ensure that individuals are protected when exposed to ionising radiation from medical equipment

IR(ME)R 2017 is broadly similar to the (repealed) 2000 version of the regulations. The main differences are that the 2017 version includes additional provisions relating to medical physics experts, licensing, and reporting of underexposures in radiotherapy. The specific objectives of these additional provisions are as follows:

- regulation 14: Introduction of formal recognition of medical physics experts (MPEs) to ensure MPEs are appropriately educated and trained
- regulation 5: Introduction of licensing for doctors and employers who administer radioactive substances for the purposes of diagnosis, treatment, or research to streamline certification processes and maintain patient safety standards
- regulations 8 and 9: Introduction of a notification requirement for underexposures in radiotherapy to enhance learning and implementation of protective measures

**2. What evidence has informed the PIR?** (Maximum 5 lines)

Stakeholder consultation: The Department of Health and Social Care (DHSC) has had regular contact with stakeholders over the last 5 years, and no major concerns regarding the regulations had been highlighted. As a result, an informal light-touch approach to stakeholder consultation (verbal feedback through video calls and written feedback via email) was deemed proportionate to obtain stakeholder views and feedback on IR(ME)R17.

Quantitative data: Monitoring data has been collected from regulators to examine the actual impact of the regulations in comparison to estimates calculated as part of the regulatory triage assessment (RTA), as well as to review any unintended consequences which have arisen as a result of IR(ME)R17. This includes:

- data on MPE recognition from RPA2000 (RPA2000 operates the certification scheme for MPEs)
- licensing data from the Administration of Radioactive Substance Advisory Committee (ARSAC)
- underexposures data from regulators

Wider literature: A literature search was conducted to gather insight into regulation enforcement activity, knowledge of the regulations among healthcare professionals, and the use of artificial intelligence (AI) in medical settings related to the use of ionising radiation. The latter was examined in response to informal feedback from stakeholders over the past five years, which informs some of the proposed amendments. Key data sources reviewed include academic literature and regulator reports.

**3. To what extent have the policy objectives been achieved?** (Maximum 5 lines)

The amendments to the regulations have been successful in introducing formal recognition of MPEs and streamlining the system for those who are licensed to use ionising radiation in medical settings. There were no reported underexposures in radiotherapy, however, to further contextualise this finding, in the 25 years prior to IR(ME)R17 coming into force there had only been one major underexposure incident.

Sign-off for Post Implementation Review: Chief economist/Head of Analysis and Minister

***I have read the PIR and I am satisfied that it represents a fair and proportionate assessment of the impact of the measure.***

Signed: *Chris Mullin* Date: 12/05/2023
Signed: *Nick Markham* Date: 10/11/2023

## Further information sheet

Please provide additional evidence in subsequent sheets, as required.

**4. What were the original assumptions?** (Maximum 5 lines)

The original assumptions of IR(ME)R 2017 are as follows:

Regulation 14: Introduction of formal recognition of medical physics experts (MPEs) to ensure MPEs are appropriately educated and trained

Regulation 5: Introduction of licensing for doctors and employers who administer radioactive substances for the purposes of diagnosis, treatment, or research to streamline the system and maintain patient safety standards

Regulations 8 and 9: Introduction of a requirement to notify regulators of underexposures in radiotherapy will enhance learning and implementation of protective measures

**Table 1:** Total increase in the cost to business (as set out in the Regulatory triage assessment, 2017):

| Year(s) | Total (£000s) | Direct (£000s) | Indirect (£000s) |
|---|---|---|---|
| **Year 1** | 66 (36 to 116) | 120 (91 to 155) | −54 (−67 to −39) |
| **Years 2-5** | 45 (18 to 90) | 99 (74 to 130) | −54 (−67 to −39) |
| **Year 6** | 57 (29 to 105) | 111 (84 to 144) | −54 (−67 to −39) |
| **Years 7-10** | 45 (18 to 91) | 99 (74 to 130) | −54 (−67 to −39) |

The above total costs are comprised of:

- The total estimated annual increase in cost to business as a result of the compulsory recognition of MPEs (Regulation 14): £12,000 (£0 to £39,000), indirect cost
- The total estimated increase in cost to business as a result of the changes to licences for the application of radioactive substances (Regulation 5; see Table 2):

**Table 2:** Breakdown of total increase in cost to business as a result of Regulation 5 (as set out in the Regulatory triage assessment, 2017):

| £000s | Total | Direct | Indirect |
|---|---|---|---|
| **Year 1** | 54 (36 to 77) | 120 (91 to 155) | −66 (−78 to −56) |
| **Years 2-5** | 33 (18 to 51) | 99 (74 to 129) | −66 (−78 to −56) |
| **Year 6** | 45 (29 to 66) | 111 (84 to 144) | −66 (−78 to −56) |
| **Years 7-10** | 33 (18 to 52) | 99 (74 to 130) | −66 (−78 to −56) |

There were no estimated costs associated with the notification of underexposures in radiotherapy amendment (Regulations 8 and 9) due to a low number of incidents.

**5. Were there any unintended consequences?** (Maximum 5 lines)

Some unintended consequences were highlighted during stakeholder consultation including:

- an increased reporting requirement due to shifts in some radiology practice impacting dose limits
- the lack of a defined programme of study in the regulations resulting in an increase in individuals using ionising radiation who should not in some instances
- challenges concerning the role of carers and comforters[1] in nuclear medicine settings

[1] 'Carers and comforters' are defined in IR(ME)R17 as "individuals knowingly and willingly incurring 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"

- IR(ME)R acting as a benchmark can result in employers not always seeking to build a better service if they receive an adequate inspection.

Technological advances, such as the use of artificial intelligence, mean that the regulations would benefit from being amended to regulate the use of new technology for exposures to ionising radiation falling within the remit of the regulations.

**6. Has the evidence identified any opportunities for reducing the burden on business?** (Maximum 5 lines)

No. Our assessment is that the regulations provide sufficient latitude for employers to adopt processes and procedures that meet the requirements of the regulations but also reflect local practice, population needs and service delivery models. This has also been supported by stakeholders. The regulations are still required to ensure patient safety while undergoing medical and non-medical exposures using medical equipment.

**7. How does the UK approach compare with the implementation of similar measures internationally, including how EU member states implemented EU requirements that are comparable or now form part of retained EU law, or how other countries have implemented international agreements?** (Maximum 5 lines)

The UK approach is broadly similar to EU member states with subtle differences that reflect the UK healthcare delivery model and availability of highly trained staff. For example, the regulations include an additional duty holder role, the 'operator' who in practice, takes responsibility for performing practical aspects of the exposure. In EU members states, the clinician takes responsibility for the whole process.

## 1. Scope of the Post-Implementation Review (PIR)

This PIR considers whether the Ionising Radiation (Medical Exposure) Regulations 2017 (IR(ME)R17), met the intended objectives. The PIR also considers the impacts of IR(ME)R since the regulations came into force on 6 February 2018.

The regulations are not considered to be particularly high profile or contentious because they have broadly remained the same since the year 2000, which is when an earlier version of IR(ME)R commenced. As a result, in accordance with PIR guidance from the Better Regulation Unit at the Department of Health and Social Care, a light touch approach to analysis has been undertaken.

In accordance with the Magenta Book guidance, this report is required to understand if IR(ME)R17:

- has achieved its original objectives as set out in the Regulatory triage assessment
- has resulted in any unintended effects
- has objectives which are still valid
- is still required and remains the best option for achieving those objectives
- can be improved to reduce the burden on business and its overall costs

## 2. Background to the IR(ME)R regulations and their objectives

IR(ME)R implement the medical exposure aspects of the European Council Directive 2013/59/Euratom, which establishes uniform basic safety standards to protect the health of patients, workers and the general public against the dangers arising from ionising radiation.

The amendments revoke and replace the Ionising Radiation (Medical Exposure) Regulations 2000, The Medicines (Administration of Radioactive Substances) Regulations 1978 (MARS), and The Medicines (Radioactive Substances) Order 1978 (MARO) regulations. The high level policy objectives[2] of the regulations are to:

- Implement the medical exposure aspects of the European Council Directive 2013/59/Euratom
- Ensure that individuals are protected when exposed to ionising radiation from medical equipment

IR(ME)R 2017 is broadly similar to the (repealed) 2000 version of the regulations. The main differences are that the 2017 version includes additional provisions relating to medical physics experts, licensing, and reporting of underexposures in radiotherapy. The specific objectives of these additional provisions are as follows:

- regulation 14: Introduction of formal recognition of Medical Physical Experts (MPEs) to ensure MPEs are appropriately educated and trained
- regulation 5: Introduction of licensing for Doctors and Employers who administer radioactive substances for the purposes of diagnosis, treatment, or research to streamline certification processes and maintain patient safety standards
- regulations 8 and 9: Introduction of a notification requirement for underexposures in radiotherapy to enhance learning and implementation of protective measures

## 3. Assessment of proportionality

[2] The Ionising Radiation (Medical Exposure) Regulations 2017 (legislation.gov.uk)

Guidance outlines that PIRs should assess the following:

- The extent to which the existing regulation is working
- Whether government intervention is still required
- Whether the regulations and the way they are implemented remain the most appropriate approach

The Better Regulation Unit outlines that the level of evidence obtained and analysed to produce a PIR should be proportionate to the measures' cost to business.

The estimated cost to business as set out in the IR(ME)R 2017 Regulatory triage assessment was £213,000 (£101,000 to £402,000) (see Table 1), and therefore significantly less than the +5million threshold, meaning it is considered to have a low cost impact. The regulations are also considered non-contentious as they have broadly remained the same since the year 2000. Therefore, in line with the Better Regulation Unit and Regulatory Policy Committee[3] guidance, a light-touch approach is deemed to be sufficient for the IR(ME)R PIR.

## 4. Evidence collection and methodology

The evidence gathered and analysed to answer these questions fall into 3 categories:

- Consultation with key stakeholders
- Review of quantitative data collected from regulatory bodies
- Review of wider literature (academic and from regulatory bodies)

Consultation with key stakeholders

A light-touch consultation was conducted by DHSC with key stakeholders, which comprised of an online group call with a representative from each of the 4 regulators[4], a representative from the UK Health Security Agency (UKHSA), and a DHSC lawyer to gather verbal feedback on the measures. Written feedback was also obtained via email from external stakeholders. A total of 8 groups were contacted as part of the consultation:

- Radiotherapy Board
- Society and College of Radiographers
- Northern Ireland Regional Medical Imaging Board
- Northern Ireland Regional Medical Physics Service
- Heads of NHS Radiation Protection Departments in Scotland
- British Institute of Radiology
- Royal College of Radiologists
- Institute of Engineering in Medicine

A total of 5 written responses were received, however non-responders may have already fed into comments made by other stakeholder groups due to a high level of cross-group membership. Furthermore, responses have been received from the 3 main staff groups (radiographers, radiologists and medical physicists) and cover all 3 modalities (radiology, radiotherapy and nuclear medicine).

Responses were also received from the following arm's length bodies or executive agencies:

- Care Quality Commission (CQC)

[3] The Better Regulation Framework (publishing.service.gov.uk)

[4] The Care Quality Commission (CQC), Healthcare Inspectorate Scotland (HIS), Healthcare Inspectorate Wales (HIW), and The Regulation and Quality Improvement Authority Northern Ireland (RQIA)

- Healthcare Improvement Scotland (HIS - Scottish IR(ME)R regulator)
- Healthcare Inspectorate Wales (HIW - Welsh IR(ME)R regulator)
- The Regulation and Quality Improvement Authority (RQIA – Northern Ireland IR(ME)R regulator)
- United Kingdom Health Security Agency (UKHSA)

The following consultation questions were asked:

1. What improvements have you seen as a result of IR(ME)R 2017?
2. What didn't work as well as you thought it might when the regulations came into force in 2018?
3. Have there been any unintended consequences?
4. Would you make changes to the regulations, and if yes what changes should be made?

Quantitative/monitoring data

- MPEs recognition data from RPA2000 (DHSC authorised assessing body) to understand how the scheme has been implemented
- Licensing data from ARSAC (the Administration of Radioactive Substances Advisory Committee) to understand how the scheme has been implemented, whether it has succeeded in streamlining processes while maintaining patient safety standards

Wider literature

- A review of regulator reports from the last 5 years was conducted to gather insight into regulation enforcement activity.
- Academic literature was sourced using searches on PubMed and ProQuest using search terms 'IR(ME)R', 'ionising radiation regulation', 'knowledge of IR(ME)R/ionising radiation legislation/regulation'. In response to stakeholder engagement over the last 5 years, a search was conducted for 'AI' and 'artificial intelligence' use in medical settings using ionising radiation. Searches were limited to publications dated between 2018 and 2022.

## 5. Are the existing regulations working? What if any have been the unintended consequences? What are the areas for improvement?

Consultation responses

Broadly speaking, all consultees are supportive of the IR(ME)R regulations. Some unintended consequences and areas for improvement were raised during the consultation process, alongside examples of how IR(ME)R has led to improvements.

All consultees commented on the role of IR(ME)R in streamlining and enforcing procedures which protect patients and the workforce. Examples referenced include 'tightening up of equipment quality control testing procedures', 'eased reporting of incidents involving equipment now that equipment and [quality assurance] is under IR(ME)R', and 'improved incident analysis and follow up...incident reporting process, and positive engagement in response to each incident, has been a particular benefit'. The consultation also highlighted the positive benefit to the workforce, such as development of the MPE role, and commitment of practitioners and employers to comply with the regulations.

Four unintended consequences were highlighted by consultees:

1. Challenges ensuring that an individual takes on the carer and comforter[5] role in nuclear medicine settings: One consultee highlighted that unless an individual attends the setting with the patient, there are challenges in assuring that the carer and comforter "knowingly and willingly" takes on the role. This can make the process of justification and consent of nuclear medicine patients challenging. In addition, if someone does not want to take on the role it is unclear how they should be treated. However, it was highlighted that a pragmatic response to this tends to be taken, through flexible procedures and guidance which defines who should be defined as a carer or comforter, which is advised by the RCR.
2. Need for increased reporting: One consultee reported that the requirement to report to the Care Quality Commission any procedural error that causes an increase in verification dose of 20% has led to a need for increased reporting as radiotherapy treatments have become more hypofractionated[6]. On some occasions, the increase in dose can be very small.
3. IR(ME)R acting as the benchmark: One consultee highlighted that the regulations are seen as the 'gold standard' rather than the 'minimum standard'. As a result, some employers may not focus on continuing to take action to improve and create an excellent service if they receive an adequate inspection.
4. Lack of a standard programme of study: One consultee reported that there is no defined approved or standard programme of study outlined in the regulations, and which could lead to an increase in the use of ionising radiation by individuals who have not received adequate training.

Of the written consultation responses (see Table 3 for summary), half (4 out of 8) referred to minor grammatical amendments to the current regulations, and three had no comment. Other areas for improvement include:

- One consultee commented on the patient safety aspect of carers and comforters; that guidance should explicitly address the issue of carers and comforters of patients who are administered a radioactive substance to ensure they receive safety guidance.
- One consultee highlighted concern about timescales to consider if the administration of radiopharmaceuticals by registered healthcare professionals only, will become a legal requirement.
- Two consultees made comments concerning learning and development.
- All consultees (either through written or verbal consultation) were supportive of the inclusion of AI as an optional equipment choice for employers and sites.

**Table 3:** Summary of key areas of improvement arising during consultation:

| **Theme** | **Summary** |
|---|---|
| Grammatical/wording/addition | The wording or formatting of current regulations could be updated for definitional clarity, and to ensure that reference to other regulations is up to date |
| Learning and development | Training requirements should be reviewed to ensure they are inclusive of the most up to date techniques and practice. In addition, there are examples where there are discrepancies concerning who should, and is, handling ionising radiation. |

[5] 'Carers and comforters' are defined in IR(ME)R17 as "individuals knowingly and willingly incurring 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"

[6] 'Hypofractioned radiotherapy' refers to treatments where the total dose of radiation is divided into large doses given over a shorter period of time in comparison to standard radiation therapy. Hypofractionated radiotherapy - British Institute of Radiology (bir.org.uk)

| | |
|---|---|
| Processes | Some regulations could be updated to make processes and procedures which enforce IR(ME)R more comprehensive, for example the inclusion of an employer procedure or quality assurance processes |
| Patient safety | In nuclear medicine, the patient becomes the source of radiation and exposure may happen outside the hospital and involve other individuals (such as carers). |
| Artificial intelligence (AI) | AI should be incorporated as an optional equipment choice |

Consultation responses concerning learning and development and a lack of clarity around who should be administering ionising radiations in some settings has been reflected in a review of wider literature. When examining regulator reports published over the last 5 years, there were a small number of instances where inspectors found that radioactive substances had been administered without the appropriate practitioners certificate or licence. There were also instances of duty holders not being formally notified of and/or included in their scope of practice under the regulations. A review of academic literature also highlighted some gaps in knowledge of the regulations among medical students and orthopaedic surgeons. A more detailed summary of this literature can be found in the Appendix.

Review of the estimated versus actual outcomes of the IR(ME)R17 amendments

*Regulation 14: Introduction of formal recognition of Medical Physical Experts (MPEs) to ensure MPEs appropriately educated and trained – Have MPEs been formally recognised upon completion of appropriate education and training?*

As of 28 October 2022, a total of 1,101 MPEs were certified by the RPA2000 regulatory body since IR(ME)R17 came into force. The majority (1,015) transferred onto the scheme, with the first 'fee-paying' MPE applications beginning in 2021. There have been 99 initial or new MPE certifications since 2019 (Table 4).

**Table 4:** Comparison of regulatory triage assessment (2017) MPEs estimates and the actual number of MPE applications

| | **Total number of MPEs** | **Number of applications** | **Exclusively non-NHS MPEs** | **Cost** |
|---|---|---|---|---|
| **RTA estimate** | 900 (800 to 900) | 50 per year | 5% (0% to 10%) | £12,000 (£0 to £39,000) per year |
| **Actual** (up to 22 October 2022) | 1,101 | 99 – initial applications between January 2019 and October 2022 | 1% | £30,070 between 2019 and 2022 |

Adjusting the Regulatory triage assessment estimates in consideration of the first fee-paying MPE applications in 2021, there was an overestimation of the total number of MPE applications (99 compared to an estimated 195 (175.5 to 214.5) over a 3.9[7] year period).

The RPA2000 is the assessing body authorised for MPE recognition and were appointed by DHSC. To become recognised, prospective MPEs are required to supply a portfolio of evidence containing evidence that they meet the criteria for knowledge-based and experience-based competence as set

[7] 3.9 years reflects the time from IR(ME)R coming into force (6th February 2018) to the latest date MPE application data was available at the time of writing

out in the DHSC approved 'Medical physics expert Competence Recognition Scheme'[8]. There are different specialities within which MPEs can practice, and Table 5 provides a breakdown of specialism for currently certified MPEs:

**Table 5:** Breakdown of specialism of current certified MPEs

| Diagnostic Radiology | Nuclear medicine | Radiotherapy | More than one certification | Small user/industry | Unrecorded |
|---|---|---|---|---|---|
| 87 | 60 | 106 | 8 | 1 | 839 |

MPEs currently with an 'unrecorded' specialism is due to grandfathering from the old to new system.

Regulation 5: *Introduction of licensing for Doctors and Employers who administer radioactive substances for the purposes of diagnosis, treatment, or research to streamline the system and maintain patient safety standards – Has the introduction of a new licensing scheme streamlined processes as well as maintained patient safety standards?*

The pre-IR(ME)R certification system required separate certificates for therapy, diagnosis and research, for each site worked at and for each research trial. IR(ME)R 2017 introduced a single type of practitioner license to cover therapy, diagnosis and research, and a site/employer license; sponsor licenses for research trials remain unchanged. These changes were intended to reduce the number of total license applications with different distribution types.

A comparison of the total number of certificate applications over the course of a 5-year period compared with the actual number of license applications under IR(ME)R17 is outlined in Table 6. The total number of certificate applications was estimated to be 8,541 and the total number of licenses issued under IR(ME)R17 is 3,920; a reduction of 4,621 applications. This demonstrates that IR(ME)R17 has been successful in streamlining license applications.

The number of license applications for research went down slightly while the number of practitioner applicants went down significantly.

**Table 6:** Comparison of previous system (certification) 2015 to16 licensing application data estimates and actual number of licenses under IR(ME)R17

| Applicant | License type | Previous system estimates (certification) | Actual number of license applications | Difference |
|---|---|---|---|---|
| Employer | New | N/A | 354 | +354 |
| | Amendment | N/A | 290 | +290 |
| | Notification | N/A | 457 | +457 |
| | Renewal | N/A | 15 | +15 |
| Practitioner | New | 5002 | 866 | -4,136 |
| | Amendment | 812 | 385 | -427 |
| | Notification | No estimate | 80 | +80 |
| | Renewal | 1017 | 1 | -1016 |
| Research | New | 1188 | 1135 | -53 |

[8] Medical_Physics_Experts_Recognition_Scheme_guidance.pdf (publishing.service.gov.uk)

| | | | | |
|---|---|---|---|---|
| | Amendment | 48 | 283 | +236 |
| | Notification | 475 | 54 | -421 |
| **Total** | **All** | **8,541** | **3,920** | **-4,621** |

*NB: Estimates are calculated to a 4.75 year period, with actual figures first year beginning on date IR(ME)17 came into force (6 February 2018) and calculated to the most recent data (October 2022). Estimate figures have been rounded to the nearest whole number. 2015 to16 estimates are based on applications data and are as included in the RTA.*

The regulatory triage assessment made an overestimation of the number of licenses to be issued (5,100 overestimation) (Table 7). The ARSAC advised that in 2020, an emergency application process was implemented to help sites adapt to the coronavirus (COVID-19) pandemic; upon examination of the data there does not appear to have been an impact on the number of licenses issued during this period.

**Table 7:** Comparison of Regulatory triage assessment estimates and actual number of licenses under IR(ME)R17

| **Applicant** | **License type** | **New system estimates (licenses)** | **Actual number of license applications** | **Difference** |
|---|---|---|---|---|
| Employer | New | 1473 | 354 | -1119 |
| | Amendment | 879 | 290 | -589 |
| | Notification | 475 | 457 | -18 |
| | Renewal | 1468 | 15 | -1453 |
| Practitioner | New | 238 | 866 | +250 |
| | Amendment | 1734 | 385 | -1349 |
| | Notification | No estimate | 80 | +80 |
| | Renewal | 1045 | 1 | -1044 |
| Research | New | 1188 | 1135 | -53 |
| | Amendment | 48 | 283 | +236 |
| | Notification | 475 | 54 | -421 |
| **Total** | **All** | **9,023 (+/- 10%)** | **3,920** | **-5,100** |

*NB: Estimates are calculated to a 4.75yr period, with actual figures first year beginning on date IR(ME)17 came into force (6th February 2018) and calculated to the most recent data (October 2022). Estimate figures have been rounded to the nearest whole number.*

In addition to licenses issued, a total of 51 license applications were rejected by ARSAC: 9 employer, 37 practitioner and 5 research applications (Table 8). This highlights the role of the licensing process to identify practice which could be potentially harmful to patient safety standards, for example not successfully demonstrating sufficient professional practical experience for the procedure applied for.

**Table 8:** Number of rejected license applications under IR(ME)R17

| **Applicant** | **License type** | **Total rejected** |
|---|---|---|
| Employer | New | 6 |
| | Amendment | 1 |

| | | |
|---|---|---|
| | Notification | 2 |
| | Renewal | 0 |
| | TOTAL | 9 |
| Practitioner | New | 31 |
| | Amendment | 5 |
| | Notification | 1 |
| | Renewal | 0 |
| | TOTAL | 37 |
| Research | New | 5 |
| | Amendment | 0 |
| | Notification | 0 |
| | TOTAL | 5 |
| **Total** | **All** | **51** |

There was an underestimation of the direct cost estimates in the Regulatory triage assessment, as outlined in Table 9.

**Table 9**: Regulatory triage assessment licensing 5-year direct cost estimates compared with actual costs (rounded to the nearest £1,000)

| **Estimated (£000s)** | **Actual (£000s)** |
|---|---|
| 219 (165 to 284) | 433 to 618:<br>*Of which:*<br>Employer = 149.5<br>Research = 283 to 468 |

Regulations 8 and 9: *Introduction of a notification requirement for underexposures in radiotherapy to enhance learning and implementation of protective measures – Is there any learning from underexposure notifications, and has this resulted in suggested protective measures?*

There has been no reported underexposure notification. Prior to IR(ME)R17 coming into force, there had only been one in the previous 25 years.

## 6. Is government intervention still required? Is the existing form of government regulation still the most appropriate approach?

Yes. The regulations provide sufficient latitude for employers to adopt processes and procedures that meet the requirements of the regulations but also reflect local practice, population needs and service delivery models. The regulations are still required to ensure patient safety while undergoing medical and non-medical exposures using medical equipment.

## 7. Next steps

This PIR has demonstrated there are no significant concerns with the current regulations. However, there will be some benefits of amendments that address some of the minor concerns.

Work has already been carried out to develop amendments that will address the minor concerns identified in this PIR and provide additional benefits.

There are proposed amendments for 24 regulations in IR(ME)R17:

- 7 amendments relate to procedures
- 16 amendments address semantic/grammatical changes or minor additions
- 1 amendment relates to learning and development
- 2 amendments relate to the inclusion of AI
- 1 amendment relates to the cost of license fees

The next steps are to evaluate the impacts of the proposed amendments, which is expected to occur later in 2023.

## Appendix: Review of wider literature

Enforcement: inspections and audits

The Care Quality Commission (CQC), Healthcare Inspectorate Scotland (HIS), Healthcare Inspectorate Wales (HIW), and The Regulation and Quality Improvement Authority Northern Ireland (RQIA) produce IR(ME)R inspection reports. Reports dated between 2018 and 2023 have been reviewed and key points related to the enforcement of the regulations are outlined in Table 10:

**Table 10:** CQC annual inspection reports[9]

| Date | Number of inspections | Actions related to 2017 IR(ME)R amendments |
|---|---|---|
| 2021 to 2022 | 14 diagnostic imaging<br>6 nuclear medicine departments<br>13 radiotherapy departments | None |
| 2020 to 2021 | 6 diagnostic imaging<br>6 nuclear medicine departments<br>8 radiotherapy departments | None |
| 2019 to 2020 | 10 diagnostic imaging<br>3 nuclear medicine departments<br>5 radiotherapy departments | A shortage in MPEs resulted in a number of enforcement notices. The CQC recommends to employers that MPEs should be 'included in procurement business cases for new equipment…have appropriate resources and time to quality assure equipment…be involved in decisions on purchasing any new piece of equipment' (p.19)<br><br>CQC set up an online form specifically for IR(ME)R license breaches to better understand employer record-keeping and data integrity. |
| 2018 to 2019 | 20 diagnostic imaging<br>3 nuclear medicine departments<br>3 radiotherapy departments | There were five instances of IR(ME)R breaches related to the administration of radioactive substances without the appropriate practitioners certificate or license across five nuclear medicine providers. |

**Table 11:** HIS annual IR(ME)R inspection reports[10]

| Date | Number of inspections | Actions related to 2017 IR(ME)R amendments |
|---|---|---|
| 2023 | 1 inspection to date | None |
| 2022 | 5 inspections across 3 NHS trusts and 2 independent healthcare service | None |
| 2021 | 5 inspections across 4 NHS trusts and 1 independent healthcare service | One NHS trust was instructed to update employer procedures to reflect the Regulation 8 criteria to report overexposure and underexposure incidents |
| 2020 | 5 inspections at NHS trusts | One NHS trust was instructed to ensure that MPEs are involved as appropriate for consultation on optimisation. |

[9] IR(ME)R annual report - Care Quality Commission (cqc.org.uk)

[10] IR(ME)R inspections (healthcareimprovementscotland.org)

| | | |
|---|---|---|
| 2019 | 1 inspection at an NHS trust | None |
| 2018 | None | None |

**Table 12:** HIW annual inspection reports[11]

| Date | Number of inspections | Actions related to 2017 IR(ME)R amendments |
|---|---|---|
| 2021/22 | 7 IR(ME)R inspections across NHS Health Boards and independent hospitals | Duty holders had not always been formally notified of their entitlement and scope of practice under the regulations. |
| 2020/21 | 5 IR(ME)R inspections across NHS Health Boards and independent hospitals | Duty holders had not always been formally notified of their entitlement and scope of practice under the regulations.<br><br>There were references to IR(ME)R 2000 regulations within some employer procedure documents. |
| 2019/20 | 3 IR(ME)R inspections – nuclear medicine not inspected | None |
| 2018/19 | 5 IR(ME)R inspections across NHS Health Boards and independent hospitals | None |

*NB: In 2020/21 inspections were undertaken remotely. Reduced inspection activity in 2019/20 due to COVID-19 pandemic.*

**Table 13**: RQIA annual inspection reports[12]

| Date | Number of inspections | Actions related to 2017 IR(ME)R amendments |
|---|---|---|
| 2020 | 4 inspections | One site was instructed to ensure that 'the entitlement of MPEs is strengthened to include formal inclusion of individual MPEs scope of practice and include the cardiology service' and another to enhance the MPE role in the nuclear medicine department in accordance with IR(ME)R17.<br><br>Three sites were instructed to ensure procedure were updated to reflect IR(ME)R17 requirements. |
| 2019 | 1 inspection | The site was instructed to update procedures to ensure significant accidental or unintended exposures are reported in accordance with IR(ME)R17. |
| 2018 | 1 inspection | None |

The Royal College of Radiologists conduct audits across a broad range of areas. There has not been an audit of compliance with IR(ME)R regulations since IR(ME)R17 came into force in 2018.

[11] Annual reports | Healthcare Inspectorate Wales (hiw.org.uk)
[12] Regulation and Quality Improvement Authority - RQIA

Training and knowledge of IR(ME)R

There have been three published academic journal articles exploring the knowledge of IR(ME)R17 among medical professionals since the regulations came into force. A 2022 study[13] in Scotland found that among 50 foundation doctors across three trauma departments in Scotland, the number of cancelled and altered radiology requests significantly decreased following the intervention of trauma-focused radiology teaching: 20% to 5%, and 25% to 10% respectively.

A 2021 study[14] received survey responses from 406 orthopaedic surgeons across England, Scotland, Northern Ireland and Wales. There is no mandatory requirement for orthopaedic surgeons in the UK to undergo formal radiation education or safety training, however orthopaedic surgeons request imaging as needed in theatre, can be the closest individual to machines and are responsible for patient safety. The majority (89%) correctly identified what IR(ME)R stands for, however 79% were not familiar with the 'employee duties' outlined in the regulations. One in five (19%) agreed that they were adequately trained in ionising radiation safety knowledge and legislation, and one in four (27%) agreed that they were adequately trained in the principles of radiation equipment in the operating theatre. In total, 29% of respondents said that they felt they were provided with a sufficient provision of radiation protection equipment.

A 2018 study[15] compared the knowledge of radiation legislation knowledge among 127 final year medical students, foundation year doctors, specialist radiology trainees and radiographers. It found that knowledge of radiation legislation was significantly lower among final year medical students and foundation year doctors in comparison to those in later stages of their careers. The study recommended that there should be formal teaching of radiation legislation within medical curriculums.

Literature Review on the Use of AI in Radiation and Ionisation Interventions

*Methods:*

This light-touch literature review provides an overview of existing research on how AI is already being used in healthcare, potential risks of AI, and future implications on workforce. A thorough search was conducted using relevant databases, national health publications, and scholarly resources. The inclusion criteria were limited to articles published within the last 5 years, which were screened for relevance and suitability.

*How is AI already being used?*

AI is set to rapidly transform healthcare; however clinical implementation of AI applications is still at an early stage[16]. AI has great potential in fields such as radiology, where AI development has focused on abnormality detection, and future development is envisioned in molecular imaging, radiogenomics, and whole population cancer screening[17].

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[13] Trauma radiology teaching for foundation doctors working within the Scottish Trauma Network improves radiology requests and patient safety: a multidepartmental quality improvement project | Postgraduate Medical Journal (bmj.com)

[14] BIR Publications

[15] BIR Publications

[16] Journal of Medical Internet Research - Role of Artificial intelligence Applications in Real-Life Clinical Practice: Systematic Review (jmir.org)

[17] BIR Publications

Adoption of AI within the NHS is, so far, relatively limited. However, there are some examples which illustrate its promise for the future:

- Addenbrooke hospital in Cambridge is using Microsoft's InnerEye system to automatically process scans for patients with prostate cancer, rapidly speeding up an otherwise lengthy process which requires hours of expert clinicians' time[18]
- HeartFlow's AI technology is being used to analyse CT scans of patients who are suspected of having coronary heart disease, diagnosing patients with suspected heart disease five times faster than previously[19]
- Google's DeepMind firm has been working with Moorfields Eye Hospital to develop AI technology that can automatically identify sight-threatening eye conditions within seconds, and rank patients in order of urgency for treatment, with equal accuracy of eye doctors with 20 years' experience[20].

*Have any risks been associated with the use of AI?*

The literature around risks associated with clinical use of AI is limited, and more research is needed to assess the benefits and challenges associated with clinical AI applications through a more rigorous methodology[21]. However, academics have raised various ethical considerations including:

- **Uneven access** – the adoption and implementation of AI in the UK to date is unevenly distributed, being more accessible to larger and more advanced hospitals[22]
- **Consent** – surveys have shown a lack of public understanding of AI and machine learning[23], therefore it should not be assumed that patients can be truly informed to provide consent[24]
- **Discrimination** – AI has historically been scrutinised for failing to incorporate diversity into its training. Notably, in 2018 cases were reported of facial recognition not differentiating faces of those from minority-ethnic groups[25]. The issue is that many AI algorithms have been developed by a mainly white male population, with data on mainly white male populations[26] [27].

*What are the implications on workforce?*

AI does have the potential to replace a small number of radiologist's roles. However, considering the current limitations that AI has, and the lack of long-term trials, wholly autonomous AI radiology does not appear to be likely over the next 10 years[28]. An AI-radiologist

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[18] AI speeds up cancer treatment | CUH
[19] NHS England » 3D heart scans on the NHS to speed up disease diagnosis
[20] Clinically applicable deep learning for diagnosis and referral in retinal disease | Nature Medicine
[21] Role of Artificial intelligence Applications in Real-Life Clinical Practice: Systematic Review - PubMed (nih.gov)
[22] The time is now: making the case for a UK registry of deployment of radiology artificial intelligence applications - ScienceDirect
[23] Artificial intelligence Select Committee Report of... - Google Scholar
[24] BIR Publications
[25] BIR Publications
[26] AI can be sexist and racist — it's time to make it fair (nature.com)
[27] BIR Publications
[28] 2022-Winning-Essay.pdf (bsnr.org.uk)

collaborative model appears to be of greater likelihood, and one which has the potential to hugely improve outcomes for patients[29]. For the foreseeable future, the function of AI in healthcare looks to be assistive rather than autonomous.

[29] 2022-Winning-Essay.pdf (bsnr.org.uk)