EXPLANATORY MEMORANDUM TO

THE IONISING RADIATIONS REGULATIONS (NORTHERN IRELAND) 2017

S.R. 2017 No. 229

1. Introduction

1.1. This Explanatory Memorandum has been prepared by the Department for the Economy ("DfE") to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Regulations are made under Articles 2(5), 17(1) to (6), 40(2) and (4), 54(1), 55(2) and paragraphs 1(1) and (2), 2 to 10, 12, 13, 14(1), 15, 19 and 20(a) and (b) of Schedule 3 to, the Health and Safety at Work (Northern Ireland) Order 1978 and are subject to the negative resolution procedure.

1.3 The Rule is due to come into operation on 1st January 2018.

2. Purpose

2.1 The Statutory Rule will revoke and replace the Ionising Radiations Regulations (Northern Ireland) 2000 (S.R. 2000 No. 375) ensuring elements of Council Directive 2013/59/EURATOM ("the Basic Safety Standards Directive" (BSSD)) relating to occupational exposure are transposed in Northern Ireland.

2.2 This instrument sets out a framework to ensure that occupational exposures to ionising radiation are kept as low as is reasonably practicable. It includes dose limits for those working with radiation and introduces a three-tiered risk-based system for regulatory control (that is notification, registration and consent of radiation practices).

2.3 Ionising radiation occurs either as electromagnetic rays, such as X-rays and gamma rays, or as particles such as alpha and beta particles and is used in a diverse range of industries and sectors including medical, nuclear, manufacturing and construction. It is also found in naturally occurring radioactive sources, such as radon. 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 machine. Internal exposure can occur via inhalation or ingestion of a radioactive substance. Although its use brings considerable benefits, it can give rise to harmful health effects, so exposure must be managed.

2.4 The key measures set out in the Regulations to control exposures are:

- carrying out a radiation prior risk assessment to consider potential doses;
- dose limits for those working with radiation - these are legal limits that must not be exceeded;
- taking steps to restrict exposure via use of appropriate control measures;

- designation of areas where high exposures are possible, control of access into these areas, and ensuring specific rules are in place to govern work activity;
- ensuring that employers who work with ionising radiation engage the services of a Radiation Protection Adviser (RPA) to provide specialist advice on compliance with the regulations.

2.5 The Regulations are supported by reviewed and updated Great Britain guidance which will provide practical advice on the new Regulations.

3. Background

3.1 The BSSD lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation and was adopted on 5 December 2013. The primary policy objective is to transpose the requirements of the Directive by its transposition date, 6 February 2018.

3.2 The Department for Business, Energy and Industrial Strategy (BEIS - formerly the Department of Energy and Climate Change (DECC)) is the lead government department for implementation of the BSSD in the UK. However, the Department for the Economy is responsible for transposing, in Northern Ireland, those aspects of the Directive which relate to occupational health and safety.

3.5 The aim of BSSD is to update and simplify existing arrangements for radiological protection by bringing five directives and an EU Commission recommendation into one directive.

3.6 The five Directives and one recommendation that have been consolidated are:

- The Basic Safety Standards, Directive 96/29/Euratom (BSSD96)
- The Medical Exposures, Directive 97/43/Euratom
- The Outside Workers, Directive 90/641/Euratom (OW)
- The Control of high activity sealed radioactive sources and orphan sources 2003/122/Euratom (HASS)
- The Public Information Directive 89/618/Euratom
- The Radon Commission Recommendation 90/143/Euratom

3.7 It also incorporates the latest recommendations from the International Commission on Radiological Protection (ICRP) published in 2007, and harmonises the EU regime with the Basic Safety Standards of the International Atomic Energy Agency (IAEA). The directives being replaced are currently implemented through a range of legislation.

4. Consultation

4.1 A consultation exercise ran in Northern Ireland from 10 August 2017 to 05 October 2017. There were approximately 450 consultees, including individuals, bodies representative of section 75 of the Northern Ireland Act 1998 and other organisations

with an interest in equality and related issues (including each member of the Northern Ireland Assembly).

4.2 A total of 5 responses were received none of which contained any adverse comments in relation to the proposals. The consultation document was also downloaded 199 times.

5. Equality Impact

5.1 The Statutory Rule has been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998. As the proposals relate primarily to workplaces they will have a justified differential impact on those of working age. The proposed Regulations increase safety standards for protection of employees (and others) against the dangers arising from exposure to ionising radiation. The revised wording at regulation 9 (6) in relation to pregnant and breastfeeding employees reflects the wording of the BSSD and provides clarification. No practical implications are anticipated.

6. Regulatory Impact

6.1 An Impact Assessment was carried out in respect of the corresponding GB Statutory Instrument and is attached to this memorandum at Annex A. The Impact Assessment was prepared detailing the costs associated with implementing the new occupational health and safety requirements of the Directive. Cost details were provided by the various industries and sectors with whom the Health and Safety Executive for Great Britain had engaged.

6.2 DfE is of the opinion that the analysis and considerations set out in the GB Impact Assessment can be applied, with modifications, to Northern Ireland.

7. Financial Implications

7.1 Overall, it is estimated that the total net present value costs over a ten year period will be approximately £390,000. As a result it is anticipated that there will be a cost to businesses and the public sector.

7.2 Health benefits as a result of the reduction in the dose limit for the eye and the graded approach are anticipated but these benefits and any related savings cannot be quantified.

8. Section 24 of the NI Act 1998

8.1 The Department has considered the matter of Convention rights and is satisfied that there are no matters of concern.

9. EU Implications

9.1 The Statutory Rule implements EU Directive 2013/59/EURATOM.

10. Parity or Replicatory Measure

10.1 In Great Britain the corresponding Regulations are the Ionising Radiations Regulations 2017 (S.I. 2017 No. 1075), which were made on 30 November 2017 with a coming into operation date of 1st January 2018.

11. Additional Information

11.1 N/a.

Department for the Economy

5 December 2017

ANNEX A

PART I

GREAT BRITAIN IMPACT ASSESSMENT

(Prepared by the Health and Safety Executive)

The Ionising Radiations Regulations 2017 (S.I. 2017/1075)

1. The following pages contain a copy of the Impact Assessment, prepared by the Great Britain Health and Safety Executive (HSE), in respect of the equivalent Ionising Radiations Regulations 2017 ("the Great Britain Regulations").

2. The Great Britain Regulations replace the previous Ionising Radiations Regulations 1999 with a single, modern set of regulations to ensure occupational exposures to ionising radiation are kept as low as is reasonably practicable.

3. The proposed approach will maintain existing health and safety protections and increase standards. It is estimated the total cost to business and the public sector will be £18.90 million over 10 years. Around £9.8 million of this will result from changes to requirements for doses to the lens of the eye of which £8.3 million will fall to the medical sector (NHS).

4. The reduction in eye dose limit for ionising radiation at work should lead to a reduction in opacities in the lens of the eyes of workers but it is not possible to quantify whether a reduction in cases of cataracts to the eye will also result (with possible savings in relation to related treatment).

5. Applying the Graded Approach system will result in the collection of up-to-date information on practices, enabling HSE to target where inspection should be prioritised. This will ensure that practices where the risk of exposure to workers and the public is higher have an increased amount of regulatory oversight relative to lower-risk sites via a risk-based proportionate inspection regime. If this leads to a reduction in ionising radiation exposures, there would be a fall in adverse health effects associated with ionising radiation, although this benefit cannot be quantified.

Title: Implementation of the occupational exposures elements of the Council Directive 2013/59/Euratom laying down the basic safety standards for protection against the dangers arising from exposure to ionising radiation – the Ionising Radiations Regulations. **IA No: HSE0099** **RPC Reference No:** **Lead department or agency:** Health and Safety Executive (HSE) **Other departments or agencies:** Business, Energy, and Industrial Strategy (BEIS)	**Date:** 08/08/2017 **Stage:** Final **Source of intervention:** EU **Type of measure:** Secondary Legislation **Contact for enquiries:** Clare.McNicholas@hse.gov.uk Michael.Zand@hse.gov.uk

Summary: Intervention and Options

RPC Opinion: Pending

Cost of Preferred (or more likely) Option (Option 1)				
Total Net Present Value	**Business Net Present Value**	**Net cost to business per year** (EANDCB in 2014 prices)	**One In, Three Out**	**Business Impact Target Status**
-£18.90	-£5.83	£0.6m (of which, in scope of the BIT: £0.0m)	Qualifying Provision (in part)	IN (rounds to zero)

What is the problem under consideration? Why is government intervention necessary?

Directive 2013/59/Euratom replaces five Directives and a European Commission recommendation with a single Directive (known as the 'Basic Safety Standards Directive'). Adopted on 5th December 2013, this covers radiological protection from a number of different perspectives, including medical, occupational and environmental. The Directive needs to be transposed by the 6th February 2018. The department for Business, Energy, and Industrial Strategy (BEIS), has overall responsibility for coordinating the implementation of the Directive; however, HSE is responsible for implementing the occupational aspects.

The Directive does not aim to change the Radiation Protection System in general. It introduces a number of new requirements with regard to occupational exposures that are presented in this Impact Assessment.

What are the policy objectives and the intended effects?

- To improve GB radiological protection**.**
- To ensure the adverse impacts of the Directive are minimised and the opportunities for simplification maximised to reduce burdens on business, whilst ensuring workers remain protected from the risks associated with ionising radiation.
- To ensure, where possible, consistency of application with other Government Departments.
- 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) and to fulfil the UK's obligations under EU law.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Alternatives to regulation cannot be considered viable, as they would not fulfil our obligations under EU law. Our preferred option is to update existing GB legislation, incorporating new provisions where necessary. The requirements will be implemented by repealing and replacing the Ionising Radiations Regulations 1999 (IRR99). We present two options, one where the costs of developing and maintaining a new notification, registration, and consent regime (the Graded Approach) are recovered from dutyholders, and one where the costs are borne by HSE. The option including cost-recovery is our preferred option, as this is in line with HM Treasury guidance.

Will the policy be reviewed? It will be reviewed. **If applicable, set review date:** 01/2023

Does implementation go beyond minimum EU requirements?		Yes		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:** N/a	**Non-traded:** N/a	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible Date:

Summary: Analysis & Evidence Policy Option 1

Description: Cost-Recover for the Graded Approach (Preferred Option)

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -18.90

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	11.7		0.8	**18.9**

Description and scale of key monetised costs by 'main affected groups'

Changes to requirements for doses to the lens of the eye lead to around half of the total costs, or around £9.8 million. £8.3 million of these are costs to the medical sector (NHS).

A new notification, registration, and consent regime (the graded approach) leads to around 12% of total costs, or around £2.2 million. This includes costs of just over £1 million for developing and maintaining a fully digital system to operate the regime, which under this option are recovered by HSE via a fee for those applying for registration and consent.

Of these £2.2 million present value costs, around £21,000 relate to the extension of consents to particle accelerators, which goes beyond the requirements of the Directive. Of these costs, only around £600 are borne by businesses.

The bulk of the remaining costs arise from time organisations will spend familiarising with the changes to the regulations (£5.3 million). These are costs to a range of sectors (including medical, nuclear, industrial, academic and research).

Other key non-monetised costs by 'main affected groups'

None

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Nil		Nil	**Nil**

Description and scale of key monetised benefits by 'main affected groups'

Nil

Other key non-monetised benefits by 'main affected groups'

The proposed approach will maintain existing health and safety protections and increase standards in some instances. Large health benefits are not expected for most changes and it has not been possible to quantify the associated improvement in health outcomes.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

- There remains some uncertainty about the current levels of exposures to the lens of the eye in the NHS, and the extent of actions the sector will need to take in order to comply – and hence costs.
- The numbers of practices registering and consenting under the Graded Approach system are also subject to uncertainty, as this is an entirely new regime.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: 0.6	**Benefits: 0**	**Net: -0.6**	**Partly in scope (rounds to nil)**

Summary: Analysis & Evidence

Policy Option 2

Description: Description: Do not Cost-Recover for the Graded Approach

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2018	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	**High:** Optional	**Best Estimate:** -18.90

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional	1	Optional	**Optional**
Best Estimate	12.0		0.8	**18.9**

Description and scale of key monetised costs by 'main affected groups'

All costs as per Option 1, except that costs of just over £1 million for developing and maintaining a fully digital system to operate the Graded Approach regime are borne by HSE rather than cost-recovered. This results in lower costs to business but higher costs to the public sector.

Other key non-monetised costs by 'main affected groups'

None

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	Nil		Nil	**Nil**

Description and scale of key monetised benefits by 'main affected groups'

Nil

Other key non-monetised benefits by 'main affected groups'

The proposed approach will maintain existing health and safety protections and increase standards in some instances. Large health benefits are not expected for most changes and it has not been possible to quantify the associated improvement in health outcomes.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

- There remains some uncertainty about the current levels of exposures to the lens of the eye in the NHS, and the extent of actions the sector will need to take in order to comply – and hence costs.
- The numbers of practices registering and consenting under the Graded Approach system are also subject to uncertainty, as this is an entirely new regime.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs:0.5	**Benefits: 0**	**Net: -0.5**	**Partly in scope (rounds to nil)**

Glossary

ACOP	Approved Code of Practice
ADS	Approved Dosimetry Services are approved by HSE to provide services that produce, maintain and summarise radiation dose records
ALARP	As low as reasonably practicable
BSSD/the Directive	Council Directive 2013/59/Euratom laying down the basic safety standards for protection against the dangers arising from exposure to ionising radiation
Bq	Becquerel
CE	European conformity marking
CIDI	Central Index of Dose Information
BEIS	Department for Business, Energy, and Industrial Strategy
DH	Department of Health
EA	Environment Agency
Effective Dose	Combined dose in all tissues and organs of the body from internal and external exposure to radiation
Equivalent Dose	Dose in particular tissue or organ from internal radiation
EMA	Employment Medical Advisor
HASS	High Activity Sealed Source
HSE	Health & Safety Executive
HSWA	Health and Safety at Work etc Act 1974
IA	Impact Assessment
ICRP	International Commission on Radiation Protection
IRR	Ionising Radiations Regulations
MHSAW	Management of Health and Safety at Work Regulations 1999
mSv	Millisievert
NORM	Naturally Occurring Radioactive Materials
ONR	Office for Nuclear Regulation
Outside Worker (OW)	A worker who carries out services in the controlled/supervised area of another employer
PET	Position Emission Tomography
PHE	Public Health England
PPE	Personal Protective Equipment
RA	Risk Assessment
REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations 2004
RPA	Radiation Protection Adviser RPS
	Radiation Protection Supervisor
RSA	Radioactive Substances Act 1993

Contents

GLOSSARY **4**

CONTENTS **5**

EVIDENCE BASE **6**

1 Problem under consideration 6
2 Ionising radiation 7
3 The Ionising Radiations Regulations 1999 (IRR99) 7
4 Rationale for intervention 8
5 Policy objectives 9
6 Description of options considered 9
7 Summary of requirements 11
8 Application of IRR99 12
9 Summary of work undertaken to inform this final stage IA 12
10 New requirements in the proposed Ionising Radiations Regulations 2017 (IRR17) 14
11 Changes to requirements on doses to the lens of the eye 14
12 Graded Approach (notification, registration, and consent) 39
13 Outside workers 52
14 Weighting Factors 53
15 Public Dose Estimation 54
16 Accidental Exposures and the Recording and Analysis of 'Significant' Events 55
17 Changes to regulation with no significant costs to business expected 58
18 Changes which potentially go beyond the scope of the Directive 62
19 Familiarisation costs 64
20 Wider impacts 69
21 Summary of monetised and non-monetised costs and benefits to business and government 70
22 Risks, assumptions and proportionality approach 71
23 Direct costs and benefits to business calculations (following OI3O methodology) and preferred option 76
24 Post Implementation Review (PIR) Plan 77

ANNEX 1: ESTIMATED NUMBER OF IRR DUTYHOLDERS BY SECTOR **79**

ANNEX 2: OCCUPATIONAL EXPOSURE WORKING GROUP MEMBERSHIP **80**

Evidence base

1 Problem under consideration

1. 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 (known as the 'Basic Safety Standards Directive 2013/59/Euratom – herein referred to as 'the Directive'). 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.

2. This revision of the Basic Safety Standards Directive builds on a lengthy history of European and UK work in the area of radiological protection. The first Basic Safety Standards Directive came into force in 1959 and has been revised several times since then, the latest being in 1996.

3. Combining five existing Directives and a Commission Recommendation has resulted in a wide-ranging Directive that covers radiological protection from a number of different perspectives, including medical, occupational and environmental (including public exposures). Whilst the new Directive does not aim to change the Radiation Protection System in general, it has introduced a number of new requirements with regard to occupational exposures that are presented in this impact assessment. The five Directives and one recommendation that have been consolidated are:

- Basic Safety Standards, Directive 96/29/Euratom (BSSD96)
- Medical Exposures, Directive 97/43/Euratom
- Outside Workers, Directive 90/641/Euratom (OW)
- Control of high activity sealed radioactive sources and orphan sources 2003/122/Euratom (HASS)
- Public Information Directive 89/618/Euratom
- Radon, Commission Recommendation 90/143/Euratom

4. The Directives being replaced are currently implemented in the UK through a range of legislation that is the responsibility of a number of different government departments.

5. HSE's regulations are made under Section 15 of the Health and Safety at Work Act (HSWA) and apply to all employers working with radiation on all sites. The occupational elements of the Directive will be transposed by updates to the Ionising Radiations Regulations 1999 (IRR99).

6. It should be noted that Section 18 of HSWA has been amended so the Office for Nuclear Regulation (ONR) has responsibility for enforcement of health and safety regulation on nuclear sites. This links with Section 68 of the Energy Act 2013, which makes 'nuclear site health and safety' one of the functions of ONR.

7. The Euratom Treaty does not apply to Defence activities and the Ministry of Defence (MOD) has not yet taken a policy decision on whether to apply all the amendments that are being made to domestic legislation to implement the Directive to defence activities. Generally, MOD is bound by health and safety requirements. In certain circumstances exemptions may however apply. Where an exemption or derogation does apply, current MOD policy is to produce outcomes that are, so far as reasonably practicable, at least as good as those required by UK legislation. For the purposes of this IA, we have

included MOD sites in our analysis, but if an exemption for these sites were to be introduced, these costs would not apply.

8. Other government departments and the Devolved Administrations are in parallel progressing work to implement the parts of the Directive for which they have policy responsibility, and will prepare separate impact assessments covering the changes they propose implementing. Implementing this Directive has provided GB with an opportunity to review and simplify our regulations to take account of operational lessons learned as well as developments in radiological protection. Northern Ireland and Gibraltar will transpose its own regulations in line with GB timescales.

9. On 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union and all the rights and obligations of EU membership remain in force. During this period, the Government will continue to negotiate, implement and apply EU legislation. The assumptions used in this impact assessment have been chosen accordingly.

2 Ionising radiation

10. 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.

11. 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. Examples of some industrial uses include: in non-destructive testing, where X-rays are used to check the integrity of welds in critical structures, such as aircraft parts; in manufacturing, where ionising radiation is used to test the quality of steel, or to check the thickness of materials such as paper or metals. It is also found in naturally occurring radioactive sources, such as radon and the processing of 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.

12. 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, for example, via inhalation or ingestion of a radioactive substance. Wounds that become contaminated with radioactive material will also give rise to radiation exposure. The application of ionising radiation can provide many benefits, such as medical uses, but can be hazardous to health if not managed correctly and could result in damage to tissues, such as skin burns, hair loss, as well as longer term damage leading to an increased likelihood of cancer.

13. Additionally, opacities in the lens of the eye and cataracts can occur in those whose eyes are exposed to ionising radiation. Following a review of the evidence in this area, the International Commission on Radiological Protection (ICRP) has concluded that the risk of opacities and cataracts is greater than previously identified, so it has recommended that the dose limit to the eye be substantially reduced. This change is discussed further in Section 11.

3 The Ionising Radiations Regulations 1999 (IRR99)

14. IRR99 sets out a framework to ensure that occupational exposures to ionising radiation are kept as low as is reasonably practicable and puts in place specific dose limits. These regulations are supported by an Approved Code of Practice (ACOP) 'Working with Ionising Radiation' and HSE

guidance.[1] ACOPs are not law but do have a special legal status; dutyholders decide on the best way for them to comply with the law, but if the advice in ACOP material is followed in relevant circumstances, dutyholders can be confident they are complying with the law.

15. The key measures set out in IRR99 to reduce exposure are:

- carrying out a prior risk assessment to consider potential doses;
- the setting of dose limits for those working with radiation; these are legal limits that must not be exceeded;
- taking steps to restrict exposure via use of the hierarchy of control[2], and use of administrative arrangements to ensure that exposure is controlled;
- designation of areas where high exposures are possible, control of access into these areas, and ensuring specific rules are in place to govern work activity;
- ensuring that employers who work with ionising radiation engage the services of a Radiation Protection Adviser (RPA) to provide specialist advice on compliance with IRR99.

4 Rationale for intervention

16. The rationale for the approach to transposition follows the UK Government's Guiding Principles for EU Legislation. Whilst ensuring that high standards of risk control are maintained, we will ensure that the UK does not go beyond the minimum requirements of the Directive, except where there are clear benefits to business from doing so, or to maintain or improve existing levels of radiological protection. Where possible, the UK will use copy-out from the Directive, except where doing so would adversely affect UK interests. HSE has identified four circumstances when, in order to minimise costs to stakeholders or to ensure we do not lessen existing levels of radiological protection, we propose to go beyond the minimum requirements of the Directive. Two areas relate to new requirements:

- implementation of the regulations on 1 January 2018, 5 weeks earlier than the transposition deadline, in order to minimise costs to business arising from changes to the dose limit for exposures to the lens of the eye;

- the extension of the requirement to apply for a consent to operate to cover certain 'high-risk' practices, which would otherwise need to register ('Graded Approach'– see Section 12.5). Due to the way HSE intends to implement this requirement, we expect this would result in lower costs to business overall.

Another two areas maintain existing standards and therefore do not introduce new requirements:

- application of dose limits to work with practices subject to notification, such as Naturally Occurring Radioactive Materials (NORM), which is required to maintain existing levels of protection;

- Immediate notification to HSE if radon is detected in the workplace above the specified level which is required to maintain existing levels of protection.

Early implementation of the regulations is discussed further below; the full rationale behind these issues is provided in Section 17.2 (Chapter 2).

[1] This can be found in HSE publication L121 "Work with ionising radiation". See: www.hse.gov.uk/pUbns/priced/l121.pdf

[2] The hierarchy of control includes elimination, substitution, use of engineering controls, use of administrative controls and personal protective clothes and equipment. More details can be found at http://www.hse.gov.uk/risk/faq.htm#hierarchy.

Implementation date

17. Member states are required to transpose the Directive by 6 February 2018. Effective implementation will ensure the UK avoids infraction proceedings and associated costs for failure to fully implement the Directive.

18. However, HSE intends to transpose the Directive on 1st January 2018 to reduce costs to stakeholders resulting primarily from the changing of the eye dose limit. Exposure to ionising radiation is calculated and assessed on a calendar year basis, to ensure that specified dose limits are not exceeded. A significant change introduced by the Directive considerably reduced the dose limit for the lens of the eye. If this new dose limit is introduced in February 2018, then there would be two dose limits for the eye in one calendar year. During HSE's extensive consultations with stakeholders on these proposals, industry representatives have reported that this will cause confusion, requiring individual dose limits to be re-calculated for the remainder of the year, which could lead to additional costs and impacts highlighted in Section 18.1 (Chapter 2).

19. HSE proposes to avoid this cost, burden and confusion to stakeholders by implementing IRR on the 1st January 2018, which is 5 weeks earlier than the EU implementation deadline. There is precedent for this approach, as transposition of the previous 1996 Directive was 5 months earlier than the transposition deadline for similar reasons. At public consultation, HSE invited views on this issue from stakeholders; the overwhelming majority of respondents supported early implementation.

5 Policy objectives

20. In considering the most appropriate method to transpose the requirements of the Directive into domestic legislation, the policy objectives are to:

- transpose the Directive in line with EU Treaty obligations;
- minimise the burdens on business by following the Government's better regulation policy and principles;
- 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.

6 Description of options considered

Do nothing

21. When considering options for transposition of the Directive within the impact assessment, the 'do nothing' option was not considered viable, as it would not deliver the policy objective and the UK's obligations under EU law. Therefore, the 'do nothing' or status quo option has not been analysed further in this IA, in accordance with Better Regulation guidance on IAs. It appears in this IA only as the notional baseline against which the other options are assessed.

Option 1: Update the Ionising Radiations Regulations 1999 and Cost-Recover for the Graded Approach

22. In this option, HSE would implement the Directive by updating ('repeal and replace') IRR99.

23. This option includes the early implementation of the regulations described above in Section 4, as this reduces burdens on businesses from the regulatory change. It also includes the maintenance of existing standards associated with practices that are notified such as Naturally Occurring Radioactive Materials (NORM) and requirements around the immediate notification of radon in the workplace above specified limits (also discussed in Section 17.2), which do not introduce new burdens on businesses.

24. This option would also deviate from copy-out in extending the requirement to apply for a consent to certain high-risk practices that would otherwise only require a registration. In the case of industrial radiography, this allows us to also remove an existing requirement to notify HSE seven days prior to commencing work. Based on our appraisal, this extension in the scope of consents is estimated to lead to net savings to business compared to copy-out (see Section 12). The other area where the scope of consents is extended is particle accelerators, and this leads to a very small additional cost to business, which qualifies as gold-plating, but which rounds to nil under the Business Impact Target.

25. Option 1 also includes the cost-recovery from dutyholders of the costs of HSE's costs for running the Graded Approach system.

26. Chapter 2 describes and assesses in detail the changes introduced to IRR99 under Option 1.

Option 2: As per Option 1 but without Cost-Recovery for the Graded Approach

27. Option 2 implements the Directive in the way described for Option 1 but with the costs for running the Graded Approach borne by HSE and not passed onto dutyholders.

28. Option 2 only differs with respect to the Graded Approach; all other changes to IRR99 are as per Option 1. Therefore, Option 2 is only assessed in Section 12 on the Graded Approach.

Options considered, but not taken forward

29. In the consultation-stage IA, we discussed an option whereby HSE would gold-plate the Directive by requiring the periodic renewal of registrations and consents in order to maintain an up-to-date database of practices. Following consultation with industry and Government, we have decided not to take this option forward into the final stage IA because we no longer assess that the regulatory value is sufficient to justify the deviation from Government transposition guidelines.

HSE's preferred Option

30. Option 1 is HSE's preferred option as this ensures that the requirements of the Directive are met and is in line with Government rules on cost recovery. However, a significant proportion of the costs recovered via fees under Option 1 would be borne by other public sector bodies and service providers e.g. schools and hospitals, so it is possible that the cost-recovery approach will not gain collective agreement across government – in which case HSE's preferred option would be Option 2. Feedback from the consultation showed approximately half of respondents supported our proposed implementation approach.

31. As the Directive is technically complex, the regulations and supporting guidance will be drafted in such a way that they remove any ambiguity and provide clarity for businesses, thereby reducing the burdens on them. To ensure that the guidance is fit for purpose HSE convened a virtual working group with stakeholders, including from industry, to help develop the guidance.

32. This approach will be supported by clear and specifically targeted communications with stakeholders, in addition to ACOP and guidance to support IRR. This will explain clearly and simply what action needs to be taken, and by whom, to demonstrate compliance.

33. HSE will continue to work collaboratively with affected stakeholders, throughout and immediately after the transposition period.

34. This preferred option (Option 1) results in a small IN under One In, Three Out of less that £100, which rounds to nil under the Business Impact Target (see paragraph 269)

Proposed Legislation

35. The requirements in the Directive relating to occupational exposures to ionising radiation will be implemented by the Ionising Radiations Regulations 2017 (IRR17).

7 Summary of requirements

36. IRR99 set out a framework to ensure that occupational exposure to ionising radiation is kept as low as is reasonably practicable and does not exceed certain limits.

37. To ensure that exposure is kept as low as reasonably practicable, IRR99 sets out a number of measures, which are detailed earlier, in paragraph 15.

38. IRR also sets out dose limits, measured in millisieverts (mSv),[3] which are legal limits which must not be exceeded. These are:

- for employees aged 18 years or over, 20 mSv in a calendar year (except that in special cases employers may apply a dose limit of 100 mSv in 5 years, with no more than 50 mSv in a single year, subject to strict conditions);
- for trainees, between 16-18 years old, 6 mSv in a calendar year; and
- for any other person, including members of the public and employees under 18 who cannot be classed as trainees, 1 mSv in a calendar year;
- for the lens of the eye, 150 mSv in a calendar year (which, under the Directive will be reduced to 20 mSv or 100 mSv in any 5 consecutive years, with no more than 50 mSv in a single year);
- for the skin, 500 mSv in a calendar year;
- for the extremities[4], 500 mSv in a calendar year.

39. If an employer identifies that an employee is likely to be exposed to a dose of three tenths of a dose limit, or above, that employee must be designated as a classified worker. Classified workers are subject to additional radiation protection measures; their doses are assessed and recorded, and they are also subject to medical surveillance.

[3] Exposure to ionising radiation is measured in Sieverts. Generally, effective doses are measured in millisieverts (mSv), with the current dose limit for members of the public being 1mSv. There are 1,000 millisieverts in a Sievert. To put this measurement into context, the current dose limit for members of the public is 1mSv, so a Sievert would be an extremely large dose.

[4] Extremities are a person's hands, forearms, feet and ankles.

8 Application of IRR99

40. IRR99 applies to all work with radiation, specifically:

- any practice which undertakes the production, processing, handling, use, holding, storage, transport or disposal of radioactive substances/operation of any electrical equipment emitting ionising radiation;
- any work (other than a practice described above) carried out in a radon-containing atmosphere, where the concentration of radon exceeds a specified limit;
- any work, not specified above, with Naturally Occurring Radioactive Materials (NORM).

41. IRR99 applies to a wide range of industries and sectors, such as:

- Nuclear
- Manufacturing
- Construction
- Engineering
- Oil and gas production
- Non-destructive testing
- Medical and dental sectors
- Education and research establishments (e.g. universities and colleges).

42. HSE enforces IRR99 at all premises except Nuclear Licenced Sites and certain Authorised sites where ONR enforces. A detailed breakdown of numbers of dutyholders can be found at Annex 1.

9 Summary of work undertaken to inform this final stage IA

9.1 Stakeholder engagement

43. HSE has led extensive stakeholder engagement during both the negotiation and transposition stages of the Directive. Primarily, engagement with stakeholders was through a working group, the Occupational Exposure Working Group (OEWG), which has around 100 members. A breakdown of the organisations represented in OEWG membership can be found at Annex 2. During the transposition stage, which started in January 2014, seven meetings were held on changes to IRR99. This was made up of four smaller working groups, two full OEWG meetings and another which mixed key stakeholders picked from the smaller working groups to test transposition proposals

44. The purpose of this engagement was to:

- invite views from as wide a pool of stakeholders as possible, given the range of affected stakeholders;

- ensure that affected stakeholders could provide valuable insight to contribute to the formation of policy proposals on key issues;

- assist HSE in gathering evidence on costs arising from the changes to support the impact assessment.

45. Engagement through working groups means that HSE has had direct contact with almost 180 stakeholders from affected industries and sectors. Some of the representatives were from trade associations and bodies, who have obtained and passed on views from their members and shared information with them to further increase awareness. In addition, more than 530 stakeholders are

members of an on-line Radiation Community of Interest, where meeting minutes and notes and updates are posted.

46. HSE has adopted a collaborative approach to consultation on the costs to business. The six working groups between September 2015 and September 2016 provided HSE with the opportunity to raise questions about potential effects. We also circulated a questionnaire in August 2016 on specific potential changes to IRR99. The questionnaire explored potential additional costs associated with these changes and received 24 responses. Assumptions in this IA have been informed through this continuous engagement.

47. HSE has also presented at a number of conferences for the Association of University Radiation Protection Officers (AURPO), the Institute of Physics and Engineering in Medicine (IPEM) and the British Institute of Non Destructive Testing (BINDT). In addition, HSE officials spoke at three conferences organised by the Society for Radiological Protection conferences prior to/during the formal consultation phase, and ran a webinar on the 'Graded Approach' for stakeholders.

48. Section 11.2 sets out further specific research HSE has undertaken to inform the assessment of costs arising from the change in dose limit to the lens of the eye.

9.2 Public consultation

49. Formal public consultation on HSE's proposed changes to IRR99 took place between February 7th and April 2nd 2017.[5] Over the 8 week consultation period, HSE received a total of 129 responses from a wide range of sectors; of these, 56 were from the medical sector and 24 from the nuclear sector. One trade union responded to the consultation. Other responses were from professional organisations and institutes, Royal Colleges, trade associations, consultants, education, local and national government.

50. The consultation sought responses on specific aspects of the proposed transposition approach, including feedback on the new regulations and suggested changes to the ACOP. There were specific questions on key changes, including on expected costs: changes to eye dose limit and classification level; recording and analysing of accidents; changes in the definition of outside workers; and the Graded Approach. Consultees were also asked to provide any further information on costs not already included in the IA.

51. The consultation highlighted that around half of respondents supported the implementation of the Directive as proposed. The main concerns raised related to the graded approach, particularly the proposed renewal periods, and those from the nuclear sector voicing concern that the requirement to seek consent duplicated nuclear licensing requirements by ONR. HSE has taken account of this feedback, removing both the need for renewals and the requirement for ONR nuclear licensed sites to seek consent to operate from HSE. The overwhelming majority of stakeholders agreed with the early implementation of the regulations.

52. The responses provided a large number of useful and detailed comments on the draft ACOP, which will be reviewed to ensure that it is easy to understand and minimises familiarisation costs. HSE has also set up a separate working group with stakeholders to specifically review the proposed ACOP and associated guidance, which additionally served to provide information from group members about expected familiarisation costs.

[5] The HSE consultation document and analysis of responses can be found at http://www.hse.gov.uk/consult/condocs/cd282.htm.

53. All responses have been thoroughly analysed and information has been used to revise assumptions in this IA where possible, as discussed in detail in the relevant sections.

10 New requirements in the proposed Ionising Radiations Regulations 2017 (IRR17)

54. When undertaking the research to inform the IA, we have adopted a proportionate approach. The Directive introduces several changes compared with IRR99. However, only two are likely to lead to significant costs to business. Therefore, we prioritised our research on those two changes. The other changes lead to lower costs to business and some are not expected to lead to any significant costs. Thus, when describing the costs and benefits below, we start with the changes that lead to the greatest additional costs.

55. The new key requirements are:

- Eye Dose: A reduction in the eye dose limit and changes to classification levels (Section 11);
- Graded Approach: Introduction of a risk-based approach to regulatory control of practices using ionising radiation (Section 12);
- Outside Workers: Change in the definition that widens the scope of the regulations (Section 13);
- Weighting Factors: Introduction of new weighting factors for dosimetry (Section 14);
- Public Dose Estimation: A requirement to estimate doses to members of the public (Section 15);
- Other changes that lead to no additional cost (Table 9 and Table 10);
- Other changes which could be viewed as potentially going beyond the minimum requirements of the Directive (Section 17.2).

11 Changes to requirements on doses to the lens of the eye

11.1 Background

56. In June 2011, the ICRP recommended that the dose limit for ionising radiation exposure to the lens of the eye (herein referred to as 'eye dose') be reduced to 20 mSv per year, 7.5 times lower than the existing occupational dose limit of 150 mSv. Based on a review of scientific research, ICRP considers there is increased risk of eye opacities and cataracts at lower doses than previously understood.

57. Based on the ICRP recommendation, the Directive introduces two changes in requirements specific to exposures to the lens of the eye:

1) A reduction in the limit for doses to the lens of the eye, from 150 mSv per year to 20 mSv per year.
2) A reduction in the level of exposure at which workers must be designated as a 'classified person' for exposures to the lens of the eye, from 45 mSv to 15 mSv per year.

58. HSE proposes to implement a provision in the Directive for the dose to be accounted over a 5 year period, such that the dose does not exceed a total of 100 mSv in any five consecutive years, or 50 mSv in any single year. This is a permissive change, as discussed in Section 11.14.1.

59. Based on extensive engagement with stakeholders (described further in the section below) the most significant impacts of these changes would most likely arise in the medical and nuclear sectors; these are analysed in detail below. Section 11.13 discusses the potential for impacts in other sectors.

11.2 Summary of research on impacts of changes to eye dose limit

Stakeholder engagement

60. As discussed in Section 9, HSE has undertaken a large amount of research and engagement with stakeholders to understand the potential impacts of the proposed regulatory changes in eye dose requirements.

61. Early discussions with stakeholders during the negotiation of the Directive suggested that the main effects of the proposed change in eye dose requirements would be on the medical and nuclear sectors. HSE consulted closely with representatives from these sectors in a series of meetings during this period to discuss the potential implications of the reduction in eye dose limit to 20 mSv.[6]

62. HSE economists used these meetings to develop a cost model of the main impacts relating to the proposed changes. The stakeholder group provided data and information to inform reasonable assumptions, which were discussed and refined in subsequent meetings. Sector representatives also reviewed several versions of a written assessment of the costs to inform revisions of the estimates, which were used to inform HSE's negotiating position on the Directive.

63. During these meetings, a number of stakeholders in the medical sector voiced their concerns that this new dose limit would lead to high costs, arising in particular from an increase in the number of classified workers within the medical sector, additional dose monitoring of workers and implementing controls to reduce exposure levels. By contrast, nuclear sector representatives have consistently advised HSE that they expect the impacts associated with the change to eye dose requirements to be limited; the nature of risks from ionising radiation in the nuclear sector, and the stringent regulatory framework in place for nuclear operators, is such that exposures already tend to be reduced to as low as reasonably practicable. Workers expected to receive significant radiation exposures tend to be already classified due to their whole body dose. Subsequent research has therefore focussed on improving HSE's understanding of the impacts in the medical sector.

64. A key uncertainty during these discussions was the existing level of eye doses received by workers in the medical sector. If current exposures are higher than the proposed dose limit or classification level, medical sector employers would need to take a number of actions to classify workers and control doses, incurring potentially large costs. The cost of actions required to comply would depend on how high the current doses are in comparison with the new dose limit.

Dosimetry research

65. To gather further information on current exposures, HSE commissioned Public Health England (PHE) to undertake dosimetry research, initially as a small scale study in 2013, then a larger follow-up study in 2015, covering a wider variety of health professionals, procedures and environments. The 2015 research obtained 100 dose measurements, covering a minimum of three months' exposures, along with 79 questionnaire responses providing information to aid the analysis, such as the procedures undertaken and type of protective equipment worn. Annualised doses estimated from the study suggest that no workers involved would receive exposures above the 20 mSv dose limit or 15 mSv classification levels, and most were considerably below these levels.

66. If the evidence from this research is representative of the whole medical sector, then providing the workload remains constant, there should not be significant costs to the medical sector due to this

[4] These included: medical sector representatives from the Royal College of Radiologists, British Institute of Radiology, Department of Health, Society of Radiological Protection, Institute of Physics and Engineering in Medicine, Health Protection Agency and NHS radiation protection advisers; and nuclear sector representatives from several nuclear employers and the Office for Nuclear Regulation.

change. HSE considers this research to be of high quality; however, the sample size was relatively small in comparison to the size of the sector and fewer than half of the questionnaires were returned with full information. Additionally, there may be some self-selection bias given that participants volunteered to take part.

67. Subsequent to this research, on HSE's request, an Approved Dosimetry Service (ADS)[7] undertook an ad-hoc analysis of doses in its dosimetry database over a six-month period. This data showed that a small proportion of doses were estimated to be above the proposed 20 mSv dose limit. In addition, HSE's own dosimetry database (Central Index of Dose Information – CIDI), which aggregates data from all Approved Dosimetry Data, shows that in 2015, five out of 15 classified workers in the medical sector had eye doses above 15 mSv, with one worker above 45 mSv.

68. In 2012, a medical sector representative provided HSE with eye dose monitoring data covering a relatively large sample (900) from several hospitals in the medical sector, which suggested a small proportion of workers were exceeding the proposed dose limit. However, it is difficult to validate the reliability of these dose measurements, as HSE has limited information about how doses were collected and how control measures were applied.

69. During the public consultation period, HSE invited the NHS to submit any available eye dose monitoring data in order to inform this impact assessment. HSE received seven submissions. While the data provided was highly variable in terms of the level of detail provided and the number of measurements undertaken (discussed further in Section 11.5.1), it supports the view that at least some NHS workers are close to or above the proposed classification level and dose limit. HSE also engaged directly with some NHS Trusts to further understand the monitoring data and the effects and costs of investments in radiation controls on doses.

Public consultation

70. HSE asked a series of specific questions in the public consultation regarding the effects of the changes to eye dose requirements in all sectors. Broadly, these covered the following aspects:

- Whether the organisation would need to classify any additional workers and, if so, how many
- Costs of additional controls required to reduce eye dose exposures
- Any other costs arising from the changes to eye dose requirements

71. Respondents provided a large amount of useful and relevant information in response to these questions, which is discussed in detail and was used to revise estimates in the relevant sections below. The responses confirmed the assessment in the consultation-stage IA that only the medical sector is likely to incur large costs from the changes to eye dose requirements. They suggested that costs associated with monitoring and some aspects of controls (lead shielding) had been underestimated, and these have been revised. They also supported the assessment that a significant number of workers in the medical sector will need to be classified; Section 11.5.1 provides further discussion of this.

[7] An Approved Dosimetry Service is approved by HSE to provide services that produce, maintain and summarise radiation dose records

Research into the effectiveness of personal protective equipment (PPE)

72. In 2014, HSE commissioned the Health and Safety Laboratory (HSL) to carry out research into the effectiveness of available PPE in the medical sector[8]. This concluded that, even in a 'worst case' scenario, it should be possible to reduce doses below the dose limit using currently available PPE.

Summary and conclusion of this section

73. HSE has undertaken extensive research to inform estimates of the costs changes to eye dose requirements, including gathering information to refine and validate the estimates made in the consultation-stage IA, which were already well-developed.

74. At a high level, the evidence gathered has supported the consultation-stage assessment that the majority of costs will be incurred by the medical sector, with much lower costs by the nuclear sector and significant impacts are unlikely in other sectors. New information has been used to revise specific estimates and assumptions for the medical sector, as described in the following sections. The assessment for the nuclear sector is unchanged from the consultation-stage IA, as evidence gathered broadly supported the assessment of low costs and did not provide information to suggest specific assumptions should be changed.

11.3 Medical sector – affected groups and costs of time

11.3.1 Affected groups

75. Clinicians and support staff can receive eye doses during medical procedures, generated by medical equipment and radiopharmaceuticals. Practitioners involved in complex interventional procedures, such as interventional radiology or cardiology, are particularly at risk of significant cumulative doses. During such procedures, practitioners often spend a prolonged period in close proximity to a radiation source, such as an X-ray used in fluoroscopy.[9] Medical establishments and workers that perform these procedures are most likely to be affected by the change in the eye dose limit and classification level.

76. Based on discussions with medical sector stakeholders, HSE expects that the vast majority of impacts will fall to medical organisations in the public sector in the NHS. Private sector medical companies are much less likely to undertake the type of complex interventional procedures expected to result in high eye doses of ionising radiation. However, many practitioners working primarily in NHS hospitals will also undertake medical work in some capacity in the premises of private hospitals. As a consequence, there is potential for some limited costs to the private sector from newly classified 'outside workers' (see Section 11.5.6).

77. HSE sought views from a representative body of the independent hospital sector during the public consultation on the impacts of these changes but did not receive any information. Therefore, we maintain our estimate that almost all of the costs arising from the changes to eye dose requirements are borne by the NHS.

[8] Research as yet unpublished.

[9] Fluoroscopy uses X-ray to provide a real-time video image on television monitors, in order to aid patient examinations and diagnosis. The main source of eye exposure in these and other interventional procedures is radiation reflected and scattered from the patient's body or other objects. In non-interventional use of X-ray, such as a chest X-ray, practitioners do not need to be close to the patient and typically operate the machine from behind a screen or from another room, meaning they do not typically receive significant ionising radiation.

11.3.2 Affected sites

78. HSE has gathered the following information about the likely number of affected sites in Great Britain (GB): [10]

- 153 Interventional Radiology and Cardiology Centres (British Cardiovascular Society);
- 12 Paediatric Cardiology Centres (National Congenital Heart Disease Audit);
- 57 Positron Emission Tomography (PET) centre sites (UK PET Research Centre);[11]
- 10 Ministry of Defence sites – military hospitals (MoD).

79. Monitoring data submitted by NHS organisations to HSE indicates that while radioactive substances used in nuclear medicine, such as Positron Emission Tomography (PET), result in eye doses, these are not at levels which are close to the proposed classification level or dose limit. Therefore, we include these sites only in estimates of reviewing risk assessments and familiarisation costs; based on the available evidence, additional classifications or controls to reduce doses are unlikely to be required.

80. This gives 232 sites in the medical sector where workers may be affected by the revised dose limit for the lens of the eye.

11.3.3 Affected workers

81. Monitoring data and reports from medical stakeholders suggest that workers most likely to be affected by the change in requirements are interventional radiologists and interventional cardiologists. Responses to the public consultation support this. These workers spend most time in close proximity to ionising radiation sources undertaking complex surgical procedures and are therefore most likely to receive high cumulative doses to the lens of the eye. Data gathered suggests that in GB there are approximately:

- 500-600 Interventional Radiologists (according to the Royal College of Radiologists);
- 650-700 Interventional Cardiologists (British Cardiovascular Society);
- 85 Paediatric Cardiologists (British Congenital Cardiac Association).

82. Therefore, a total of between 1,235 and 1,385 workers are most likely to be affected by the revised dose limit; we take 1,300 workers as a rounded midpoint. For the purposes of this IA we categorise these as 'higher risk' workers, i.e. those likely to receive the highest doses.

83. Discussions with stakeholders suggested that some other workers in the categories listed below may also carry out work leading to radiation eye doses:

- vascular surgeons performing Endovascular Aneurysm Repair procedures;
- those performing Endoscopic Retrograde Cholangiopancreatography (ERCP);
- PET production, PET administrations and mobile PET services;
- radiopharmacy technicians;
- gastroenterologists;
- cyclotron engineers;
- nurses and other support staff assisting in interventional procedures, working close to the patient and radiation source.

[10] HSE obtained these estimates by contacting the organisations cited (except where a web source is provided in a footnote)

[11] See: www.ncri-pet.org.uk/pet_facilities.php. PET is a nuclear medicine, functional imaging technique that is used to observe metabolic processes in the body

84. It has not been possible to obtain specific estimates of the numbers of the other affected workers within these groups. However, a survey for the Society for Radiological Protection of members in 2012 suggested that around 8,600 NHS employees in England work in some capacity with ionising radiation and will be in scope of the change to eye dose limit and classification level.[12] Scaling this up to include NHS workers in Scotland and Wales, using the proportion of total NHS workers in Great Britain working in England (around 82%), gives approximately 10,400 affected NHS workers in GB (rounded estimate).

85. Additionally, up to 50 clinicians in MoD military hospitals may be affected by the changes (at least, in terms of needing to become aware of changes and review risk assessments – see Section 11.4). Including these gives a (rounded) estimate of 10,500 affected workers in the medical sector (including MoD medics).

86. This number will include the 1,300 'higher-risk' workers estimated above. Subtracting these from the estimated 10,500 total affected workers leaves a rounded estimate of around 9,200 'lower risk' workers – that is, those who are less likely to receive high doses.

11.3.4 Costs of time

87. Estimates of the full economic costs (FEC) of time are based on salary information provided by representatives in the NHS, and converted to 2016 prices, except where noted below:

- NHS doctors (clinicians) have an FEC of between £35.64 and £65.84 per hour, depending on whether they are a registrar or consultant. We take the midpoint of £50.74 per hour;
- A Radiation Protection Supervisor (RPS) has an FEC of £31.53 per hour;[13]
- An operational/departmental manager has an FEC of £39.21 per hour;
- A divisional manager has an FEC of £53.94;
- A radiation protection advisor (RPA) has an FEC of £53.14 per hour.

88. These costs have been reviewed against estimates provided in the public consultation and are within the range of responses, so are maintained. The roles of these workers and how they are affected by the regulatory changes are described in the sections that follow.

11.4 Medical sector – revising risk assessments, raising awareness, providing advice & training

11.4.1 Revising risk assessments

89. Medical sector employers are required to undertake risk assessments (RAs) covering risks from ionising radiation, as per Regulation 7 of the IRR99, along with other work-related risks (covered by the Management of Health and Safety at Work Regulations 1999 (MHSWR)). RAs under IRR99, and also IRR17, are required to consider, amongst other things, the risks posed by sources of ionising radiation,

[12] The Society for Radiological Protection (SRP) received responses which suggested around 675 affected workers across 12 NHS Trusts, or approximately 56 workers per Trust. SRP considered that the sample of Trusts, although small, was representative. HSE has therefore multiplied the estimate of 56 workers per Trust across the 154 Acute NHS Trusts in England.

[13] The hourly rate for an RPS is taken from ASHE 2015(p), 1181: Health services and public health managers and directors – the mean value of £25.99, uprated by 19.8% to account for non-wage costs, and inflated to 2016 prices using the ONS wage index for Health and Social Work Activities (K5BC).

estimated doses for those who may be exposed, and monitoring or dosimetry data, to determine what control actions are required to reduce doses to comply with legal requirements on exposures.

90. Employers would need to review these RAs in light of the revised eye dose limit to identify where the dose limit may be exceeded and what further control action might be required. To inform this review, employers may also need to undertake additional monitoring of eye doses, if sufficient information is not already available. Additional monitoring costs are assessed separately in Section 11.5.5.

91. The number of RAs and the time taken to review them will depend on the number and complexity of uses of ionising radiation. In addition, there is likely to be considerable variation in practice; discussions with medical sector representatives suggest that some centres risk assess specific equipment or activities, so will tend to have more RAs, while others have assessments covering areas or a broader range of activity. Stakeholders have stated that, on average, each employer at the 232 sites may need to revise between three and five RAs. Taking four as the midpoint gives a total of around 930 RAs across the medical sector.

92. RAs should be reviewed as a matter of course under the requirements of MHSWR. Information provided by Radiation Protection Advisors (RPAs) in the medical sector in recent discussions was that RAs are reviewed every three years – that is, 1/3 of RAs are reviewed each year under business as usual on average. This leaves two-thirds, or around 620, additional RAs reviewed because of the change in eye dose limit.

93. Information provided by stakeholders and discussions with HSE Radiation Specialist Inspectors suggests that, although practices will vary, revising RAs would primarily require input from three staff:

- an Operational / Departmental Manager with responsibility for health and safety;
- a Radiation Protection Advisor (RPA);
- a Radiation Protection Supervisor (RPS).[14]

94. The amount of involvement from each worker will vary considerably across sites and between RAs, depending on local practice. Information provided by medical sector representatives involved in RAs suggests that, on average, they might each spend around 45 to 75 minutes revising a typical RA. Taking an hour per each worker as the midpoint and valuing at the costs of time set out in Section 11.3.4 gives an average total cost of time per RA of around £120.

95. In addition, each RA revision would require 30 minutes from a clinician (at a cost of around £51 per hour, taking the midpoint) or £25 per RA. Adding this to the costs per RA above gives a total cost of time per RA of around £150. This means that the total economic cost for the time spent revising additional all 620 additional RAs is around £92,000. This is a one-off cost, incurred in the first year of the regulatory change.

96. Only limited comments were received on this assessment during the public consultation, which did not indicate that the assumptions should be revised. Given that existing risk assessments should

[14] The roles of an RPA and RPS can be summarised as follows:

An RPA's role is to provide competent advice to a dutyholder to assist them in carrying out the actions they must take to comply with IRR. They will assist with requirements such as risk assessments, designation of controlled and supervised areas, dose assessment and dose recording, and drafting contingency plans.

An RPS is appointed to assist employers in ensuring that the arrangements put in place by the employer to protect workers are adhered to. In particular they will supervise the work along with arrangements put in place for work in supervised or controlled areas. They are trained to understand the Regulations, the rules that are in place, and what to do in an emergency.

already take account of eye doses and revision should not be an onerous task, we consider that this is a reasonable estimate of costs of additional activity, taken together with the costs assessed in the next section.

11.4.2 Raising awareness, providing advice & training

97. The consultation-stage IA estimated costs arising from activity in each NHS organisation to raise awareness of the changes in requirements, provide advice regarding changes in practices or controls, and deliver any training needed. These estimates totalled one-off costs of around £400,000 in the NHS. For this final-stage IA, HSE has estimated total costs to the sector arising from activity to familiarise with the whole regulatory package – see Section 19. Therefore, to avoid double counting, we do not estimate familiarisation with eye dose changes separately here.

11.5 Medical sector - classifying workers and monitoring non-classified workers

11.5.1 Newly classified workers

98. Under the proposal, the dose level at which employers are required to designate a worker as a classified person would fall from 45 mSv per year to 15 mSv per year. Employers should classify workers where it is "reasonably foreseeable" that they will exceed the classification dose level. The doses received by classified workers must be monitored so that the employer can check that they are being kept as low as reasonably practicable, and that dose limits are not exceeded. Medical surveillance is also required for classified workers to ensure that they remain fit to work with ionising radiation.

99. HSE has used two broad types of evidence (gathered both before and after the consultation-stage IA) to inform an estimate of the number of workers that will need to be newly classified due to the change in the classification dose level:

- Monitoring data from the NHS giving annual levels of exposures of affected workers, which can be compared against the proposed classification level. This includes formal dosimetry research undertaken by PHE for HSE, as described in Section 9

- A specific question in the consultation document, which asked respondents to estimate how many workers their employer expects to classify as a result of the change in classification level.

Monitoring data

100. As described in Section 9, research undertaken by PHE for HSE in 2015 found no doses exceeding or close to the new classification level, suggesting that very few, if any, additional workers would need to be classified.

101. Following the consultation-stage IA, HSE invited NHS organisations to share further eye dose monitoring data. The data provided was highly variable in terms of the level of detail provided and the number of measurements undertaken, and the sample of NHS organisations and workers is not representative of the NHS as a whole. Overall, the number of individuals monitored totalled around 140. Data on annualised doses showed around 1 in 20 of those workers monitored may have doses at a level at which NHS employers would classify their workers.

Consultation responses

102. The consultation document asked respondents to provide an estimate of the number of additional workers their employer expects to classify as a result of the change in classification level. Figure **1** below summarises the responses received.

103. Of 51 responses from the medical sector, 22 indicated that they would not need to classify additional workers. The most common response of those who would need to classify workers was 2-5 (15 responses), though a significant number (14) answered that they would need to classify more than this. The responses were provided by NHS employers of a range of sizes, though larger employers were overrepresented.

Figure 1 - estimates of the number of classified workers per NHS employer provided via public consultation[a]

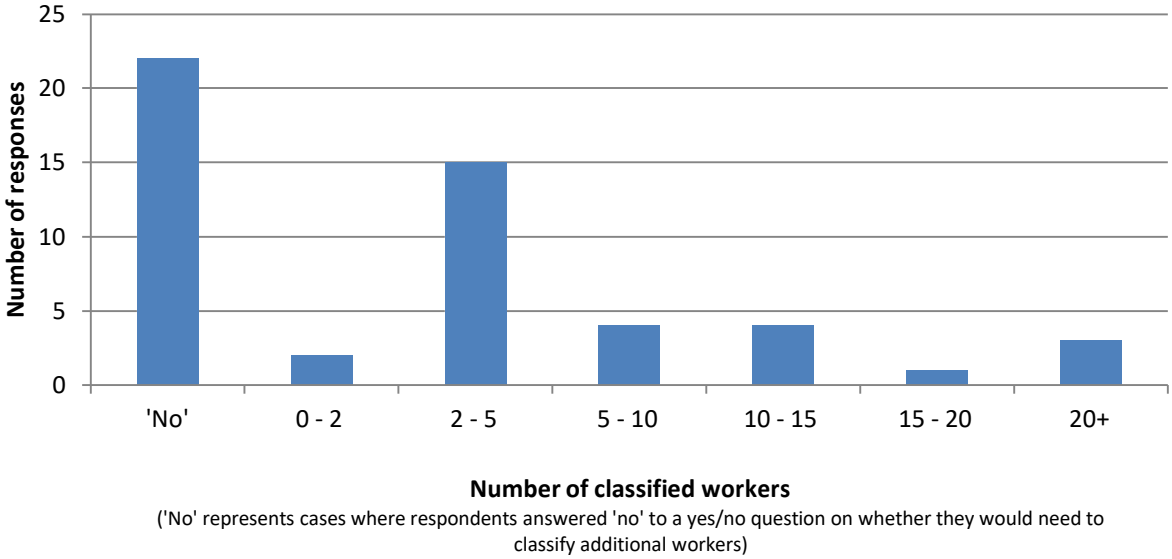


Figure 1 Notes

[a] A joint response from the Institute of Physics and Engineering in Medicine (IPEM), the Royal College of Radiologists (RCR), the Society and College of Radiographers (SCoR), and the British Institute of Radiology (BIR), which cover the professionals and activities most likely to be affected by the changes to eye dose requirements, suggested between 2 and 5 per NHS employer on average would need to be classified. Given this, and the nature of other responses, we do not expect that the estimates for those who selected the 20+ category would be significantly higher than 20.

Discussion

104. There is clearly a considerable variation between NHS employers in both the level of exposures and the number of additional workers that may need to be classified. This may be due to several factors besides the total number of workers affected, including differences in local control practices and types or frequency of procedures undertaken. Differences in estimates of new classifications may also reflect a more cautious approach by some employers in classifying workers at a dose lower than the classification level, or a cautious response by organisations which have not yet undertaken sufficient monitoring to provide an informed estimate.

105. The consultation-stage IA estimated 300 newly classified workers across the NHS, based primarily on information provided by the medical sector during the negotiation phase of the Directive. At the time HSE considered this an overestimate, based on the high quality dosimetry research undertaken by PHE. Extrapolating the consultation responses to the NHS sector as a whole would result in an estimate of around more than double our consultation-stage estimate.

106. However, there are several reasons why extrapolating from the consultation responses may represent an overestimate. Firstly, the larger NHS employers were overrepresented in the consultation responses; we would therefore expect the average to be lower across the NHS population as a whole.

107. Secondly, the monitoring data submitted by NHS employers, and undertaken by PHE on behalf of HSE, does not support the level of additional classified workers suggested by the consultation responses.

108. Thirdly, NHS employers plan to implement additional controls to reduce exposures from current levels, given the significantly lower dose limit, as assessed in detail in Section 11.6. Research undertaken by the Health and Safety Laboratory is clear that implementing the controls assessed should reduce exposures to considerably below the classification level as well as the dose limit, and this is supported by monitoring data provided by – and discussions with – NHS employers who have recently upgraded their controls, as well as several consultation responses. Accounting for this suggests that additional classifications may be substantially lower than an assessment of current exposures would indicate.

109. On the balance of the available evidence and the arguments presented above, we consider that the original estimate of 300 additional classified workers across the NHS is a reasonable estimate, and maintain this assumption for this final stage assessment.

110. Some NHS representatives have reported that more clinicians could become classified in the future, as new interventional procedures using ionising radiation become more common, and clinicians undertake a greater number of complex interventional procedures. We do not have sufficient information available to estimate the level of increase that might occur, or the types of procedures that may be involved, in order to incorporate this into the analysis.

11.5.2 Initial medicals for classified workers

111. Initial medicals must be undertaken face-to-face with an Appointed Doctor.[15] HSE medical inspectors estimate that the employer would incur a fee of around £120 each for these medicals. This fee would include the costs of the Appointed Doctor's time to travel to and attend the appointment.

112. It would take around 2 to 3 hours of the classified worker's (expected to be an interventional radiologist or cardiologist) time to travel to and attend the appointment – 2.5 hours is used as the midpoint. In advance of the medical, it would take an RPA 5 to 10 minutes per worker to request dose reports from ADS and send these to the Appointed Doctor. Applying the costs of time set out in Section 11.3.4, this gives a cost of time per medical of around £130.

113. Adding the cost of the medical and of the doctor and RPA's time, this gives a total of around £250 per medical, or an estimated total one-off cost in the first year of around £75,000 across the 300 newly classified workers.

114. Cost estimates received during the public consultation broadly supported the assumptions made above.

11.5.3 Annual medical reviews for newly classified workers (after the initial year)

115. Annual medical reviews can be conducted either face-to-face or 'paper-based', with information about the individual's health provided in written form. Currently, one in five annual medicals must be face-to-face; this is also advised in cases where assessment in person is needed, such as where health

[15] Doctors recognised by HSE to carry out statutory medical surveillance

issues are suspected. HSE medical inspectors expect around 25% of medical reviews per year to be face-to-face which equates to around 75 per year.

116. We expect the cost of annual face-to-face medical reviews to be the same as initial face-to-face medical examinations, that is £250 per medical (including cost of medical plus the cost of the classified clinician's and RPA's time). This gives a total annual cost of face-to-face medicals of around £19,000, starting in the second year.

117. HSE medical inspectors estimate that 75% or 225 of the annual medicals would be paper-based. These take considerably less time to conduct than face-to-face medicals, hence are charged by Appointed Doctors at a lower fee. HSE medical inspectors advise that typical fees are around £80 per medical.

118. As with the face-to-face medicals, it would take an RPA 5-10 minutes per worker to request dose reports from the ADS and send these to the Appointed Doctor. It is not thought that the classified person would need to spend any time on the paper-based reviews, since they do not typically need to provide additional information beyond that collated by the RPA/employer.

119. Taking these costs together and multiplying by the annual number of paper-based medicals gives an estimated cost also of around £19,000. Adding this to the estimated cost of annual face-to-face medicals gives a total annual cost of medicals of £38,000, starting in the second year.

120. Cost estimates received during the public consultation broadly supported the assumptions made above.

11.5.4 Dosimetry and record keeping costs for additional classified workers

121. Employers would be required to undertake eye dosimetry (measurements of radiation doses to the eye) for the 300 newly classified workers. They would also need to keep a formal dose record and provide dose measurements to an Approved Dosimetry Service (ADS). These could entail additional costs, as described below.

122. Each newly classified worker would require an eye dosemeter supplied by an ADS – estimated by a provider to cost £8 per issue.[16] Assuming a new dosemeter will be issued monthly for classified workers, the yearly cost of dosemeters is around £95 per worker. Each would also require a dose record, managed by an ADS, at an estimated cost of around £18 per worker per year.

123. There may also be additional administration and supervision costs relating to:

- RPAs reviewing doses and estimating doses for lost or damaged dosemeters.
- A small additional administrative requirement, at most 5 minutes per classified worker per year, for the responsible staff member (either an RPS or an RPA) to inform the ADS of the type of PPE worn, which is necessary for accurately estimating dose to the lens of the eye where two dosemeters are worn.
- There may be some costs associated with distributing new dosemeters, collecting used dosemeters and returning them to the ADS. As this activity will already be undertaken in

[16] Dosemeters are devices that measure exposure to ionising radiation. There are a number of different types of dosemeter available. Eye dosemeters are attached to a headband worn positioned either centrally on the forehead, or over the eye. Dosemeters are periodically returned to the ADS for evaluation and recording of doses on a worker's dose record.

hospitals for workers currently classified due to whole body doses, and the number of additional classified workers at 300 is less than 1.5 newly classified worker per site (across the 232 affected sites) the additional cost is expected to be minimal.

124. We add 15 minutes of an RPS or RPA's time, at an average cost of £42 per hour, to account for this additional activity.

125. Adding all of the above gives an annual cost per newly classified worker of around £130. Across all 300 newly classified workers, this gives a total annual cost for monitoring classified workers of around £37,000 (from the first year).

11.5.5 Additional monitoring of non-classified workers

126. In practice, most 'higher-risk' workers in the medical sector are already monitored for whole body doses but are not routinely monitored for eye doses. The previous section estimates costs of additional monitoring for newly classified workers. Employers may also need to carry out additional monitoring of eye doses for non-classified higher-risk workers. While the requirement to undertake monitoring has not changed, NHS stakeholders report that the more stringent classification level and dose limit could mean that more workers will need to be monitored, or be monitored more closely, to ensure these levels are not exceeded.

127. The number of workers requiring additional monitoring is uncertain, though discussions with the medical sector and HSE Specialist Inspectors suggest that some additional eye dosimetry, for example using headband dosemeters, would be required. The additional costs involved would be limited to the cost of the additional dosemeter; as we expect that whole body doses for these workers are already monitored, any further administrative requirement for eye dose measurements would be negligible.

128. HSE does not prescribe the way in which monitoring must be carried out for non-classified persons. Medical sites may opt to monitor a sample of workers undertaking similar activities, rather than monitoring each worker, which would reduce costs.

129. On this basis, the consultation stage IA estimated that around 25% of non-classified high-risk workers (around 250) would require additional eye dosimetry, who would be monitored by being issued with a new dosemeter every 2 months (6 times a year), at a cost of around £48 per year per worker. This gave estimated annual cost across all non-classified workers requiring additional monitoring of around £12,000 (from the first year).

130. Medical sector respondents to the public consultation commonly raised increased monitoring costs as a significant additional cost of the proposals, and several stated that the costs in the impact assessment had been underestimated. However, these responses provided limited detail about what monitoring arrangements are in place now and for which staff additional monitoring would be required (e.g. which type of staff, and whether this additional monitoring would be for newly classified or non-classified workers). Some mentioned that this would be for audit requirements and to demonstrate that staff were not exceeding the classification level.

131. Only four responses provided estimates of additional monitoring costs, all between £1,500 and £2,000 per annum. It is unlikely that these costs will apply to all NHS organisations – indeed, only around a half of medical sector respondents mentioned additional monitoring costs. Given this, we estimate that 50% of sites will incur additional monitoring costs, at a cost of £1,750 per annum (taking the midpoint of the responses to the consultation) – resulting in annual costs of £200,000 from the first year.

132. This significant increase in costs from the consultation-stage IA reflects a greater (though undefined) number of workers requiring monitoring for eye doses than previously estimated – consistent with reports of relatively few NHS workers currently being monitored for eye doses.

11.5.6 Additional Classified Outside Workers

133. Impacts associated with the change in the definition of outside workers introduced in IRR17 are assessed in Section 13. The impacts assessed in this section relate to the expected increase in the number of classified outside workers as a result of the lower classification level for eye doses – which is not affected by the change in the definition of outside workers.

134. A classified outside worker is a classified person who carries out services in a controlled or supervised area for another organisation who is not their employer – for example, an employee of one NHS Trust carrying out work activities in the controlled area of another, perhaps for training or demonstration purposes. A clinician carrying out work in any building within their own employer's estate, or who works under a formal employment contract for different employers on a part-time basis (e.g. working 2 days a week for one NHS employer, 2 days a week for another NHS employer, and 1 day a week employed by a private hospital), is not an outside worker. In the majority of cases where medical sector workers are undertaking services for more than one employer, they will be doing so under a formal employment contract and not as an outside worker.

135. The employer of a classified outside worker is required to ensure that the worker has a radiation passbook. The passbook records doses incurred during work in controlled areas of other organisations to ensure that total cumulative doses can be monitored. Medical sector stakeholders anticipate an increase in the number of classified outside workers, caused by the expected increase in the number of workers classified due to eye doses.

136. Discussions with medical sector stakeholders suggest that classified outside workers are most likely to be interventional cardiologists (excluding paediatric cardiologists), who undertake interventional work in hospitals operated by other NHS organisations. The number of such workers is uncertain; information provided by medical sector stakeholders suggests that around 25% of the total number of adult cardiologists could undertake work as an outside worker. Applying this proportion to the approximately 150 interventional cardiologists classified due to the new eye dose limit, gives an estimate of around 40 additional classified outside workers.

137. Each of these workers would require a passbook costing around £20, which would last on average for about 12 years (estimates provided by an ADS). This gives an annual average cost for passbooks of around £1.70 per worker.

138. In addition, it would take a RPA 0.25 hours per entry to estimate and enter the dose into the passbook, and provide additional dosemeters, at a cost of around £53 per hour or £13 per entry. HSE Specialist Inspectors expect that entries will be made in the passbook on a monthly basis (12 entries per year), giving an estimated total number entries of around 460. This gives a total annual cost of the RPA's time of approximately £6,100.

139. Based on discussions with medical sector stakeholders, outside workers will work for between one and three other organisations. As a conservative assumption, we assume for the purposes of this assessment that, on average, two additional dosemeters will be required for each additional outside worker, at a cost of around £95 each per year. This gives a total annual cost of dosemeters of around £7,200.

140. Adding all the estimates of annual costs in this section gives a total estimated annual cost for additional outside workers in the medical sector of around £13,000 (from the first year). As described earlier, some outside workers may undertake work for private hospitals. However, it is unclear what proportion of the costs estimated here will fall to private hospitals. Given the low costs, it is not proportionate to undertake further work to disaggregate this cost and we assume all costs are borne by the NHS, as the primary employer of these workers. Responses to the public consultation did not suggest that these cost estimates should be revised.

11.6 Medical sector - additional controls to reduce eye doses

141. In the medical sector, there is a range of engineering controls and PPE in use to protect against radiation doses. Research by the Health and Safety Laboratory for HSE in 2012 found that:

i) the most common controls used in the medical sector to protect the eyes are leaded glass screens and leaded eyewear; and
ii) even in a 'worst case dose scenario', correct use of these controls would bring eye doses within the proposed 20 mSv dose limit.

142. Research undertaken by PHE for HSE suggests that medical sector employers would need to take very little, if any, action to reduce eye doses below the new limit. This is contrary to representations by NHS stakeholders that they would need to supply additional leaded eye wear or install new glass screens to meet the new eye dose limit, either because existing equipment provides insufficient protection or because equipment is not currently supplied to all workers/areas that will need it.

143. Costs estimated in the consultation-stage IA were based on information provided by NHS representatives in consultation during the negotiation phase of the Directive and during HSE's development of the domestic regulations pre-consultation. To gather information to refine these estimates, HSE asked specific questions in the public consultation about additional controls that would be needed to comply with the new eye dose requirements, and associated costs. HSE also engaged directly with some NHS stakeholders to further understand costs.

144. The additional information gathered during this period confirmed that some NHS employers will need to implement additional controls, and that the types of controls assessed in the consultation-stage IA were broadly the correct ones.[17] Of the 49 from the medical sector who responded to a question about whether additional controls would be needed, 38 answered 'yes', while 11 answered 'no. Where respondents provided details about these controls and associated costs, have been used to revise the estimates made in Sections 11.6.1 and 11.6.2.

11.6.1 Cost of supplying additional protective leaded eyewear

145. Employers, as part of the RA process, will need to assess the adequacy of the provision of existing eye protection. NHS representatives believe that some designs in use may not offer sufficient

[17] A small number of responses stated that they may also use surgical drapes to meet reduce doses. These are placed over the patient during procedures to protect patients and staff from radiation scatter (which is an important source of eye lens exposures for medical staff). As only a small number of respondents mentioned these, we do not include them in our estimates.

Nine respondents to the public consultation also raised concerns that the HSE-approved method for measuring doses does not account for reduction in doses from protective eyewear. Respondents argued that this could lead to situations were measured doses are higher than actual doses, resulting in greater control costs or other impacts, such as the rationing of shifts for consultants with high workloads to reduce their doses. HSE awaits submissions from Approved Dosimetry Services for the approval of different methodologies to measure eye dose, which would account for protective eyewear. If these are approved by HSE, the additional costs raised should not be incurred.

side protection against scatter radiation. Some practitioners also do not routinely use protective glasses (either because they have not been supplied with them or because they have chosen not to wear them, as the risk of harm was previously perceived to be low due to the higher prior-to-revised ICRP recommendations). Where the RA and monitoring data show that individuals may exceed the new eye dose limit, they may need to be supplied with new protective eyewear, with associated costs.

146. There is considerable uncertainty regarding the extent of new pairs of eyewear required, due both to the size, complexity and variation in practices of the medical sector, and the lack of monitoring data for eye doses. Discussions with RPAs in the NHS, and an HSE Radiation Specialist Inspector with experience working in the medical sector, suggest that there will be variation in the practice of issuing eyewear. Employers supply protective eyewear primarily to interventional rooms, where they are pooled for use by clinicians and support staff working in the room, while also supplying eyewear to individuals. Individuals with corrective prescription glasses will require individual protective eyewear tailored to their prescription.

147. A plausible 'typical' scenario is that senior clinicians most commonly involved in complex interventional procedures (such as consultant cardiologists and radiologists) will be issued with their own protective eyewear (if monitoring data or a risk assessment shows that they require it), while eyewear will also be supplied to interventional rooms for use by other clinicians and support staff involved in interventional procedures. The consultation-stage assessment made the following assumptions, based on information from NHS representatives and discussions with HSE Radiation Specialist Inspectors, to assess potential costs of supplying eyewear:

1. Newly classified workers (300): Considering that the 15 mSv classification level is close to the 20 mSv eye dose limit, we assume that any worker who may exceed this classification level will be provided with a new pair of protective eyewear. This gives 300 pairs of protective eyewear.

2. Non-classified 'high risk' workers (1,000): These are interventional cardiologists or interventional radiologists with estimated doses below the 15 mSv classification level and 20 mSv eye dose limit. As such, the majority are not likely to require additional controls. However, it is possible that that some may be near the classification level and so may be supplied with new protective eyewear to ensure that they do not exceed the eye dose limit. In the absence of suitable monitoring information, we assumed that 25% of these workers will receive new eyewear, giving an estimate of 250 pairs.

3. Interventional rooms: Information provided by an RPA in the medical sector suggests that, although the number of interventional rooms per site will vary greatly (from between 2 and 10), five interventional rooms per medical site is a reasonable average – around 875 across all 175 affected sites (those sites described in Section 11.3.2, excluding PET centres, as monitoring data shows that exposures at these sites are not close to the dose limit). These rooms may contain around four pairs of protective leaded eyewear for clinicians and support staff. It is unlikely that all of these glasses will need to be replaced; we have assumed that around half will be. This gives approximately 1,800 pairs of eyewear issued to interventional rooms.[18]

148. Combining these assumptions gives an estimate of a total of 2,300 pairs of eyewear issued across the medical sector in the first year, or around 13 pairs per each of the 181 NHS organisations

[18] The original estimate in the consultation-stage IA included only interventional radiology and cardiology centres in the calculation of interventional rooms. This has been corrected to include all sites described in Section 11.3.2, excluding PET centres.

that provide acute care (see Annex 1 for estimates of organisation numbers).[19] Eight respondents to the public consultation provided information on the number of additional pairs required. Besides one higher response of 40 pairs, all responses were between 10 and 20 pairs, with an average (of all eight responses) of 17 per organisation.

149. While this is higher than our consultation-stage estimate, we consider that the consultation responses broadly corroborate our initial analysis because i) a significant minority (around 1 in 5) of medical sector respondents stated that they do not need additional controls; and ii) larger NHS employers were overrepresented in the responses. On this basis, we maintain the estimate of 2,300 additional pairs of protective eyewear required across the NHS in the first year.

150. The cost of these protective glasses is estimated to be between about £110 and £730 per pair depending on the protection offered, whether a prescription is required, and, if so, the complexity of the prescription (based on a study by the Health and Safety Laboratory for HSE). Taking the midpoint of £420, the total cost of new protective eyewear may be around £960,000 in the first year. Fourteen respondents to the consultation provided estimates of the costs per pair, with an average of £380. Although our original estimate is slightly higher, it is very close so we will maintain it; the higher cost leaves contingency for any additional administrative / logistical costs in distributing the eyewear.

151. Protective leaded eyewear will need to be replaced periodically due to wear and tear (including breakages) or users' changes in prescription. It is estimated by the Society for Radiological Protection that 20% of eyewear issued as a result of the proposed eye dose limit will need to be replaced each year. This gives an estimated annual cost of approximately £190,000 (from the second year onwards).

11.6.2 Ceiling-mounted lead glass screens

152. It may be necessary for some employers to review the type of ceiling–mounted lead screens currently in use, to ensure they provide adequate protection to meet the reduced eye dose limit. Medical sector stakeholders report that, generally, as refurbishments have taken place, the screens have also been updated to higher specification models. However, some facilities may still be using equipment which has an insufficient thickness of lead or which cannot be used on either or both sides of the patient (which can be necessary to protect all workers who need to be close to the patient in interventional procedures).

153. As with protective eyewear, the number of additional mounted screens that would need to be installed is uncertain. The number per site would depend on the number of interventional rooms per site, the type and frequency of procedures undertaken, and the specification of existing screens installed.

154. The consultation-stage assessment made the following estimates, based on information provided by medical sector stakeholders during negotiation phase of the Directive and the development of the proposed regulations:

- around two-thirds of the affected sites (140) may need to have some screens replaced[20]
- an average of around two to four screens required per site (between 40% and 80% of the average of 5 interventional rooms per site requiring one screen to be replaced). Taking the midpoint (around three), this gives an estimate of around 410 screens replaced in total.

[19] The analysis here assesses the average number of glasses per NHS employer rather than on the basis of sites described in Section 11.3.2 in order to facilitate comparison with public consultation responses. Respondents were asked to estimate compliance costs for their organisation as a whole, rather than per site.

[20] The original estimate in the consultation-stage IA included only interventional radiology and cardiology centres in the calculation of interventional rooms. This has been corrected to include all sites described in Section 11.3.2, excluding PET centres.

155. Several responses to the public consultation confirmed earlier reports that, following the ICRP recommendation for a lower eye dose limit, many NHS Trusts have upgraded protective equipment to a higher specification during routine refurbishments. Information gathered during a telephone interview with such an NHS Trust is that the additional cost of installing higher specification equipment during a refurbishment is relatively low (around £1,000), and that refurbishments take place around every 10 years when equipment reaches the end of its service life.

156. Taking a 10 year refurbishment cycle, and assuming that refurbishments are evenly distributed through time, we assume that 10% of rooms have been refurbished to the required standard each year in the baseline (i.e. before the change in IRR) since the Directive was adopted at the end of 2013 – which is when we assume NHS organisations will have become aware of the change in ICRP recommendation.[21] On this basis, we estimate that 40% of the affected sites will have already refurbished rooms between 2014 and 2017 inclusive (up to the point of the implementation of the proposed regulations on 1st January 2018). For the purposes of this final-stage Impact Assessment, the costs associated with this work are sunk costs, and will not be included in the analysis. 60% of sites have not refurbished and will incur additional costs from complying with IRR17.[22] This replaces the assumption of two-thirds of sites needing upgrades in the consultation-stage assessment.

157. We apply this 60% to the 232 sites minus the 57 PET centres, since lead screening would not be used in that context, giving 105 sites that have not yet refurbished their rooms.

158. The consultation responses suggested a higher number of screens per site required than the three estimated in the consultation-stage assessment, with nine responses giving an average answer of six screens per site. Although this may reflect larger-than-average Trusts responding to the consultation, it seems that this was underestimated and we adjust this to five screens per site. This gives a total of 530 screens to be replaced across all affected sites.

159. The consultation-stage IA estimated the cost of a new screen to be between about £2,400 - £5,000 (quote given by a provider) with a best estimate of around £3,700. In addition, it is estimated that installation will add about another 10% onto the cost of the screen giving a total cost per screen of around £4,100 (taking the midpoint of the purchase cost above). The responses to the public consultation very closely matched this, with 12 respondents quoting an average of £4,000 per screen. Therefore, we maintain this unit cost for the IA.

160. A small number of responses to the consultation, including from the Institute of Physics and Engineering in Medicine (IPEM), raised additional costs arising from the downtime of theatres and managerial input into the specification and procurement of suitable equipment. To account for this, we add one day of theatre downtime at a cost of £2,000 per day, per screen installed, based on information provided by consultees. We do not add costs of specification and procurement to avoid double counting with costs revising risk assessments and raising awareness, providing advice and training (assessed in Section 11.4.2), which includes time to advise additional controls needed.

[21] The ICRP published its "Statement on Tissue Reactions" recommending the new eye dose limit in 2011, the same year that the draft BSSD was proposed by the European Commission. However, we take the date that the Directive was adopted (December 2013), as this is likely to be when most NHS Trusts became aware of the new recommendations and changes to EU law.

[22] This is likely to overestimate costs for those who would in the baseline have refurbished in 2018 and instead would need to do so earlier (in 2017) to comply with the regulations. These costs are strictly 'brought-forward' by a few months but to simplify the analysis we apply the full costs.

161. Adding this to the unit installation cost estimated above gives a total cost per screen installed of around £6,100. Multiplying this unit cost by the estimated 530 additional screens **a total one-off cost of around £3.2 million**.

11.7 Total costs to the medical sector

162. Total one-off costs to the medical sector estimated in the preceding sections amount to around £4.3 million, occurring in the first year.

163. Some recurring annual costs start in the first year of the appraisal period, while some start in the second. The equivalent annual recurring cost is £460,000.

164. The total present value of costs to the medical sector, applying a 3.5% discount rate, is £8.3 million over the 10-year appraisal period.

165. All costs are assumed to fall to the public sector (NHS).

11.8 Nuclear sector – numbers affected and costs of time

11.8.1 Numbers affected

166. There are 40 nuclear sites in scope of IRR: 36 nuclear sites licensed by the Office for Nuclear Regulation (ONR), plus 4 MoD nuclear sites where IRR applies.

167. According to HSE's CIDI, around 20,000 workers are already classified in the nuclear industry. Feedback from nuclear sector stakeholders is that between 5 and 10% of these already-classified workers would be affected by the changes in eye dose requirements – that is, those who are most likely to receive significant eye doses. Taking the middle of this range (7.5%) gives around 1,500 affected classified workers.

168. In addition, nuclear sector stakeholders have advised HSE that a small number of unclassified workers would require additional monitoring for doses to the lens of the eye, to ensure that they do not exceed the lower classification level or dose limit. While most nuclear workers are already routinely monitored for whole body doses, they are not thought to be regularly monitored for eye doses due to the currently higher limit. The number is uncertain, though could be around 250 workers across the industry requiring additional monitoring for eye doses, according to nuclear sector stakeholders.

169. This gives a total (rounded) number of around 1,800 workers most likely to be affected by the change in requirements to eye doses in the nuclear sector. These workers are most likely to need to familiarise with the new requirements and have additional monitoring for eye doses. Responses to the public consultation supported the consultation-stage assessment that no additional workers in the nuclear sector will need to be classified due to the reduction in classification level.

11.8.2 Cost of time

170. The full economic costs of time used in this analysis of the nuclear sector are as follows:

- A decommissioning glovebox worker[23] has an FEC of between £26 and £84 per hour, with a best estimate of about £55 per hour. This is based on information from stakeholders.

[23] A glovebox is a sealed container which contains the source of radiation. Workers' protected hands are placed inside the glovebox to undertake decommissioning work.

- A Radiation Protection Supervisor (RPS) has an FEC of £40 per hour
- A health and safety manager has an FEC of £40 per hour
- A Radiation Protection Advisor (RPA) has an FEC of around £60 per hour

171. The costs of time for an RPS, RPA and a health and safety manager have been revised based on information provided by industry stakeholders during the public consultation period.

11.9 Nuclear sector - communicating the change in requirements and determining any further action needed

11.9.1 Cost of revising Risk Assessments (RAs)

172. HSE asked nuclear sector employers to advise how many hours would be spent revising RAs in light of the proposed change in eye dose limit. Two responses suggested that around 45 hours of staff time per site could be required. Although this evidence is very limited, further discussions with the nuclear industry representatives suggest that this is a reasonable assumption. Multiplying this across all 45 nuclear sites regulated or authorised by ONR gives a total of around 2,000 hours of staff time to revise RAs across the nuclear sector.

173. The time spent on revision of RAs is expected to be split between the following workers in the following proportions, based on feedback from stakeholders:

- One third will be undertaken by a Radiation Protection Adviser (RPA)
- One third by a health and safety manager;
- One sixth will be undertaken by a Radiation Protection Supervisor (RPS);
- One sixth will be undertaken by the decommissioning and glovebox workers.

174. This gives a weighted average cost of time per hour of around £50 (taking the midpoint of ranges). Multiplying by the estimate of 1,800 hours across the nuclear sector gives a total one-off cost of revising RAs of around £89,000.

11.9.2 Raising awareness of the proposed dose limit for the lens of the eye

175. The consultation-stage IA estimated costs arising from activity in each nuclear site to raise awareness of the changes in requirements, provide advice regarding changes in practices or controls, and deliver any training needed. These estimates totalled one-off costs of around £130,000 in the nuclear sector. For this final-stage IA, HSE has estimated total costs to the sector arising from activity to familiarise with the whole regulatory package – see Section 19. Therefore, to avoid double counting, we do not estimate familiarisation with eye dose changes separately here.

11.10 Nuclear sector - additional monitoring for classified and non-classified workers

11.10.1 On-going cost resulting from additional eye dosimetry for already-classified workers

176. Whilst no workers will need to be classified as a result of the proposed dose limit for the lens of the eye, as discussed earlier, around 1,500 already classified workers will be affected by the proposed dose limit and would need additional eye dosimetry.

177. Each would require eye dosemeters. It is estimated by stakeholders and HSE that these would cost around £95 per worker per year (see paragraph 122 – medical sector assessment), giving an annual cost for all workers of about £140,000. It is not thought that there would be any additional record-keeping cost, as classified workers will already have such records.

178. In addition, it would take an RPA between about 2 and 5 minutes per worker, with a best estimate of about 3.5 minutes, to inform an ADS of the type of PPE worn. Valued at a cost of time of £60 per hour, this gives a total cost of RPA time of around £5,300.

179. This gives a total annual cost of additional dosimetry for classified workers of around £150,000.

180. In addition, nuclear sector stakeholders have advised that there may be some small administrative costs in recording eye doses on the dose record for some of the estimated 5,000 existing classified outside workers in the nuclear sector affected by the proposed changes. As these are all classified workers, the additional eye dosimetry costs for these workers are included above. The additional administrative cost of recording the eye dose measurement into the dose record is expected to be minimal (a couple of minutes per worker), so is not proportionate to quantify further.

11.10.2 On-going monitoring costs for non-classified workers likely to be getting significant eye doses

181. As per Section 11.8.1, information provided by the nuclear sector suggests that around 250 non-classified staff may require routine monitoring for eye dose.

182. Each would require a dosemeter to measure eye dose. It is estimated by stakeholders and experts within HSE that these would cost around £32 annually, or around £8,000 across the 250 non-classified workers requiring additional monitoring.[24] As these workers are not classified, the employer would not be required to keep a dose record, so we have not estimated record-keeping costs.

183. There will also be a small amount of administrative time (2 to 5 minutes) for the RPA to inform the ADS of the type of PPE worn for each non-classified worker, which is important for accurately estimating dose to the lens of the eye. Valued at a cost of time of £60 per hour, this gives a total cost of RPA time of around £900.

184. The total annual cost of this routine monitoring for non-classified workers is therefore estimated to be £8,800.

11.11 Nuclear sector - costs of additional shielding in areas with non-uniform fields

185. Discussions with industry stakeholders suggests that additional shielding may be necessary for work involving non-uniform fields, which are more likely to result in doses of ionising radiation to the eye.[25] Additional shielding will either come in the form of lead shielding or additional respirator visors. According to stakeholders, there are two areas with non-uniform fields in GB that would require lead shielding, at a cost of £2,100 each (or £4,200 in total).

186. In addition, it is estimated that workers carrying out ponds decommissioning work with stored radioactive material may require 1,000 additional respirator visors, at a cost of around £52 each – or £52,000 in total. This gives an estimated total cost of additional shielding of around £57,000.

[24] A provider has estimated that dosemeters cost £7.93 per issue. HSE estimate that non-classified workers will be issued with a new one quarterly, or four times per year.

[25] A non-uniform radiation field occurs when the radiation source is scattered in various directions

187. One response to the public consultation raised additional costs for controls in nuclear decommissioning work, which is consistent with the assessment made here.

11.12 Total costs to the nuclear sector

188. Based on the estimates described in this section, total one-off costs to the nuclear sector due to changes in the eye dose limit and classification level may be around £150,000 in the first year. Total annual costs are estimated at around £160,000, starting in the first year of the appraisal period. Over the ten-year appraisal period, and discounted at a rate of 3.5% per year, the present value of these costs is around £1.5 million.

189. This includes costs to MoD-owned and -operated sites, which are public sector – four of the 40 affected nuclear sites. On this basis, around 90% of the total costs, or £1.4 million, fall to sites operated by private businesses; and 10% of the costs, or £150,000 to the public sector. [26]

11.13 Potential impacts of the change in eye dose requirements on other sectors

190. Ionising radiation is used in a number of other sectors. HSE's engagement with stakeholders raised veterinary practices, dentistry, and non-destructive testing (NDT) as potential activities in scope of the eye dose changes.

191. Expert advice from HSE Radiation Specialist Inspectors suggests there will be no impact on dentists, since they typically operate X-ray machines from outside the room and so will not receive significant radiation doses. Engagement with the British Institute of Non-Destructive Testing has confirmed that the NDT sector will not be affected by the change in eye dose requirements, as the radiation sources used in testing are enclosed.

192. Ionising radiation used by most small veterinary practices is limited to X-ray and used in the same way as dentists (operated away from the X-ray machine, typically outside the room) and therefore radiation doses received by vets and practice staff would be low.

193. Other more specialist examinations, for example those involving radiopharmaceuticals, fluoroscopy and cardiology procedures should only take place in specialist centres where specialised equipment and processes are in place. According to the Royal College of Veterinary Surgeons, there are 65 practitioners registered as specialists in diagnostic imaging and 35 practitioners registered as specialists in cardiology.

194. The level of risk increases with the number of procedures carried out and not all of these practitioners would necessarily carry out extensive work with ionising radiation.

195. HSE understands that routine monitoring of veterinary practitioners does not take place, so there is no information available on likely doses. Although we believe that there will be no impact from the reduction of the eye dose limit on small veterinary practices, specialist centres may need to increase monitoring.

[26] There is some uncertainty regarding whether some of the remaining 36 sites – specifically, the 23 that are government owned but contractor operated and controlled – should be classified as public or private sector under the Better Regulation Framework Manual Guidance. HSE has taken a cautious approach in classifying all of these sites as private so as not to underestimate costs to business. This is consistent with the public / private split for nuclear sites applied in previous BIT assessments produced by ONR and scrutinised by the RPC.

196. Both the British Veterinary Association and the British Dental Association are members of HSE's Occupational Exposures Working Group (OEWG) for the development of IRR17. HSE has not received any information from these associations regarding significant costs arising from the changes to eye dose requirements, either via the OEWG or the public consultation. The one response to the public consultation from a veterinary practice did not expect additional costs. On this basis, we conclude that while there is potential for some costs to these sectors, particularly to specialist veterinary centres as above, these are likely to be small and we do not seek to quantify them further.

197. Ionising radiation is used in universities for a diverse range of research projects covering the fields of science, engineering and medicine. HSE has engaged with the Association of University Radiation Protection Officers via OEWG and received 10 responses from the academic sector to the public consultation. Information received during these engagements and public consultation confirm the view of HSE Radiation Specialist Inspectors that the change in the eye dose limit will not lead to significant additional costs in the academic sector, besides some small additional monitoring costs and potential for minor additional protective eye wear costs (which may in any case occur in medical settings), as they do not carry out practices that have a significant eye dose risk.

11.14 Eye dose - other impacts not costed

11.14.1 Provisions to account for eye doses over five years

198. HSE will implement a provision in the Directive which will allows for the eye dose limit, as well as whole body ('effective') dose limit, to be averaged over a five year period ('five-year averaging'), such that the dose does not exceed a total of 100mSv in any five consecutive years, subject to a maximum of 50mSv in any single year. Although IRR99 contains a provision for five-year averaging of whole-body doses, it does not for eye doses, so this is a new provision.

199. The Directive requires five-year averaging to be "as specified in national legislation". HSE will set out the conditions in IRR17 (see paragraph 203 below) that dutyholders must comply with to adopt five-year averaging. In complying with these conditions, dutyholders may incur some costs.

200. Given that the cumulative five-year dose is the same as the annual dose limit over five years, the benefit in practical terms to employers will be limited to those workers with highly variable annual exposures – for example, a worker who exceeds the dose limit in Year 1 but will be below the dose limit in the remaining years. Without the provision for five-year averaging (that is, under an annual dose limit), such workers in this scenario would either be unable to undertake certain work with ionising radiation or need to implement potentially costly controls to reduce doses in the 'high dose' year.

201. Neither HSE nor ONR have ever received notification of the use of five-year averaging, even though this facility currently exists for whole body dose. Therefore, HSE expects the use of five-year averaging for eye doses to be relatively limited, and stakeholder feedback indicates that this will not have high take-up if introduced. The medical sector is more likely to apply five-year averaging than the nuclear sector, given medical sector views and limited monitoring data that current eye doses for some workers may exceed the proposed limit. The lack of monitoring data for the medical sector hinders a more informed analysis of this.

202. In any case, this provision is 'permissive'; employers can opt to make use of it (by ensuring that they meet criteria to be set out by HSE) but are not required to adopt a five-year average. Therefore, employers will only choose to do so if they expect that the benefits of five-year averaging will exceed the costs of meeting the specific criteria set out below. Following paragraph 1.2.24 of the Better Regulation Framework Manual (July 2016), and given the uncertainty over the expected uptake of 5-year

averaging, we assume that the benefits to business of 5-year averaging will at least be equal to the costs and do not quantify this further.

203. The conditions that HSE is expected to set out will state, in general terms, when five-year averaging is permitted. HSE would not consider that the use of five-year averaging is justified to facilitate the transition between the current eye dose limit (150 mSv) and the new limit (20 mSv),or to make use of this provision retrospectively when an employee has been exposed over the annual dose limit and the dutyholder wishes to avoid possible enforcement action. HSE would also require that the dutyholder notifies HSE in advance to using five-year averaging, with the rationale for doing so and agreeing they will still keep exposures as low as reasonably practicable and that a dose of 50mSv in a single year is not exceeded. The dutyholder will also be required to inform their ADS of the intention to take this up, so doses can be recorded and measured correctly. Possible uses of this provision will be to carry out procedures which would have a substantial benefit to health which would otherwise not be carried out.

11.14.2 Additional approvals for Approved Dosimetry Services (ADS)

204. Employers must ensure that radiation doses for classified workers are systematically assessed and recorded by a Dosimetry Service approved by HSE (an 'Approved Dosimetry Service', or ADS). Not all existing ADS are approved to measure and monitor eye doses. Representatives from both medical and nuclear sectors have reported that existing ADS may not have capacity to deal with an increase in the number of classified workers, meaning additional Dosimetry Services may need to be approved for eye doses. These Dosimetry Services would incur costs from time taken to compile applications to HSE, and from a fee charged by HSE to recover administrative overheads and staff time spent on reviewing applications.

205. Requirements for the approval of Dosimetry Services are unchanged. Dosimetry Services which apply for Approval would do so in response to an increase in market demand for services, due to the change in classification level for eye doses, and where they perceive a commercial benefit from doing so. As such, this is not a direct impact to business, as discussed in paragraphs 1.2.2 and 1.2.3 of the Better Regulation Framework Manual (July 2016). The additional costs to ADSs from carrying out their dosimetry functions for workers receiving dose monitoring (such as managing and issuing dose meters, keeping dose records), are already included in the IA as costs to employers in Sections 11.5.4 and 11.10, as employers (which have the legal duty to undertake this monitoring) pay ADSs for these services.

206. HSE analysis based on stakeholder feedback suggests that, in any case, the total costs of additional Approvals will be in the low tens of thousands of pounds, so it is proportionate not to assess this further.

11.15 Eye Dose - Health benefits

207. The lens of the eye is normally transparent. Exposure of the lens to ionising radiation over a number of years can result in changes in its structure, resulting in opacification and reduced passage of light to the retina. The initial opacities usually do not have an effect on vision; therefore, the individual is not aware of them. The identification of these early changes would require an assessment by a specialist eye doctor. These opacities may progress, resulting in visual impairment, where they are more generally referred to as cataracts.

208. Cataracts are common in the general population and become more common with increasing age. Other risk factors for the development of cataracts include smoking, high alcohol intake, diabetes, certain medications and prolonged exposure to sunlight. This makes an assessment of any health

benefits from the reduction in eye dose limit for ionising radiation at work difficult. A lack of monitoring data on current eye lens exposures in the medical sector, which is likely to see the largest impact of the reduced eye dose limit, further hinders an assessment. A change in the number of cataracts due to exposure to ionising radiation is the relevant health outcome to measure health benefits.

209. The key document in respect of the reduction in eye dose limit from 150 mSv to 20 mSv adopted into the Directive comes from ICRP Publication 118.[27] ICRP acknowledges that much of the evidence regarding exposure of the lens of the eye to ionising radiation over time refers to opacities rather than cataracts. ICRP 118 states that there are "uncertainties about the progression of opacities into cataracts". Therefore, while the reduction in the eye dose limit should reduce lens opacities, a similar reduction in cataracts is more uncertain - even if there were better data on the current level of exposures.[28]

210. Due to the uncertainties outlined above, a quantitative assessment of the change in cataracts, or its economic impact in monetary terms, is not possible. To give an illustration of the potential benefits, the next paragraphs will summarise some of the available evidence on the cost per cataract case to society.

What is a typical cataract treatment case?

211. An individual experiencing symptoms due to a cataract may visit an optometrist or their general practitioner for assessment. Subsequent referral to an ophthalmologist would be required to confirm the diagnosis and consider treatment. Left untreated, the majority of cataract cases progress to a stage where vision and daily activities are seriously affected and surgery is required to prevent blindness.[29] Cataract removal is usually a short procedure (30-45 minutes) carried out as day surgery[30], with most patients being back at work within a week.[31] An individual may require prescription glasses after cataract surgery or a change to their previous prescription.

Costs to the NHS

212. Costs to the NHS of cataract surgery will include the cost of the procedure, cost of ophthalmologist time and optometrist appointment costs and prescriptions when delivered through the NHS. The NHS Price Tariff for 2016/17 estimates the cost of a cataract procedure to be from £911 for a single eye phacoemulsification (cataract extraction and lens implant) to £2095 for non-phacoemulsification cataract surgery, which will be used as a range.[32] The Price tariff estimates that first attendance at outpatient services costs around £120 and follow up attendance costs around £80 at an Ophthalmologist. This assessment assumes that the costs of a sight test and any prescription glasses

[27] Available at: http://www.icrp.org/publication.asp?id=ICRP%20Publication%20118

[28] A study by Bitarafen et al (2015) analysed the risk of developing cataract from radiation in the staff working in interventional laboratories compared to nurses with no history of ionising radiation exposure to the head. These included staff members from electrophysiology, paediatric, adult laboratories or a number of locations. Of 81 cardiology interventional staff and physicians used in the study, 59 (62.1%) had right eye opacity and 63 (66.3%) had left eye opacity, indicating that most of the participants working in cardiology interventional laboratories (regardless of their working site) had lens opacity either in the left or in right eye ($P < 0.001$) (Bitarafan et al, 2015). HSE must consider the possibility of having a cataract in either eye to be a likely situation.

[29] Baltussen et al (2004) Cost-effectiveness analysis of cataract surgery: a global and regional analysis Available at: https://www.ncbi.nlm.nih.gov/pubmed/15298224

[30] See: http://www.nhs.uk/conditions/Cataract-surgery/Pages/Introduction.aspx

[31] See: https://www.rcseng.ac.uk/patient-care/recovering-from-surgery/cataract-surgery/recovery-tracker/

[32] See: https://www.gov.uk/government/publications/nhs-national-tariff-payment-system-201617 The national prices for 2016/17 are based on the currencies and prices adopted under the Enhanced Tariff Option (rolled over prices) with adjustments for efficiency, cost uplifts and a small number of manual adjustments '. The cost uplifts take into account pay, drugs and other operating costs (such as medical, surgical and laboratory equipment and fuel).

necessary following surgery will be subsidised by the NHS as the majority are over the age of 60, which will cost around £100.

213. **The overall costs to the NHS are estimated to be around £1200- £2400 per cataract case**.

Costs to the individual, family and friends

214. Though cataracts are treatable and recovery time is relatively short, there will be some impact on the quality of life of those living with a cataract, between the time that daily activities are affected, the cataract is diagnosed, and the individual undergoes surgery. Some evidence suggests that the length of this period varies across the UK.[33] Limited research examines the effect of cataracts on the quality of life, and the evidence is somewhat mixed. One Finnish study[34], which assessed the changes in reported health-related quality of life pre- and post-surgery for 219 patients, concluded that the mean utility gain after surgery was relatively small.[35] However, a review article in the journal Clinical Interventions in Aging[36] found research showing improved general health and improved wellbeing post-cataract surgery. Given the uncertainty in the evidence available, we are unable to quantify the effects of cataracts on quality of life for this assessment, or give an idea of the scale of these impacts.

215. We are able to provide some illustrative estimates of opportunity costs to individuals, related to cataract operations. There are opportunity costs associated with attending appointments and surgery, including any associated travel time. Assuming the outpatient procedures takes around half a working day in total (including travel), this will give a unit cost of around £35 using the DH estimate the cost of a patient time at £9.24.[37]

216. The opportunity cost of surgery will also include recovery time. For those who do not work (e.g. retirees, as many of the individuals suffering from cataracts will likely be) this will reduce the amount of unpaid production (for example, informal care for friends and relatives, or volunteering) the individual can provide. For simplicity, we assume that the individual can provide no unpaid production during the recovery time of 1 week. Applying estimates in the DH 2013 Wider Societal Benefits methodology report gives an average of 40 hours unpaid production per week, costed at £9.24 per hour, or around £370 that could be lost in unpaid production per case.[38]

217. **We are not able to provide estimates of the overall costs to the affected individual per cataract case, as the estimates provided above are illustrative and meant only to give a sense of the nature and scale of the impacts expected**.

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[33] See: : Surgery deferred. Sight denied", 2013.Available at: https://www.rnib.org.uk/campaigning-policy-and-reports-hub-eye-health/eye-health-reports

[34] Räsänen, P., Krootila, K., Sintonen, H., Leivo, T., Koivisto, A.-M., Ryynänen, O.-P., … Roine, R. P. (2006). Cost-utility of routine cataract surgery. *Health and Quality of Life Outcomes*, *4*, 74. http://doi.org/10.1186/1477-7525-4-74

[35] Räsänen, P., Krootila, K., Sintonen, H., Leivo, T., Koivisto, A.-M., Ryynänen, O.-P., Roine, R. P. (2006). Cost-utility of routine cataract surgery. *Health and Quality of Life Outcomes*, *4*, 74. http://doi.org/10.1186/1477-7525-4-74. Available at: https://www.ncbi.nlm.nih.gov/pubmed/17010185

[36] Morris, D; Fraser, Scott G; Gray, C (2007) Cataract surgery and quality of life implications. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2684074/

[37] Department of Health (2013) Methodology for estimating "Wider Societal Benefits" as the net production impact of treatments. Available at: www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/NICE-technology-appraisals/DH-Documentation-for-Wider-Societal-Benefits.pdf

[38] The Department of Health (DH) estimates that general unpaid production for those retired varies by gender and age. Taking an average of estimates for a 65 year old man and women, as given by the current state pension age, gives an estimate of 171.9 hours per month. This equals 2,063 hours per year, and around 40 hours per week.

Costs to the employer

218. There are some potential costs to employers from the disturbance to production / output to cover worker absence, sick pay and any compensation payments. However most cataracts occur in over 60s, who are less likely to be in work due to retirement. The recovery period for cataracts is relatively short which will also mean that **costs to employers will be low**.

Costs to society

219. It has not been possible to estimate the total costs to society per case of cataract. The above analysis has estimated the costs to the NHS of treating cataracts, as well as giving a sense of the types and of costs to the individuals affected and employers, including the scale of some of these costs. It should be noted that any reduction in the number of cataracts as a result of the lower eye dose limit is likely to take many years, possibly decades, to materialise, so once discounted to the present day, the value would be significantly lower.

220. In summary, there is high uncertainty in all aspects of this analysis. We have limited information on current eye lens exposures to ionising radiation. It is uncertain to what extent the opacities in the lens of the eye developed as a result of that exposure then progress into cataracts. The impacts of a single case of cataracts on society are also uncertain. There is some data on costs to the NHS, as well as some indications of the scale of the costs to employers, but the evidence on impacts on the individuals affected is limited and mixed, so this remains a significant gap. We are therefore unable to make any sensible assessment of whether the potential health benefits in this area are likely to compensate for the increased costs associated with the new requirements.

12 Graded Approach (notification, registration, and consent)

221. The Directive introduces a risk-based approach to regulatory control of practices using ionising radiation. This approach requires organisations to inform the competent authority (HSE) about work with ionising radiation, which provides information for HSE to undertake appropriate inspections commensurate with the magnitude and likelihood of exposures resulting from the practice. This approach is known as the 'graded approach'. There are three tiers: notification (for practices with the least risk), registration, and consent to operate (for practices with the highest risks).

222. HSE will implement the graded approach in a way that maintains health and safety standards, whilst minimising the costs to business and any requirements that go beyond the scope of the Directive. In practice, this means that HSE will only request necessary information and will use the information to more accurately target inspections and other interventions on highest risk practices. Thus, more information will be required for the higher risk practices than lower risk practices. The information will be sufficient to demonstrate compliance with the Directive requirements, whilst also providing information on risk profiles to inform HSE's risk-based inspection programme.

223. This final-stage IA presents 2 options for implementing the Graded Approach

- Option 1, wherein costs of the system required for implementing the Graded Approach would be recovered from dutyholders

- Option 2, wherein costs of the system required for implementing the Graded Approach would be borne by HSE

224. Both these options include deviations from copy-out in extending the requirement to apply for a consent to certain high-risk practices that would otherwise only require a registration. This is in two

areas: industrial radiography and particle accelerators. The cost implications of each of these are presented separately.

225. Three components make up the costs to businesses and other organisations from implementing the graded approach: the number of practices notifying, registering or applying for consent to operate; the administrative time spent by organisations gathering any information required to make an application, plus the time spent completing an online application form; and the costs incurred by HSE to set up and run the system (which are reflected in the application fees proposed to be charged by HSE in option 1). These are assessed in turn below.

12.1 Number of practices notifying, registering and seeking consent to operate

226. Employers will have a duty to make an application to HSE under the appropriate tier of the graded approach for work that uses, generates or is affected by ionising radiation (a 'practice').[39] Employers will need to make a separate application for each different practice they undertake, meaning a given employer may need to make more than one application, under the same or different tiers of the graded approach.

227. HSE has estimated the number of practices expected to apply under each tier, and the public / private split for each sector, based on a range of sources: applications under authorisation/ licensing regimes operated by other UK regulators, contacting industry / professional bodies, interdepartmental business register (IDBR) data, information provided by other government departments, and expert assessments of HSE Radiation Specialist Inspectors and sector experts with experience and knowledge of the sectors affected. These estimates have been reviewed since the consultation-stage IA and refined where possible based on further research and new information gathered via the sources described above.

12.1.1 Notifications of low-risk practices

228. Notification applies to the practices with least risk. That includes work with small quantities of radioactive material, or work to decontaminate affected areas, such as in the recovery phase from an emergency situation. The Directive requires dutyholders carrying out such practices to notify HSE. This requirement is not, in itself, additional to current requirements under IRR99.

229. However, the Directive requires all existing notified practices to be re-notified under the regulations. The number re-notifying will not be equal to the number of existing notifications for two reasons. Firstly, many of those who would have previously notified would now need to register or apply for a consent to operate under the changes.

230. Secondly, certain practices that were previously exempt from notification may no longer be exempt, as the exemption levels have changed. It is difficult to estimate the effects of this on the number of practices in scope, but HSE estimates that the effect would not be large.

231. Overall, HSE expects that the number of notifications would be low. Currently, HSE only has around 350 extant notifications for work in radon-affected areas[40] (the vast majority of expected notifiable practices), although we estimate that the actual numbers of practices taking place would

[39] IRR17 defines a practice as work involving the production, processing, handling, disposal, use, storage, holding or transport of radioactive substances; or the operation of any electrical equipment emitting ionising radiation and containing components operating at a potential difference of more than 5kV, which can increase the exposure of individuals to ionising radiation

[40] Radon is a radioactive gas that can be emitted naturally from some rocks or soils. Workplaces exposed to radon do not fall into any particular sector, but are exposed through their location, particularly if the workplace is (partly) below ground level.

number several thousand. We do not expect that notifications will achieve 100% compliance, despite HSE's efforts to publicise the changes, as radon-affected practices are too disparate, low-risk and unlikely to be aware that they have obligations to begin with. As such, we estimate that the number of renotifications in the first year would be no more than 500, which covers the number of current radon notifications, plus an allowance for other low-risk activities. Around 97% of these are expected to be from private sector businesses, based on IDBR data.

12.1.2 Registrations

232. Under the Graded Approach, registration is required for any work that requires the operation of radiation generators or accelerators, or the use of radioactive sources. This is a new requirement with no equivalent under IRR99. HSE estimates that this applies to around 25,000 practices, of which 43% are public sector practices (particularly in health care and dentistry). In practice, HSE expects that 100% compliance for registrations is unlikely, given the range of sectors and level of previous requirements for many of the practices in question. However, wo do not have a suitably robust estimate for how much less than 100% the compliance might be, and so we have used 100% in this impact assessment as a simplifying assumption and to avoid the risk of underestimating the costs.

233. Each practice would only need to register once and would need to provide new information to HSE only in the event of a material change in the nature of the work with ionising radiation (see Section 12.4). However, there will be additional registrations in future years from new businesses undertaking work in scope of the requirements. The Office for national Statistics (ONS) business demography data suggests new business registrations across all sectors amount to approximately 11% of the total active businesses.[41] Applying this only to the private businesses (as the number of public sector organisations is expected to remain stable) gives an estimate of around 1,600 new businesses registering under the graded approach each year (using the simplifying assumption that the business population remains stable).

234. Table 1 summarises the types of organisations expected to register in the first year of the appraisal period.

[41] ONS Business Demography Data (2015). Estimated taking the number of new enterprise births in the sectors where the practices are estimated to need to register as a proportion of total active enterprises in those sectors in the previous year, averaged over the six-year period 2010 to 2015.

Table 1 – Estimated number of registrations by sector

Sector	**Number (Total)**	Number (Private)	Number (Public)	Proportion private businesses)
Defence Contractors	**25**	25	0	100%
Medical (NHS + private hospitals)	**360**	90	270	25%
Medical (NHS + private hospitals)- of which are Acute Trusts	*180*	*0*	*180*	*0%*
Medical (NHS + private hospitals)- of which are Mental Health Trusts	*55*	*0*	*55*	*0%*
Medical (NHS + private hospitals)- of which are Community Providers	*34*	*0*	*34*	*0%*
Medical (NHS + private hospitals)- of which are private hospitals	*90*	*90*		*100%*
Dental	**12,000**	3,600	8,400	30%
Veterinary	**2,900**	2,900		100%
University and further education colleges	**500**	475	25	95%
Secondary Schools (England + Wales)[a]	**2,400**	600	1,800	25%
Secondary Schools (Scotland)[a]	**110**	28	83	25%
Museums	**250**	160	90	64%
Particle Accelerators	**200**	19	180	9.5%
Industry uses (including radiography, X-ray detection devices, XRF analysers and others)	**5,300**	5,300	0	100%
Exposure to naturally-occurring radioactive materials (NORM)	**1,000**	1,000	0	100%
Total in the first year	**25,000**	**14,000**	**11,000**	**57%**

Table notes

[a] For local authority (LA) maintained secondary schools, the LA is the duty holder responsible for registering rather than the school. LAs often maintain several secondary schools. The estimate used in this analysis is the sum of the number of local authorities which maintain secondary schools, plus the number of non-LA maintained secondary schools (academy, free and independent secondary schools), based on information provided by CLEAPSS.

12.1.3 Consent to operate

235. The Directive lists the highest-risk practices that would require the highest tier of approval, which HSE is terming 'consent to operate'. It also lists the information needed so that a consent can be granted. HSE has estimated that there will be around 2,000 applications for consents in the first year, of

which around 69% are from private business, and 31% from the public sector.[42] As for registrations, we estimate that each year there will be around 16% new applications from private businesses entering the market each year (or around 210).[43] Therefore, around 2,000 applications for consent will be received in the first year, and around 210 each year following that. As for registrations (see paragraph 232), we do not expect 100% compliance with consents, but we use it here as a simplifying assumption.

236. **Table 2** summarises the types of organisations expected to apply for consent to operate in the first year of the appraisal period.

[42] The number of applications for consent to operate is based on type of practice (for example, the discharge of radioactive material into the environment) rather than on sector. Therefore, the estimates of costs borne by business (instead of the NHS) are not precise (as both a business or a hospital may be discharging radioactive material, for example). Where uncertain, we have attributed costs to the private sector.

[43] This is based on ONS Business Demography data, weighted according to the sectors from which practices are estimated to apply for contributions.

Table 2 - Estimated number of dutyholders applying for consent by sector

Sector	**Number (Total)**	Number (Private)	Number (Public)	Proportion private businesses)
Medical (NHS +private)	**400**	38	360	9.5%
Medical (NHS +private) of which are Deliberate medical administration of radioactive substances	*200*	*19*	*180*	*9.5%*
Medical (NHS +private) of which are radiopharmacies	*200*	*19*	*180*	*9.5%*
Veterinary	**40**	40	-	100%
Varied industrial uses (including discharge of radioactive waste to the environment and decommissioning, import and export, and high activity sealed sources)[a]	**1,500**	1,300	250	83%
Varied industrial uses of which are Operation, Decommissioning or closing of any facility for the long term storage or disposal of radioactive waste	*500*	*380*	*130*	*75%*
Varied industrial uses of which are practices discharging significant amounts of radioactive material into the environment	*500*	*380*	*130*	*75%*
Varied industrial uses of which are 'other'	*510*	*510*	*-*	*100%*
Total in the first year	**2,000**	**1,300**	**720**	**69%**

Table notes

[a] This group includes practices carried out by some universities. Where practices of this nature might be carried out for medical purposes, this will be done by the dutyholders captured within the medical (NHS and private) groups in this table.

12.2 Administrative time

12.2.1 Time and cost to apply per organisation

237. Businesses and other organisations that need to notify, register or apply for consent to operate will incur administrative costs in doing so. HSE expects that the time required for each submission should be relatively low. An organisation will need to provide basic information about the business (name, address, contact information etc.) and, additionally for registrations and consents, to confirm (by selecting 'yes' or 'no') that they comply with various requirements in the Ionising Radiations Regulations (including those existing requirements under IRR99 and those changed or introduced under IRR17. The costs of complying with the new requirements are assessed elsewhere in this IA). Consent applications will also need to provide specific information about exposure levels relating to certain dose limits. All of

this information should already be known by the organisation if they are currently complying with IRR99. Entering the information will be via a simple online system.

238. The number of questions will increase with each tier. A notification will involve answering around 10 questions, with 17 questions for a registration and around 30 for an application for consent. The time taken to complete an application will increase correspondingly. HSE made the estimates in Table 3 for administrative time in the consultation-stage IA.

Table 3 – Estimates of administrative time in the consultation-stage IA (minutes)

	# questions	Gather information	Enter information
Notification	10	0	20
Registration	17	30	10
Consent	30	80	15

239. HSE sought to test these assumptions in two ways: an online survey of participants in an HSE webinar on the graded approach, attended by representatives of a range of sectors (around 150 attended, of which 31 completed the survey); and a questionnaire circulated to members of the HSE Radiation Community of Interest (COI) (17 answered the survey, 9 provided specific information on administrative time/cost). HSE also received a small number of responses during the public consultation about these estimates.

240. Although a significant minority agreed with the time assumptions made (around a quarter of respondents to the webinar online survey agreed), most responses indicated that the time had been underestimated. Narrative responses to the COI questionnaire and during the public consultation suggested that additional time would be required for large, multi-site organisations – in NHS organisations and universities in particular – where there would be a need to coordinate the necessary information from several departments into the hands of the individual responsible for completing an application.

241. HSE has reviewed the information provided in these responses and, through discussions with HSE Specialist Inspectors with knowledge of the sectors and information required, has revised estimates of administrative time for the following sectors: NHS organisations, universities, and local authorities maintaining multiple secondary schools. For these, we estimate 1 day of time (7.5 hours) to gather information for a consent application, and ½ day (3.75 hours) for a registration application.

242. These revisions take account of activity to coordinate the necessary information into one place. They do not take account of some estimates provided for employers spending time checking compliance with the regulations across their organisations, since this is something that employers should be doing routinely and is not a new requirement introduced by the Graded Approach or by the broader changes introduced under IRR17 (Section 19 estimates the additional time employers will spend familiarising with the new regulatory requirements).

243. The time estimates for gathering information in other sectors are unchanged, as these are considered reasonable averages across the range of sectors and business sizes covered. The new time

estimates are summarised in Table 4 below.[44] We apply an average full economic cost of time of £27.72 per hour[45] to these time estimates to calculate the total administrative costs.

Table 4 – Revised estimates of administrative time for the final-stage IA in the first year of implementation

	# of questions	Information gathering (minutes)		Entering information (minutes)	Average cost of time per application	
		NHS/ academic	Other sectors	All sectors	NHS / academic	Other sectors
Notification	10	0	0	20	£9	£9
Registration	17	225	30	30	£120	£28
Consent	30	450	80	45	£230	£58

244. However, these full costs would only be borne by existing organisations applying in the first year. For new entrants after the first year, under IRR99, they would have had to apply for a notification anyway; therefore the additional administrative cost for them would have to be netted-off against that administrative cost for a notification.

Table 5 – Revised estimates of administrative time for the final-stage IA after the first year of implementation

	# of questions	Information gathering (minutes)		Entering information (minutes)	Average cost of time per application	
		NHS/ academic	Other sectors	All sectors	NHS / academic	Other sectors
Notification	10	0	0	0	£0	£0
Registration	17	225	30	10	£110	£18
Consent	30	450	80	25	£220	£49

12.2.2 Numbers of organisations applying

245. As summarised in paragraph 231, we expect around 500 practices to notify. Table 1 (in section 12.1.2) and Table 2 (in section 12.1.3) show, respectively, the estimated number of registrations and of dutyholders applying for consent, by sector.

246. As explained in Section 12.2.1, the time and the cost to apply for registrations and consents will depend on the type of organisation and will divide into two groups: NHS, local authorities that maintain multiple schools, & universities; and all other applicants. Grouping together the relevant categories in Table 1 and Table 2 (see footnotes for details), the number of practices in these groups are estimated as follows:

[44] HSE has also amended an inconsistency in the estimates of administrative time to enter information onto the online system for registrations and consents (these were previously estimated at 10 and 15 minutes respectively, which was lower than the time to complete a notification).

[45] This is an average based on the mean hourly wage rates for Health and Safety Officers (SOC3567), £18.60, Health Professionals (221), £28.35, and Science, Research, and Engineering Professionals (21), £21.21 in ASHE 2015, published by ONS. These were uprated by 19.8% to account for non-wage costs, which is in turn based on data on labour costs available from Eurostat (http://ec.europa.eu/eurostat/web/labour-market/labour-costs/main-tables). Finally, it was inflated to 2016 prices. Although wages will vary between organisations and sectors, we consider this to be a reasonable average across the wider range of sectors affected.

- NHS applicants: around 450 registrations and 540 consents in the first year.[46]

- Local authorities that maintain multiple secondary schools: around 180 registrations and no consents in the first year.[47]

- Universities: around 160 registrations and 160 consents in the first year. All universities are treated as private and so subject to a birth rate of new enterprises each year of around 11%.[48] This means that each year, around 18 new registrations and 18 new consents would be required by new entrants.[49]

- This gives around 800 registrations in the first year and 700 consents subject to the higher administration cost, and each year around 18 new registrations and 18 new consents.

247. This leaves around 24,000 registrations subject to the standard administration cost in the first year and around 1,600 new registrations subject to standard administration cost in each subsequent year.

248. Also, this leaves around 1,300 consents in the first year subject to the standard administration cost and around 190 new consents subject to the standard administration cost in each subsequent year.

12.2.3 Summary of administration costs under the graded approach

249. Applying the costs of time per application to the total number of applications for each tier gives the following estimates of administrative costs:

- Notifications: around £4,600 in the first year and no additional cost in subsequent years

- Registrations: around £770,000 in the first year, and around £31,000 in each subsequent year

- Consents: around £230,000 in the first year, and around £13,000 in each subsequent year

250. This gives an **estimated ten-year present value cost of around £1.3 million**. Of this, around £850,000 is borne by the private sector and around £500,000 by the public sector.

12.3 Registration and Consents Fees – Option 1

251. Under option 1 HSE would charge a fee for registration and consents to cost-recover for the design, operation and maintenance of the graded approach, including the IT system – in line with

[46] Includes for registrations: 180 Acute Trusts, 55 Mental Health Trusts, 34 Community Providers, and 180 registrations for particle accelerators (one per Acute Trust) (see Table 1); and for consents: 180 for deliberate medical administration of radioactive substances, 181 for radio pharmacies, and 180 for 'discharging significant amounts of radioactive material into the environment (one each per Acute Trust) (see Table 2).
[47] Based on information provided by CLEAPSS
[48] Estimated based on the birth rate of new enterprises for SIC Code 854 (Tertiary education) in the ONS Business Demography data. Although this churn rate is specific to the tertiary education sector as a whole, it might not strictly reflect births and deaths of universities, which we would expect to be more stable than smaller further education providers. However, in the absence of specific data for universities, we apply this rate of churn.
[49] This includes 160 consents for 'discharging significant amounts of radioactive material into the environment' – one consent per university.

guidelines set out in HM Treasury 'Managing Public Money' (2013).[50] As per the current arrangement, HSE does not propose to charge for notifications.

252. HSE has assessed the costs of implementing a fully digital system and proposes to set a flat, one-off fee of £25 per application for registrations and consents to recover these costs. Applying this fee to the numbers of practices registering and applying for consent in Section 12.1 gives total estimated fees of £680,000 in the first year and £45,000 each year thereafter. Over the 10 year appraisal period, this leads to £1,000,000 total fees, of which £730,000 are costs to business and £290,000 are costs to the public sector.

12.4 Notification of material changes

253. HSE would also need to be notified if there are material changes to the information that dutyholders submitted with their original application (for any of the tiers of the graded approach). The provision of this information is necessary to ensure that HSE is provided with up to date information on practices, which enables HSE to operate a risk-based approach to inspection. This is already required for notifications received under IRR99, but the Graded Approach is broader in scope than our current requirements so more dutyholders may have to notify us of material changes. However, we only expect any additional material changes to be generated from changes to circumstances that form part of a consent, as this is the area with the greatest relevant change in information requested.

254. We estimate that the administration cost to the organisation of completing a material change is about equal to that for completing a notification, as the amount of information required is similar – that is about £9 (see Table 4). No fee would be charged.

255. It is not possible to estimate the number of practices that would need to notify HSE about these material changes. However, based on a cost of around £9 per material change and a total number of consents at any time of around 2,000 (see Table 2), if every consent-holder applied for a material change every year, the cost would come to around £18,000 per annum. In reality, this is far too high an estimate, as under the current notification system, HSE estimates we receive material changes for no more than around 2% of extant notifications each year and the changes brought in by IRR17 will not substantially increase this. As such, we have estimated the costs arising from notifications of material change to be **minimal**.

12.5 Extending the scope of consents

256. Under both Option 1 and Option 2, HSE would go beyond copy-out of the Graded Approach as set out by the Directive by requiring that certain high-risk practices apply for a consent, rather than for a registration. HSE also proposes to remove an existing provision for industrial radiography work to be notified to HSE seven days prior to commencement – made possible by the way that HSE intends to extend the scope of consents for industrial radiography practices.

257. Stakeholder feedback during the public consultation was largely supportive of the extensions of scope described below. The extension for industrial radiography is expected to result in net savings to businesses, while the extension for particle accelerators leads to very small costs. HSE therefore proposes to implement this approach.

[50] See https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/454191/Managing_Public_Money_AA_v2_-jan15.pdf

12.5.1 Extending the scope of consents for industrial radiography and removing the requirement to notify HSE seven-days prior to commencing work

258. Strictly implementing the requirements set out in the Directive would result in certain work activities within GB (industrial radiography and industrial irradiation) requiring both a consent to operate and a registration for the different types of practice carried out. Specifically, the use of a High Activity Sealed Source (HASS) would require a consent, whereas the use of a radiation generator would require registration, but these pieces of equipment would be used for the same work activity.

259. Additionally, HSE Radiation Specialist Inspectors consider that radiation generators pose at least as great a risk as HASS and so these should be regulated in a consistent way; that is, they should both require a consent. Therefore, HSE is considering using the flexibility allowed within the Directive to require the overall work activity to be consented for these practices, which would cover work with both HASS and radiation generators. Doing so would create two new practices requiring consent, "Industrial Radiography" and "Industrial Irradiation", and affect an estimated 165 Industrial radiography dutyholders and 15 industrial irradiation dutyholders.

260. Extending the scope of consents in this way goes beyond the minimum requirements of the Directive, by requiring the use of radiation generators to be consented instead of registered. However, HSE believes that this would introduce consistency to the regulatory approach taken to these work practices. Moreover, HSE expects that it would not result in any significant additional costs to the dutyholders above those described in Sections 12.2 and 12.3, for the reasons described below; in fact, for some there could be savings.

261. Firstly, without this extension of consents, some dutyholders would need to make two applications: an application for consent for the use of HASS, and to register the use of a radiation generator. If consents were extended as above, they would only need to apply for one consent (under the appropriate 'consentable' practice defined above), which would cover the use of both types of equipment. As they would not need to register the use of a radiation generator separately, this would avoid the costs associated with registration (around £28 administrative costs (see Table 4); plus, for Option 1, the £25 fee (see Section 12.3)).

262. However, there may be a small number of dutyholders who use radiation generators only. These would experience an increase in costs relative to copy-out, as they would need to apply for a consent, rather than register. These dutyholders would bear an additional administrative cost of around £30 (i.e. the difference between the administrative cost for a consent and for a registration in Table 4), though the fee paid (under Option 1) would be the same. Advice from HSE Radiation Specialist Inspectors is that this would be outweighed by the number of dutyholders who use both HASS and a radiation generator. Overall, any resulting net reduction in costs is likely to be small, given the small number of dutyholders affected.

263. Given the small numbers of practices and uncertainties, we assume that although there is potential for a small net-saving from the combined consentable practice for HASS and radiation generators, the effect is likely to be minor and we make the simplifying assumption that the effects described in paragraphs 261 and 262 **net to zero**.

264. Secondly, HSE would receive additional information for the industrial radiography sector as a whole when extending consents in this way, which could provide assurance that suitable levels of risk assessment and management are being employed by the applicants. HSE is proposing to use the consent information requirements specified by the Directive to remove the current administrative procedure of requiring notification to HSE seven days in advance of any site radiography (industrial radiography that does not take place on the industrial radiographer's premises). HSE would place

specific conditions in consents for site radiography practices, which would require, as presently, that practices implement a 7-day period between the commissioning and commencement of work to enable consultations between client and contractor to take place, to review risk assessments and to allow any necessary variations to be incorporated into the local rules. This, while not changing the rest of the requirements practices need to comply with, would enable the removal of the existing administrative requirement for practices to notify HSE in advance of every instance of site radiography.

265. There are an average of 5,000 seven-day notifications sent to HSE each year. Businesses could save around £4 for every notification not required, based on each application taking 10 minutes to complete (an assessment based on the amount of information required and comparison with the other notifications in the Graded Approach) and a cost of time of £24.29 per hour.[51] On average, an estimated 5,000 applications would not be required per year, meaning businesses would incur savings against the baseline of around £20,000 per annum. This results in **savings to businesses over the appraisal period of around £170,000 in present value terms**.

12.5.2 Extending the scope of consents to particle accelerators

266. HSE also proposes to use the flexibility allowed within the Directive to require another extension to consents for a practice – the use of particle accelerators. Particle accelerators are capable of giving lethal radiation exposures in seconds, and so HSE considers them equivalent to the risks generated by practices that are subject to consent by the Directive. HSE estimates that this extension to consents would capture around 19 commercial and academic dutyholders and around 180 NHS Trusts. As these practices are not part-captured by existing consent requirements, there would be additional costs associated with this proposal.

267. Therefore, HSE would expect to receive around 200 additional applications for consents from what was calculated in earlier sections.

268. The NHS Trusts would see an additional administrative cost of around £110 (i.e. the difference between the administrative cost for a registration and that for a consent, see Table 4), though the fee (under Option 1) would be the same (£25). Across the 180 NHS Trusts, this gives a total additional cost to the NHS Trusts in the first year of around £20,000.

269. For the private dutyholders, they would see an additional administrative cost of about £30 (see Table 4), while fees (under Option 1) would be the same at £25. Across the 20 commercial / academic dutyholders, this gives a total additional cost in the first year of around £600. These private dutyholders would be subject to churn in our model and so new entrants would bear a similar cost in the future, but the numbers of new entrants is so low that we consider the cost to be minimal in this analysis. Technically, this additional cost to the private dutyholders constitutes an IN of around £70 under One In, Three Out. However, as INs and OUTs are rounded to the nearest £100,000 under the Business Impact Target, this IN rounds to zero.

12.5.3 Summary of the costs and savings of Options 1 and 2

270. Table 6 and Table 7 summarise the costs and savings under Options 1 and 2.

[51] This is an average based on the mean hourly wage rates for Health and Safety Officers (SOC3567), £18.60, and Science, Research, and Engineering Professionals (21), £21.21 in ASHE 2015, published by ONS. These were uprated by 19.8% to account for non-wage costs, which is in turn based on data on labour costs available from Eurostat (http://ec.europa.eu/eurostat/web/labour-market/labour-costs/main-tables). Finally, it was inflated to 2016 prices.

271. Options 1 and 2 differ in that under Option 1, HSE recovers the costs of the graded approach system from duty holders via a fee (so the costs are spread between private and public sector organisations), while HSE does not recover these costs under Option 2 (so the costs of the system are entirely borne by the public sector). Total costs are equivalent under Options 1 and 2.

272. Options 1 and 2 are Qualifying Regulatory Provisions, but their IN rounds to nil.

Table 6: Summary of costs and savings (net present value) - Option 1

	Total	**Business**	**Public sector**
Notifications	£4,600	£4,500	£130
Registrations	£1,900,000	£1,300,000	£630,000
Consents (excepting particle accelerators and industrial radiography)	£420,000	£280,000	£140,000
Extending consents to particle accelerators only - additional costs	£21,000	£600	£20,000
Extending consents to industrial radiography - additional costs	-£170,000	-£170,000	Nil
Notifications of material changes	Minimal	Minimal	Minimal
Total	**£2,200,000**	**£1,400,000**	**£790,000**

Totals may not appear to sum due to rounding

Table 7: Summary of costs and savings (net present value) - Option 2

	Total	**Business**	**Public sector**
Notifications	£4,600	£4,500	£130
Registrations	£1,900,000	£640,000	£1,300,000
Consents (excepting particle accelerators and industrial radiography)	£420,000	£210,000	£220,000
Extending consents to particle accelerators only - additional costs	£21,000	£600	£20,000
Extending consents to industrial radiography - additional costs	-£170,000	-£170,000	Nil
Notifications of material changes	Minimal	Minimal	Minimal
Total	**£2,200,000**	**£680,000**	**£1,500,000**

Totals may not appear to sum due to rounding

12.6 Summary of the costs from the graded approach

273. Table 8 summarises the costs under the graded approach for Options 1 and 2. Both options go beyond copy-out of the Directive, since they require that certain high-risk practices apply for a consent, rather than for a registration. However, because of the way that HSE proposes to implement this extension for industrial radiography, doing so would be expected to lead to net savings to businesses of around £170,000.The table therefore also shows what the Present Value costs would look like for each of the options if:

a) We did not extend the scope of consents to either area
b) We extended the scope of consents for industrial radiography (which leads to net savings), but not to particle accelerators (which leads to net costs). 1b and 2b are therefore, in effect, the 'do minimum' options, where only deviations from copy-out that lead to net savings are implemented.

Table 8: Present Value Costs from all Graded Approach options

	Total	Business	Public sector
Option 1 (with cost recovery)	£2,200,000	£1,400,000	£790,000
Option 1a (with cost recovery) – what costs would look like without the extension of consents	£2,400,000	£1,600,000	£770,000
Option 1b (with cost recovery) – what costs would look like with the extension of consents for industrial radiography, but not for particle accelerators	£2,200,000	£1,400,000	£770,000
Option 2 (without cost recovery)	£2,200,000	£680,000	£1,500,000
Option 2a (without cost recovery) – what costs would look like without the extension of consents	£2,400,000	£850,000	£1,500,000
Option 2b (without cost recovery) – what costs would look like with the extension of consents for industrial radiography, but not for particle accelerators	£2,200,000	£680,000	£1,500,000

Totals may not appear to sum due to rounding

12.7 Graded Approach - Health benefits

274. The current arrangements do not allow for sufficient information to be collated about the practices being carried out and their risk profile. Applying the graded approach system set out above would result in the collection of up-to-date information on practices, enabling HSE to target where inspection should be prioritised. This would ensure that practices where the risk of exposure to workers and the public is higher have an increased amount of regulatory oversight relative to lower-risk sites via a risk-based proportionate inspection regime. If this leads to a reduction in ionising radiation exposures, there would be a fall in adverse health effects associated with ionising radiation, although this benefit cannot be quantified.

13 Outside workers

275. Under current requirements, an outside worker is a classified worker who carries out services in the controlled or supervised area of another organisation, when that organisation is not their employer. This has already been discussed with respect to eye dose and the medical sector in Section 11.5.6.

276. The Directive extends the definition to **any worker** who carries out services in the controlled or supervised area of another employer. The intention of the updated definition is that all outside workers, including non-classified outside workers, have the same level of protection as normal employees (those formally employed by the organisation for which they are undertaking the work with radiation) relating to training, instruction, protective equipment, dose monitoring and entering of controlled and supervised areas.

277. The advice of HSE Radiation Specialist Inspectors and Government Legal Department is that several existing regulations in IRR99 and MHSWR contain provisions which are equivalent to the

requirements of the Directive – and the proposed IRR17 – for non-classified outside workers. Changesmade to IRR17 serve to clarify these responsibilities.

278. During the development of the proposed regulations, HSE engaged with stakeholders from the medical, nuclear, non-destructive testing, education and oil and gas sectors to understand how employers currently treat workers that enter controlled areas (employees and outside workers, including non-classified outside workers). The consensus from these discussions was that employers already treat these workers equally.

279. However, feedback from the public consultation raised concerns about additional costs relating to the change in the definition of outside workers, particularly with regards to training and dose monitoring in the medical sector. HSE has reviewed these responses and, given the existing requirements, cannot identify additional costs arising from compliance activity that is not already required under the current regulations.

280. Therefore, we conclude that there are no additional costs from this change, beyond familiarisation with the new guidance and regulation text. The consultation feedback suggests some misunderstanding about the existing and proposed requirements relating to outside workers. HSE will ensure that clear guidance is provided on this issue.

14 Weighting Factors

281. HSE will adopt new radiation and tissue weighting factors set out in the Directive. These weighting factors allow ADSs to estimate the effective and equivalent doses from external and internal radiation.[52] Applying the new tissue weighting factors will take account of the latest scientific data to calculate radiation dose and to determine whether exposures received by workers exceeds the classification and/or dose limits.

282. HSE discussed this issue in two dosimetry working groups in 2015 which were made up of ADSs and employers. One of the ADSs (Public Health England) stated that the changes brought in by the Directive would require them to update their suite of software modules for internal dosimetry, at a one- off cost of around £250,000. These updates will take account of several other factors introduced by the Directive. [53]

283. PHE licenses this software to other ADSs, which they use to calculate internal doses. There are 33 ADSs in the UK, a proportion of which (around 8) are approved to measure internal dose. Some / all of these development costs are likely to be passed on to licensees of the software (other ADSs), but these would be indirect costs. There may also be small costs associated with integrating IMBA (dosimetry software) with the in-house databases used by these ADSs, but it is not proportionate to estimate these given the small number of organisations affected.

284. HSE enquired with two ADSs that provide external dosimetry services about how they would use the revised tissue or radiation weighting factors when measuring whole body radiation dose. These confirmed that they, and other external dosimetry services, would not use the tissue weighting factors

[52] **Equivalent dose** is the amount of radiation absorbed by body tissues, multiplied by the relevant radiation weighting factor, which accounts for the type of radiation and the energy carried by the radiation.

Effective dose is the sum of all equivalent doses to tissues, with each multiplied by the relevant tissue weighting factor (to give an effective 'whole body dose').

[53] These changes include: Updates to biokinetic and dosimetric models; new calculations of absorbed fractions with new voxel phantoms; use of updated nuclear decay data; calculation of sex-averaged effective dose.

for external dosimetry, as they assume that the person is exposed to a uniform radiation field. Additionally, they confirmed that radiation weighting factors are not used to measure operational dose quantities. Therefore, there are no additional IT or administration costs to these organisations for the purposes of external dosimetry.

285. Given that external dosimetry services do not use these tissue or radiation weighting factors in their calculations, there should be no changes in the number of classified workers due to external doses.

286. There is, however, potential for changes to estimates of committed effective doses – and therefore the number of classifications – due to use of the new tissue weighting factors in internal radiation; however, it is not possible to know this at this time, or even the potential magnitude / direction of the change, because the dose coefficients for internal exposure which incorporate the new tissue and radiation weighting factors have not yet been published by ICRP and the IMBA software is still in development.

287. Therefore, we are able to estimate **one-off software update costs of £250,000**. No respondents the public consultation raised concerns with, or costs arising from, the change in weighting factors, so it is unlikely that there will be other significant costs.

15 Public Dose Estimation

288. To implement the Directive there will be a new requirement on employers to estimate ionising radiation doses to members of the public, arising from work activities the employers undertake using ionising radiation. If an initial estimation (screening assessment) suggests that the practice could give a dose of radiation to the public over 0.3 mSv in a year, then the dutyholder will have to do a more realistic assessment of doses to the public. A realistic assessment would only need to be undertaken once, but must be reviewed if practices change significantly.

289. The new Directive requires Member States to specify when a realistic assessment of public doses is required. The current environmental regulations and the guidance of IRR99 capture the recommendation from the National Radiological Protection Board (now PHE) that the dose constraint[54] to the public on a single new source should not exceed 0.3 mSv per year. HSE (and the Environment Agency) has chosen to set the trigger level for a realistic assessment at the 0.3 mSv dose constraint, as this is considered the most proportionate approach and maintains consistency with the approach under environmental regulations.

290. IRR99 already require a prior risk assessment, which requires the employer to know the nature and magnitude of the risks to employees and other persons arising from the hazards identified from that work. Therefore, employers should already know the level of exposure from any work from their risk assessments, and so an initial estimation (screening assessment) of dose to the public should not incur significant costs. Additionally, as above, employers that are meeting the 0.3 mSv dose constraint in current environmental regulations, which is also recommended in current IRR guidance, should have public exposures below the level trigger level for a realistic assessment of doses.

291. Many stakeholders already carry out this public dose assessment under current environmental regulations and HSE will not require repetition of this. Therefore, this requirement only leads to additional costs for those businesses that do not already carry out these calculations. Based on stakeholder consultations undertaken throughout the transposition period, HSE expects that the

[54] Dose constraints differ from dose limits in that, unlike dose limits, they are not a level of dose that should not be exceeded. They are an upper bound of individual doses which are used to define optimisation options for a given radiation source.

businesses affected are mainly those in the non-destructive testing and medical sectors, and any business using x-ray fluorescence (XRF) analysers. There are around 1,500 employers in these sectors across GB (around 90% of which are private sector), though, as above, it is expected that only a relatively small proportion of these will have to carry out a realistic assessment of doses (i.e. where the initial estimation in the risk assessment suggests that exposures could be over 0.3 mSv per year).

292. Responses to a questionnaire circulated to representatives of affected sectors before public consultation indicated that it would take stakeholders between 1 and 6 hours to undertake a realistic assessment of doses. At the cost of time of £24.29, as used in paragraph 265, this is estimated at a cost of between £24 and £146 per assessment, with a best estimate of £85. If all 1,500 employers in the affected sectors needed to undertake this, this would lead to cost to organisations of between £36,000 and £210,000, with a best estimate of £125,000 (of which £110,000 are costs to business).

293. It is difficult to estimate the number of businesses that would need to undertake a realistic assessment following the initial screening currently undertaken as part of the risk assessment. As above, this will only be required where the initial screening indicates that the 0.3 mSv source dose constraint is exceeded, which should not be commonplace. HSE Radiation Specialist Inspectors expect that, at most, one in five (20%) of the affected employers would need to undertake a realistic assessment. This would reduce costs to around £25,000 in the first year.

294. As stated earlier, employers will need to review the public dose estimate when the use of ionising radiation has changed significantly. It has not been possible to estimate how frequently this might occur. However, the costs should be very low; if 10% of affected organisations per year need to review their assessment, this would lead to total additional costs of around £2,500 per year. Given the low cost, we do not consider it proportionate to investigate this further and so do not account for this in the costs assessment.

295. New entrants to the market in the affected sectors may also need to undertake a realistic assessment of public doses. Using an estimate of 15% of new business start-ups each year, based on ONS Business Demography Data for the 'Technical Testing and Analysis' sector, gives 200 new businesses each year (applying the 15% to the 1,300 affected private sector businesses only). Applying the estimate of 20% of businesses (40) needing to undertake a realistic assessment gives annual costs of £3,400 per year for new businesses from the second year onwards (best estimate), or £26,000 present value across the 10-year appraisal period.

296. Adding one-off costs for existing businesses and one-off costs for new entrants each year gives **total costs of around £51,000 net present value across the 10 year appraisal period, of which £48,000 are to private businesses.** Responses to the public consultation did not suggest that fulfilling this requirement will lead to large costs, which supports this estimate. HSE will provide clear guidance to ensure that it is clear when realistic assessments are required and that they are undertaken in a proportionate manner.

297. There is potential for some small but unknown public health benefits arising from this change. Ensuring that businesses which do not estimate the dose to the public for environmental regulations do this under occupational legislation, means that the possible dose to the public from all practices will be known and can be controlled under the public dose limit of 1 mSv.

16 Accidental Exposures and the Recording and Analysis of 'Significant' Events

298. HSE proposes some small changes to the existing arrangements to take account of the requirements of the Directive, which states that employers should record and analyse "significant

events" (as they are referred to in the Directive) and to ensure that accidental exposures and doses[55] are recorded in the dose record. The intention of this change is to ensure that accidents are properly identified, recorded and investigated, so that causes of accidents can be addressed in order to reduce their frequency and severity in the future.

299. The Directive does not define significant events. HSE, through consultation with industry stakeholders, has interpreted this to mean an event which can lead to an accidental exposure. HSE's discussions with stakeholders highlighted that the term 'significant events' in the Directive is confusing to businesses and other organisations. Interpreting the term via existing and understood terms (that is, an event leading to an accident whereby exposure occurs) provides certainty and clarity to businesses and ensures that they do not record and analyse events that they do not need to – avoiding additional and unnecessary costs. HSE considers that this definition minimises costs to business while fulfilling the requirements of the Directive.

300. 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. This plan should be rehearsed at suitable intervals. To fulfil the requirements of the Directive, HSE proposes to add to this, so that employers would also be required to record and analyse any event which causes, or potentially causes, the enactment of a contingency plan.

301. We asked about the potential costs from this requirement in a questionnaire circulated in July 2016 (see Section 9). Of the 21 respondents who responded to the question, 16 confirmed that this is something that they always do and therefore they would not incur any additional costs from the change. The other five respondents stated that they do it most or some of the time. However, they were unable to determine how many additional events they may need to record or analyse. Based on these responses and the feedback from other stakeholder engagement prior to consultation, we assumed for the consultation-stage IA that the majority of stakeholders already meet the proposed requirement and that this requirement is considered standard practice; therefore, costs would be limited.

302. Also, dutyholders would be required to record any accidental exposure from enactment of the contingency plan separately on dose records. Discussions with ADS stakeholders prior to public consultation suggested that there is scope to do this in the 'free text' part of a data entry in existing databases. Therefore, we expected the cost of recording one accidental exposure to be negligible, as ADSs would choose the easiest way to record it, requiring no structural changes in databases, nor one-off changes in processes.

303. Any administrative costs to the employer arising from informing the ADS of an accident should also be minimal and similar to existing arrangements that a company will make with the ADS to record overexposures, where the dose record also has to be altered.

304. Based on the above, the consultation-stage IA concluded that there would be no significant additional costs from this change. In order to test this assessment and get input from a broader group of stakeholders, we asked at public consultation:

- If stakeholders already record and analyse events that could cause a contingency plan to be triggered
- If not, how many additional events they would need to record
- The costs of doing so.

[55] An accident being defined as a "non-routine situation or event where immediate action would be required to prevent or reduce the exposure to ionising radiation of employees or any other persons "

305. Two thirds of respondents to the public consultation answered that they already analysed and recorded events which triggered a contingency plan. This included all respondents from nuclear and defence sectors. Those who answered they do not do this were from the academic and medical sectors.[56]

306. However, it is evident that many respondents did not fully understand the scope of the proposed requirements. A relatively large number stated that the requirements were unclear, meaning they were unable to say how many additional events they may need to record or associated costs; several of those that answered that they do currently record and analyse events thought that they may need to do more depending on how they would apply in practice.

307. This commonly related to small spills of radioactive substances (for example, in nuclear medicine), with several respondents stating that there were 'hundreds of such events'. The HSE guidance will be clear that small spillages on impervious surfaces that should not lead to additional exposures would not need a contingency plan, so we discount these responses in the analysis that follows.

Medical sector

308. Two thirds of respondents from the medical sector stated that they already analysed and recorded events. On this basis, we estimate that one third of the 181 NHS employers – i.e. 60 – will need to record and analyse additional events. Relatively few respondents provided an estimate of the number of events per year, though those who did typically gave answers that ranged from two to 10. Most answers were towards the lower end of this range, so we take 3 per year as a best estimate, which HSE Radiation Specialist Inspectors consider is a reasonable average. This gives around 180 additional events per annum to be recorded and analysed across the medical sector.

309. Several members of staff will be involved in analysing/investigating an event. HSE draft guidance states that the Radiation Protection Advisor, management, affected employees and their representatives should be involved. Consultation respondents provided a range of estimates for staff time, which would be dependent on the scale and complexity of the incident.

310. Based on these responses, discussions with HSE Radiation Specialists Inspectors, and draft HSE guidance about what the analysis / investigation will involve, we make the following estimates for an average incident, valued at the costs of time in the medical sector set out in Section 11.3: 3 hours each for a RPA (at £53 per hour), RPS (at £32 per hour), and a representative from departmental/divisional management (at £39 per hour); 1 hour for the individual involved in the incident to provide evidence (at £51 per hour – estimated at the average rate of a doctor applied in Section 11.3). This gives a total staff time of 10 hours per event, at a combined cost of time of around £420.

311. Multiplying across the estimated 180 events in the NHS per year gives a total annual cost of around £76,000 per year.

[56] A relatively large number of respondents from the health and safety / radiation protection consultancy sector – many from the same company – also answered that they do not record and analyse these events. These consultancies provide advice to employers and are not, for the most part, the responsible radiation employer; therefore, they would not be responsible for fulfilling the duty discussed here and would be answering based on experience of the organisations and sectors they advise. Given this, we have included the relevant information provided by these respondents in the cost estimates that follow but have not attributed costs to the consultancy sector.

Academic sector

312. It is unlikely that schools would undertake procedures complex enough to need contingency plans as detailed in the regulations. Therefore, we estimate costs for the 135 universities that are members of Universities UK[57], who we consider are most likely to conduct research using radioactive substances that may lead these events.

313. Three-quarters of respondents from the academic sector answered that they do not currently record and analyse events. However, we do not expect that all universities would routinely undertake work with radioactive sources that could lead to these events. Given this, we estimate that around half of the 135 universities (i.e. 68) need to record and analyse additional events.

314. Academic sector respondents provided few specific estimates of the number of additional events per employer, or the staff time involved in analysing these. In the absence of further data, we apply the same assumptions as from the medical sector, which are also broadly consistent with those provided by the consultancy sector. Applying an average of three events per employer per year, at staff cost per event of £420, gives an estimate for the academic sector of around £86,000 per year.

Summary

315. **Total costs to medical and academic sectors are around £160,000 per annum, or around £1.4 million present value over the 10 year appraisal period.** Of these total costs, £740,000 are to the private sector (universities) and £660,000 are to the public sector (NHS). Based on the information received during informal stakeholder consultations and the public consultation, we do not expect significant additional costs to other sectors.

316. If the effect of this regulatory change is to ensure that more incidents are analysed and lesson are learned about their causes, this may reduce the number of these events per year (as is the aim of this change). The total costs of recording and analysing these incidents would fall as a consequence. However, since this is speculative we do not account for any decrease and assume these annual costs are constant for the ten year appraisal period.

16.1 Accidental exposures and 'significant events' - Health benefits

317. Formally requiring stakeholders to record and analyse events that cause, or potentially cause, the contingency plan to be enacted will increase robustness in ensuring that incidents are logged, and causation explored to avoid such incidents occurring in future. Recording any accidental exposure on the dose record within the "free text" field is a low-cost option to ensure that this exposure is flagged for future reference and can be located to be factored into any assessment made for the exposed person.

17 Changes to regulation with no significant costs to business expected

17.1 Changes required to IRR99 required to implement the Directive

318. There are several proposed changes to IRR99 required to implement the Directive which HSE believes should not lead to significant additional costs to businesses, based on consultations with stakeholders. Table 9 summarises these changes and the reasons why these are not expected to give rise to significant costs.

[57] See http://www.universitiesuk.ac.uk/facts-and-stats/Pages/higher-education-data.aspx

319. HSE asked in the public consultation whether consultees agreed with the assessment of no significant costs made in Table 9. Respondents did not make any comments which contradicted this assessment. Some comments sought clarification about the process for HSE approval of dose estimation via calculation methodologies. HSE will provide clear guidance on this.

Table 9 IRR99: Summary table of changes to regulation required to implement the Directive with no significant costs to business expected

Short description	What is the change?	Why are there no costs to business?
Dosimetry – dose and medical record retention	Currently, the employer (or contracted ADS) must keep dose and medical records for 50 years after the last entry in the record. This will change so that all dose records and medical records have to be kept for the period of working life and afterwards until the worker has or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure to ionising radiation. There is no requirement for employers to destroy records after the specified period.	During stakeholder engagement to date, industry representatives, (particularly those in the nuclear and medical sectors) have informed HSE that they keep records for longer than the new requirements, often indefinitely, for insurance or compensation purposes. They would maintain this practice under the new requirements and therefore do not expect any additional costs.
Radon – annual average	Currently, any work carried out in an atmosphere containing radon at a concentration greater than 400 Bq m^{-3} over a 24-hour period, is in scope of the IRR99. This value has now changed to an annual average concentration greater than 300 Bq m^{-3}.	Calculations carried out by PHE have shown that a 24-hour average of 400 Bq m^{-3} is equivalent to an annual average of 300 Bq m^{-3}. Therefore, there is no change to the existing value, so there will not be any additional impacts on business.
Dose Limitation - under 18s	Currently, there are no specific dose limits for non-trainee employees under 18, as there is an assumption that all employees under 18 will be trainees. However, IRR99 do not explicitly prohibit under 18s from working with ionising radiation. Implementing the Directive will introduce a requirement that young persons under the age of 18 will be prevented from carrying out any work where they are likely to be exposed to ionising radiation (i.e. as non-trainee/non-apprentices or students).	In England the school leaving age is 18. While this does not preclude part-time work with ionising radiation for those under the age of 18, consultations with stakeholders suggest that this is extremely unlikely to occur. In Scotland and Wales, the school leaving age is still 16. HSE has contacted the Scottish and Welsh Governments with this proposal. Both have said that in their knowledge no one is employed in work with ionising radiation below the age of 18.
Estimation of dose via calculation methodology approved by the Competent Authority	IRR99 set out circumstances where the dose may be estimated. The Directive states that if a calculation method is used then this must be approved by the Competent Authority. HSE currently does not require approval of calculation methodologies, so this is a new requirement.	When consulted at a dosimetry subgroup, the consensus view of stakeholders across a range of industries was that approvals for calculations would be infrequent and therefore costs would low. HSE will therefore require any calculations to be submitted on a case-by-case basis for approval to build up a bank of methods which are approved for use. Based on stakeholder consultations to date, HSE expects the number of submissions to be limited. HSE will make

Short description	What is the change?	Why are there no costs to business?
		clear that the process for gaining approval of calculation methods will not be burdensome or involve a formal process; it only require the dutyholder to contact HSE to discuss their proposed methodology.

17.2 Changes to IRR99 not associated with the Directive

320. HSE proposes to make some minor changes to IRR99 which are not related to changes in the Directive. These are not expected to lead to significant costs (or savings) for the reasons described below. HSE did not receive any comments from the public consultation which suggested significant costs or other adverse effects from these changes:

Table 10: IRR99: Summary table of changes not associated with the Directive with no significant costs to business expected

Short description	What is the change?	Why are there no costs to business?
Removal of Subsidiary Dose Limit for the Abdomen of a Woman of Reproductive Capacity	IRR99 contains a subsidiary dose limit for the abdomen of a woman of reproductive capacity of 13 mSv in any consecutive three month period. This limit is not part of the Directive and the experience of HSE inspectors is that it is rarely applied in practice, since exposures are much lower. In addition to the existing annual dose limit of 20 mSv for employees, there are provisions that require all radiation exposures to be ALARP and one that requires that a pregnant woman does not have conditions of exposure that are likely to lead to an effective dose to the foetus of more than 1 mSv during the declared term of pregnancy. These provisions are considered sufficient to protect an unborn child.	Though in principle there are potential *savings* to business because an existing requirement is being removed, HSE does not expect any change in control practices, given the other requirements described (which will continue to apply in IRR17).
Change in period for appeals against Appointed Doctor's decision on medical fitness for work	Currently, classified workers who are aggrieved by the decision of an Appointed Doctor have a time limit of three months to raise an appeal with HSE. HSE proposes reducing this to 28 days for consistency with other regulations.	HSE receives very few appeals under IRR – around 1-2 per year on average, though none for several years. In theory, this change could lead to appeals being submitted earlier than previously (i.e. those that would currently be submitted between 28 days and three months), or it could reduce the number of appeals in cases where it is not possible to appeal in the shorter timeframe. However, HSE will exercise discretion in this time limit for mitigating circumstances.

Appointed doctors - removing the legal requirement for to appoint 'in writing'	IRR99 requires an Appointed Doctor to be 'in writing', which takes the form of a Certificate of Appointment, if the applicant can demonstrate they meet requirements for qualifications, training and competence set out on the HSE website.[58] HSE proposed to remove the requirement to appoint 'in writing' from the regulations, in order to enable any future changes to the system of Appointed Doctors to be made consistently across several different regulations. However, HSE has no plans to change its administrative system for appointing doctors in the foreseeable future.	Given that the current system for appointing doctors will remain in place, and HSE appointment provides quality assurance for businesses that use Appointed Doctors, HSE does not expect any significant change in practice.

18 Changes which potentially go beyond the scope of the Directive

321. Where possible, the UK has used copy-out from the Directive. However, there are a limited number of instances where it has been necessary to deviate from this to minimise costs to business, or to make use of the flexibility allowed in the Directive to uphold or improve standards of radiological protection.

18.1 Cost saving – early implementation of the regulations

322. To meet EU obligations, new Ionising Radiations Regulations must be UK law by February 2018. Current dose recording arrangements under IRR99 require that exposure to ionising radiation is calculated and assessed on a calendar year basis, to ensure that specified dose limits are not exceeded. In particular, new requirements significantly reduce the dose limit that relates to radiation exposure to the lens of the eye. If this new dose limit were introduced in February 2018 (five weeks into the calendar year), it would mean two dose limits would apply in one calendar year.

323. Discussions during HSE's stakeholder consultation have highlighted that this will cause confusion for businesses and other organisations, and would require individual dose limits to be re-calculated for the remainder of the year. Recalculation to account for implementation of the new dose limit five weeks into the calendar year could cost around £30,000 – 35,000 for each service that calculates dose (known as ADSs), based on information provided by an ADS. There are 33 ADSs in total giving an estimated one-off cost of around £1.1 million.

324. HSE proposes to avoid this cost, burden and confusion to stakeholders by implementing IRR17 on the 1st January 2018, which is 5 weeks earlier than the EU implementation date. HSE consulted with members of the OEWG on proposals for early implementation. These proposals included implementing only the dosimetry-related changes at the start of the calendar year, or implementing all requirements at the start of the calendar year. Stakeholders strongly supported early implementation of all requirements to coincide with the dose year (including those from the nuclear and medical sectors, and the Society for Radiological Protection (SRP)), as this would minimise scope for confusion regarding the date at which different requirements apply. There is a precedent for this approach, as transposition of the 1996 Directive was 5 months earlier than the transposition deadline for similar reasons.

[58] See http://www.hse.gov.uk/doctors/information.htm

325. The overwhelming majority of respondents to the public consultation agreed with this proposal, with strong support across all sectors.

18.2 Maintaining existing standards of radiological protection:

326. In order to maintain existing standards of radiological protection, HSE proposes to keep the following existing requirements, which go beyond the minimum requirements of the Directive but do not impose significant additional costs to businesses compared with the 'do nothing' baseline:

Applying dose limits to notifiable practices, such as work with naturally occurring radioactive materials (NORM)

327. IRR99 apply dose limits for exposure to radiation to all work including work with NORM. HSE is aware that NORM work can give rise to exposures close to or exceeding the limit for classification of workers. The new Directive does not extend dose limits to work with notifiable practices, such as some work with NORM, meaning that – if the approach of the Directive was implemented – there would be no explicit limits to restrict exposure to workers or the public. HSE considers that this would lessen the standards of radiological protection and so proposes to maintain the current regulatory position of applying dose limits to work with NORM and other notifiable practices.

328. Even if these dose limits did not apply to notifiable practices, such as NORM, employers would still be required, under existing legislation, to keep exposure to NORM to ALARP. Disapplication of the dose limits for these practices would also not remove these practices from other requirements of the regulations. For example, the employer would still have to risk assess, cooperate with other employers and take relevant control measures. Additionally, employers carrying out specified work with NORM would still need to notify or register with HSE under the Graded Approach.

329. HSE consulted on this change in the public consultation with respect to NORM and did not receive any comments suggesting that maintaining this requirement is considered overly burdensome or disproportionate. Therefore, we conclude that any savings from disapplying the dose limits to notifiable practices would be low and disproportionate to the increased risks of exposure to radioactive materials.

Radon

330. Existing arrangements state that if radon is detected in the workplace above a certain level then the employer must notify HSE immediately. The requirements set by the Directive would mean that notification was only required once the dutyholder had detected that radon was present above the specified level, and had tried and failed to remediate below this level. HSE considers that during the remediation period (which is not time-limited) workers and the public can be exposed to an uncontrolled high level of radon and HSE would not be aware of this exposure as the dutyholder is not required to notify. Therefore, HSE's view is that this provision is confusing, difficult to enforce and lessens radiological protection significantly, and we propose that current arrangements are maintained.

331. Implementing the requirements in the Directive would not result in significant savings to business. Under the existing requirements, HSE receives a small number of notifications per year (around 10-15). The process of notifying HSE is similar to that described under the 'notification' tier of the Graded Approach, providing limited information already known to the business via a digital process.

332. The effect of implementing radon notification in line with the Directive (this is, requiring notification only if remediation has not been successful) would be a small reduction in the 10-15 notifications per year, assuming that a proportion of businesses were able to remediate and would not

therefore need to notify HSE. Any associated administrative savings negligible and would not justify the reduction in radiation protection standards.

18.3 Extending scope of consents

333. As discussed in detail in Section 12.5, HSE is proposing to extend the scope of consents to include practices that would otherwise be registered. This goes beyond the minimum requirements of the Directive.

334. In the case of industrial radiography, the extension in consents would allow the removal of a requirement for work to be notified to HSE seven days in advance of commencement, which leads to present value savings to business relative to the baseline of around £170,000.

335. In the case of particle accelerators, this leads to small additional costs to businesses and the public sector. These costs would be classified as gold-plating, and, as explained in paragraph 269, the costs to business are therefore in scope of One In, Three Out, albeit rounding to zero in terms of their contribution to the Business Impact Target.

19 Familiarisation costs

336. There will be costs to affected dutyholders who spend time familiarising with the changes in regulatory requirements and associated ACOP and guidance, and determining what actions, if any, are needed. These costs will depend on a number of factors: the size of the affected organisations; the type of work they undertake; the extent to which the regulatory changes affect this work; the way they receive information about regulatory changes and how engaged they are with regulatory developments.

337. HSE has worked to implement the Directive in the least burdensome way possible, only exceeding the requirements of the Directive where we assess that this is actually net-beneficial to dutyholders or to uphold standards of radiation protection to protect workers and the public. To develop the written guidance and ACOP, HSE has formed a guidance consultation group comprised of representatives from professional and industry bodies from the main sectors affected. Feedback from this group and from the public consultation has been used to ensure that the regulations, ACOP and guidance have been written in such a way that it will be easy for organisations to understand their main duties. HSE has also used information provided by this group to inform estimates of familiarisation costs.

338. Familiarisation costs would be one-off, transitional costs, which we estimate will occur in the first year of the appraisal period. We estimate additional costs for existing organisations only; new entrants would, without the regulatory change, still need to familiarise with duties of a similar nature and complexity to those proposed, so the amount of resource expended in familiarising would be equivalent.

339. Organisations across the relevant sectors will be affected by IRR17 in very different ways, meaning there will be large variations in the amount of time and resource organisations in each sector need to spend familiarising with them. Developing bespoke estimates for each sector affected would be disproportionate. Instead, we estimate familiarisation time using the following steps:

- **Undertake an initial, qualitative assessment of familiarisation time by sector** to assess whether familiarisation time for the typical organisation in each sector would be high, medium low, or very low. This assessment drew on the expertise of HSE Radiation Specialist Inspectors, as well as consultation feedback, and is a composite of several factors:

i) the extent to which the organisations in the sector are affected by the change in the regulations, driven by the complexity and extent of use of ionising radiations;

ii) the typical size of organisations in the sector; and

iii) the degree to which the organisations in the sector are already familiar with the regulations and changes to them.

- **Group sectors by this high, medium, low, and very low assessment**

- **Estimate familiarisation time for each group (high/medium/low/very low)**. We made specific estimates for each of those sectors deemed 'high' (nuclear, NHS and universities). To inform these estimates, HSE asked members of the guidance consultation group to complete a questionnaire on the process their primary employer would undertake to familiarise with the regulations and the associated costs; and this was adjusted through further consultation with respondents and with HSE sector experts to account for any familiarisation activity that would have taken place anyway due to, for example, refresher training for staff. Broad estimates of familiarisation time for medium, low and very low groups were based on HSE's extensive stakeholder consultation, including the public consultation, regarding the extent to which different sectors are affected by the regulations, and expert assessment by HSE Radiation Specialist Inspectors.

340. Table 11 sets out the groups, time assumptions and rationale for this assessment. We apply an average cost of time of £27.72 per hour, based on an average of wage rates in the Annual Survey of Hours and Earnings for 'Health and Safety Officers' (3367), 'Health professionals' (221), and 'Science, research, engineering professionals' (21).[59]

341. Applying the wage rates above to the time estimates in Table 11 gives total one-off estimated familiarisation costs of around £5.3 million in the first year, of which around £2.3 million are costs to private businesses; and around £3.0 million to the public sector. These costs are expected to apply to Options 1-4 presented in this IA; the options do not differ sufficiently to affect the level of familiarisation required.

342. The consultation-stage impact assessment included the costs of time spent by employers to familiarise with the changes in eye dose requirements: raising awareness of changes within an organisation, and providing advice and training regarding the new requirements (see Section 11.4.2). The one-off costs totalled around £530,000 across the medical and nuclear sectors. To avoid double-counting with the familiarisation costs estimated above, which cover all changes to the regulations, we have removed the consultation-stage estimates of familiarisation costs for eye dose from this assessment.

[59] Annual Survey of Hours and Earnings 2015 (Revised). Uprated by 19.8% to account for non-wage costs and inflated to 2016 prices using the ONS Seasonally Adjusted Average Earnings Index.

Table 11: Estimates of familiarisation time by

Familiarisation assessment (H/M/L/VL)	Number of practices[a]	% private	Time per practice (hours)	Total time per sector (hours)	Description	Sectors included
High (nuclear)	**40**	**90%**	**350**	**14,000**	Nuclear sector is comprised of large organisations with extensive procedures and documentation for radiation protection, which will need to be reviewed and updated following the implementation of the proposed regulations. Organisations are highly engaged with the regulations and regulatory developments. Businesses in the sector will be affected by most or all of the changes to the regulations. Large estimates of familiarisation time provided by nuclear sector members of the guidance consultation group.	ONR Nuclear Licensed Sites, plus MoD nuclear authorised sites.
High (Acute NHS Trusts)	**181**	**0%**	**350**	**63,000**	NHS Acute Trusts are very large and make extensive use of ionising radiations in diagnosis and treatment, involving many staff and sites per organisation. The sector will be affected by most or all of the changes to the regulations. Large estimates of familiarisation time provided by medical sector members of the guidance consultation group. Some responses from the sector to the public consultation indicated that the some requirements (e.g. outside workers and significant events) may be difficult to understand, indicating a large amount of familiarisation time.	NHS Acute Trusts and organisations in England, Scotland and Wales
High (Universities)	**160**	**100%**	**50**	**8,000**	Universities are not affected to the same extent by the changes to the regulations as nuclear and NHS Acute Trusts. However, universities are typically very large, multi-site organisations with an extensive and diverse use of ionising radiation for research purposes, meaning that a relatively large number of staff will need to familiarise.	Universities and higher education providers (excluding further education colleges) permitted to award degrees.

Familiarisation assessment (H/M/L/VL)	Number of practices[a]	% private	Time per practice (hours)	Total time per sector (hours)	Description	Sectors included
Medium	**1,800**	**81%**	**7.5**	**13,000**	Organisations are affected by some of the changes to the regulations. Some dissemination of information throughout organisation may be required.	Independent hospitals and NHS Mental Health and Community Trusts; non-destructive testing (industrial radiography) and industrial irradiators; sealed source disposal; use of depleted uranium; radioactive waste disposal; practices with high-activity sealed sources; and the operation, decommissioning or closing of any facility for the long term storage or disposal of radioactive waste.
Low	**24,000**	**56%**	**3.8**	**91,000**	Organisations are affected by a small number of the changes to the regulations and/or are typically small individual practices (e.g. vets and dentists). A relatively small number of staff are likely to need to familiarise with the requirements; most will need only to familiarise with graded approach while some may need to undertake a public dose estimation.	Dental and veterinary practices; secondary schools and further education colleges; other industrial practices such as electron beam welders , ion implanters, x-ray detection devices, XRF analysers , well logging; importers and exporters of products with deliberately added radioactive substances; museums and aviation preservation practices; and those were work involves exposure to other naturally occurring radioactive materials (NORM).

Familiarisation assessment (H/M/L/VL)	Number of practices[a]	% private	Time per practice (hours)	Total time per sector (hours)	Description	Sectors included
Very low	**500**	**97%**	**0.5**	**250**	Organisations in these sectors only need to re-notify HSE under the Graded Approach. These organisations are only incidentally affected by ionising radiation, are not affected by any other changes, and are likely to have a low engagement with the regulations. Many of these businesses are unlikely to spend significant time familiarising with the changes.	Businesses with radon levels above the action level and others that are subject to the notification requirement in the Graded Approach. .

Table notes

[a] The number of **practices** are taken from HSE estimates of those notifying, registering and applying for consent to operate under the graded approach (see Section 12). One organisation may undertake more than one different practice, and so may be required to make more than one notification, registration or consent . This means there is likely to be some double-counting of organisations – and therefore familiarisation time – by basing estimates on the number of practices, particularly likely for the 'Medium' and 'low' groups. There is insufficient data available to adjust for any double-counting, meaning familiarisation costs are likely to be overestimated

20 Wider impacts

20.1 Health impacts

343. Sections 11.15 (eye dose changes), 12.7 (Graded Approach), 15 (public dose estimation), and 16.1 (analysing and recording events that trigger contingency plans) summarise the potential health and safety benefits of the proposal. HSE's proposed approach will at least maintain existing health and safety protections and increase standards in some instances. Large health benefits are not expected for most changes; the largest potential health benefits relate to the reduction in eye dose limit, discussed in Section 11.15. It has not been possible to quantify the associated improvement in health outcomes for the reasons described in that section.

20.2 Small business impacts

344. There is no small business exemption given the health and safety implications of not complying with the Regulations, which are not proportionate to the number of employees. Exempting small businesses from the majority of requirements in this impact assessment would not implement the Directive and so would risk EU infraction proceedings.

345. The two changes which go beyond the Directive (implementing early on January 1st 2018; and extending the scope of consents), are assessed to be less costly than transposing the Directive without these adjustments, so it would be detrimental to small and micro businesses to exempt them.

20.3 Other wider impacts

346. Wider impacts have been considered and no impacts have been identified for:

- Statutory Equality Duties;
- Human Rights;
- Justice System;
- Rural Proofing;
- Social Impacts;
- Competition (the Directive is being implemented across Europe and so it is not anticipated there will be any competition impacts);
- Environmental; and
- Sustainable development.

21 Summary of monetised and non-monetised costs and benefits to business and government

Table 12 Present Value Costs from the Implementation of IRR, comparing all options, in millions of £ (table to 3 significant figures)

	Total			Business			Public Sector		
	Total Present Value	Transition Costs	Recurring Costs per year	Total Present Value	Transition Costs	Recurring Costs per year	Total Present Value	Transition Costs	Recurring Costs per year
Option 1									
Eye Dose - Medical Sector	£8.25	£4.31	£3.94	£0.00	£0.00	£0.00	£8.25	£4.31	£3.94
Eye Dose - Nuclear Sector	£1.50	£0.15	£1.36	£1.35	£0.13	£1.22	£0.15	£0.01	£0.14
Graded Approach	£2.20	£1.70	£0.50	£1.41	£0.91	£0.50	£0.79	£0.79	£0.00
Outside Workers	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00
Weighting Factors	£0.25	£0.25	£0.00	£0.00	£0.00	£0.00	£0.25	£0.25	£0.00
Public Dose Estimation	£0.05	£0.03	£0.03	£0.05	£0.02	£0.03	£0.00	£0.00	£0.00
Accidental Exposures	£1.39	£0.00	£1.39	£0.74	£0.00	£0.74	£0.66	£0.00	£0.66
Familiarisation costs	£5.26	£5.26	£0.00	£2.29	£2.29	£0.00	£2.98	£2.98	£0.00
Total Costs - Option 1	**£18.90**	**£11.70**	**£7.22**	**£5.84**	**£3.35**	**£2.49**	**£13.10**	**£8.35**	**£4.73**
Option 2 (all costs as per other options, except Graded Approach)									
Graded Approach	£2.20	£2.04	£0.16	£0.68	£0.52	£0.16	£1.52	£1.52	£0.00
All other costs	£16.70	£10.00	£6.72	£4.42	£2.44	£1.98	£12.30	£7.56	£4.73
Total Costs - Option 2	**£18.90**	**£12.00**	**£6.88**	**£5.10**	**£2.96**	**£2.15**	**£13.80**	**£9.08**	**£4.73**

Totals may appear not sum due to rounding. Greyed-out numbers are actually zero, rather than rounding to zero.

347. Table 12 summarises the monetised costs and benefits to dutyholders from changes to IRR under Options 1 and 2.

22 Risks, assumptions and proportionality approach

348. Sections 9 and 11.2 describe the considerable level of evidence gathering undertaken to inform this IA. This has involved extensive stakeholder engagement via a number of stakeholder working groups, surveys of affected dutyholders, and research commissioned by HSE specifically to inform this impact assessment and policy development. HSE has built upon the large amount of work done for the consultation-stage IA to develop monetised estimates of all significant costs and benefits (except for health benefits due to the reduction in eye dose limit, as discussed in Section 11.15.

349. HSE is confident the level of research undertaken means that it has identified the key impacts and has minimised the risk of unintended consequences. Table 13 below summarises the additional research HSE has undertaken to address the key uncertainties from the consultation-stage IA, and any refinements to the analysis made as a consequence.

Table 13 – Summary of steps taken to address main evidence gaps since consultation-

Source of uncertainty	Expected effect (text as per the consultation-stage IA)	Scale (text as per the consultation-stage IA)	Research undertaken to inform the final IA	Changes to analysis in the final IA
Changes to requirements on doses to the lens of the eye (Section 11)				
1. The current level of exposures to the lens of the eye in the medical sector.	The level of current exposures relative to the classification and dose limits for eye dose will determine the number of additional controls required and classifications of workers (see next two rows).	Changes to eye dose requirements account for the majority of costs in this assessment, and the current level of exposures is the main determinant of potential costs. Therefore, changes in information about the current level of eye doses in the medical sector will have a potentially large effect on total costs.	HSE invited NHS employers to submit eye dose monitoring data and received 7 responses. The HSE public consultation also asked specific questions about whether employers (from all sectors) would need to classify additional workers and, if so, how many. HSE received 111 responses to these questions, with specific estimates of classification numbers from 30.	HSE has reviewed all of the information received and has concluded that the consultation-stage assessment of 300 classified workers is appropriate, so is maintained.
2. The number of workers who will become newly classified in the medical sector due to the reduction in the classification level for eye dose.	New information may lead to costs increasing or decreasing. Current estimates are based on information provided by NHS stakeholders, which is somewhat contrary to dosimetry research undertaken by PHE. HSE therefore expects that it is more likely that current costs have been overestimated.	Additional classified workers result in ongoing costs from dose monitoring and medical surveillance. Changes in the number of newly classified workers could therefore have a 'medium' effect on total costs.		
3. The number of additional controls required in the medical sector to reduce exposures below the eye dose limit.	New information on additional controls required may lead to costs increasing or decreasing. Current estimates are based on information provided by NHS stakeholders, which is somewhat contrary to dosimetry research undertaken by PHE. HSE therefore expects that it is more likely that current costs have been overestimated.	The largest costs in this impact assessment arise from additional measures in the medical sector to control eye doses. Changing assumptions underlying this estimate would therefore have a potentially large effect on costs.	HSE asked a specific question in the public consultation about whether employers would need to implement additional controls as a result of the changes and, if so, to provide details of the costs. HSE also had direct discussions with a small number of NHS sector stakeholders who had recently implemented additional controls.	Responses broadly supported the assessment of costs of protective eyewear, so these are maintained. Estimates of the costs of lead screens have been revised, both in terms of the number of additional screens required (which has fallen overall) and the unit installation costs (which has increased).

Source of uncertainty	Expected effect (text as per the consultation-stage IA)	Scale (text as per the consultation-stage IA)	Research undertaken to inform the final IA	Changes to analysis in the final IA
4. Eye dose – impacts to the private medical sector. HSE currently has limited information about the potential impacts of the change in eye dose requirements in the private medical sector	The assessment of changes to eye dose requirements does not currently include costs specifically to the private medical sector, although some costs currently accounted as NHS costs may arise to providers who also undertake private medical procedures. Adding any costs will increase total costs.	Consultation with medical sector stakeholders so far suggests that the private medical sector does not routinely undertake the same complex interventional procedures as the NHS, which potentially lead to high eye doses. However, changes to eye dose requirements lead to the largest estimated costs in this IA. Therefore, the scale of any additional costs may be 'medium' relative to other costs in this IA.	HSE directly contacted the Association of Independent Healthcare Organisations (AIHO) to raise their awareness of the public consultation.	HSE did not receive a response from the AIHO and has had little engagement from the private medical sector during the development of the regulations. We therefore conclude that the assessment of no significant costs to the sector, other than small costs relating to outside workers and familiarisation costs, is appropriate.
Graded Approach (notifications, registrations and consents) (Section 12)				
5. Estimate of the number of practices notifying, registering or consenting	The costs may go up or down.	Any large changes to the numbers of practices would have an equivalent effect on costs – though this is not expected	Review of IDBR, applications under authorisation/licensing regimes operated by other UK regulators, contacting industry bodies, and expert assessments of HSE Radiation Specialist Inspectors and sector experts with experience and knowledge of the sectors affected.	HSE has revised the estimates of the number of practices under each tier of the graded approach.

Source of uncertainty	Expected effect (text as per the consultation-stage IA)	Scale (text as per the consultation-stage IA)	Research undertaken to inform the final IA	Changes to analysis in the final IA
6. The fees that HSE intends to charge for registration and consent are currently not known	The monetised costs under the graded approach will increase when the fee amount is known	The estimated costs will increase once this cost is monetised	Thorough assessment of the costs to HSE of implementing the graded approach, and the expected cost recovery rates, though discussions with operational and finance colleagues.	HSE has included an estimate of the costs to businesses and other organisations of fees in Section 12.3.
7. The time taken to complete notification, registration and consent are estimates based on internal expert judgement	This could increase or decrease costs	The effect is not expected to be large	Online survey during HSE webinar with stakeholders on the Graded Approach, plus questionnaire to HSE Radiation Community of Interest.	HSE has revised time assumptions for large, multi-site organisations for NHS organisations, universities and local authorities that maintain multiple secondary schools.
Outside Workers (Section 13)				
8. Costs of changes to requirements relating to outside workers	Stakeholders suggested some costs in response to a survey but did not provide sufficient information to estimate	The costs are expected to be small as we anticipate that they only apply to a subset of dutyholders, and that they are one-off costs	HSE has sought further legal advice and determined that there is no change in requirements in practice.	No costs estimated from this change.
Weighting Factors (Section 14)				
9. Weighting factors – costs of updating systems, and potential changes to the number of classified workers	Existing assessment excludes some costs to ADSs of updating databases to reflect the new weighting factors. Including these would increase costs. If the new weighting factors increase the number of classified workers, this will increase costs, and the reverse if the number of classified workers falls.	The costs of updating databases is expected to be low (at most the low hundreds of thousands) relative to other costs in this IA. The changed weighting factors are not expected to lead to a vast change in the number of classified workers, so the effect on costs is not expected to be large.	HSE has engaged further with ADSs to understand any additional database costs and the potential implications of the change in weighting factors for the number of classified workers.	No additional costs expected to those assessed in the consultation-stage IA.

Source of uncertainty	Expected effect (text as per the consultation-stage IA)	Scale (text as per the consultation-stage IA)	Research undertaken to inform the final IA	Changes to analysis in the final IA
Public Dose Estimation (Section 15)				
10. The number of dutyholders that will have to carry out a more realistic dose assessment and the frequency at which dutyholders will need to review their public dose estimates	This is expected to be small because it only applies to 1200 stakeholders	Small impact on 1200 stakeholders	HSE enquired with the Environment Agency about the scope of the requirements for public dose estimation under environmental regulations. HSE also consulted on these changes in the public consultation but received very few specific comments on the change.	Small change (increase) to the number of dutyholders affected. Otherwise, the analysis has been maintained from the consultation-stage IA. No information was received to suggest that it should be refined and the total costs estimated are small.
Accidental Exposures and the Recording and Analysis of 'Significant' Events (Section 16)				
11. Accidental exposures – costs associated with separate recording of accidents. There is uncertainty about the number of businesses who currently do not record accidents separately, and the frequency of accidents that would need to be recorded separately.	We have not been able to quantify associated costs at this stage, so any estimate would increase costs.	Stakeholder consultation so far suggests that any costs are likely to be relatively low.	HSE asked specific questions during the public consultation about the number of additional events employers expect to record and analyse, and the associated costs.	Analysis has been revised based on the consultation responses, with specific estimates made for medical and academic sectors.

23 Direct costs and benefits to business calculations (following OI3O methodology) and preferred option

350. Under Option 1, HSE would recover costs for the graded approach. **This is the preferred option**. The societal NPV is estimated at a cost of around £18.9 million, of which around £5.8 million would be borne by private businesses. The EANDCB in 2014 prices and 2015 present values would be around £0.6 million.

351. Option 2 is identical to Option 1 in all aspects other than that the costs of the graded approach would be borne by HSE rather than by private businesses. The total NPV to society is estimated to be a cost of around £18.9 million (the same as Option 1), but the amount borne by private businesses is lower at around £5.1 million. The EANDCB in 2014 prices and 2015 present values is estimated at around £0.5 million.

352. Options 1 and 2 are both Qualifying Regulatory Provisions under the Business Impact Target, but their INs are minimal and round to zero.

353. Option 1 is the preferred option, as it minimises costs to businesses, maintains health and safety standards while keeping them reflective of differing risks by practice and fulfils HSE's obligations on managing public money.

24 Post Implementation Review (PIR) Plan

1. **Review status:** Please classify with an 'x' and provide any explanations below.

	Sunset	X	Other review		Political		Other		No plan to

2. **Expected review date** (month and year, xx/xx):

0	1	/	20	23

Rationale for PIR approach:

Describe the rationale for the evidence that will be sought and the level of resources that will be used to collect it.

- **Will the level of evidence and resourcing be low, medium or high? (See Guidance for Conducting PIRs)**

  The Ionising Radiations Regulations 2017 (IRR 17) are neither contentious nor high profile, and are based on international standards of radiological protection supported by industry stakeholders. This would suggest a low to medium level PIR in terms of scale and proportionality. However, IRR17 implements a sizeable Directive which makes numerous changes to existing requirements. While many of these changes are small in isolation they represent a substantial overall impact when taken together (as estimated in this impact assessment). This therefore suggests that a higher level of resourcing may be required. It should also be considered that a substantial proportion of these costs are one-off, which will allow more limited action to reduce burdens on business as a result of the review.

  In conclusion, considering that the IRR17 changes are widely accepted and not contentious, but reflecting the large number of changes and their combined impact (which is substantial, albeit with a high proportion of costs being one-off), it is proposed that the level of evidence and resourcing for the PIR be set as **medium**.

- **What forms of monitoring data will be collected?**

  No new or additional monitoring data will collected. As such the following monitoring data - which is currently collected - will be collated and analysed in order to inform the PIR as well as add context and guide any primary research which is undertaken:

  - Central Index of Dose Information (CIDI), which collates data on ionising radiation exposures from Approved Dosimetry Services (ADS).

  - Numbers of notifications, registrations and consents made under the Graded Approach system

  - Notifications of overexposures to HSE, as well as data on accidents notified to ADSs and recorded separately on dose records

- **What evaluation approaches will be used? (e.g. impact, process, economic)**

The PIR will assess whether IRR17 have met their objectives and are still 'fit for purpose'.

The evaluation approaches used within the PIR will therefore be impact (what difference have the IRRs made and how can they be improved) and economic (what have been the actual costs and benefits of the regulations to business and wider society).

- **How will stakeholder views be collected? (e.g. feedback mechanisms, consultations, research)**

  Due to the far-reaching remit of the regulations, there is no single representative group which can be consulted in order to gauge the impact of IRR17 (i.e. affected sectors include medical, nuclear, defence, general industry, academic, etc.). Conversely, the regulations do not affect all businesses, so use of a general business survey or omnibus is also not appropriate. As such, stakeholder and duty-holder views will be collected in a proportionate way via primary research using sector-specific focus groups and/or interviews and small-scale surveys. In addition, it may also be possible to follow up respondents to the public consultation for IRR17.

  Stakeholder views will be collected using primary research.

Annex 1: Estimated number of IRR dutyholders by sector

Section 12.1 of the Evidence Base describes how these numbers were estimated.

Nuclear:

Including all civil nuclear operators and MoD sites, there are 40 nuclear sites in scope of IRR.

Medical/veterinary:

There are approximately 180 acute NHS employers which will have to comply with IRR. Additionally, there are 55 NHS mental health employers and 34 community health providers which may also carry out work with radiation. This may be from the use of X-rays and interventional radiology to nuclear medicine. There are around 90 private health care providers (members of the Association of Independent Healthcare Organisations) who will also carry out similar procedures to the NHS but are not as likely to carry out as many complex procedures.

It is estimated that there are around 12,000 dental practices that will use radiation sources such as X-rays in work. Veterinary practices are likely to use X-rays or deliberately administer radioactive substances. There are an estimated 2,900 dutyholders which carry out these practices.

Research and teaching:

There are approximately 500 Universities, further education colleges and other institutions that provide courses leading to recognised degrees, (160 of which are Universities) which may use radiation sources for practical and research purposes. There are also an estimated 50 industrial research dutyholders.

Some secondary schools will have radioactive sources for teaching and practical use. There are around 2,500 secondary school dutyholders in England, Wales and Scotland that may use and hold sources (which is comprised of local authorities with maintained secondary schools, academy and free state schools, and independent schools).

Other industries:

There are around 65 practices which undertake site radiography and 100 practices which undertake enclosure radiography. Additionally, there is a range of other diverse industries that undertake work with radiation, such as: sealed source disposal; use of depleted uranium; radioactive waste disposal; practices with high-activity sealed sources; and the operation, decommissioning or closing of any facility for the long term storage or disposal of radioactive waste. These account for around 3,000 dutyholders.

Other practices such as electron beam welders (20 estimated practices), ion implanters (5 estimated practices), industrial irradiators (15 estimated practices), XRF analysers (1000 estimated practices), x-ray detection devices (2,000), well logging (20 estimated practices), museums (estimated 250) and aviation preservation sector (70 estimated practices) also use radiation sources.

There are around 50 scrap metal dealers and metal processors which hold radioactive sources, an estimated 20 docks and ports of entry dutyholders, and an estimated 300 dutyholders involved in the transport of radioactive material.

Radon/Naturally Occurring Radioactive Materials:

According to PHE there could be around 20,000 workplaces where radon is present above the level specified in the regulations. These will include some of the dutyholders identified above, since levels of radon depend on geographical location. However, HSE only has around 350 extant notifications for work in radon-affected areas.

The amount of NORM practices in the UK is uncertain, but we have estimated around 1,000 based on the best available HSE sector intelligence.

Annex 2: Occupational Exposure Working Group membership

AMEC
Association of University Radiation Protection Officers
Atomic Weapons Establishment
Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care
Babcock
Blue Lights Working Group
British Aviation Preservation Council
British Dental Association
British Institute of Non-Destructive Testing
British Institute of Radiology
British Nuclear Medicine
Society British Veterinary
Association Cast Metals
Federation Confederation of
British Industry
Consortium of Local Education Authorities for the Provision of Science Services
Business, Energy, and Industrial Strategy
Department Of Environment Northern Ireland
Defence Science Technology Laboratory -
MoD Department for Transport
Environment Agency
EDF/British Energy
Engineering Construction Industry Association
GE Healthcare
HSE Northern Ireland
Institute of Physics and Engineering in Medicine
Local Authorities Working Group
Magnox sites
National Farmers Union
Natural Resources
Wales NHS (various
trusts)
NPV Diagnostics
Northern Ireland Environment Agency
Nuclear Emergency Arrangements Forum
Nuvia
Oil and Gas UK
Office for Nuclear Regulation
Office of Rail and Road
Public Health England
Panel on Gamma and Electron Irradiation
Radman Associates
Rolls Royce
Royal College of Ophthalmologists
RSRL Ltd
Scottish Environmental Protection Agency
Siemens
Society of Radiographers
Scottish Government
Sellafield sites
Society for Radiological Protection
UNITE the union
University of Oxford
Welsh Assembly Government

PART II

NORTHERN IRELAND COSTS AND BENEFITS

Ionising Radiations Regulations (Northern Ireland) 2017

General

1. The Department for the Economy is of the opinion that the analysis and considerations set out in the Great Britain Impact Assessment can, as appropriate, be applied, on a proportionate basis, to Northern Ireland.

Costs and Benefits

2. The Department for the Economy is of the opinion that the analysis and considerations in the Great Britain Impact Assessment) can be applied on a proportionate basis to Northern Ireland as follows:

    - Eye dose – medical sector
    - Graded approach but excluding fees to be charged by HSE and which HSENI does not propose charging
    - Public dose estimations
    - Accidental exposures
    - Familiarisation costs excluding nuclear industry costs (there is no nuclear industry in Northern Ireland).

3. Overall, it is estimated that the total net present value costs over a ten year period will be approximately £390,000.

4. As a result it is anticipated that there will be a cost to businesses and the public sector. Other than where the use of ionising radiation may be involved there is no impact on charities, social economy enterprises or voluntary bodies.

5. Health benefits as a result of the reduction in the dose limit for the eye and the graded approach are anticipated but cannot be fully quantified.

Conclusion

6. There is no alternative to the introduction of revised Regulations in order to meet the requirements of the BSSD as failure to do so would risk the UK being subject to infraction proceedings.

7. The Department for the Economy is satisfied that this represents a fair and reasonable view of the expected impact in Northern Ireland.