Title: Post Implementation Review of the Ionising Radiations Regulations 2017 (IRR17) **PIR No:** HSE-PIR2022-002 **Original IA/RPC No: HSE0099** **Lead department or agency:** Health and Safety Executive **Other departments or agencies:** None **Contact for enquiries**: Richard Broughton richard.broughton@hse.gov.uk	Post Implementation Review **Date: 21/12/2022** **Type of regulation: EU** **Type of review: Statutory** **Date measure came into force:** **01/01/2018** **Recommendation: Keep** **RPC Opinion: N/A (de minimis)**

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

To maintain or improve current levels of occupational health and safety and radiological protection; transpose the Basic Safety Standards Directive 2013 (BSSD13) in line with EU Treaty obligations; ensure the adverse impacts of the Directive are minimised; ensure, where possible, consistency of application with other Government Departments; bring the UK regime in line with the latest recommendations from the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA).

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

The evidence was gathered primarily through an online survey directed to a wide range of stakeholders with clear links to ionising radiation and impacted by IRR17. The survey gathered 154 responses with 152 used for analysis. Recent reviews of the wider regulatory framework for ionising radiation were reviewed for relevant scoping and content. Enforcement and administrative data was also examined.

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

The regulations came into force 1 January 2018. A majority of respondents believed that a) the regulations improved protection a little or a lot; b) that regulations effectively minimised their risk of exposure to ionising radiation; and c) there were no undue burdens or compliance difficulties. An alternative approach that imposes less burden while maintaining protection was not identified or supported by a majority of correspondents. Associated costs are estimated to be relatively low.

Sign-off for Post Implementation Review: Chief economist

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

Signed: ***Edward Woolley*** Date: 25/10/2022

Further information sheet

Please provide additional evidence in subsequent sheets, as required.

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

That the regulations would help maintain the generally good standards in respect of controlling the risks associated with exposure to ionising radiation in the workplace and at minimal additional cost to business. The present value of total costs was originally estimated to be £22m, with a cost to business per year (EANDCB) of £0.77m (2022 prices). The regulations transpose the relevant requirements of BSSD13 as they apply to the ionising radiation hazard.

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

Very few were identified by respondents and where they were, they were relatively minor and so not costed. Some were anticipated and accounted for in the initial impact assessment. Nevertheless, a minority of organisations, mainly in the health sector, did report unintended consequences and so may consider administrative and financial burdens to be higher than they expected.

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

The evidence review showed strong majority support for the regulations and that non-legislative alternatives would not provide the same benefits. Some employers in discrete areas, had some concerns over requirements, which we believe justifies some targeted intervention subject to priorities.

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)

We have not considered the approach of other EU members states given the UK is no longer a member. At the invitation of the UK Government, the IAEA carried out a full review in 2019 of the UK's approach to controlling the risks associated with exposure to ionising radiation, which included these regulations, against expectations in IAEA standards. This concluded they were broadly fit for purpose with no recommendation to change or replace legislation.

Title: Post Implementation Review of the Ionising Radiations Regulations 2017 (IRR17) **PIR No:** HSE-PIR2022-002 **Original IA/RPC No: HSE0099** **Lead department or agency: HSE** **Other departments or agencies:** None **Contact for enquiries**: Richard Broughton **richard.broughton@hse.gov.uk**	Post Implementation Review **Date: 21/12/2022** **Type of regulation: Domestic** **Type of review: Statutory** **Date measure came into force:** **01/01/2018** **Recommendation: Keep** **RPC Opinion: N/A (de minimis)**

Introduction

This PIR is the evaluation tool that fulfils the statutory requirement to review the Ionising Radiations Regulations 2017 [1](IRR17) at least every 5 years, as required by Regulation 43 of IRR17. This PIR report will be published by 1 January 2023 to meet the statutory requirement. The purpose of the PIR is to assess:

- set out the objectives intended to be achieved
- the extent to which the Regulations have achieved their objectives,
- whether the objectives remain appropriate and
- if so, the extent to which they could be achieved with a system that imposes less regulation.

The Ionising Radiations Regulations 2017 (IRR17) came into force on 1 January 2018 and replaced the 1999 regulations.

IRR17 implements most of the Basic Safety Standards Directive 2013[2] (BSSD13) made under the Euratom Treaty[3], which as members of Euratom the UK was at the time obliged to do. Adopted on 5th December 2013, BSSD13 covered radiological protection from a number of different perspectives, including medical, occupational and environmental. IRR17 introduced a number of changes to the then current Ionising Radiations Regulation 1999 (IRR99) which, while small in isolation, represent a substantial overall impact taken together. The main new requirements in IRR17 were:

- a reduction in the eye dose limit and changes to classification levels;
- the introduction of a risk-based approach to regulatory control of practices using ionising radiation (referred to an a 'graded approach');
- changes in the definition of outside workers that widens the scope of the regulations;

[1] https://www.legislation.gov.uk/uksi/2017/1075/contents/made
[2] https://www.legislation.gov.uk/eudr/2013/59/contents
[3] Council of the European Union, General Secretariat of the Council, *The Euratom Treaty : consolidated version 2016*, Publications Office, 2016, https://data.europa.eu/doi/10.2860/865952

- the introduction of new weighting factors for dosimetry; and
- a requirement to estimate doses to members of the public.

Ionising radiation occurs either as electromagnetic rays, such as X-rays and gamma rays, or as particles, such as alpha and beta particles. It occurs naturally from radioactive decay of radioactive substances (such as radon gas and its decay products), but can also be produced artificially. Ionising radiation is used in a diverse range of industries and sectors including manufacturing, construction, nuclear, engineering, oil and gas production, non-destructive testing, medical, and research. There may also be work with materials containing naturally-occurring radionuclides, such as ores of tin, lead and copper. Although its use brings considerable benefits, it can give rise to harmful health effects, so exposure must be managed.

People can be exposed to ionising radiation both internally and externally. External exposure can be from a radioactive material or a radiation generator such as an X-ray set. Internal exposure can occur by, for example, inhalation or ingestion of a radioactive substance. The application of ionising radiation can provide many benefits, such as medical uses, but it can be hazardous to health if not managed correctly and can result in damage to tissues, such as skin burns, hair loss, as well as longer term damage leading to an increased likelihood of cancer.

IRR17 is a part of a package of regulations that provide for controlling the risks to health from exposure to ionising radiation. This framework, or parts of it, has been the subject of two recent, separate reviews and examinations.

First and in respect of the ionising radiation risk, the International Atomic Energy Agency (IAEA)[4] evaluated the totality of the UK's regulatory framework against the expectations set out in the IAEA's General Safety Requirements (GSR) [5] series in a full IAEA UK Mission October 2019. Demonstrating alignment with the IAEA's GSR series is a key pillar of the UK Government's commitment to good on-going safety standards now the UK is no longer a member of the Euratom framework.

The Government's Regulatory Horizons Council (RHC) advises Government of the fitness of current regulatory arrangements in respect of new and emerging technologies. The first RHC report[6] published in 2021 was on the emerging fusion energy sector and concluded that current arrangements of which IRR17 are a pillar were broadly fit-for-purpose.

This PIR and this report of the review gathered and then summarises the evidence from stakeholders, and employers working with ionising radiation in the main. The IAEA and RHC examinations and reports are supporting context for some of the report's conclusions. This report has also gathered data from HSE operational activity, primarily enforcement, as well as more general administrative data on the 'graded approach' process to inform its conclusions on whether IRR17 achieved its initial objectives, whether they remain fit for purpose' and the actual costs and benefits of the regulations to businesses and wider society.

[4] https://www.gov.uk/government/publications/nuclear-and-radiological-safety-review-of-the-uk-framework-2019
[5] See for example: https://www.iaea.org/publications/8930/radiation-protection-and-safety-of-radiation-sources-international-basic-safety-standards
[6] https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-fusion-energy-regulation

1. What were the policy objectives of the measure?

The UK played a full and active role in the negotiations that resulted in revisions to the BSSD in 2013. The UK supported the revisions and the purpose of the Euratom Treaty and supported therefore the various requirements within in respect of worker protections. The main policy objectives of IRR17 set out in the final impact assessment were therefore to:

- Maintain or improve current levels of occupational health and safety and radiological protection, ensuring that workers and the public remain protected from risks to their health and safety arising, or likely to arise from, exposure to ionising radiation;
- Transpose BSSD13 in line with EU Treaty obligations; and
- Ensure the adverse impacts of BSSD13 are minimised and the opportunities for simplification maximised to reduce burdens on business, following the Government's better regulation policy and principles.

In addition, the Explanatory Memorandum[7] (EM) to the IRR17 explained the wide scope of the BSSD13's requirement to control exposures, which go beyond worker exposures to for example public exposures. The EM also explained various international developments that were reflected in the BSSD13 revisions. IRR17 therefore looked to:

- Ensure, where possible, consistency of application with other Government Departments; and
- Bring the UK regime in line with the latest recommendations from the International Commission on Radiological Protection and the International Atomic Energy Agency.

2. What evidence has informed this PIR?

The evidence review resources were in line with a proportionate approach to PIRs. This decision was based upon the following factors:

- The impact on businesses was estimated to be low: the equivalent annual net direct costs to business (EANDCB) in the impact assessment (IA) was £0.6m (below the £5m *de minimis* threshold
- The IRR17 changes were widely accepted by the sector during the consultation, were not contentious, and their costs were assessed to be primarily 'one-off' (as opposed to ongoing)
- Two recent reviews of the regulations, or parts of them, have been conducted (by the IAEA, and the RHC) which found they were largely fit for purpose.

The main method used to answer the PIR questions was a stakeholder survey. The regulations are relevant to all workers and employers using ionising radiation. This includes (but is not limited to): NHS acute trusts and other NHS and private healthcare providers including dentists and veterinary practices; civil nuclear operators and the MoD; universities, colleges and schools; manufacturing; construction; engineering; industrial researchers; oil and gas production; relevant trade unions; and non-destructive testing.

In additional, those working with the regulations in an advisory or service capacity, such as consultants and Approved Dosimetry Providers, were also included as stakeholders.

The survey was open from 25 April to 30 May 2022.

A survey using an online questionnaire was considered appropriate, opening the consultation widely, with the potential for a larger number of responses without much increase in analytical resources.

[7] https://www.legislation.gov.uk/uksi/2017/1075/pdfs/uksiem_20171075_en.pdf

The principal engagement approaches used to gather evidence were:

- Direct emails sent to stakeholders known to HSE through previous engagement, or to professional associations/representative groups with a clear link to ionising radiation.
- A notification and invite to take part was included in HSE's Radiation eBulletin. Stakeholders were encouraged to pass the invite on to others deemed relevant, and evidence suggests this did happen.

The response to the survey met expectations at 154 substantive responses received, though with two from overseas 152 were considered and informed this analysis. No follow-up was considered necessary given the substantive nature of the comments and because the responses were considered representative of the range of employers, that is, no employer-group was deemed under-represented. To some extent this was expected, given the sector is in the main mature and IRR17 is the most recent iteration of Regulations that have been on statute since the 1960s with therefore a generally well-engaged sector.

3. To what extent have the policy objectives been achieved?

Objective: Transpose BSSD13 in line with EU Treaty obligations

As with all Regulations made to transpose requirements whilst the UK was a member of the EU, one main objective was to transpose in accordance with relevant Treaty obligations. IRR17 were made to the timescales required by the obligations in BSSD13 made under the Euratom Treaty. The IRR17 were in practice implemented five weeks ahead of the transposition deadline of 6 February 2017. This was to ensure that businesses could continue calculating exposures to ionising radiation on a calendar year basis. Implementing on the formal transposition deadline would mean two dose limits would apply in the calendar year 2018, which would cause confusion, have potential health and safety implications for workers, and introduce additional costs to business.

Objective: Maintain or improve current levels of occupational health and safety and radiological protection, ensuring that workers and the public remain protected from risks to their health and safety arising, or likely to arise from exposure to ionising radiation.

A large majority of respondents (78%) believed that IRR17 improved protection a little or a lot. Only a small minority (3%) thought they had worsened protections with the remainder (19%) suggesting they had made little difference. Suggestions that protections had been worsened were all made by health sector respondents, however, the number of responses from this sector was good and so this view represents a minority within the sector. In addition, the few responses provided little information on why protections were worsened and so together with these being a minority, it was considered disproportionate to investigate further.

A majority (98%) of respondents who worked directly with ionising radiation believed the IRR17 effectively minimised their risk of exposure to ionising radiation, with therefore less than 1 in 10 considering they do not. Of those who work indirectly, 37 out of 38 responses suggested they did.

Where it was felt the risk of exposure was not minimised there was some suggestion this was due to regulations being only one part of securing good risk management. Self-regulation is as important. HSE would not disagree with this as a policy position: good management of workplace

risks relies on a mix of interventions within what is primarily a self-regulatory framework where those who create risks are best placed to manage them and to do so, understand their legal duties. The majority view that the regulations do help reduce the risk of exposure would suggest IRR17 play a role within this mix.

> Objective: To ensure the adverse impacts of the Directive are minimised and the opportunities for simplification maximised to reduce burdens on business, following the Government's better regulation policy and principles.

A majority of respondents did not report undue burdens or compliance difficulties and consider that a system that imposes less burden is not feasible while maintaining protection. However, there was a substantial minority of respondents who suggested there is room for reducing burdens on businesses. The issues raised are primarily from NHS acute trusts and the education sector, though there is no specific issue which is raised by more than a small minority of respondents. Several of the recurring issues raised have been identified as relating to the Approved Code of Practice (ACOP) and/or guidance, and not to the changes in the regulations made in IRR 2017.

The health and education sectors are significant employers working with ionising radiation and the acute health sector particularly. We therefore believe that subject to priorities there is scope for targeted interventions with these two sectors to better explain the purpose of the regulations. This is because some of the issues raised – for example, the view that IRR17 has resulted in more health employees being deemed classified workers by acute health trusts – represent a misinterpretation of requirements rather than being a reflection of what the regulations or the supporting guidance requires.

On the second part of this objective, the survey carried out as part of this PIR asked specifically about the original cost assumptions in the final Impact Assessment[8] (IA) accompanying IRR17. This provided evidence that the final IA for IRR17 had **not** underestimated the costs to business. A cost benefit analysis and report is attached to this PIR at Annex 2, along with a detailed discussion. Some aspects are picked up and discussed in the following sections of the PIR. However, a summary of cost estimates can be found in table 1 below.

Table 1. Summary of Costs (millions of £, 2022 prices, 2 significant figures (s.f.))

	Present Value of Total Costs	**Equivalent annual costs to business (EANDCB)**	**Average Ongoing Costs per Year[9]**
2017 IA	22	0.77	0.96
2022 PIR (low - best - high)	15 - 19 - 26	0.57 - 0.61 - 0.66	0.38 - 0.75 - 1.3

To summarise, costs are not significantly different to those estimated in the 2017 IA. While the best estimate of total costs is lower than originally estimated, we cannot say with confidence that total costs *are* lower, as the original estimate of total costs is still within the range of estimated costs in this PIR. Business costs (EANDCB) estimated in this PIR are slightly smaller than those estimated in the 2017 IA, for reasons explained in Annex 2.

[8] https://www.legislation.gov.uk/ukia/2017/161/pdfs/ukia_20170161_en.pdf

[9] This is all ongoing costs (public and private) averaged over a ten-year period.

The only cost areas that could be argued to have changed significantly are:

- Registration-related costs, due to a lower than expected number of registrations (which we mention later); and,
- Costs to universities of recording and analysing accidental exposures / 'significant events', but then this reflects that no universities reported recording additional events.

Objective: Ensure, where possible, consistency of application with other Government Departments

On 29 September 2011, the European Commission published a proposal to replace five Directives and a Commission recommendation relating to safety standards for protecting workers, the public and the environment from the effects of ionising radiation with a single Basic Safety Standards for Radiological Protection Directive. This is BSSD13 referred to in this PIR. This proposal incorporated the latest recommendations from the International Commission on Radiological Protection, and seeks to harmonise the EU regime with the Basic Safety Standards of the International Atomic Energy Agency. The Directive was adopted on 5 December 2013 and must be transposed into UK law by 6 February 2018.

Combining five existing Directives and a Commission Recommendation resulted in a wide-ranging Directive that covers radiological protection from a number of different perspectives, including medical, occupational and environmental (including public exposures).

Other government departments and the Devolved Administrations progressed work to implement the parts of the Directive for which they have policy responsibility in parallel, and the totality of this work was overseen by the cross-Government group on exposures chaired by the Department for Business, Energy and Industrial Strategy (BEIS). They will prepare separate impact assessments covering the changes they implemented. This BEIS-chaired group was the forum through which consistency in application was assured.

Objective: Bring the UK regime in line with the latest recommendations from the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA).

The UK considers and as appropriate reflects the decisions of the ICRP in respect of radiological protection. This was generally done previously by implementing relevant European Directives where ICRP recommendations were reflected. BSSD13 made recommendations for changes to eye dose limits in response to recommendations by the ICRP in 2011 and so in transposing through IRR17 the regime now reflects these changed limits which have been generally supported by employers.

BSSD13 was developed almost in parallel with IAEA revisions to their General Safety Requirements (GSR) series, which is recognised as relevant international good practice. Both the IAEA and BSSD13 revisions looked to bring some consistency in approaches to controlling all exposure to ionising radiation, not just that exposure due to work activities but also due to medical interventions. By transposing BSSD13 through IRR17, the UK regime developed to reflect IAEA expectations.

4. What were the original assumptions?

Original assumptions about the costs and benefits in the final IA.

The 2017 impact assessment (hereafter referred to as 'the 2017 IA') estimated costs for two different policy options (which it called 'Option 1' and 'Option 2'). Option 1 was implemented in 2018, and so this option is the focus of the cost benefit analysis conducted as part of this PIR (hereby referred to as 'this CBA'). Table 2 below provides a summary of the costs of Option 1 estimated in the 2017 IA[10].

Table 2. Costs estimated in the 2017 IA (millions of £s, 2022 prices, 2 s.f.)

Broad cost area	Present Value of Total Costs	Ongoing Costs per Year
Eye Dose - Medical Sector	9.5	0.53
Eye Dose - Nuclear Sector	1.7	0.18
Graded Approach	2.5	0.067
Outside Workers	Nil	Nil
Weighting Factors	0.29	Nil
Public Dose Estimation	0.058	0.0034
Accidental Exposures	1.6	0.19
Familiarisation costs	6.0	Nil
Total Costs	**22**	**0.96**

Source: The 2017 IA

Each row in the table represents a broad cost area, each of which are made up of several individual costs. On grounds of proportionality, only some of these individual costs have been re-estimated in the CBA accompanying this PIR. The 2017 IA also only calculates 'best-estimates' of costs, it does not attempt to estimate ranges of costs (despite occasionally stating ranges in its assumptions). This is in contrast to the approach taken by this CBA, which estimates a range for all costs.

Actual costs and benefits of the regulation and its effects on business.

The individual cost areas which are reassessed in this CBA are summarised in Table 3 below. These cost areas were selected based on the size of their ongoing costs (as estimated by the 2017 IA), internal expert opinion as to whether these costs are likely to have changed, and the perceived resource required to re-estimate each cost area. As can be seen, while only around half of total costs are reassessed, the vast majority (around 90%) of ongoing costs are reassessed.

Table 3. Summary of cost areas from the 2017 IA which are reassessed in this CBA (millions of £s, 2022 prices, 2 s.f.)

Broad Cost Area	Specific Cost Area	Present Value of Total Costs	EANDCB[11]	Ongoing Cost per Year

[10] Costs from the 2017 IA have been inflated by 14.9% to be presented in 2022 prices.
[11] Some cost areas do not contribute to the EANDCB, and so are marked as 'nil'. This is because all medical sector costs were assumed to fall on the NHS (public sector).

Eye Dose – Medical Sector	Monitoring of non-classified workers	2.0	Nil	0.23
	Protective Eyewear	2.8	Nil	0.20
Eye dose – Nuclear Sector	Monitoring of already-classified workers	1.5	0.15	0.17
Graded approach	Registrations - administrative time	1.2	0.086	0.031
	Registrations - fees	0.93	0.076	0.035
Accidental exposures	Medical	0.76	Nil	0.088
	Universities	0.85	0.098	0.098
Total (reassessed)		**9.9**	**0.41**	**0.85**
All other costs (not reassessed)		12	0.35	0.11
Total		**22**	**0.77**	**0.96**

This CBA has reassessed the main ongoing costs to duty holders of the additional requirements introduced by IRR17. We have made updated cost estimates, primarily drawing upon industry stakeholders' reported experiences.

This CBA estimates a present value of total costs of the changes introduced by IRR17 of between £15m and £26m, with a best estimate of £19m. We estimate average ongoing costs of between £0.38m and £1.3m per annum, with a best estimate of £0.75m per annum.

Table 4 below compares cost estimates made by the 2017 IA, and the updated cost estimates made by this CBA.

Table 4. Comparison of costs estimated in this CBA and in the 2017 IA (millions of £s, 2022 Prices)

Broad Cost Area	Specific Cost Area	Present Value of Total Costs		Average Ongoing Cost per Year	
		2017 IA	2022 PIR (low - best - high)	2017 IA	2022 PIR (low - best - high)
Eye Dose - Medical Sector	Monitoring of non-classified workers	2.0	0.55 - 1.3 - 2.5	0.23	0.063 - 0.16 - 0.29
	Protective Eyewear	2.8	0.19 - 1.6 - 5	0.20	0.0096 - 0.082 - 0.25
Eye dose - Nuclear Sector	Monitoring of already-classified workers	1.5	0.87 - 1.3 - 1.7	0.17	0.10 - 0.15 - 0.20
Graded approach	Registrations - administrative time	1.2	0.82	0.031	0.029
	Registrations - fees	0.93	0.68	0.035	0.032
Accidental exposures	Medical	0.76	0.38 - 1.7 - 3.8	0.088	0.044 - 0.20 - 0.44
	Universities	0.85	Nil	0.098	Nil
Total (Reassessed)		**9.9**	**3.5 - 7.5 - 15**	**0.85**	**0.28 - 0.65 - 1.2**
All other costs (Not reassessed)		12	12	0.11	0.11
Total		**22**	**15 - 19 - 26**	**0.96**	**0.38 - 0.75 - 1.3**

More information on the underpinning evidence that informs this CBA is in Annex 2.
The CBA concludes that the costs are well below the current *de minimis* threshold and broadly in line with those estimated in the 2017 final IA.

One area where there are differences is in the anticipated number of registrations. As the Annex notes this is probably due to an initial lack of knowledge on the part of employers in respect of which category of authorisation their practice rather than active non-compliance though this cannot be discounted.

Assessment of risks or uncertainties in evidence base

This CBA only assesses the economic impacts of the additional requirements introduced by IRR17 (i.e. the differences between IRR99 and IRR17). Legislative arrangements for controlling the risks to workers and others health associated with exposure to ionising radiation are long-established in GB. The previous 1999 Regulations (which were themselves preceded by 1985 Regulations and others going back to the 1960s) were well-established and on-going engagement with employers working with ionising radiation had shown little concern with requirements. In addition, estimating these impacts would require a substantial amount of resource inconsistent with a low resource approach to the PIR.

This CBA also focusses on reassessing the main ongoing costs identified in the 2017 IA. The 2017 IA identifies a very large number of individual costs, most of which were one-off costs (costs that occurred in 2018). Reassessing every cost would impose a disproportionate burden on industry stakeholders, who would be asked to provide information about these costs. One-off costs have already occurred and cannot be impacted by current decision making. While the estimation of one-off costs may have further assisted HSE in understanding whether their original estimates were

accurate (and hence may have further facilitated better impact assessments in the future), it has been deemed disproportionate to investigate further.

The non-random sample limited the interpretation of the results to being representative of the achieved sample only. However, the achieved sample (described further in the evidence review, (Annex 1)) is sufficiently broad to have captured a range of views from across sectors and business sizes.

Not all the identified costs from the IA were followed up in this PIR because the work required to investigate all of them was deemed disproportionate to the costs involved. This risk was mitigated by following-up on the largest costs and costs which were ongoing (and therefore could be subject to intervention).

This CBA estimates costs using ranges to reflect uncertainties in the estimates made, and total costs estimated by the 2017 IA fall well within these ranges. While the best estimate of total costs made by the CBA are slightly lower than those made by the 2017 IA we cannot say with confidence that actual costs are lower, as both estimates are subject to some uncertainty.

5. Were there any unintended consequences?

Out of 148 respondents to the survey, 39 (about 26%) said they were aware of unintended consequences. This means that 109 (about 74%) said they were not. Unintended consequences identified were mostly negative though anticipated e.g. disproportionate requirements relative to risk and increased administrative burdens with associated cost. Others included direct costs such as the increased number of workers becoming classified.

The most frequently reported unintended consequences were expected and accounted for in the initial impact assessment. Nevertheless, the issues raised have highlighted that a minority of organisations, mainly in the health sector and the acute health function, consider burdens to be higher than they had expected. We have covered this elsewhere in the report and it may, in part, be due to interpreting the regulations, ACOP or guidance in such a way that leads to a larger amount of work than is necessary. Nonetheless this is further support for some consideration of a targeted intervention subject to priorities, clarifying expectations and requirements.

Changes in the interpretation or enforcement of the regulations by HSE, rather than change in the regulations themselves, were also raised and again by acute health trusts. HSE has considered this and as context, such changes have arisen from operational intelligence and have been made to improve health outcomes. One explanation for this view that the changes are disproportionate, may be that some respondents are unaware of the incidents that led to the change in enforcement approach.

Two other unintended consequences were raised which suggested inconsistency in the ACOP and guidance, one related to the use of signs and the other to the necessity of special procedures.

6. Has the evidence identified any opportunities for reducing the burden on business?

To understand stakeholder views on whether the existing form of regulation is still the most appropriate, respondents were asked if the regulatory aims could be achieved in a way that led to less burden on business, if they had any difficulties in complying, and an open question allowing room for additional comments.

A majority of respondents (75%) found no particular aspects of the current regulations difficult to comply with, however, 25% did find difficulties in compliance. As we mentioned earlier, issues with IRR17 were raised primarily by NHS acute trusts and the education sector, though there is no specific issue which is raised by more than a small minority of respondents. Several of the recurring issues raised have been identified as relating to the Approved Code of Practice (ACOP) and/or guidance, and not to the changes in the regulations made in IRR 2017. Aspects of the regulations that *were* considered difficult to comply with were primarily related to the administrative burden they caused. A professional body also suggested that compliance is hindered by dissemination - educating those who need to comply can take considerable time.

Secondary schools and local authorities (who perform related tasks on behalf of other organisations, including some education establishments) identified different compliance concerns to NHS acute trusts. Two schools said the costs associated with the regulations made them difficult to comply with. This included the cost of disposal, cost of RPS, and the time needed to carry out the RPA role. The alternative suggestions focussed on reviewing the regulations regarding the low-risk sources used in schools (which are reported to be equivalent to domestic smoke alarms) with the aim of reducing costs for schools. There were two suggestions that the complexity of the regulations, especially relating to radon gas, made compliance difficult. The alternative suggestion was not for alternative regulations, but a simplified guidance document.

Respondents were asked if the aims of the Ionising Radiations Regulations 2017 could be achieved with a system that imposes less burden on businesses. About 28% didn't know. Of those that provided a definitive answer, 62% said no while about 38% said yes. Those working in universities, local authorities and NHS acute trusts were more likely to suggest a less burdensome system was possible.

The broad support for the regulations would not suggest legislative change is required to address the concerns raised.

Either way, the broader international context needs to be recognised. The IAEA have examined, at the request of the UK Government, the totality of the UK framework for protecting against the health risks associated with exposure to ionising radiation when compared to the IAEA's expectations set out in the good practice guidance series. Whilst the IAEA concluded the current arrangements were broadly fit-for-purpose they did make recommendations for change, which the Government accepted, and these recommendations are being delivered. Any change to these regulations would likely attract the attention of the IAEA who would, as when they last examined the UK's approach, take a view on the extent to which the UK reflected international good practice.

However, and in conclusion, it is worth noting again that the health and education sectors are significant employers working with ionising radiation and the acute health sector particularly. We therefore believe that based on responses from these sectors and subject to priorities and resources there is scope for targeted interventions with these two sectors to better explain the purpose of the regulations. This is because some of the issues raised – for example, the view that IRR17 has resulted in more health employees being deemed classified workers by acute health trusts – represents a misinterpretation of requirements rather than being a reflection of what the regulations or the supporting guidance requires.

Annex 4: Evidence Review for the Ionising Radiations Regulations 2017 – Post Implementation Review

Authors: David Bayliss, Rachel Wilson

Date: 09/09/2022

Contents

Summary

- The main source of evidence to inform the post-implementation review was a stakeholder consultation. 152 respondents from a wide range of sectors making use of ionising radiation contributed.

- There is clear evidence of support for the main policy objective to maintain or improve current levels of occupational health and safety and radiological protection, ensuring that workers and the public remain protected from risks to their health and safety arising, or likely to arise from, exposure to ionising radiation (97% of 141 respondents felt the regulations had maintained or improved radiological protection).

- A large majority of respondents believe that the regulations are effective in minimising workers' risk of exposure to ionising radiation (98 of 106 who worked directly with ionising radiation, and 37 of 38 who did not work directly with ionising radiation).

- On the better regulation principles[12], the evidence suggests that the regulations are working well. The majority of respondents reported no unintended consequences or costs and no difficulty complying with the regulations. The majority view was that the aims of the regulations could not be achieved with a system that imposed less burden on business.

- A minority reported concerns with the regulations. Respondents from NHS acute trusts and education sectors were most likely to highlight concerns. The most prevalent issues concerned administrative burdens, changes to worker classification, and regulations relating to outside workers. On the whole, the issues raised were factored into the initial impact assessment[13].

- Some of the issues raised did not pertain directly to the changes in the regulations, but changes in enforcement practices.

[12] https://www.gov.uk/government/publications/better-regulation-framework
[13] https://www.legislation.gov.uk/ukia/2017/161/pdfs/ukia_20170161_en.pdf

Introduction

1. This evidence review has been undertaken by the Health and Safety Executive (HSE) to accompany and support the Post-Implementation Review of the Ionising Radiations Regulations (2017) (IRR17).

2. The Ionising Radiations Regulations 2017 came into force on 1 January 2018, repealing and replacing the Ionising Radiations Regulations 1999 (IRR99). IRR17 implements most of the Basic Safety Standards Directive 2013 made under the Euratom Treaty, which as members of Euratom the UK was at the time obliged to do.

3. The main policy objectives and intended effects of the Ionising Radiations Regulations 2017 were:

    A. Maintain or improve current levels of occupational health and safety and radiological protection, ensuring that workers and the public remain protected from risks to their health and safety arising, or likely to arise from, exposure to ionising radiation.

    B. Transpose the Directive in line with EU Treaty obligations.

    C. To ensure the adverse impacts of the Directive are minimised and the opportunities for simplification maximised to reduce burdens on business, following the Government's better regulation policy and principles.

    D. To ensure, where possible, consistency of application with other Government Departments.

    E. To bring the UK regime in line with the latest recommendations from the International Commission on Radiological Protection (ICRP) and the International Atomic Energy Agency (IAEA).

4. As part of Better Regulation, IRR17 Regulation 43 requires a review of the effectiveness of, and need for, continuing with Regulations, with a report setting out the conclusions of the review produced and published within five years of the date the Regulations came into force (by 1st January 2023) and, thereafter, on a repeating five-yearly cycle.

5. Ionising Radiations Regulations 2017 is a part of a package of regulations that provide for controlling the risks to health from radiation. This framework, or parts of it, has been the subject of two recent reviews. First and in respect of the ionising radiation risk, the International Atomic Energy Agency (IAEA) evaluated the UK's regulatory framework against the expectations set out in the IAEA's General Safety Requirements series in their full UK Mission autumn 2019. Demonstrating alignment with GSR series is a key pillar of the UK Government's commitment to good on-going safety standards now we are no longer members of the Euratom framework. IRR17 aligns in many respects to the GSR series and so major reform and/or change risks attracting the IAEA's attention with subsequent reputational risk.

6. Separately, the Government has announced its intention for the UK to be a world leader in fusion technology and power and its regulation through proportionate control. The Government's advisory Regulatory Horizons Council (RHC) in their report on fusion[14] last year concluded that the current regulatory framework was fit for purpose and IRR17 is a major pillar of this. A recent Green paper on fusion and regulation[15] concluded the same.

[14] https://www.gov.uk/government/publications/regulatory-horizons-council-report-on-fusion-energy-regulation
[15] https://www.gov.uk/government/consultations/towards-fusion-energy-proposals-for-a-regulatory-framework

7. HSE is a co-regulator with the Office for Nuclear Regulation (ONR) for IRR17, with ONR regulating licensed nuclear facilities and some transport activities. The HSE is the Government policy lead for workplace health and safety and so led this first PIR of IRR17, with the agreement of the ONR.

Proportionality of the approach

8. The level of resourcing put into the evidence review was low, in line with a proportionate approach to PIRs. This decision was based upon the following factors:

    - The impact on businesses was estimated to be low: the equivalent annual net direct cost to business (EANDCB) in the Impact Assessment (IA) was £0.6m (well below the £5m de minimis threshold).

    - The IRR17 changes were widely accepted by the sector during the consultation, were not contentious, and were primarily one-off costs to business.

    - Two recent reviews of the regulations, or parts of them, have been conducted (by the International Atomic Energy Agency, and Regulatory Horizons Council) and found they were largely fit for purpose and that there is little scope for change.

Key questions for the PIR

9. The evidence review for this PIR considered the following questions:

    I. To what extent has the regulation achieved its policy objectives?
    II. Have there been any unintended effects?
    III. What have been the actual costs and benefits of the regulation?
    IV. How do these compare with the estimated costs and benefits?
    V. Is the existing form of regulation still the most appropriate approach?

Methods

10. The evidence review aimed to answer the key questions in a proportionate manner with a low burden on businesses. The research was conducted in-house. Existing evidence that could be used to support the PIR was utilised, including IAEA and RHC reports and data from the 'graded approach'[16]. To supplement this, stakeholder engagement was undertaken to collect views and experiences on implementing the regulations.

Stakeholder consultation

11. The main method used to answer the PIR questions was a stakeholder survey. The regulations are relevant to all workers and employers using ionising radiation. This includes (but is not limited to): NHS acute trusts and other NHS and private healthcare providers including dentists and veterinary practices; civil nuclear operators and the MoD; universities, colleges and schools; manufacturing; construction; engineering; industrial researcher; oil and gas production; and non-destructive testing. In additional, those working with the regulations in an advisory or service capacity, such as consultants and Approved Dosimetry Providers, were also included as stakeholders.

[16] The graded approach is a risk-based approach to regulatory control of practices using ionising radiation in which different levels of information are required from HSE depending on the use.

12. With the aim of engaging efficiently with a wide range of stakeholders, a survey using an online questionnaire was considered appropriate. This approach meant we could open the consultation widely, with the potential for a larger number of responses without much increase in analytical resources.

13. The questionnaire (reproduced in Appendix 1) was designed to be simple and quick to complete to maximise participation, with an estimated completion time of between 5 and 12 minutes per response (depending on sector-based routing).

14. Time for follow-up was built into the schedule, enabling any responses that raised further substantial questions to be further investigated.

Sample

15. A comprehensive list of stakeholders from which to draw a random sample did not exist and there was no obvious way of generating one. Therefore, instead of a sampling approach, we aimed to invite all known stakeholders to complete the questionnaire. This involved two approaches. Firstly, direct emails were sent to stakeholders known to HSE through previous engagement, or to professional associations/representative groups with a clear link to ionising radiation. Secondly, HSE included a notification and invite to take part in the Radiation eBulletin. Stakeholders were encouraged to pass the invite on to others deemed relevant, and evidence suggests this did indeed happen.

16. The survey was open from 25th April to 30th May 2022.

Limitations of the approach

17. The main limitations are:

    a. The non-random sample limits the interpretation of the results to being representative of the achieved sample only. It is encouraging that the achieved sample (described in the findings) is sufficiently broad to have captured a range of views from across sectors and business sizes.

    b. Not all of the identified costs from the IA were followed-up in this PIR because the work required to investigate all of them was deemed disproportionate to the costs involved. This risk was mitigated by following-up on the largest costs and costs which were ongoing (and therefore could be subject to intervention). In addition, respondents had opportunity to raise further issues, including a question asking directly about unintended costs.

Summary of regulations

18. Below is a summary of the main changes introduced as part of the Ionising Radiations Regulations 2017.

Main changes

Eye dose limits: a reduction in the eye dose limit and changes to classification levels.

Graded approach: introduction of a risk-based approach to regulatory control of practices using ionising radiation.

Outside workers: change in the definition that widens the scope of the regulations.

Public dose estimation: a requirement to estimate doses to members of the public.

Accidental exposures and the recording and analysis of significant events: change in the scope of events which require recording and analysis.

Additional changes
Dosimetry and medical record retention: change in the minimum period dose and medical records must be retained for.

Atmospheric radon: change in the measurement level of exposure to atmospheric radon that brings workers in scope of the Ionising Radiations Regulations.

Under 18 exposure: introduction of blanket coverage of workers aged under 18, preventing them from carrying out any work likely to lead to exposure to ionising radiation.

Calculation of estimated doses: a new requirement that the methodology for estimating doses is approved by a competent authority.

Subsidiary dose limit: Removal of the subsidiary dose limit for the abdomen of a woman of reproductive capacity.

Fitness for work appeal period: Change in the period for appeals against the appointed doctor's decision on medical fitness for work.

Appointed doctor process: removal of the legal requirement for Appointed Doctor to be 'in writing'.

Findings

Respondent characteristics

19. The stakeholder consultation resulted in 154 responses to the questionnaire. Two responses were removed on the basis that the respondents place of work was not in GB, leaving 152 for analysis. The respondents were employed in a range of business activities, as detailed in table 1.

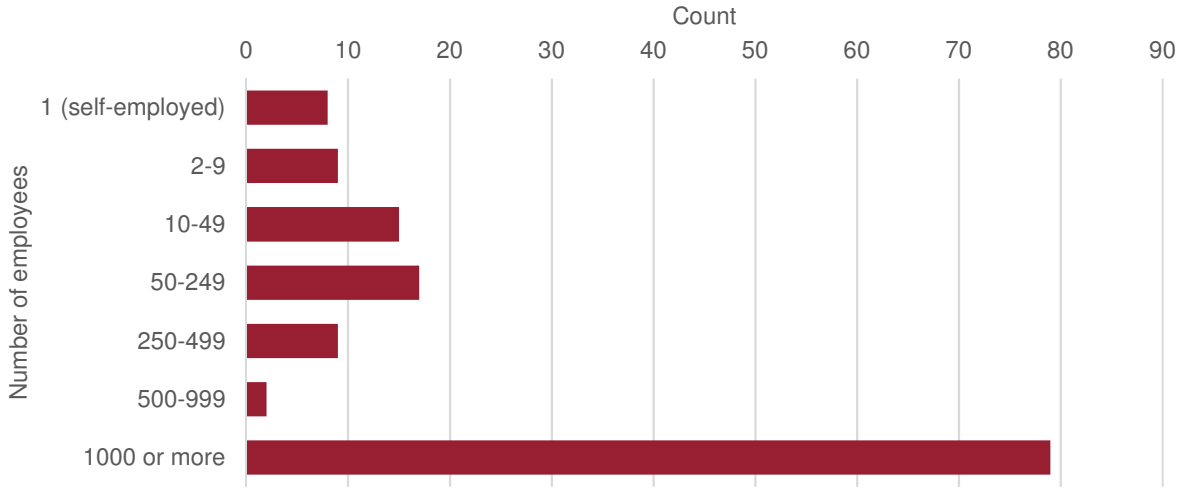
Table 1. Number responses by sector

Sector	**Number of respondents**
Medical: NHS acute	48
Medical: dental practice	8
Other medical, including private health care, NHS community health, NHS mental health, and veterinary practices.	8
Nuclear (all civil nuclear operators and Ministry of Defence)	18
Academic: university	11
Academic: secondary school and FE	6
Manufacturing	11
Local authority	5
Other sectors*	37

*Sectors with fewer than five respondents included: manufacturing, local authority, industrial research, non-destructive testing, engineering, construction, oil and gas production, general industry, approved dosimetry service provider, broadcast/telecommunication, cultural heritage, emergency service, consultancy, facilities management, transport and logistics, heritage/museums, mining and tunnelling, government department/agency, and professional bodies.

20. The respondents represented businesses of varied sizes, as shown in Figure 1 (underlying data for each Figure in this report can be found in Appendix 2). Large businesses of 1,000 or more employees made up the majority of responses (79 of the 145 who provided this information).

Figure 1. Number responses by size of business



21. Responses were sought both from organisations (especially with a view to collecting organisational level cost data) as well as individual workers who are protected by these regulations. 70 of the responses were from people answering on their own behalf, while 53 answered on behalf of a single organisation or representative group. A further 20 responded as

consultants working across multiple organisations. Of the remaining nine cases four entered a bespoke answer which could not be classified into one of the above, and five did not provide any answer to this question.

22. The respondents' were asked their job roles to provide context to their responses. Summarising these open text responses definitively is difficult due to the varied role descriptions. 55 respondents had a management or general health and safety lead role. 37 respondents were Radiation Protection Advisors, three were Radiation Protection Supervisors, while a further nine had less a specific radiation safety role such as 'radiation safety lead'. 16 respondents were radiographers. The remaining respondents were clinical scientists, clinical consultants, and a further 19 fit into none of these groups.

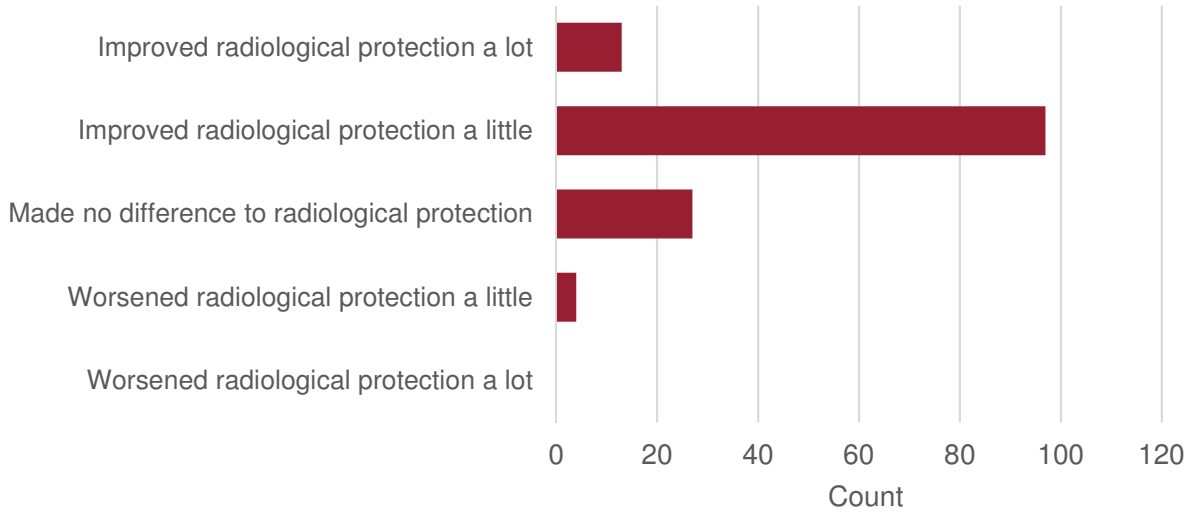
Has IRR17 achieved its policy objectives?

23. Of the full set of objectives outlined on page 4, objective A and C were the subject of primary research to inform this evidence review. Objectives B, D and E are addressed in the PIR report.

Objective A: **Maintain or improve current levels of occupational health and safety and radiological protection, ensuring that workers and the public remain protected from risks to their health and safety arising, or likely to arise from exposure to ionising radiation.**

24. Respondents were asked whether they thought the introduction of the Ionising Radiations Regulations 2017 in Great Britain had improved or worsened radiological protection. As can be seen from Figure 2, a large majority believed the regulations improved protection a little or a lot (78% of those providing a view on this question). 19% believed the regulations had made no difference, while 3% (4 of the 141 valid responses) believed they had worsened protection. An additional seven respondents answered 'don't know'.

Figure 2. 'In your opinion, has the introduction of Ionising Radiations Regulations 2017 in Great Britain…'



25. The four respondents who thought protection had worsened were from various health-related sectors: two from NHS acute trusts, one dental practice, and one ‘medical: other’. There were a total of 56 responses provided to this question from these sectors, and so the four are a small minority.

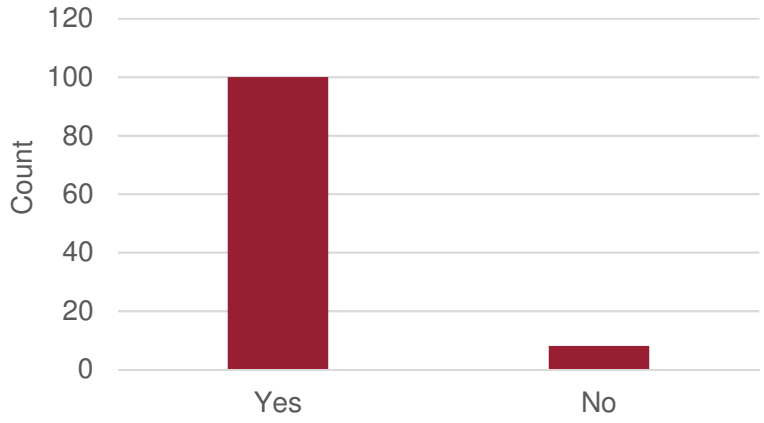
26. Two of the respondents who suggested the updated regulations had worsened radiological protection gave explanations which contained no suggestion that radiological protection had actually worsened (their responses instead focusing on perceived enforcement issues).

27. One respondent from an NHS acute trust suggested that the regulations led to bad safety practice (and therefore worsened protection) because they were perceived as impractical and disproportionate in places. This was the only such comment out of 48 respondents from acute trusts, suggesting this is an isolated issue.

28. The only other suggestion that the regulations had worsened protection is related to radon levels in underground facilities. The respondent suggested (in answer to a later question) that a passage of text from IRR99 be restored to rectify this. This has been passed on to HSE’s operational experts.

29. Of all respondents, 108 said they worked directly with ionising radiation. When asked whether they feel the regulations effectively minimise their risk of exposure to ionising radiation, 92% agreed they did (98 of 106 who answered), while the remaining 8% did not (see Figure 3).

Figure 3. ‘As a worker covered by the Ionising Radiations Regulations, do you feel they effectively minimise your risk of exposure to ionising radiation?’



30. Respondents who did not work directly with ionising radiation were asked more generally whether they felt the regulations effectively minimise exposure. Of the 38 responses to this question, 37 agreed and one disagreed.

31. Of the explanations provided for not thinking that the regulations minimised exposure, several focussed on the minimal change in the regulations (from IRR99 to IRR17) and did not identify any actual exposure risk. A further two respondents (from NHS acute trusts) identified a risk that was due to compliance/enforcement, not due to regulatory change. For example:

"Regulations do nothing, implementation and practice are key. I do not think inspections are sufficient to have any practical impact if individuals are not self-regulating in the first place."

32. One comment that did identify a risk, identified a known risk across workplace health and safety, in which the workforce becomes complacent because of the proliferation of warning notices. This was raised by a respondent working in the dental sector, who suggested the problem had arisen due to a change in the way the regulations were enforced (not a change in the regulations themselves).

Objective C: To ensure the adverse impacts of the Directive are minimised and the opportunities for simplification maximised to reduce burdens on business, following the Government's better regulation policy and principles.

33. This objective is concerned with the overarching purpose of the post-implementation review, and as such is covered in more detail in the following sections of this evidence review.

34. The majority of respondents do not report undue burdens or compliance difficulties, and consider that a system that imposes less burden is not feasible while maintaining protection.

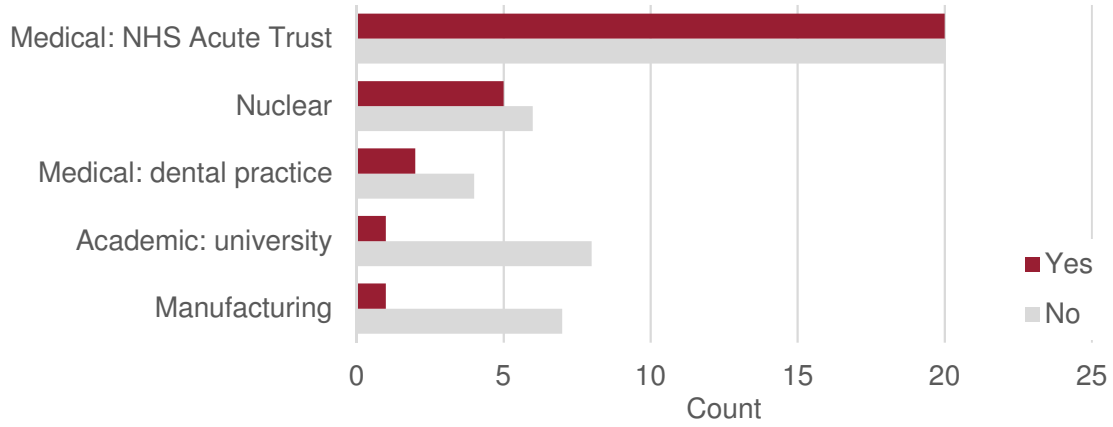
35. There is however a substantial minority of respondents who suggest there is room for reducing burden on businesses. The issues raised are primarily from NHS acute trusts and the education sector, though there is no specific issue which is raised by more than a small minority of respondents. Several of the recurring issues raised have been identified as relating to the Approved Code of Practice (ACOP) and/or guidance, and not to the changes in the regulations made in IRR17. The issues raised are described in more detail in the following sections.

Have there been any unintended effects?

36. Respondents were asked if they were aware of any benefits arising directly from the regulations. Overall, 61% were not aware of any benefits (72 of 119 who answered this question), and 39% were. Figure 4 shows that benefits were more likely to be reported in some sectors than others. Around half of NHS acute trusts and Nuclear sector respondents reported benefits, while this was true of just one in nine university sector respondents.

37. On the whole, the benefits raised related to the *intended* benefits of the regulations and so are not additional to the benefits previously considered. Explanations of the perceived benefits show support for the regulations in raising awareness, improving clarity and increasing worker safety. This includes support for processes such as risk assessments, which some respondents identify as problematic in response to other consultation questions.

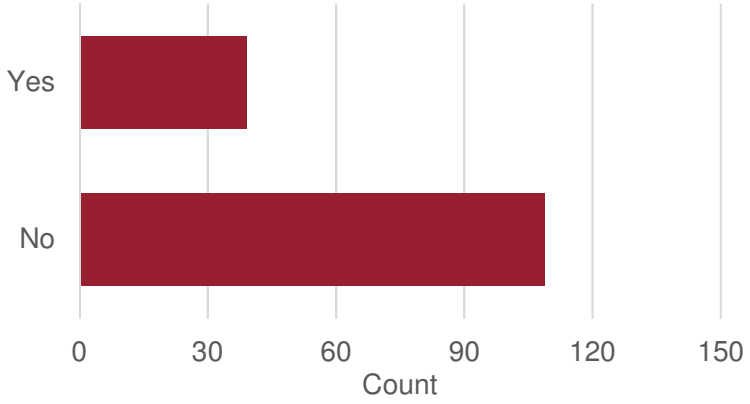
Figure 4. ‘Are you aware of any benefits arising directly from the Ionising Radiations Regulations 2017 changes?’



Showing sectors with 5 or more responses. n=74

38. Respondents were asked if they were aware of any unintended consequences arising from the Ionising Radiations Regulations 2017. Around one quarter of respondents said they were (39 of 148 who answered this question), while three quarters were not (see Figure 5).

Figure 5. ‘Are you aware of any other unintended consequences (positive or negative) arising from the Ionising Radiations Regulations 2017?’



39. The unintended consequences raised were mostly negative, though the majority were anticipated consequences which have been previously considered. The key themes identified were:

- Administrative burden and associated costs
- Difficulty applying the regulations relating to outside workers
- Large number of workers becoming classified
- Disproportionate measures relative to risk

40. The administrative burden is reported to arise from demands on staff time (including staff resourcing issues) and direct costs, mainly associated with the higher number of classified workers (6 NHS acute trust respondents) and changes to the definition of outside workers (4 NHS acute trust respondents). Some increase in administration costs was expected, as well as costs associated with classified workers and the definition of outside workers, and these were accounted for in the initial impact assessment. Nevertheless, the issues raised have highlighted that a minority of organisations consider the burdens as higher than they expected. Review by operational and policy colleagues suggests this may, in part, be due to interpreting the regulations, ACOP or guidance in such a way that leads to a larger amount of work than is necessary.

41. Changes in the interpretation or enforcement of the regulations by HSE, rather than change in the regulations themselves, were also raised. In particular, the need to classify staff based on potential doses from accident scenarios. The administrative burden generated from additional classification of workers in response to possible accident scenarios was raised by several NHS acute trust respondents as being disproportionate, and viewed by some as having no impact on radiation protection. Such changes have arisen from operational intelligence and have been made to improve health outcomes. One explanation for the minority held view that these changes are disproportionate, may be that some respondents are unaware of the incidents that led to the change in enforcement approach.

42. Other aspects that were raised as disproportionate include regulations for perceived low-risk sources used in teaching environments (raised by a local authority and FE college), and the designation of controlled areas for the use of XRF analysers (raised by a manufacturer).

43. Two unintended consequences were raised which suggested inconsistency in the ACOP and guidance. One related to the use of signs and the other to the necessity of special procedures.

What have been the actual costs and benefits of the regulation compared to with the estimated costs and benefits?

44. The cost benefit analysis (CBA) assesses the actual costs against those estimated in the impact assessment. The updated cost estimates in the CBA generally agree with those estimated in the 2017 impact assessment. The revised best estimates are presented in Table 2 below.

Table 2. Summary of Costs (values in millions of £, 2022 prices, to two significant figures)

	Present Value of Total Costs	**Equivalent annual costs to business (EANDCB)**	**Average Ongoing Costs per Year4**
2017 IA	22	0.77	0.96

2022 PIR (low - best - high)	15 - 19 - 26	0.57 - 0.61 - 0.66	0.38 - 0.75 - 1.3

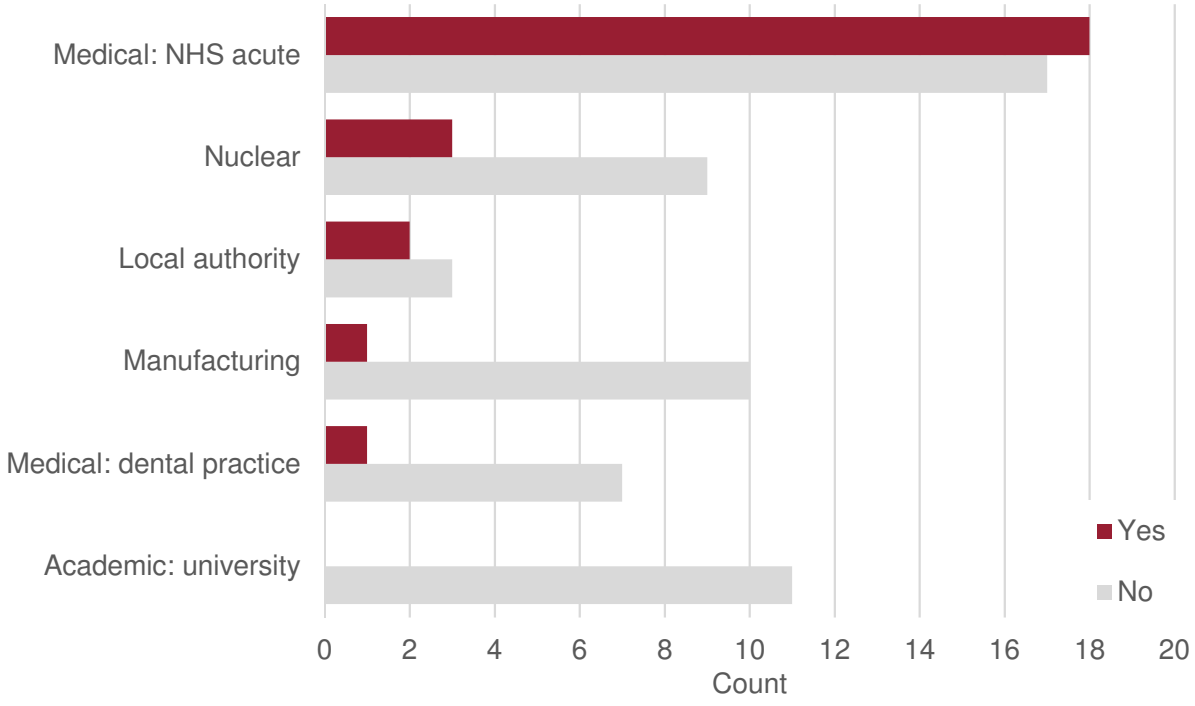
Is the existing form of regulation still the most appropriate approach?

45. To understand stakeholder views on whether the existing form of regulation is still the most appropriate, respondents were asked if the regulatory aims could be achieved in a way that led to less burden on business, if they had any difficulties in complying, and an open question allowing room for additional comments.

Compliance difficulties

46. A minority of one quarter of respondents found parts of the regulations difficult to comply with (33 of 132, versus 99 who did not). This was most prevalent in respondents working in NHS acute trusts, around half of whom (18 of 35) suggested parts of the regulations were difficult to comply with (see Figure 6). Secondary school and local authority respondents were also more likely than average to report finding parts of the regulations difficult to comply with (secondary schools are not presented in Figure 6).

Figure 6. 'Are there any particular aspects of the current regulations that your organisation finds difficult to comply with?'



Showing sectors with 5 or more responses. n=82

NHS acute trusts

47. 18 respondents from NHS acute trusts raised aspects of the regulations that were difficult to comply with (out of 48 NHS acute trust respondents altogether, with 17 saying there were no compliance difficulties, and 13 either 'don't know' or missing). The aspects of the regulations that were considered difficult to comply with were primarily related to the administrative burden they caused. A professional body also suggested that compliance is hindered by dissemination; educating those who need to comply can take considerable time.

48. The regulations relating to outside workers were the most frequently referred to as being difficult to comply with (6 mentions by NHS acute trusts), with specific elements such as difficulty in providing training, cooperation between employers, and the information transfers required before an outside worker visits the site.

49. Respondents were asked for alternative suggestions for particular aspects of the regulations that were difficult to comply with. In relation to the outside worker difficulties, respondents suggested:

    - Giving approved dosimetry services a role in sharing dose records between employers.
    - Following a more risk-based approach: exchanging information only if risk assessment suggested it was necessary.
    - Self-certification for outside workers managed by a separate authority.
    - Assessment based on conversation with the outside worker at the point of entering a controlled area.
    - Only sharing dose information if measured doses are above 0 or where annual dose to date exceeds 0.5mSv.

50. Four NHS acute trust respondents raised administrative burdens associated with classification and the associated definitions and dosimetry. The particular issue was around staff who were judged to have an extremely low risk resulting from an accident, but who nevertheless required classification according to the perceived HSE stance on this issue. Ambiguity in the definitions of surrounding risk were also raised. The increase in classified workers as a result creates a burden on staff that is reported as unachievable given staffing pressures. Alternative suggestions included:

    - Raise the threshold for a reasonably foreseeable incident.
    - More scope for organisations to follow Radiation Protection Advisor (RPA) advice and site-specific risk assessment rather than a literal interpretation of ACOP.

51. Four NHS acute trust respondents raised training as a significant administrative burden. Particular aspects raised include the management of refresher training (especially in areas where staff are not directly involved in working with ionising radiation) and auditing: the need to record and provide evidence of relevant training. The lack of IT capability to facilitate this requirement was raised by two respondents. No alternative suggestions were made.

52. Two NHS acute trust respondents raised the administrative burden of complying with contingency plan live rehearsals. Difficulties included the amount of staff time these take up, again related to staffing pressures across trusts. Specifically, one respondent also noted that "hitting the emergency power kill buttons in x-ray rooms… cannot be rehearsed due to the risk of damage to the equipment."

53. As an alternative, it was suggested that all staff undergo one rehearsal, followed by audits rather than further rehearsals.

Secondary schools and local authorities

54. Secondary schools and local authorities (who perform related tasks on behalf of other organisations, including some education establishments) identified different compliance concerns to NHS acute trusts. Two schools said the costs associated with the regulations made them difficult to comply with. This included the cost of disposal, cost of RPS, and the time needed to carry out the RPA role. The alternative suggestions focussed on reviewing the regulations with regard to the low risk sources used in schools (which are reported to be equivalent to domestic smoke alarms) with the aim of reducing costs for schools.

55. Two respondents suggested that the complexity of the regulations, especially relating to radon gas, made compliance difficult. The alternative suggestion was not for alternative regulations, but a simplified guidance document.

Nuclear sector

56. 3 out of 16 respondents from the nuclear sector raised aspects of the regulations that their organisations found difficult to comply with. Each respondent raised different issues, suggesting they may be isolated difficulties within the sector, though they did correspond to issues raised by respondents from NHS acute trusts. The issues raised were the contingency plan live rehearsals and the large number of classified workers due to definition of reasonably foreseeable risk (in relation to ACOP 433[17]).

57. Alternative suggestions from the nuclear sector were:
    - In place of regular live rehearsals, action required should account for total holdings (similar to REPPIR 2019[18] [Radiation (Emergency Preparedness and Public Information) Regulations]) and use desktop exercises with live events reduced to once every three years.
    - Provide more clarity on what is 'reasonably foreseeable' in the context of ACOP 433.

58. One respondent also raised the management of outside contractor registration as a compliance difficulty, due to large number of different and regularly changing organisations that provide contractors. Alternative suggestions were:
    - Consider extending the exemption for Nuclear Licenced Sites for notification to cover registration and consent as the radiological aspects are already regulated by ONR.
    - Consider having the Nuclear Site Licensee hold the registration / consent rather than every individual contractor working on the site.

Other sectors

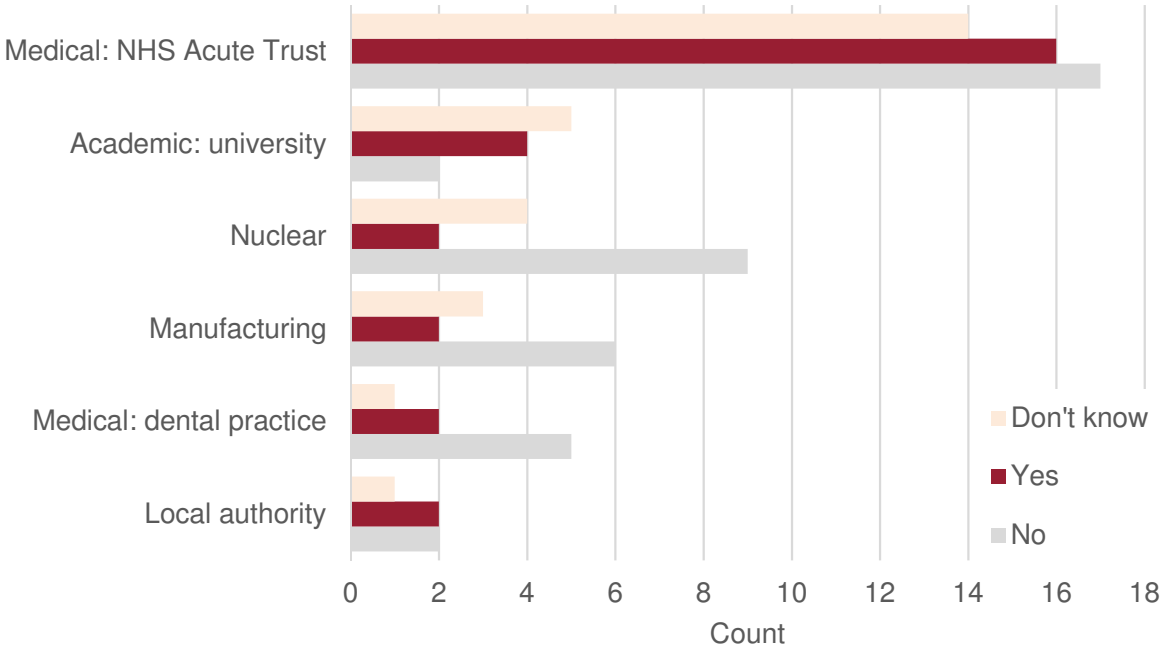
59. Two respondents (one in the dental sector and one in the veterinary sector) suggested that there were compliance difficulties with fitting the recommended fail-safe lighting. One respondent suggested that alternative lighting systems should be permitted until a fail-safe version is readily available.

[17] https://www.hse.gov.uk/pubns/priced/l121.pdf
[18] https://www.legislation.gov.uk/uksi/2019/703/contents

A system that imposes less burden?

60. Respondents were asked if the aims of the Ionising Radiations Regulations 2017 could be achieved with a system that imposes less burden on businesses. Just over a quarter didn't know (41 of 147 that answered the question). Of those that provided a definitive answer, nearly two thirds said no (66 of 106) while over one third said yes (40 of 106). Those working in universities, local authorities and NHS acute trusts were more likely to suggest a less burdensome system was possible (see Figure 7).

Figure 7. 'In your opinion, could the aims of the Ionising Radiations Regulations 2017 be achieved with a system that imposes less burden on business?'



Showing sectors with 5 or more responses. n=97

61. Respondents were asked to explain how they think the aims of the regulations could be achieved with a system that imposes less burden on business. Some responses covered issues and suggestions already raised. Below are suggestions that identify additional burdens or alternative approaches not yet presented.

NHS acute trusts

62. Nine (of 48) NHS acute trust respondents provided an explanation of how they thought a system that imposes less burden on business could be achieved. Relating to the burden of classifying workers who are perceived to be at very low risk, one respondent suggested distinguishing between low- and medium- risk workers to reduce the number of classified workers (and associated time and costs burden):

> *"[The] provision for "monitored but not classified" it could greatly reduce the burden on healthcare while still providing HSE avenues for enforcement should risks not be appropriately managed."*

63. One respondent suggested changes to ACOP so that it explicitly suggests the use of alternative dosimeter locations where monitoring fingertip or eye doses was not practical. They suggest this would reduce the costs and improve infection control.

64. In apparent reference to 'local rules', one respondent suggested "some parts could just be standardized rather than our re-writing the interpretation of said regulations. Standardised templates for employers to use would benefit us greatly and then we would only need to locally customize."

65. More generally, one respondent noted that it would reduce administrative burden if HSE would share examples of good practice obtained during inspection, and provide more detail of accidents/incidents with the purpose of sharing learning points.

Secondary schools and local authorities

66. The three suggestions made by the schools sector all focussed on reducing controls to be commensurate with the perceived risk:
    - *"Reduce the school standard holding allowance and reduce controls to reflect this"*
    - *"Total exemption for schools using the standing school holding (as per CLEAPSS guidance L93)"*
    - *"Review the IRR in relation to low risk sources that are found in domestic items such as smoke detectors so that they are risk-proportionate and not so costly to comply with by schools, such as for disposal."*

Other sectors

67. Two suggestions focussed on reducing burden arising from the complexity of the regulations. One respondent suggested that guidance should be tailored to specific sectors (e.g. schools, large NHS trusts, small hospitals with one x-ray room) to reduce burden. Another suggested "clearer interpretation of guidance and updates to the ACOP."

68. Other suggestions to reduce the burden on businesses include:

    - Allowing more flexibility in determining the periodic test frequency for radiological instrumentation [nuclear sector].
    - Simplifying paperwork so it is easier to complete and universally understood [manufacturing sector].
    - Less change over time regarding interpretation for regulations [industrial sector].

Additional comments

69. Respondents were asked if they had any further comments. 23 of the 152 respondents provided comments. Six were positive reflections of the regulations and/or value ACOP and guidance.

70. Five respondents from four different sectors suggested that utilising more inspections and the inspectorate more generally would be beneficial to encourage compliance.

Suggestions include undertaking more inspections, having more communication with NHS chief executives to add weight to RPA recommendations, and focussing inspections on contractors, suppliers and installers of ionising radiation equipment.

71. The remaining comments repeated previous issues raised.

Appendix 1: Stakeholder questionnaire

The questionnaire below was implemented in Microsoft Forms.

Ionising Radiations Regulations 2017 - Policy Review

Background

The Ionising Radiations Regulations 2017 introduced the following changes:

Main changes

- *Eye dose limits*: a reduction in the eye dose limit and changes to classification levels.
- *Graded approach*: introduction of a risk-based approach to regulatory control of practices using ionising radiation.
- *Outside workers*: change in the definition that widens the scope of the regulations.
- *Public dose estimation*: a requirement to estimate doses to members of the public.
- *Accidental exposures and the recording and analysis of significant events*: change in the scope of events which require recording and analysis.

Additional changes

- *Dosimetry and medical record retention*: change in the minimum period dose and medical records must be retained for.
- *Atmospheric radon*: change in the measurement level of exposure to atmospheric radon that brings workers in scope of the Ionising Radiations Regulations.
- *Under 18 exposure*: introduction of blanket coverage of workers aged under 18, preventing them from carrying out any work likely to lead to exposure to ionising radiation.
- *Calculation of estimated doses*: a new requirement that the methodology for estimating doses is approved by a competent authority.
- *Subsidiary dose limit*: Removal of the subsidiary dose limit for the abdomen of a woman of reproductive capacity.
- *Fitness for work appeal period*: Change in the period for appeals against the appointed doctor's decision on medical fitness for work.
- *Appointed doctor process*: removal of the legal requirement for Appointed Doctor to be 'in writing'.

To review the regulations in full go to: https://www.legislation.gov.uk/uksi/2017/1075/contents, otherwise **please continue to question 1**.

Section 1. About you

Please complete the following questions so that we can understand your responses in the context of your role and organisation.

1.In what capacity are you responding?

- On behalf of a single organisation
- On behalf of a representative group, network or other body that covers multiple organisations

2.What is the name of the organisation you work for?

- As a consultant that works across multiple organisations
- On your own behalf, as an individual worker
- Other

3.Approximately how many people work in your organisation?

- 1 (self-employed)
- 2-9
- 10-49
- 50-249
- 250-499
- 500-999
- 1000 or more
- Don't know

4.What is your job role?

Section 2. Regulatory objectives

5.In your opinion, has the introduction of the Ionising Radiations Regulations 2017 in Great Britain...

- Improved radiological protection a lot
- Improved radiological protection a little
- Made no difference to radiological protection
- Worsened radiological protection a little
- Worsened radiological protection a lot
- Don't know

6.Please explain why you think radiological protection has worsened.

Section 3. Costs associated with the regulation changes

Information you provide in this section will help us review costs associated with the regulation changes.

6.So that we can show you relevant questions in this section, please select the sector that best represents the main focus of your organisation.

(If you work across multiple sectors, for example as a consultant, please choose the one you work with the most).

- Medical: NHS acute
- Medical: NHS mental health
- Medical: NHS community health
- Medical: private health care
- Medical: dental practice
- Medical: veterinary practice
- Nuclear (all civil nuclear operators and Ministry of Defence)
- Academic: university
- Academic: FE college
- Academic: secondary school
- Local authority
- Industrial research
- Manufacturing
- Construction
- Engineering
- Oil and gas production
- Non-destructive testing
- Approved dosimetry service provider
- Other

Lower eye dose limit

8. Prior to the introduction of the Ionising Radiations Regulations 2017, the Health and Safety Executive estimated that around 8% of already-classified workers in the nuclear sector would require additional eye dosimetry as a result of the lower eye dose limit.

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low
- Much too low
- Don't know

9. What percentage of already-classified workers in the nuclear sector would you say have required additional eye dosimetry as a result of the lower eye dose limit?

Best estimate (%):

10.The Health and Safety Executive originally estimated the cost of providing additional eye dosimetry for already classified workers to be around £100 per worker per year (mainly resulting from the provision of eye dosemeters).

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low
- Much too low
- Don't know

11. What would you say is the cost of providing additional eye-dosimetry for already-classified workers, per worker per year?

Best estimate (£, per worker, per year):

Recording and Analysis of 'Significant' Events
The Ionising Radiations Regulations 2017 placed an additional duty on duty holders to record and analyse events which cause the enactment of a contingency plan.

Your organisation/the organisations you work with, may have already been recording and analysing some or all such events before the Ionising Radiations Regulations 2017 came into force. In the questions that follow we would like to know about any **additional** recording and analysing of events due to the regulations: that is, events which would not have been recorded or analysed under the previous regulations.

12. Has your university/the universities you work with recorded and analysed any additional events as a result of the Ionising Radiations Regulations 2017 requirement?

- Yes
- No
- Don't know

13. If you represent or work across multiple universities, approximately what proportion of those universities have recorded additional events?
(If not applicable, please leave blank).

Best estimate (%):

14. On average, how many additional events are recorded and analysed per year?
(If you work across multiple universities, please give an average of those that do record additional events).

Best estimate (number of events per year):

15. Prior to the introduction of the regulations, the Health and Safety Executive estimated that

multiple persons would be involved in recording and analysing accidental safety-significant incidents, taking a combined total of **10 hours per event** on average.

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low
- Much too low
- Don't know

16. What would you say is the average amount of time involved in recording and analysing each event?

(Please provide your estimate in terms of person-time. E.g. if it took 2 people 5 hours each, please enter 10 hours).

Best estimate (hours):

Recording and Analysis of 'Significant' Events

The Ionising Radiations Regulations 2017 placed an additional duty on duty holders to record and analyse events which cause the enactment of a contingency plan.

Your Trust/the Trusts you work with, may have already been recording and analysing some or all such events before the Ionising Radiations Regulations 2017 came into force. In the questions that follow we would like to know about any **additional** recording and analysing of events due to the regulations: that is, events which would not have been recorded or analysed under the previous regulations.

17. Has your Trust/the Trusts you work with, recorded and analysed any additional events as a result of the Ionising Radiations Regulations 2017 requirement?

- Yes
- No
- Don't know

18. If you represent or work across multiple Trusts, approximately what proportion of those organisations have recorded additional events?

(If not applicable, please leave blank).

Best estimate (%):

19. On average, how many additional safety-significant events are recorded and analysed per year in your Trust?
(If you work across multiple Trusts, please give an average of those Trusts that do record additional events).

Best estimate (number of events per year):

20. Prior to the introduction of the regulations, the Health and Safety Executive estimated that

multiple persons would be involved in recording and analysing events which cause the enactment of a contingency plan, taking a combined total of **10 hours per event** on average.

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low
- Much too low
- Don't know

21. What would you say is the average amount of time involved in recording and analysing each event?
(Please provide your estimate in terms of person-time. E.g. if it took 2 people 5 hours each, please enter 10 hours)

Best estimate (hours):

Lower eye dose limit
The Ionising Radiations Regulations 2017 introduced lower dose limits for ionising radiation exposure to the lens of the eye.

22. When the Ionising Radiations Regulations were introduced, did your NHS Trust, or the Trusts you work with, have to issue additional pairs of protective leaded eyewear as a result of the regulations?

- Yes
- No
- Don't know

23. If you represent or work across multiple Trusts, approximately what proportion of those Trusts had to issue additional eyewear?
(If not applicable, please leave blank).

Best estimate (%):

24. Approximately how many additional pairs of protective leaded eyewear did your NHS Trust have to issue when the regulations were first introduced?
(If you work across multiple Trusts, please give an average of those Trusts that issued additional eyewear.)

25. Approximately what proportion of the additional pairs of protective leaded eyewear need to be replaced each year (due to wear and tear for example)?

Best estimate (%):

Lower eye dose limit
The Ionising Radiations Regulations 2017 introduced lower dose and classification limits for ionising radiation exposure to the lens of the eye. This may have led to the need to carry out additional monitoring of eye doses for non-classified workers, to ensure they do not exceed the new classification limit.

Your organisation may have already been monitoring many non-classified workers' eye-doses before the regulations came into force. In the following questions we would like to know about any **additional** monitoring of eye doses due to the regulations: that is, monitoring which would not have taken place under the previous regulations.

26. Does your organisation, or the organisations you work with, carry out additional monitoring of eye doses for **currently non-classified workers**, as a result of the lower dose limits introduced in the Ionising Radiations Regulations?

- Yes
- No
- Don't know

27. If you represent or work across multiple Trusts, approximately what proportion of those Trusts carry out additional monitoring of eye doses for currently non-classified workers?

(If not applicable, please leave blank).

Best estimate (%):

28. What would you say is the cost of additional monitoring of eye doses for currently non-classified workers in your NHS Trust per year?
(If you work across multiple Trusts, please give an average of those Trusts that carry out additional monitoring).

Best estimate (£, per Trust, per year):

29. Thinking about these non-classified workers that receive additional monitoring, does their work relate to Interventional Radiology, Cardiology, or Positron Emission Tomography (PET)?

- Yes, all of them
- Yes, some of them
- No
- Don't know

The graded approach
The Ionising Radiations Regulations 2017 introduced the 'graded approach' in which organisations that work with ionising radiation are required to either notify, register or gain consent from the Health and Safety Executive.

30. Does your organisation/the organisations you work with, carry out practices which require **registration** with the Health and Safety Executive under the Ionising Radiations Regulations 2017?

- Yes
- No
- Don't know

31. Prior to the introduction of the regulations, the Health and Safety Executive estimated that it would take an organisation around 4 hours of one person's time to gather necessary information and subsequently apply to **register** with the Health and Safety Executive, per registration.

(This estimate assumes compliance with other aspects of the regulations, such as having already conducted a Radiation Risk Assessment).

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low
- Much too low
- Don't know

32. What would you say is the amount of time taken, per registration, to gather the necessary information and subsequently apply to register with the Health and Safety Executive?
(Please provide your estimate in terms of person-time. E.g. if it took 2 people 2 hours each, please enter 4 hours)

Best estimate (hours):

33. Please briefly describe the main tasks included in your time estimate and estimate the amount of time taken for each task.

The graded approach
The Ionising Radiations Regulations 2017 introduced the 'graded approach' in which organisations that work with ionising radiation are required to either notify, register or gain consent from the Health and Safety Executive.

34. Does your organisation/the organisations you represent, carry out practices which require **registration** with the Health and Safety Executive under the Ionising Radiations Regulations 2017?

- Yes
- No
- Don't know

35. Prior to the introduction of the regulations, the Health and Safety Executive estimated that it would take an organisation around 1 hour of one person's time to gather necessary information and subsequently apply to **register** with the Health and Safety Executive, per registration.

(This estimate assumes compliance with other aspects of the regulations, such as having already conducted a Radiation Risk Assessment).

Do you think that estimate was:

- Much too high
- Too high
- About right
- Too low

- Much too low
- Don't know

36. What would you say is the amount of time taken, per registration, to gather the necessary information and subsequently apply to register with the Health and Safety Executive?
(Please provide your estimate in terms of person-time. E.g. if it took 2 people 30 minutes each, please enter 1 hour)

Best estimate (hours):

37. Please briefly describe the main tasks included in your time estimate and estimate the amount of time taken for each task.

Section 4. Other costs, benefits and unintended consequences

The original impact assessment of the Ionising Radiations Regulations 2017 changes identified the main costs to business in the following areas:

- Changes to requirements on doses to the lens of the eye
- Graded approach (notification, registration, and consent)
- Outside workers
- Public dose estimation
- Accidental exposures and the recording and analysis of 'significant' events
- Familiarisation costs

38. Are you aware of any other costs arising directly from the Ionising Radiations Regulations 2017 changes?

- Yes
- No
- Don't know

39. Please provide a brief description, and estimated cost, for those other costs areas.

40. Are you aware of any benefits arising directly from the Ionising Radiations Regulations 2017 changes?

- Yes
- No
- Don't know

41. Please provide a brief description of those benefits.

42. Do you personally work with ionising radiation?

- Yes
- No
- Don't know

43. As a worker covered by the Ionising Radiations Regulations, do you feel they affectively minimise your risk of exposure to ionising radiation?

- Yes
- No
- Don't know

44. Please explain why you do not feel the regulations affectively minimise your risk of exposure.

Other costs, benefits and unintended consequences

45. Do you feel the Ionising Radiations Regulations 2017 affectively minimise risk of exposure to ionising radiation?

- Yes
- No
- Don't know

46. Please explain why you do not feel the regulations affectively minimise risk of exposure to ionising radiation.

Other costs, benefits and unintended consequences

47. Are you aware of any other unintended consequences (positive or negative) arising from the Ionising Radiations Regulations 2017?

- Yes
- No

48. Please provide a brief description

Section 5. Fit for purpose regulation

49. Are there any particular aspects of the current regulations that your organisation finds difficult to comply with?

- Yes
- No
- Don't know

50. Please explain which aspects are difficult to comply with and why.

51. If you have an alternative suggestion for how a particular aspect of the regulations could be improved, please enter this below.

52. In your opinion, could the aims of the Ionising Radiations Regulations 2017 be achieved with a system that imposes less burden on business?

- Yes
- No
- Don't know

53. Please explain how you think the aims of the regulations could be achieved with a system that imposes less burden on business.

Section 6. Further comments

54. If you have any further observations or comments about the Ionising Radiations Regulations 2017, please enter these below:

55. Finally, as part of this research, the Health and Safety Executive may want to contact you again to clarify, or get further information, on the responses you provided.

If you are happy for the Health and Safety Executive to re-contact you, **please provide your email address**:

<END OF QUESTIONNAIRE>

Appendix 2: Data tables for Figures 1 to 7

Figure 1. *Approximately how many people work in your organisation?*

	Count
1 (self-employed)	8
2-9	9
10-49	15
50-249	17
250-499	9
500-999	2
1000 or more	79

Figure 2. 'In your opinion, has the introduction of Ionising Radiations Regulations 2017 in Great Britain…'

	Count

Worsened radiological protection a lot	0
Worsened radiological protection a little	4
Made no difference to radiological protection	27
Improved radiological protection a little	97
Improved radiological protection a lot	13

Figure 3. ‘As a worker covered by the Ionising Radiations Regulations, do you feel they effectively minimise your risk of exposure to ionising radiation?’

	Count
Yes	98
No	8

Figure 4. ‘Are you aware of any benefits arising directly from the Ionising Radiations Regulations 2017 changes?’

	Count	
	No	**Yes**
Manufacturing	7	1
Academic: university	8	1
Medical: dental practice	4	2
Nuclear	6	5
Medical: NHS Acute Trust	20	20

Figure 5. ‘Are you aware of any other unintended consequences (positive or negative) arising from the Ionising Radiations Regulations 2017?’

	Count
No	109
Yes	39

Figure 6. ‘Are there any particular aspects of the current regulations that your organisation finds difficult to comply with?’

	Count	
	No	**Yes**
Academic: university	11	0
Medical: dental practice	7	1
Manufacturing	10	1
Local authority	3	2
Nuclear	9	3
Medical: NHS acute	17	18

Figure 7. ‘In your opinion, could the aims of the Ionising Radiations Regulations 2017 be achieved with a system that imposes less burden on business?’

	Count

	No	Yes	Don't know
Academic: university	2	4	5
Local authority	2	2	1
Medical: NHS acute	17	16	14
Medical: dental practice	5	2	1
Nuclear (all civil nuclear operators and Ministry of Defence)	9	2	4
Manufacturing	6	2	3

Annex 5: The Costs and Benefits of the Ionising Radiations Regulations 2017 (IRR17)

Introduction

1. The Ionising Radiations Regulations 2017 (IRR17) replaced the Ionising Radiations Regulations 1999 (IRR99) on 1st January 2018. IRR17 introduced a number of new requirements relating to occupational exposure. This report analyses the economic impacts of these new requirements[19].

2. This report focusses on re-estimating ongoing costs identified in the 2017 Impact Assessment[20] (hereafter referred to as 'the 2017 IA'). Ongoing costs (as opposed to costs that have already occurred) can be impacted by current and future policy decisions. As is the case with many health and safety interventions, estimating benefits in monetary terms is challenging and is deemed disproportionate for this PIR. A qualitative discussion of benefits can be found in Section 7.

3. The core findings of this cost benefit analysis (CBA) can be found summarised in Table . Costs estimated in this updated CBA generally agree with those estimated in the 2017 IA. Moreover, these costs, when compared with other regulatory packages are relatively small[21].

Table 1. Summary of Costs (millions of £, 2022 prices, 2 s.f.)

	Present Value of Total Costs	**Equivalent annual costs to business (EANDCB)**	**Average Ongoing Costs per Year**[22]
2017 IA[23]	22	0.77	0.96
2022 PIR (low - best - high)	15 - 19 - 26	0.57 - 0.61 - 0.66	0.38 - 0.75 - 1.3

4. Considering the relatively low costs estimated by the 2017 IA, a proportionate approach has been taken conducting this CBA (see Section 2 for further details).

5. This report starts with a summary of the costs estimated in the 2017 IA; then sets out the proportionality approach taken by this CBA and assumptions used; and a section detailing research undertaken to inform the CBA follows. Section 5 then extensively details how costs have been estimated in this CBA. These estimates are summarised in Section 8.

[19] See Section 2 for further discussion of this focus.
[20] https://www.legislation.gov.uk/ukia/2017/161/pdfs/ukia_20170161_en.pdf
[21] See paragraph 15 and footnote 28 for further discussion of this point.
[22] This is all ongoing costs (public and private) averaged over a ten-year period.
[23] Costs from the 2017 IA (with the exception of 'Registration fees costs') have been inflated by 14.9% to be presented in 2022 prices. See paragraph 18 for further detail.

1 The 2017 IA

1.1 Overview of Estimated Impacts

6. The 2017 IA estimated costs for two different policy options (which it called 'Option 1' and 'Option 2'). Option 1 was implemented in 2018, and so this option is the focus of this CBA.
7. Table below provides a summary of the costs of Option 1 estimated in the 2017 IA[24]. The 2017 IA estimated an EANDCB of £0.77m (2022 prices).

Table 2. Costs estimated in the 2017 IA (millions of £s, 2022 prices, 2 s.f.)

Broad cost area	Present Value of Total Costs	Ongoing Costs per Year
Eye Dose - Medical Sector	9.5	0.53
Eye Dose - Nuclear Sector	1.7	0.18
Graded Approach	2.5	0.067
Outside Workers	Nil	Nil
Weighting Factors	0.29	Nil
Public Dose Estimation	0.058	0.0034
Accidental Exposures	1.6	0.19
Familiarisation costs	6.0	Nil
Total Costs	**22**	**0.96**

Source: The 2017 IA

8. Each row in
9. **Table** represents a broad cost area, each of which are made up of several individual costs. On grounds of proportionality, only some of these individual costs have been re-estimated in this CBA. Those costs which are not re-estimated are assumed to be as estimated in the 2017 IA and are inflated to 2022 prices. This is discussed further in Section 2.

10. The 2017 IA only calculates 'best estimates' of costs; it does not attempt to estimate ranges of costs (despite occasionally stating ranges in its assumptions). This is in contrast to the approach taken by this CBA, which estimates a range for all costs[25].

2 Scope and Proportionality approach

11. This CBA only assesses the economic impacts of the additional requirements introduced by IRR17 (i.e. the differences between IRR99 and IRR17). Legislative arrangements for controlling the risks to workers' and others' health associated with exposure to ionising radiation are long-established in GB. The previous IRR99 Regulations (which were themselves preceded by 1985 regulations) were well-established, and on-going engagement with employers working with ionising radiation had shown little concern with the requirements. The well-established requirements that have not

[24] Costs from the 2017 IA have been inflated by 14.9% to be presented in 2022 prices. See paragraph 18 for further detail. For simplicity and given the purpose of this table to give a broad overview of costs, all costs have been inflated. This is in contrast to other figures presented in this analysis, where registration fees costs (a specific cost area making up part of Graded Approach costs) are not inflated. This does not impact the total cost figures displayed.

[25] This is discussed further in Section 3.

changed in IRR17 are vast and no prior research has been undertaken to identify their economic impact. As such, estimating these impacts would require a substantial amount of resource. Conversely, estimating only the additional impacts of IRR17 allows analysts to build on the research conducted in the 2017 IA, making it a lower-resource approach. The approach taken has been deemed proportionate by HSE policy makers and has been approved as such by HSE's Evaluation Working Group.

12. This CBA focuses on reassessing the main ongoing costs identified in the 2017 IA. The 2017 IA identifies a very large number of individual costs, most of which were one-off costs (costs that occurred in 2018). Reassessing every cost would be high resource for HSE and impose a disproportionate burden on industry stakeholders, who would be asked to provide information about these costs. One-off costs have already occurred and cannot be impacted by current decision-making. While the estimation of one-off costs may have further assisted analysts in understanding whether their original estimates were accurate (and hence may have further facilitated better impact assessments in the future), it has been deemed disproportionate to extend the amount of resource already dedicated both by HSE and industry stakeholders in pursuit of this end.

13. The individual cost areas which are reassessed in this CBA are summarised in Table below. These cost areas were selected based on the size of their ongoing costs (as estimated by the 2017 IA), internal expert opinion as to whether these costs are likely to have changed, and the perceived resource required to re-estimate each cost area. As can be seen in Table , while only around half of total costs are reassessed, the vast majority (around 90%) of ongoing costs are reassessed.

Table 3. Summary of cost areas from the 2017 IA which are reassessed in this CBA (millions of £s, 2022 prices[26], 2018 Present Value, 2 s.f.)

Broad Cost Area	Specific Cost Area	Present Value of Total Costs	EANDCB[27]	Ongoing Cost per Year
Eye Dose – Medical Sector	Monitoring of non-classified workers	2.0	Nil	0.23
	Protective Eyewear	2.8	Nil	0.20
Eye dose – Nuclear Sector	Monitoring of already-classified workers	1.5	0.15	0.17
Graded approach	Registrations - administrative time	1.2	0.086	0.031
	Registrations - fees	0.93	0.076	0.035
Accidental exposures	Medical	0.76	Nil	0.088
	Universities	0.85	0.098	0.098
Total (reassessed)		**9.9**	**0.41**	**0.85**
All other costs (not reassessed)		12	0.35	0.11
Total		**22**	**0.77**	**0.96**

[26] Costs from the 2017 IA (with the exception of 'Registrations – fees') have been inflated by 14.9% to be presented in 2022 prices. See paragraph 18 for further detail.
[27] Some cost areas do not contribute to the EANDCB, and so are marked as 'nil'. This is because all medical sector costs were assumed to fall on the NHS (public sector).

14. Costs which are not reassessed as part of this CBA (displayed in **Table** as 'all other costs'), are assumed to be as estimated in the 2017 IA (and are inflated to 2022 prices) for the purposes of this CBA. This facilitates a fair comparison of total costs estimated in the 2017 IA and those estimated in this CBA.

15. As costs are relatively small compared to other regulatory changes[28], a proportionate approach has been taken to re-estimating costs. The value of this CBA is to check whether any costs seem to be significantly greater than were estimated in 2017 (hence potentially requiring further attention), rather than to make precise cost estimates. As such, analysts have been selective in deciding which assumptions to update, as detailed in Section 3.

3 Assumptions, Risks and Uncertainties

16. The 2017 IA estimated the impacts of IRR17 over a 10-year appraisal period, from the start of 2018 to the end of 2027. This CBA maintains the same appraisal period. Hence, it estimates costs that have already occurred (up to 2022); and makes renewed estimates of projected costs up to the end of 2027.

17. The 2017 IA presented costs over time in terms of present values, using a discount rate of 3.5% to do so. This assumption is maintained in this CBA, as is recommended by central government guidance[29]. Furthermore, the 2018 present value base year used in the 2017 IA is carried forward into this CBA.

18. Unless otherwise stated, costs are presented in 2022 prices. This allows for a fair comparison of costs estimated by the 2017 IA and the CBA. Furthermore, it displays cost estimates in terms that will be most familiar to decision-makers (present-day prices). In order to display costs from the 2017 IA in 2022 prices, an GDP deflation factor of 14.9% has been used. This is based on the latest GDP deflators[30] (a statistic produced by HM treasury which can be viewed as a measure of general inflation in the domestic economy). For reasons explained in Section 5.5.1, registration fees costs are not inflated.

19. Some assumptions from the 2017 IA have been updated in this CBA, whilst others have not. Generally, resource has been focussed to update assumptions that were made by the 2017 IA based on predictions made by stakeholders (for example, estimates of how much additional PPE they would purchase in the future). Conversely, assumptions that are based on actual statistics (for example, the number of NHS Trusts in GB) are often deemed by analysts and internal experts as less likely to change significantly and hence not updated. This is noted and more explanation is given where necessary in the relevant sections below. This approach is in line with the

[28] For example, the EANDCB falls well below the £5m de minimis threshold, and so is considered too small to be considered against the business impact target, as per Better Regulation guidance: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf .

[29] https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1063330/Green_Book_2022.pdf

[30] The 2017 IA estimated costs in 2016 prices. At the time of writing, the most recent GDP deflator series stated the following GDP indices: 2016 = 89.548, 2021 = 100. The same deflator series estimated GDP growth of 2.85% from 2021 to 2022. This gives GDP deflation of 14.9% from 2016 to 2022 (1.0285/89.548). Source: https://www.gov.uk/government/statistics/gdp-deflators-at-market-prices-and-money-gdp-june-2022-quarterly-national-accounts

proportionality approach set out in Section 2 – to check whether costs may be significantly greater than those estimated in the 2017 IA, rather than to make precise cost estimates.

20. COVID-19, and hence disruption to 'normal' business activity occurred for a significant proportion of the period that IRR17 has been in force. As such, respondents to our survey (described in Section 4) may draw heavily upon their experiences of these abnormal times when asked about costs. Alternatively, they may draw upon more normal experiences (as the survey was in the field in 2022, after most COVID-19 disruption had passed). Therefore, cost estimates produced in this CBA may be disproportionately influenced by COVID-19 circumstances, or indeed not consider them enough.

21. This CBA produces ranges in cost estimates ('high' and 'low' estimates) to account for uncertainties such as those described in paragraph 20.

4 Research and evidence gathering

22. The core sources of evidence used to inform this CBA are summarised below:

- A survey, sent to various stakeholder groups, forms the main evidence source for this CBA. The survey asked about the specific cost areas identified in **Table** . In total, 154 responses were received. Two responses were removed on the basis that the respondents' place of work was not in the GB, leaving 152 for analysis. Further discussion of the survey, including a summary of respondent characteristics can be found in the Evidence Review (Annex 1).

- A review of the results of this survey, conducted by a panel of internal experts.

- HSE's internal database of registered work with ionising radiation has been used to estimate costs of the Graded Approach.

- As discussed in paragraph 19, some assumptions from the 2017 IA have been brought forward into this CBA. Where proportionate, internal expert opinion has been used to verify these assumptions.

5 Costs

5.1 Medical: Monitoring of non-classified workers

23. IRR17 reduced the dose limit and classification limit for ionising radiation exposure to the lens of the eye. Before the introduction of the new limit, HSE undertook a large amount of research and engagement with stakeholders to understand the potential impacts of this. As part of this exercise, NHS stakeholders reported that they may carry out additional monitoring of eye doses for non-classified workers (hereby referred to as 'additional monitoring'), constituting an additional cost. This cost is assessed in Section 11.5.5 of the 2017 IA.

5.1.1 Estimates from the 2017 IA

24. The 2017 IA estimated that 232 sites in the medical sector may be affected by the revised eye dose limits (see Section 11.3.2 of the 2017 IA). It goes on to estimate that 50% of these sites may incur additional monitoring costs, giving 116 sites.

25. The 2017 IA estimated that each site would incur monitoring costs of £1,750 per annum (2016 prices). This gives annual costs of around £200,000 from the first year of the appraisal period (2016 prices). Inflating these costs to 2022 prices gives ongoing costs of around £230,000 per annum, at a present value of around £2.0m.

26. The 2017 IA estimated that the vast majority of impacts from the changes to eye does limits would fall on the NHS (see Section 11.3.1 of the 2017 IA). Therefore, as a simplifying assumption, all such costs were assumed to fall on the NHS (the public sector), (see Section 11.7 of the 2017 IA).

5.1.2 Estimates from this CBA

27. As part of the survey described in Section 4, we asked stakeholders from the medical sector whether their organisation carried out additional monitoring. Only respondents on behalf of NHS Acute Trusts said that they did[31]. Of respondents responding on behalf of individual NHS Trusts, 35% (8 of 23 respondents) stated that their organisation conducted additional monitoring. The average response to those providing an estimate across multiple Trusts (12 respondents) was that 80% of Trusts conducted additional monitoring. Based on these results, internal experts deem it reasonable to assume that between 35% and 80% of NHS Trusts conduct additional monitoring, with a midpoint best estimate of 58%.

28. The 2017 IA estimated there to be 181 NHS Acute Trusts in Great Britain, and that this number would remain constant throughout the appraisal period (2018-2027). More recent publicly available statistics are not presented in a format required for this analysis. Internal experts judge that the estimate used by the 2017 IA is unlikely to vary significantly over the appraisal period, and so it is used in this analysis. While this figure seems lower than the 232 'sites' used by the 2017 IA, this should not impact costs as one NHS Trust can contain multiple sites (e.g., multiple hospitals), and this analysis asks stakeholders about costs on a per-Trust basis. This change in approach has been made for social research purposes (other cost areas are assessed on a per-Trust basis, and so maintaining this format is likely to improve stakeholder understanding and ease of response).

29. Combining estimates from paragraphs 27 and 28 gives an estimated number of affected NHS Trusts between 63 and 145, with a best estimate of 104.

30. Respondents to HSE's survey were then asked to estimate the cost of this additional monitoring per Trust per year. The average response (of 12 responses) was £1,500 (2022 prices). Based on interpretation of responses, internal HSE experts deem it reasonable to assume that additional monitoring costs between £1,000 and £2,000 with a best estimate of £1,500 per affected Trust per year.

31. Hence, total costs are estimated to be between £63,000 and £290,000 per annum, with a best estimate of £160,000 per year (from the first year). This gives a present value of costs over the 10-year appraisal period of between £0.55m and £2.5m, with a best estimate of £1.3m. All costs are assumed to fall upon the public sector.

[31] Other than NHS Acute Trusts, this question received only two other responses: from an NHS Community Health Trust and an NHS Mental health Trust.

5.2 Medical: Supplying additional protective leaded eyewear

32. As discussed in paragraph 23, IRR17 introduced new eye dose limits. The 2017 IA identified that, as a result of this, the NHS may need to supply additional protective leaded eyewear to its staff. This cost is assessed in Section 11.6.1 of the 2017 IA.

5.2.1 Estimates from the 2017 IA

33. The 2017 IA estimated that around 2,300 additional pairs of eyewear would be issued by NHS Acute Trusts in the first year of the appraisal period. It also assumed that 20% of this eyewear would need to be replaced in each subsequent year due to 'wear and tear'. This gives 460 additional pairs supplied each year, from the second year of the appraisal period.

34. The 2017 IA estimated that one pair of protective glasses would cost between £100[32] and £730, and used a midpoint best estimate of £420 in its analysis (2016 prices).

35. Combining these assumptions gave one off costs of £960,000 in the first year, and ongoing costs of £190,000 per year from the second year (2016 prices). Inflating these costs gives £1.1m one-off costs, and £220,000 ongoing costs per annum, with a total present value of £2.8m (2022 prices).

36. As explained in paragraph 26, all of these costs were assumed to fall on the NHS (the public sector).

5.2.2 Estimates from this CBA

37. As part of the survey described in Section 4, we asked stakeholders from NHS Acute Trusts whether their Trust supplied additional eyewear as a result of the new eye dose limits. Of respondents responding on behalf of individual NHS Trusts, around half (10 of 21 responses) stated that their Trust supplied additional eyewear. The average response to those providing an estimate across multiple Trusts (12 respondents) was that 75% of Trusts supplied additional eyewear. Based on these results, internal experts deem it reasonable to assume that between 50% and 75% of NHS Trusts supply additional eyewear, with a midpoint best estimate of 63%.

38. Applying these proportions to 181 NHS Acute Trusts discussed in paragraph 28 gives between 91 and 136 Trusts supplying additional eyewear, with a midpoint best estimate of 113 Trusts.

39. Stakeholders were asked to provide an estimate of the number of additional pairs purchased per affected NHS Trust upon the introduction of IRR17. 17 responses were received giving an average estimate of 17 pairs per Trust. Based on an analysis of all responses, internal experts deem it reasonable to assume that between 10 and 25 with a best estimate of 17 additional pairs of protective eyewear were purchased in the first year of the appraisal period.

40. Stakeholders were also asked to provide an estimate of how often these glasses were replaced. 16 responses were received, giving an average estimate of 10% per year, and so this is assumed in this analysis. Combining the assumptions stated in paragraphs 38 - 40 gives estimates of the total additional pairs of glasses supplied shown in

	Year	2018	2019	2020	2021	2022	2023	2024	2025	2026	2027

[32] The 2017 IA reports £110, but actually uses a figure £104.67 in its calculations. Hence it is presented rounded down here.

Number of pairs supplied	Low	910	91	91	91	91	91	91	91	91	91
	Best	1900	190	190	190	190	190	190	190	190	190
	High	3400	340	340	340	340	340	340	340	340	340

41. Table *4* below.

Table 4. Number of additional pairs of protective eyewear supplied over time (rounded to 2.s.f.)

	Year	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Number of pairs supplied	Low	910	91	91	91	91	91	91	91	91	91
	Best	1900	190	190	190	190	190	190	190	190	190
	High	3400	340	340	340	340	340	340	340	340	340

42. Inflating the 2017 IA's estimates of the cost of a pair of protective glasses into 2022 prices gives a range of £120 to £840, with a midpoint best estimate of £480. Based on desk research conducted by internal experts, these estimates have been judged to be broadly reasonable, and so are used in this analysis.

43. Applying this range of costs to the figures stated in

44. Table *4* gives one off costs of between £110,000 and £2.9m with a best estimate of £920,000 in

	Year	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024**	**2025**	**2026**	**2027**
Number of pairs supplied	Low	910	91	91	91	91	91	91	91	91	91
	Best	1900	190	190	190	190	190	190	190	190	190
	High	3400	340	340	340	340	340	340	340	340	340

the first year, and ongoing costs of between £11,000 and £290,000, with a best estimate of £92,000 per annum from the second year. This gives a present value of total costs of between £0.19m and £5.0m, with a best estimate of £1.6m.

45. As in the 2017 IA, all costs are assumed to fall on the public sector (NHS).

5.3 Nuclear Sector: Additional Monitoring of Classified Workers

46. As discussed in paragraph 23, IRR17 introduced new eye dose limits. The 2017 IA identified that, as a result of this, the nuclear sector may carry out additional monitoring of eye doses for its already-classified workers. This cost is assessed in Section 11.10.1 of the 2017 IA, drawing upon assumptions made in sections 11.8.1 and 11.8.2.

5.3.1 Estimates from the 2017 IA

47. The 2017 estimated there to be around 20,000 already-classified workers in the nuclear sector, based on analysis of HSE's Central Index of Dose Information (CIDI). Of these workers, the 2017 IA estimated that 7.5% (1,500 workers) would require additional monitoring.

48. The 2017 IA estimated that the cost of conducting this monitoring would cost around £100 per worker per year in total (2016 prices), including the cost of purchasing eye dosemeters and administrative time spent by radiation protection advisors.

49. Combining these assumptions gave total ongoing costs of around £150,000 per annum from the first year of the appraisal period (2016 prices). Inflating this to 2022 prices gives costs of around £170,000 per annum, with a present value of total costs over the appraisal period of around £1.5m.

50. The 2017 IA estimates that 90% of these costs will fall on the private sector, and 10% on the public sector.

5.3.2 Estimates from this CBA

51. Since the 2017 IA was written, the way in which data is stored in HSE's CIDI has changed, making it more difficult to produce an estimate of the number of classified workers in the nuclear sector. Internal specialist opinion is that the number of classified workers is highly unlikely to have grown[33] since the 2017 IA's estimate was produced, hence it has been deemed disproportionate to produce an updated estimate. This CBA therefore assumes there to be around 20,000 classified workers in the nuclear sector throughout the appraisal period.

52. As part of the survey described in Section 4, we asked stakeholders from the nuclear sector about the proportion of already-classified workers who have required additional monitoring as a result of the new eye dose limits. Most respondents (5 of 9) agreed with the 2017 IA's estimate of 7.5%. Based on alternative estimates provided, HSE internal experts deem it reasonable to assume that between 5% and 10% with a best estimate of 7.5% of these workers have received additional monitoring of eye doses. This gives an estimate of between around 1,000 and 2,000 workers, with a best estimate of 1,500 workers.

53. The survey also asked about the cost of this monitoring. Again, most respondents (9 of 11) agreed with the 2017 IA's estimate of £100 per worker per year. It is therefore assumed in this CBA that monitoring of each worker in the nuclear sector costs £100 per year (2022 prices)[34].

54. Combining the assumptions stated in paragraphs 52-53, gives ongoing costs of between £100,000 and £200,000 per year, with a best estimate of £150,000 per year, from the first year of the appraisal period. This gives a total present value of costs of between £0.87m and £1.7m, with a best estimate of £1.3m (2022 prices).

55. The 2017 IA assumes that 90% of these costs will fall on the private sector, and 10% on the public sector. These assumptions are deemed reasonable by internal experts, and so are used in this analysis to estimate the EANDCB (reported in Section 8).

5.4 Registrations: Administrative costs

56. IRR17 introduced a risk-based approach to regulatory control of practices using ionising radiation, known as the 'graded approach'. This approach requires organisations to inform HSE about their work with ionising radiation. There are three tiers: notification (for practices with the least risk), registration (for practices with medium risks), and consent to operate (for practices with the highest

[33] This is based on discussions with nuclear sector stakeholders.

[34] While the 2017 IA's estimate of £100 was in 2016 prices, the survey conducted for this PIR was sent out in 2022. It is therefore deemed more likely that respondents would draw on more recent experiences and hence be answering in terms of 2022 prices. Any slight uncertainty caused by this question is mitigated by the use of a wide range in the assumed number of workers that receive additional monitoring.

risks). Each tier requires organisations to provide HSE with a different amount of information (more information for practices with higher risks). This approach replaced the approach taken by IRR99, under which organisations only had to notify HSE of their work with ionising radiation. Providing HSE with additional information takes time which could have been spent carrying out other activities, and hence constitutes an additional cost to organisations.

57. The 2017 IA estimated that registrations would account for 70% of total ongoing administrative costs brought about by the graded approach[35], therefore this CBA will focus on re-estimating costs brought about by registrations on grounds of proportionality. These costs are addressed in Section 12.2 of the 2017 IA.

5.4.1 Estimates from the 2017 IA

58. The 2017 IA segmented its analysis into two groups:
    - Organisations for which providing information takes more time (hereafter referred to as 'high-time organisations'). This group includes the NHS, universities, and local authorities that maintain multiple schools.
    - Organisations for which providing information takes less time (hereafter referred to as 'low-time organisations'). This group includes all other organisations that need to register their work, for example dental practices[36].

59. The 2017 IA estimated that high-time organisations would take 4.25 hours to gather necessary information and register with HSE, and the same process would take 1 hour for low-time organisations.

60. The 2017 IA assumed a cost of time of £27.27 per hour (2016 prices), giving a cost per registration of around £120 for high-time organisations, and around £28 for low-time organisations. When IRR17 was first introduced, all organisations had to register qualifying practices, even if they had already notified HSE of that practice under IRR99. After the first year of the appraisal period, however, new registrations would have had to notify under IRR99 anyway. Therefore, some of the time organisations spend registering after the first year is not additional. Hence, the 2017 IA assumed slightly lower costs per registration after the first year: £110 for high-time organisations and £18 for low-time organisations.

61. The 2017 IA estimated there to be 800 registrations from high-time organisations and 24,000 registrations from low-time organisations in the first year of the appraisal period (hence subject to the full cost of a registration). After the first year of the appraisal period, the 2017 IA estimated there to be around 18 high-time registrations, and 1,600 low-time registrations per year.

62. From this, the 2017 IA estimated the administrative costs of registrations to be around £770,000 in the first year of the appraisal period, with around £31,000 of ongoing costs in each subsequent year (2016 prices). Inflating to 2022 prices gives costs of around £880,000 in the first year, and ongoing costs of £35,000 per year from the second year. This gives a present value of total costs of £1.2m.

63. The 2017 IA estimated that around 64% of total present value costs fall on the private sector[37].

[35] See paragraph 249 of the 2017 IA.
[36] A more detailed breakdown of affected sectors can be found on page 42 of the 2017 IA.
[37] This is based on separately estimating costs for the public sector and private sector, using information provided in Section 12 of the 2017 IA (which gives details of the estimated proportion of registrations in the public and private sectors). It is deemed disproportionate to detail these calculations here.

5.4.2 Estimates from this CBA

64. As part of the survey described in Section 4, we asked stakeholders from both high-time and low-time organisations about how long it took them to gather necessary information and subsequently register with HSE. Forty-four responses were received from high-time organisations, and 61 responses were received from low-time organisations. The majority of stakeholders from both groups agreed with the estimates made by the 2017 IA (4.25 hours and 1 hour respectively). Based on analysis of alternative estimates given by stakeholders, internal experts deem it reasonable to maintain the assumptions from the 2017 IA.

65. Assuming that wages have not varied significantly in real terms since the 2017 IA made its estimates, and given that time spent per registration is estimated to have not changed from the 2017 IA's estimate, the only other factor which could cause total costs to change is the number of registrations received by HSE. Hence, this CBA adjusts overall costs in line with the total number of registrations received. This approach implicitly assumes that the proportion of registrations from high time and low time organisations is as estimated by the 2017 IA. This approach aims to give a sense of whether costs have significantly increased or decreased, rather than to make a precise cost estimate, in line with the proportionality approach set out in paragraph 15.

66. The actual number of registrations received by HSE are presented in **Table 5** below. Based on these figures, this CBA assumes that there were around 16,000 registrations in the first year of the appraisal period. As can be seen, registrations after the first year dip somewhat during 2020 and 2021. This may have been caused by COVID-19-related disruption, potentially meaning that there were fewer new businesses registering than would usually be the case. As not to underestimate costs over the 10-year appraisal period, this CBA assumes there to be around 1,460 new registrations per year, from the second year (the average number of registrations received over 2019 and 2022, when there was less COVID-19 related disruption).

Table 5. The number of registrations received by HSE

Year	2018	2019	2020	2021	2022
Number of Registrations	16181	1437	1009	1351	1476[a]

a: This estimate is based on the number of registrations received by HSE in the first 6 months of 2022 (738), extrapolated over the remaining 6 months.

67. The 2017 IA estimated there to be, in total, around 25,000 registrations in the first year, and 1,600 registrations per year from the second year. Therefore, this analysis estimates there to have been around 35% fewer registrations in the first year, and 8% fewer registrations per year from the second year than was anticipated by the 2017 IA. Internal experts interpret this discrepancy as having two possible causes. Firstly, the estimates made in 2017 were just that, estimates, and so could not have been expected to be exactly right. Secondly, internal experts judge that the discrepancy is, at least in part, caused by an initial lack of knowledge on the part of employers in respect of which category of authorisation their practice falls into. The subsequent ongoing figure remaining lower than expected may indicate more active non-compliance[38].

68. Reducing total costs estimated by the 2017 IA (see paragraph 62) by the percentages stated in paragraph 67 gives one off costs of around £570,000, and ongoing costs of around £33,000 per annum from the second year (2022 prices). This gives a present value of total costs of around £820,000.

[38] The 2017 IA's estimates of the number of registrations are based on an assumption of 100% compliance, and predicted that actual figures would likely be lower than estimated (see Section 12.1.2 of the 2017 IA).

69. The 2017 IA estimates that 57% of registrations in the first year and 100% of registrations from the second year would be from the private sector[39]. This analysis therefore assumes that 57% of one-off costs and 100% of ongoing costs fall on the private sector.

5.5 Registrations: Fees Costs

70. As described in paragraph 56, IRR17 introduced the 'graded approach', requiring organisations to either notify, register, or gain consent for their work with ionising radiation. HSE charges a £25 per application for registrations and consents, to cost-recover for the design, operation and maintenance of the graded approach. This constitutes an additional cost to organisations, and is assessed in Section 12.3 of the 2017 IA.

71. Registrations make up the vast majority of total applications for which HSE charges a fee[40], and so are focussed on in this CBA on grounds of proportionality.

5.5.1 Estimates from the 2017 IA

72. The 2017 IA estimated there to be 25,000 registrations in the first year, and 1,600 registrations per year from the second year. Applying the fee of £25 per registration gave one-off costs of £630,000 in the first year, and ongoing costs of around £40,000 per annum from the second year (2016 prices). This gives a present value of total costs of around £930,000 (2016 prices).

73. The £25 fee has not changed since the 2017 IA was conducted, and so the costs presented in paragraph 72 also represent 2022 prices.

74. The 2017 IA estimates that 57% of registrations in the first year and 100% of registrations from the second year would be from the private sector. Hence, 57% of first year fees costs and 100% of ongoing fees costs were estimated to fall upon the private sector.

5.5.2 Estimates from this CBA

75. As stated in paragraph 66, this analysis assumes there to be 16,000 registrations in the first year of the appraisal period 1,460 new registrations per year from the second year. Applying the £25 fee to these figures gives one-off costs of around £400,000 in the first year, and ongoing costs of around £36,000 per annum. This gives a present value of total costs of around £680,000.

76. The 2017 IA estimates that 57% of registrations in the first year and 100% of registrations from the second year would be from the private sector. This analysis therefore assumes that 57% of one-off costs and 100% of ongoing costs fall on the private sector.

5.6 The Recording and Analysis of Accidental Exposures

77. IRR99 requires dutyholders to identify reasonably foreseeable accidents before work is undertaken with ionising radiation, to restrict exposure from these possible accidents, and to protect those that could be affected. It also requires that a contingency plan should be prepared for possible accidents.

[39] This was based on an assumption that the number public sector organisations would remain stable, while there would be new businesses in the private sector.
[40] See Section 12.2.2 of the 2017 IA for further detail.

78. IRR17 added to this requirement, so that employers would also be required to record and analyse any event which causes, or potentially causes, the enactment of a contingency plan. Based on stakeholder consultation, the 2017 IA assumed that the majority of dutyholders already met the proposed requirement before the implementation of IRR17. The 2017 IA did identify, however, that some stakeholders from the academic and medical sectors did not analyse and record such events, meaning that they may need to spend additional time doing so under IRR17, constituting an additional cost of the regulations. This cost is assessed in Section 16 of the 2017 IA.

5.6.1 Estimates from the 2017 IA

The medical sector

79. The 2017 IA estimated that one third of NHS Acute Trusts would need to record and analyse additional events. The 2017 IA assumed there to be 181 NHS Acute Trusts, giving about 60 who may incur additional costs. The 2017 IA estimated that these 60 Trusts would need to record and analyse 3 additional events per year, giving around 180 additional events per year in total.

80. The 2017 IA identified that multiple members of staff would be involved in recording and analysing each event, at an average cost of time of about £42 per hour (2016 prices)[41]. The 2017 IA assumed that the recording and analysis of each event would take 10 hours in total (spread across multiple staff members), giving a cost of £420 per event (2016 prices)

81. This gave annual costs of around £76,000 per year from the first year. Inflating to 2022 prices gives costs of around £88,000 per year, with a total present value of £760,000 over the 10-year appraisal period.

The academic sector

82. The 2017 IA assumed there to be around 135 universities in GB which are most likely to carry out work which may lead to such events. The 2017 found that a number of stakeholders from the academic sector did not record and analyse these events, and on this basis estimated that around half (68) of the 135 universities may need to do so under IRR17.

83. The 2017 IA received few academic sector estimates of the number of events that occur in these universities, and the time burden of each event. Hence, it carried forward assumptions made for the medical sector: 3 additional events per year for each affected organisation, at a cost of £420 per event.

84. Combing the assumptions of stated in paragraphs 82-83 gave ongoing costs of around £86,000 per year from the first year (2016 prices). Inflating these costs to 2022 prices gives ongoing costs of around £100,000 per year, with a total present value of around £850,000 over the 10-year appraisal period.

5.6.2 Estimates from this CBA

[41] This is based on taking a weighted average of the costs of time stated in paragraph 310 of the 2017 IA.

The medical sector

85. As part of the survey described in Section 4, we asked stakeholders from NHS Acute Trusts whether they recorded and analysed additional events as a result of IRR17. Of respondents responding on behalf of individual NHS Trusts (27 respondents), around a quarter stated that their Trust did so. The majority of stakeholders providing an estimate across multiple Trusts (3 of 4 responses) supported a view that the proportion of Trusts recording additional events was lower than that estimated by the 2017 IA. Based on these results, internal experts deem it reasonable to assume about a quarter of NHS Acute Trusts record and analyse additional events.

86. As explained in paragraph 28, that analysis assumed there to be 181 Acute NHS Trusts. This gives about 45 Acute NHS Trusts recording and analysing additional events.

87. The survey also asked stakeholders about the number of additional events that each affected Trust records and analyses per year. Ten stakeholders provided a specific estimate, with an average response of 6 events per Trust per year. Based on an analysis of the spread of alternative responses, internal experts deem it reasonable to assume that between 2 and 10 additional events, with a best estimate of 6 additional events are recorded and analysed per Trust per year. This gives between around 91 and 450 with a best estimate of 270 additional events per year.

88. As detailed in paragraph 80, the 2017 IA identified that multiple members of staff would be involved in recording an analysing event. Given that the survey described in Section 4 already asked quite a large number of cost questions to NHS stakeholders, it was deemed disproportionate and potentially harmful to survey engagement to ask them to disaggregate the amount of time spent analysing and recording events by staff member. Instead, we asked stakeholders to estimate the total amount of time spent per event, and assume that the staff members involved, associated proportions of time spent, and real wages to be as estimated in the 2017 IA[42].

89. Eleven respondents provided a specific estimate of time spent, with an average response of 15 hours per event in total. Based on an analysis of all responses, internal experts deem it to be reasonable to assume that NHS Acute Trusts spend between 10 and 20 hours, with a best estimate of 15 hours analysing and recording each event.

90. Inflating the average cost of time estimated by the 2017 IA (stated in paragraph 80) to 2022 prices gives a cost of time per hour of around £49. Applying this to the assumptions stated in paragraph 89 gives a cost per event of between about £490 and £970, with a best estimate of £730.

91. Applying this cost to the number of events estimated in paragraph 87 gives a total cost of between £44,000 and £440,000 with a best estimate of £200,000 (2022 prices). This gives a present value of total costs over the 10-year appraisal period of between £380,000 and £3.8m, with a best estimate of £1.7m (2022 prices).

The academic sector

92. Our survey also asked stakeholders from the Universities whether their organisation recorded and analysed additional events as a result of IRR17. Out of 11 responses, 10 stated that they did not, and one stated that they did not know.

[42] See paragraph 310 of the 2017 IA for further detail.

93. This is in line with expectations, given the quality of the data collected for the 2017 IA. The 2017 IA estimated a potential cost based on stakeholder reports that they did not record and analyse events before the introduction of IRR17. This does not automatically imply that the sector regularly incurred accidents with ionising radiation that lead to the enactment of a contingency plan. Further, the 2017 IA reports that few academic sector respondents gave estimates of the number of events that may occur. This initial lack of certainty by stakeholders means that zero additional events does not contract initial expectations.

94. Based on the evidence presented, this CBA assumes zero costs to the academic sector.

6 Other costs

95. As part of the survey discussed in Section 4, stakeholders were asked whether they were aware of any other costs arising from the regulations, beyond those assessed by the 2017 IA. Overall, nearly two-thirds said they were not aware of additional costs (79 of 121 who answered this question).

96. Those that did state that they were aware of additional costs were invited to provide further details. Some respondents detailed costs that were considered by the 2017 IA, and hence were considered for estimation in this CBA as part of a prioritisation exercise detailed in paragraphs 12-0. For example, 7 respondents mentioned costs associated with classifying additional workers.

97. Cost mentioned which were not assessed in the 2017 IA included costs associated with a perceived change in the radon action level, and a need to improve lighting systems. All such responses were reviewed by internal experts and policy colleagues, and are deemed to not be additional requirements of the regulatory changes made under IRR17. For example, the radon action level stated in IRR17, while presented in a different format, is equivalent to the action level which was in place under IRR99[43].

98. Based on the evidence presented in this section, we conclude that there have been no notable, additional costs of the IRR17 changes that were not considered by the 2017 IA. This is not surprising, as HSE consulted extensively with stakeholders prior to the implementation of IRR17.

7 Benefits

99. As set out in Section 0, this report analyses the impacts of regulatory changes made under IRR17. As is the case with many health and safety interventions, accurately estimating benefits in monetary terms presents numerous methodological challenges. Doing so is therefore deemed disproportionate for this PIR. Instead, a qualitative discussion of benefits follows.

100. As part of the survey discussed in Section 4, stakeholders were asked whether they were aware of any benefits arising directly from the changes made by IRR17. 39% of respondents were aware of benefits (47 of 119 who answered the question), while 61% were not. Explanations of the perceived benefits show support for the regulations in raising awareness, improving clarity and increasing worker safety.

[43] See page 60 of the 2017 IA for further detail.

101. A main policy intent for these regulations was to secure improvements in worker health and safety whilst minimising costs to business. Such improvements are secured through a mix of interventions of which legislation in the form of regulations is an important pillar. It is encouraging that of those who identified benefits, clarity of requirements was identified as well as (which may be linked) raised awareness. It is encouraging too that improved worker safety was identified given that clarity in requirements and awareness of them is important for this.

8 Summary

102. In summary, this CBA has reassessed the main ongoing costs to duty holders of the additional requirements introduced by IRR17. We have made updated cost estimates, primarily drawing upon industry stakeholders' reported experiences.

103. This CBA estimates a present value of total costs of the changes introduced by IRR17 of between £15m and £26m, with a best estimate of £19m. We estimate average ongoing costs[44] of between £0.38m and £1.3m per annum, with a best estimate of £0.75m per annum.

104.

105. Table below compares cost estimates made by the 2017 IA, and the updated cost estimates made by this CBA. As can be seen, total costs estimated by this CBA (both total present value and total ongoing costs) are not significantly different to those made by the 2017 IA. This CBA estimates costs using ranges to reflect uncertainties in the estimates made, and total costs estimated by the 2017 IA fall well within these ranges. While the best estimate of total costs made by the CBA are slightly lower than those made by the 2017 IA we cannot say with confidence that actual costs are lower, as both estimates are subject to some uncertainty[45].

Table 6. Comparison of costs estimated in this CBA and in the 2017 IA (millions of £s, 2022 Prices, 2 s.f.)

Broad Cost Area	**Specific Cost Area**	**Present Value of Total Costs**		**Average Ongoing Costs per Year**[46]	
		2017 IA	**2022 PIR (low - best - high)**	**2017 IA**	**2022 PIR (low - best - high)**
Eye Dose - Medical Sector	Monitoring of non-classified workers	2.0	0.55 - 1.3 - 2.5	0.23	0.063 - 0.16 - 0.29
	Protective Eyewear	2.8	0.19 - 1.6 - 5	0.20	0.0096 - 0.082 - 0.25
Eye dose - Nuclear Sector	Monitoring of already-classified workers	1.5	0.87 - 1.3 - 1.7	0.17	0.10 - 0.15 - 0.20
Graded approach	Registrations - administrative time	1.2	0.82	0.031	0.029

[44] Ongoing costs averaged over a 10-year period.
[45] For example, both analyses rely heavily on surveys of stakeholders who were not selected at random (stakeholders chose to respond), and base some assumptions on relatively small sample sizes.
[46] Ongoing costs are averaged over the 10-year appraisal period, meaning that ongoing costs that start in the second year of the appraisal period appear to be slightly smaller in this table. This approach is taken to aid comparison with the 2017 IA.

	Registrations - fees	0.93	0.68	0.035	0.032
Accidental exposures	Medical	0.76	0.38 - 1.7 - 3.8	0.088	0.044 - 0.20 - 0.44
	Universities	0.85	Nil	0.098	Nil
Total (Reassessed)		**9.9**	**3.5 - 7.5 - 15**	**0.85**	**0.28 - 0.65 - 1.2**
All other costs (Not reassessed)		12	12	0.11	0.11
Total		**22**	**15 - 19 - 26**	**0.96**	**0.38 - 0.75 - 1.3**

106. The only specific cost areas that could be argued to have changed significantly in this CBA are:

- Lower than expected costs associated with the Graded Approach (Registrations). This is driven entirely by a lower than forecast number of registrations having been received by HSE. As discussed paragraph 67, this may be caused in part by non-compliance of duty holders.
- Lower than expected costs to universities of recording and analysing accidental exposures. As discussed in paragraph 93, this is likely caused by better quality data having been collected for this CBA, and the ability of stakeholders to state their actual experiences rather than to predict impacts prior to IRR17 coming into force.

107. This CBA estimates a total EANDCB of between £0.57m and £0.66m, with a best estimate of £0.61m, compared to the 2017 IA's best estimate of £0.77. A summary of costs to business can be found in **Table *7*** below. These figures have been calculated using assumptions about the proportion of costs which fall on the private sector, which can be found at the end of each sub-section in Section 5.

108. The EANDCB estimated by this CBA is slightly smaller than that estimated by the 2017 IA. This is (unsurprisingly) driven by the changes in cost estimates for the specific areas stated in paragraph 106. The EANDCB estimated in this CBA falls well below the £5m de minimis threshold, and hence is considered to small to be considered against the business impact target (BIT) [47].

Table 7. Summary of costs to the private sector (millions of £s, 2022 Prices, 2 s.f.)

Broad Cost Area	**Specific Cost Area**	**Present Value of Costs to Business**		**EANDCB**	
		2017 IA	**2022 PIR (low - best - high)**	**2017 IA**	**2022 PIR (low - best - high)**
Eye Dose - Medical Sector	Monitoring of non-classified workers	Nil	Nil	Nil	Nil
	Protective Eyewear	Nil	Nil	Nil	Nil
Eye dose - Nuclear Sector	Monitoring of already-classified workers	1.3	0.78 - 1.2 - 1.6	0.15	0.091 - 0.14 - 0.18

[47] As per Better Regulation guidance: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/916918/better-regulation-guidance.pdf

Graded approach	Registrations - administrative time	0.74	0.57	0.086	0.066
	Registrations - fees	0.66	0.51	0.076	0.059
Accidental exposures	Medical	Nil	Nil	Nil	Nil
	Universities	0.85	Nil	0.098	Nil
Total (Reassessed)		**3.6**	**1.9 - 2.2 - 2.6**	**0.41**	**0.22 - 0.26 - 0.31**
All other costs (Not reassessed)		3.0	3.0	0.35	0.35
Total		**6.6**	**4.9 - 5.3 - 5.7**	**0.77**	**0.57 - 0.61 - 0.66**