Health and Safety Executive for Northern Ireland

Proposals for the Ionising Radiations Regulations (Northern Ireland) 2017

Consultative Document

August 2017

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Contents

This Consultative Document is based on the Consultative Document "Consultation on the implementation of Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation – Occupational health and safety" issued by the Health and Safety Executive in Great Britain (HSE), whose assistance is gratefully acknowledged.

If you are reading this document on a computer screen and would prefer a printed version, it can be obtained on request. Furthermore, if you require a more accessible format an Executive Summary is available in Braille, large print, on disc or audiocassette, or in Irish, Ulster Scots and other languages of the minority ethnic communities in Northern Ireland. To obtain a summary in one of these formats, please contact David Beck at the address shown at paragraph 34.

Introduction

1. This consultation relates to implementation, in Northern Ireland, of Directive 2013/59/EURATOM laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation. In order to transpose the requirements of the directive which relate to occupational health and safety the Health and Safety Executive for Northern Ireland (HSENI) is proposing to revoke and replace the Ionising Radiations Regulations (Northern Ireland) 2000 (IRR 2000).

2. Other Government departments are, in parallel, progressing work to implement the parts of the Directive for which they have policy responsibility, and will prepare separate consultations covering the changes they propose implementing. It is also anticipated that HSENI will conduct a consultation on proposed changes to the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPIR 2001) in due course.

3. This Consultation Document seeks your:

- views on the proposed transposition approach;
- feedback on the new regulations, supporting ACOP and draft guidance; and
- views on the initial assessment of the costs and benefits of the proposed changes.

Background

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

5. 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

6. 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.

7. Directive 2013/59/Euratom was adopted on 5 December 2013. The Department for Business, Energy and Industrial Strategy (BEIS – formerly the Department of Energy and Climate Change (DECC)) has overall UK government responsibility for implementing the revision of the Basic Safety Standards Directive (BSSD) as it is known, which must be transposed and implemented (its requirements brought into law) across all Member States by 6th February 2018.

8. 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 BSSD to defence facilities. 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.

9. Further information on the Directive can be found on HSE's website: http://www.hse.gov.uk/aboutus/europe/euronews/dossiers/radiationprotect.htm

10. On 23 June, 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 the impact assessment have been chosen accordingly.

The Basic Safety Standards Directive (BSSD)

11. The BSSD lays down minimum requirements for protection against the dangers arising from exposure to ionising radiation. The new Basic Safety Standards Directive consolidates and updates existing Euratom provisions for protection against the harmful effects of ionising radiation by replacing five existing Directives and a Commission Recommendation. It covers occupational, medical and public exposure. 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. HSENI is transposing those elements that relate to occupational exposure in Northern Ireland.

Overall the Directive aims to ensure that:

- minimum standards for ionising radiation are introduced across all Member States;
- dutyholders minimise the risks from ionising radiation to which workers, the public and others may be exposed; and
- risks from ionising radiation are controlled.

What is ionising radiation?

12. 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. 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 effects, so exposure must be managed.

13. 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 lead to radiation exposure. 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. There is no "safe" level of exposure to ionising radiation and high doses, such as those expected in an uncontrolled exposure, can kill within a short period of time.

Current legislative provisions for exposure to ionising radiation in NI

14. The Management of Health and Safety Regulations (Northern Ireland) 2000 covers the general duties which employers have towards employees and members of the public, and employees have to themselves and to each other. Additionally two existing sets of regulations cover the requirements regarding exposures to ionising radiation at work, and protection of the public through emergency preparedness for radiation emergencies.

The Ionising Radiations Regulations (Northern Ireland) 2000

15. IRR 2000 sets out a framework to ensure that occupational exposures to ionising radiation are kept as low as is reasonably practicable. The key measures set out in IRR 2000 to reduce exposure are:

- carrying out of a prior risk assessment to consider potential doses;
- the setting of dose limits for those working with radiation – these are legal limits to ensure that exposure is controlled;
- taking steps to restrict exposure via use of the hierarchy of control[1], and use of administrative arrangements;
- 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; and
- ensuring that employers who work with ionising radiation engage the services of a Radiation Protection Adviser (RPA) to provide specialist advice on compliance with IRR 2000.

[1] 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 see, hierarchy of control.

16. These regulations are supported by an HSE Approved Code of Practice (ACOP) 'Working with Ionising Radiation' which is approved for use in Northern Ireland and also HSE guidance.[2]

Transposition approach

17. During the policy development process, a number of regulatory approaches were considered and analysed. However alternatives to legislation cannot be considered as they would not fulfil our obligations under EU law. Our preferred option is to update existing legislation, incorporating new provisions where necessary. The requirements will be implemented by revoking and replacing IRR 2000. Where possible we will use copy out, unless doing so decreases clarity in a way that has an adverse impact on health and safety and could result in unnecessary burdens on business.

18. This preferred transposition approach takes account of the Government's policy on transposing Directives and its commitment to regulating only where necessary. In order to minimise costs to stakeholders or to ensure we do not lessen existing levels of radiological protection, or to reduce burdens on business, we have gone further than the minimum requirements of the Directive in some areas. In addition, as part of our implementation of the 'Graded Approach' we have extended the scope of licensing so that practices that pose the same risks are subject to the same regulatory controls, as well as requiring renewal of registrations and licenses to ensure that we have up to date information on which to base our interventions. This overall approach aligns the transposition of the Directive with current domestic regulation and health and safety policy, avoiding any overlap or contradiction. It also implements the Directive in a way that is proportionate to the risks and takes into account existing controls and therefore minimises the impact on businesses.

19. Along with structured information sessions by HSE there has been informal discussion, on some of the changes, between HSENI and the health trusts which are the main stakeholders in Northern Ireland As part of the development of this proposal, unnecessary or additional changes for industry and stakeholders have been minimised to ensure protection of workers.

20. HSENI's consultation is based on the following three options:

Option 1: Do minimum – Update the Ionising Radiations Regulations (Northern Ireland) 2000

Option 1 is presented as the 'do minimum' option, which demonstrates the costs and benefits of implementing the Directive in a way that does not introduce new requirements which go beyond the scope of the Directive. In this option, HSENI would implement the Directive by updating ('revoke and replace') IRR 2000.

Option 2: As per Option 1 but with a requirement for the renewal of licences and registrations under the 'Graded Approach'

Option 2 implements the Directive in the way described for Option 1 but contains an additional requirement for licences and registrations under the 'Graded Approach' to

[2] This can be found in HSE publication "L121 working with ionising radiations".

be renewed periodically. This goes beyond the scope of the Directive and results in additional costs to business. However, this is necessary to provide up-to-date information on dutyholders and ensure the effective operation of the Graded Approach system.

Option 3: As per Option 2 but with an extension to licencing requirements to cover certain high-risk practices to ensure consistency in the regulatory approach.

Option 3 contains all of the same provisions as Option 2 but extends the requirements for licencing under the 'Graded Approach' to cover certain high-risk practices, which would need to register under Option 2. While licensing is a more stringent requirement than registration, extending licences in this way may reduce costs to business compared with Option 2 (which does not extend licences).

Further details of the impact of this change can be found in the 'Consultation Impact Assessment' (Annex 3 Section 6)

Why are new regulations needed?

21. New regulations are needed because some of the requirements of the Directive go further than our existing legislation. A draft of 'The Ionising Radiation Regulations (Northern Ireland) 2017' is at Annex 1. Please note the draft regulations will be subject to legal checks and further consideration following the consultation which may require amendments to be made.

What will the new regulations mean for stakeholders?

22. Many of the requirements of the BSSD are already part of the UK's health and safety regime and are covered by existing legislation and practices, including IRR 2000, REPPIR 2001 and the Management of Health and Safety Regulations (Northern Ireland) 2000. Where possible the UK was successful in keeping the changes to the existing regulatory framework to a minimum.

Changes to the Ionising Radiation Regulations (Northern Ireland) 2000

23. Dose Limit for exposure to the lens of the eye and implementation of the Directive.

24. One of the changes to be introduced relates to one of the dose limits for radiation exposure to the lens of the eye, with a reduction of equivalent dose from 150 mSv to 20 mSv in a year.

25. IRR 2000 currently requires that exposure to ionising radiation is calculated and assessed on a calendar year basis, so if this new dose limit is introduced in February 2018, the transposition deadline, it would mean two dose limits would apply in one calendar year. This will cause confusion, requiring individual dose limits to be re-calculated for the remainder of the year which, if done incorrectly, could have health and safety implications for workers. It will also introduce additional costs for businesses. We therefore propose to transpose the BSSD on 1st January 2018 five weeks before the transposition deadline, and because of the links within IRR we propose implementing the entire amended regulatory package on this date.

Further details of the impact of this change can be found in the 'Consultation Impact Assessment' (Annex 3 paras 20 – 21).

26. Graded Approach

Another change that is likely to result in additional costs for stakeholders is the introduction of a new three tiered risk-based system of regulatory control called the 'Graded Approach'. The BSSD refers to these levels as notification, registration, and licensing and the higher the radiation protection risk associated with the work, the greater the requirements. It requires the Competent Authority (HSENI) to have in place a positive system of authorisation whereby they grant permission to dutyholders for higher risk activities through registration and licensing. We are investigating implementation options for the 'Graded Approach', and it is our intention to develop an on-line system that is proportionate, cost effective and as far as possible minimises the impact on both dutyholders.

27. To ensure that we have sufficient information to inform our inspection regime we propose periodically renewing licenses and registrations. We also propose extending licensing requirements to a small number of further practices where the risks are considered to be the same, if not higher, than those the Directive requires to be licensed. This will ensure a consistent regulatory approach to higher radiation risk industries.

28. HSENI is proposing to use the licencing information requirements specified by the Directive to remove the current administrative procedure of requiring notification to HSENI seven days in advance of any site radiography. Restrictions could be placed on site radiography practices within specific conditions in any licence documentation issued, thus enabling the removal of the existing requirement to notify HSENI seven days in advance of every instance of site radiography. Further details of the impact of this change can be found in the Consultation Impact Assessment' (Annex 3 paras 190 – 211 and 225 – 226).

29. The other new key requirements that stakeholders will have to consider are:

- **Weighting factors**: Introduction of new weighting factors for dosimetry. HSENI will adopt the new radiation and tissue weighting factors. Guidance on methodology will be provided.
- **Record retention:** Change from 50 years to not less than 30 years retention after the last day of work. HSENI propose to accept the BSSD approach.
- **Notification and recording of significant events**: HSENI have interpreted 'significant event' as an event which results in an accident. Currently, IRR 2000 does not require the recording and analysis of an accident and so HSENI propose to link this to the IRR 2000 requirement for contingency plans.
- **Outside workers**: the definition of outside workers in the regulations to be amended to include all those who work with radiation to ensure outside workers are afforded the same protection as those workers employed by the employer responsible for the work.

- **Public dose estimation**: Procedures are required that estimate the dose to members of the public. Although environmental regulations cover most practices, IRR 2000 will be amended to cover those that do not. Guidance on methodology will be provided.
- **Appointed doctor:** HSENI intend to remove the requirement for a registered medical practitioner to be appointed 'in writing' for the purposes of these Regulations.
- **Authorisation of the whole body dose limit in special cases:** HSENI will authorise the application of an effective dose limit of 100 mSv over five years (with no more than 50 mSv in a single year) rather than dutyholders only giving prior notification.
- **Dosimetry services:** The BSSD requires the recognition of the ability of dosimetry services to perform certain dosimetry functions by the competent authority. HSENI is to adopt the BSSD terminology of "recognition" in place of "approval" as part of revising the current dosimetry service regime. The timing of this change will draw industry and wider stakeholder attention to the differences between old procedures and the new one.
- **Authorisation of 5 year averaging for dose limit to lens of the eye:** Dutyholders can make use of this flexibility but this will be subject to conditions specified by HSENI.
- **Radon:** IRR 2000 expresses the radon reference level over a 24 hour period, while the BSSD expressed the reference level on an annual basis. Calculations show the current IRR 2000 requirement is equivalent to the annual average in BSSD. HSENI will therefore adopt the value in the BSSD.

Specific details of the potential impacts of these changes can be found in the Consultation Impact Assessment (Annex 3).

<u>Proposed additional policy changes to IRR 2000 that are beyond the scope of the Directive.</u>

30. The following proposals have not been assessed during the stakeholder engagement process to develop the GB impact assessment. They have been identified as possible changes during policy development and review of the GB equivalent Regulations to IRR 2000.

- **Removal of Subsidiary Dose Limit for the Abdomen of a Woman of Reproductive Capacity** – HSENI propose removal of the subsidiary dose limit for the abdomen of a woman of reproductive capacity. The 13 mSv limit is not part of BSSD and evidence indicates the limit is rarely used. In addition to the 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 thought sufficient to protect an unborn child.
- **Equipment used for medical exposure (Reg 32) and comforters and carers:** Department of Health (DoH) is planning to implement all of the

requirements of the BSSD's Medical Exposures Chapter. This could mean that clinical aspects of Regulation 32 (of IRR), and regulation of exposure to comforters and carers will be moved to new DoH regulations.

- **Appeals process**: Medical appeals by an employee currently made to HSENI within three months of the employee being notified of the Appointed Doctor's decision. HSENI propose introducing a time limit of 28 days for consistency with other regulations.
- **Naturally Occurring Radioactive Material (NORM) – application of dose limits**: BSSD states specifically that dose limits shall apply to all authorised (registered and licensed) practices, but only requires that work with NORM is notified and so not subject to dose limits. Currently, dose limits apply to all work with radiation, including work with NORM, and so disapplying the dose limits is lessening radiological protection. HSENI therefore propose to keep the current requirements even though they go beyond the requirements of the BSSD.
- **Radon notification prior to remediation**: BSSD requires notification for workplaces that exceed the national radon reference level (annual average not higher that 300 Bq m^{-3}) only after remediation action has failed to reduce the level of radon below this reference level. Current requirements are that HSENI has to be notified if radon is detected above the reference level. Adopting the BSSD requirements could lessen radiological protection so HSENI propose that notification of radon levels above the reference level is required regardless of remediation activity.

Proposed changes to HSE Approved code of practice supporting Ionising Radiation Regulations 1999

IRR 1999 Para and regulation No	Current ACOP text	**Change in ACOP text**
11 Reg 2(1)	In the special case of substances containing naturally occurring radionuclides used in work other than a practice, their activity cannot be disregarded for the purposes of radiation protection where their use is likely to lead to employees or other people receiving an effective dose of ionising radiations in excess of 1 millisievert in a year.	**Possible Addition.** The identified industries using NORM listed in BSSD may be considered as a new schedule in IRR. This list is not exhaustive so further

		numerical quantification of NORM to help industry is required.
45 Reg 7	This prior risk assessment should enable the employer to determine: **(a)** what action is needed to ensure that the radiation exposure of all persons is kept as low as reasonably practicable (regulation 8(1)) **(b)** what steps are necessary to achieve this control of exposure by the use of engineering controls, design features, safety devices and warning devices (regulation 8(2)(a)) and, in addition, by the development of systems of work (regulation 8(2)(b)); **(c)** whether it is appropriate to provide personal protective equipment and if so what type would be adequate and suitable (regulation 8(2)(c)); **(d)** whether it is appropriate to establish any dose constraints for planning or design purposes, and if so what values should be used (regulation 8(3)); **(e)** the need to alter the working conditions of any female employee who declares she is pregnant or is breastfeeding (regulation 8(5)); **(f)** an appropriate investigation level to check that exposures are being restricted as far as reasonably practicable (regulation 8(7)); **(g)** what maintenance and testing schedules are required for the control measures selected (regulation 10); **(h)** what contingency plans are necessary to address reasonably foreseeable accidents (regulation 12); **(i)** the training needs of classified and non-classified employees (regulation 14); **(j)** the need to designate specific areas as controlled or supervised areas and to	**Addition** to further clarify the link between prior risk assessment and the requirements for leak testing.

	specify local rules (regulations 16 and 17); **(k)** the actions needed to ensure restriction of access and other specific measures in controlled or supervised areas (regulation 18); **(l)** the need to designate certain employees as classified persons (regulation 20); **(m)** the content of a suitable programme of dose assessment for employees designated as classified persons and for others who enter controlled areas (regulations 18 and 21); **(n)** the responsibilities of managers for ensuring compliance with these Regulations; and **(o)** an appropriate programme of monitoring or auditing of arrangements to check that the requirements of these Regulations are being met.	
59 Reg 8(1)	Dose sharing should not be used as a primary means of keeping exposures below the dose limits. Rather, the radiation employer should give priority to improving engineering controls and adopting other means of restricting exposure, including changing the methods of work. However, if a choice has to be made between restricting doses to individuals and restricting doses to a group of persons, priority should be given to keeping individual doses as far below dose limits as is reasonably practicable.	**Partial deletion** – First sentence to remain as ACOP, the remaining text redrafted and move to guidance.
71 Reg 8(1)	Radioactive materials, including those in the form of sealed sources, should not be held or directly manipulated in the hand (or close to the hand) if it is practicable for the task to be completed by other means, unless the skin of the hand is unlikely to receive a significant dose and the employee is unlikely to become significantly contaminated with radioactive substances.	**Delete –** move to guidance
79 Reg 8(2)	Where reasonably practicable, work involving exposure to external radiation must be done in a room, enclosure, cabinet or purpose-made structure which is provided with adequate	**Paragraph redrafted** to focus on key information.

	shielding. In other cases, adequate local shielding should be used as far as reasonably practicable. Shielding, including beam collimation, will normally be adequate if designed to reduce dose rates below 7.5 microsieverts per hour in specific locations where persons will be working. If the device is designed for use in public areas or where there is continuous access to the working area by employees or other persons not directly involved in the work, the shielding should be designed to reduce dose rates to the lowest level that is reasonably practicable. In this case, the dose rate should be so low that it is unnecessary to designate the area around the device as a supervised area.	Radiation store included in 2nd paragraph to make it clear that radiation stores must not present a risk.
81 Reg 8(2)	Fluoroscopic devices should be provided with viewing facilities which do not permit direct vision of the fluoroscopy screen.	**Potential deletion** HSE is checking with stakeholders over the validity of this paragraph in current operations.
83 Reg 8(2)	Radiation employers should give priority to the containment of radioactive substances as a means of preventing dispersal or contamination. Where such containment alone is not sufficient to give the required protection, ventilation should be provided. A building, room or enclosure being built or modified for work with unsealed radioactive material should incorporate design features which take into account the risk of contamination likely to arise from the work. In particular, radiation employers should take steps to ensure ease of cleaning and decontamination of worktops, floors, etc. There should also be provision for safe decommissioning or dismantling of equipment which may have become internally contaminated.	**Partial deletion** – keep first 2 sentences as ACOP, rest move to guidance
87 Reg 8(2)	Where control systems permit, interlocks or trapped key systems should be provided and properly used where they can prevent access to high dose rate enclosures (for example in which employed persons could receive an	**Minor amendment** to clarify content as to what a high-

	effective dose greater than 20 millisieverts or an equivalent dose in excess of a dose limit within several minutes when radiation emission is under way). They should be fitted so that the control system will ensure an exposure: (a) cannot commence while the access door, access hatch, cover or appropriate barrier to the enclosure is open; (b) is interrupted if the access door, access hatch, cover or barrier is opened; and (c) does not recommence on the mere act of closing a door, access hatch, cover or barrier.	dose rate is
111 Reg 8(2)	The radiation employer should require a check to be made with a suitable radiation monitoring instrument after each exposure using high dose rate sealed source equipment (such as that generally used for industrial radiography or processing of products) unless reliance can be placed on effective devices to ensure that the equipment has been restored to a safe state. The purpose is to establish that the sealed source has fully retracted to its shielded position and that the area is safe to enter.	Addition to paragraph to make it clear that employees carrying out this work must wear a dosemeter with an audible warning on entry to a high dose area.
114 Reg 8(2)	The term 'adequate' in regulation 8(2)(c) refers to the ability of the equipment to protect the wearer. The term 'suitable' refers to the correct matching of the equipment to the job and the person. To be considered 'adequate and suitable' personal protective equipment should be correctly selected and used.	**Delete** – Redraft and link to existing HSE guidance on PPE.
126 Reg 8(3)	It should always be appropriate to use dose constraints in restricting exposure for carers and comforters. Department of Health (DoH) are planning to implement all of the requirements of the BSSD's Chapter VII that pertain to medical exposure as defined within Article 4 ie exposure incurred by patients and asymptomatic individuals as part of their diagnosis or treatment, carers and comforters and research volunteers. It is anticipated that aspects relating to these exposures, currently included in Regulation 32 (of IRR), and	**To be decided:** Article 6.1 of BSSD requires dose constraints to be established for carers and comforters.

	regulation of exposure to comforters and carers may be moved to new DoH regulations. Regulation of aspects relating to occupational and public exposure resulting from medical practices will be retained by HSENI.	
165 Reg 10(1)	All active engineering controls and design features (eg local exhaust ventilation systems), safety features (eg electromechanical interlocks) and warning devices should be subjected to a regime of examination and test at suitable intervals.	**Delete** – repeats Reg 10(1)(b)
181 Reg 11(1)	Assessments of effective dose and equivalent dose from external radiation for the purpose of comparison with the dose limits specified in Schedule 4 of the Regulations should be made using the values and relationships in Annex II of Council Directive 96/29/Euratom[3].	**Paragraph retained** reference to Directive updated
183 Reg 11(1)	For the assessment of compliance with the dose limits relating to members of the public, realistic estimates should be made of the average effective dose (and where relevant equivalent dose) to representative members of the appropriate reference group for the expected pathways of exposure.	**Delete** – move text to regulations
216 Reg 13(1)-(3)	To be suitable, a radiation protection adviser will need to possess the specific knowledge, experience and competence required for giving advice on the particular working conditions or circumstances for which the employer is making the appointment.	**Delete** – redraft text into guidance
232 Reg 13(4)	Radiation employers who need advice in relation to plans for off- site emergencies should provide, or may arrange to share, a specialised radiation protection unit. Such units should be distinct from production and operational units and authorised to perform radiation protection tasks.	**Delete –** as IRR and REPPIR not developed in parallel this not required in IRR
248 Reg 16(1)	Special procedures should always be necessary to restrict the possibility of significant exposure, and therefore employers should designate controlled areas, in cases where:	**Paragraph retained** and expanded to include ACOP 249 (b)

	(a) the external dose rate in the area exceeds 7.5 microsieverts per hour when averaged over the working day; **(b)** the hands of an employee can enter an area and the 8-hour time average dose rate in that area exceeds 75 microsieverts per hour; **(c)** there is a significant risk of spreading radioactive contamination outside the working area; **(d)** it is necessary to prevent, or closely supervise, access to the area by employees who are unconnected with the work with ionising radiation while that work is under way; or **(e)** employees are liable to work in the area for a period sufficient to receive an effective dose in excess of 6 millisieverts a year.	
249 Reg 16(1)	In addition, an area should be designated as a controlled area if the dose rate (averaged over a minute) exceeds 7.5 microsieverts per hour and: (a) the work being undertaken is site radiography; or (b) employees untrained in radiation protection are likely to enter that area, unless the only work with ionising radiation involves a radioactive substance dispersed in a human body and none of the conditions in the previous paragraph apply. In this context, site radiography means any radiography of inanimate objects other than that which is carried out in an enclosure or cabinet that restricts the dose rate (averaged over a minute) outside the enclosure to 7.5 microsieverts per hour.	**Deletion.** Bullet (b) to be combined with paragraph 248.
272 Reg 17(1)	Written local rules must identify the key working instructions intended to restrict any exposure in that controlled or supervised area. The details given in these rules should be appropriate to the nature and degree of the risk	**Deletion** – the first sentence is moved to regulation in

	of exposure to ionising radiations. The rules must cover work in normal circumstances and also the particular steps to be taken to control exposure in the event of a radiation accident, as set out in the contingency plan required by regulation 12. Local rules for a controlled area should include a summary of the arrangements for restricting access into that area, including the written arrangements covering those who are not classified persons.	line with the Directive). The rest of the paragraph either replicates the regulation or is only appropriate for guidance.
339 Reg 19(1)	For areas designated on the basis of external radiation, adequate monitoring must include measurement of dose rates (averaged over a suitable period if necessary). For areas designated on the basis of internal radiation, adequate monitoring should include measurements of air activity and surface contamination where appropriate, taking into account the physical and chemical states of the radioactive contamination. In either case, the monitoring must be sufficient to indicate whether levels of radiation and contamination are satisfactory for continuing work with ionising radiation.	**Delete** – final sentence to go into guidance, remainder into regulations
341 Reg 19(1)	Employers carrying out the monitoring should be familiar with the proper use of the instruments and know how to interpret and record the results correctly.	**Delete** – move to guidance
347 Reg 19(2)	Monitoring instruments used for measuring external radiation should be suitable for the nature and quality of the radiation concerned. Instrumentation used for measurements of air activity and surface contamination should be suitable for the physical and chemical state of the radioactive materials present.	**Delete –** sufficiently covered moving para 339 into regulation and guidance
348 Reg 19(2)	Monitoring equipment should normally be tested and thoroughly examined at least once every year.	Retain: Add text to link this to Regulation 7 (prior risk assessment)
355 Reg 19(3)	All instruments should be individually calibrated before first use and as part of the annual examination and test.	**Delete –** move to guidance

356 Reg 19(3)	Qualified persons should possess the necessary expertise in instrumentation, theory and practice appropriate to the type of instrument to be tested.	**Delete** – move to guidance
362 Reg 19(4)	Suitable monitoring records should include the date, time and place of monitoring and confirm that controlled and supervised areas are correctly designated and show where levels are being approached which may require investigatory or remedial action to be taken. For areas designated on the basis of external radiation there should be an indication of the nature and quality of the radiation in question. For areas designated on the basis of internal radiation the results should indicate the nature and physical and chemical states of radioactive contamination unless this is inappropriate.	**Delete** – Move first sentence to guidance. The text from the second sentence onwards will be moved into regulation 19(1) via copy out from the Directive.
409 Reg 21(5)	Entries in passbooks should only be made by people who have been authorised by the approved dosimetry services or the appropriate employer to make such entries. Suitable arrangement should include written instructions, specifying who does what and when, unless this would clearly be inappropriate in the circumstances.	**Partial deletion** – keep first sentence as ACOP, rewrite second sentence as guidance
415 Reg 22(1)-(2)	The employer's investigation should take account of the following where relevant: **(a)** details of the pattern of work of the individual such as the time spent in particular controlled and supervised areas; **(b)** measurements from any additional dosemeter or direct reading device worn by the person concerned; **(c)** individual measurements made on other employees carrying out the same work with ionising radiations; and **(d)** the results of monitoring for controlled and supervised areas carried out in accordance with regulation 19.	**Delete –** Move to guidance
420	An estimate of the dose received should be	**Retained**

Reg 23(3)-(8)	regarded as much greater than or much less than the original entry in the dose record for a particular period if: **(a)** the dose received differs from the original entry in the dose record by at least 1 millisievert for recorded doses of 1 millisievert or less; or **(b)** the dose received differs from the original entry in the dose record by a factor of 2 or more for recorded doses in excess of 1 millisievert but less than the relevant dose limit; or **(c)** the dose received differs from the original entry in the dose record by a factor of 1.5 or more for recorded doses above the relevant dose limit.	**and redrafted** to clarify requirement
421 Reg 23(3)-(8)	The employer's investigation into the circumstances of the exposure should take account of: **(a)** relevant information provided by the approved dosimetry service; **(b)** details of the pattern of work of the individual such as the time spent in particular controlled and supervised areas; **(c)** measurements from any additional dosemeter or direct reading device worn by the person concerned; **(d)** individual measurements made on other employees carrying out the same work with ionising radiations; and **(e)** the results of monitoring for controlled and supervised areas carried out in accordance with regulation 19.	**Full deletion**, information moved to guidance
422 Reg 23(3)-(8)	The information used to estimate the dose received will be adequate if it: (a) shows that there is reasonable cause to believe that the dose received by the classified person was much greater than or much less than the dose recorded in the dose record; and	**Full deletion**, moved to guidance.

	(b) includes sufficient information to permit a reliable reconstruction of the exposure conditions for the person during the relevant dose assessment period. The investigation report should at least include the information in (a) and (b).	
446 Reg 24(2)	Adequate medical surveillance should include: **(a)** a medical examination before first being designated as a classified person in a post involving work with ionising radiations; **(b)** periodic reviews of health at least once every year; **(c)** special medical surveillance of an employee when a relevant dose limit has been exceeded; **(d)** determining whether specific conditions are necessary; and **(e)** a review of health after cessation of work where this is necessary to safeguard the health of the individual.	**Delete** – moved to regulations to comply with Directive
447 Reg 24(2)	The nature of the medical surveillance for each individual should take account of the nature of the work with ionising radiation and that individual's state of health.	**Delete** – moved to regulations.
448 Reg 24(2)	Medical surveillance carried out following an investigation under regulation 25 should include a special medical examination of the individual if that person has received an effective dose of ionising radiation in excess of 100 millisieverts in a year or an equivalent dose of at least twice any relevant annual dose limit.	**Full deletion** Not required due to the previous ACOP paragraph 446 being moved to regulation.
466 Reg 24(7)-	The records made available to the appointed doctor or employment medical adviser before	**Delete** – move to

(8)	the periodic review of health is carried out should always include any relevant records of sickness absence for the person as well as the health record and copies of the summaries of the dose record provided by the approved dosimetry service and retained in accordance with regulation 21 (7).	guidance
483 Reg 27(3)	The purpose of a leak test is to show that the mechanisms for preventing dispersal of radioactive substances are functioning as intended. The assessment required by regulation 7 should identify potential ways in which containment could be lost and their likelihood of occurring. A test method and a frequency of testing should then be chosen that is capable of detecting leakage of radioactivity from the source or article before a radiation risk arises. Where testing is appropriate under normal operating conditions, the interval between tests should not exceed two years.	**Partial removal** – final sentence remains ACOP, and second sentence captured in ACOP 45 - rest redrafted into guidance
493 Reg 28	The procedures for accounting should ensure that the location of radioactive substances is known and, as a consequence, losses of significant quantities can quickly be identified. A frequency for checking the location of the source should be determined, taking account of the likely movement of the source, its potential for being displaced and its susceptibility to damage. For portable sources, such as radiography sources and portable gauges, the check should be at least on each working day.	**Retain** – addition of "theft" into the accounting requirements based on specialist knowledge.
494 Reg 28	Other examples of intervals at which the location of a source should be updated are: **(a)** for static sources securely attached to machines the interval between checks may be up to one month, providing that additional checks are carried out following any maintenance or repair which could have affected the source; and **(b)** for sources located within patients, the interval between checks should be compatible with the clinical treatment of that patient.	**Delete** – move to guidance

522 Reg 31(2)	It is appropriate to carry out a critical examination if there may be radiation protection implications arising from the way in which an article is being or has been erected or installed.	**Delete** – move to regulations
523 Reg 31(2)	Matters on which the radiation protection adviser should be consulted include the plans for installing the equipment, the nature and extent of any tests undertaken as part of the critical examination and the acceptability of any test results.	**Delete** – explain in guidance (link to regulation13)
538 Reg 32(3)-(4)	A suitable quality assurance programme establishes those planned and systematic actions necessary to provide adequate confidence that equipment will satisfy the requirements of regulation *32(1*). The extent of the programme will depend on the nature and range of equipment in use. In drawing up a quality assurance programme make it clear: • who has responsibility for organising the various elements, • who will carry out testing or dose assessment and • who has responsibility for acting on any adverse findings. <u>Department of Health (DoH)</u> are planning to implement all of the requirements of the BSSD's Chapter VII that pertain to medical exposure as defined within Article 4 ie exposure incurred by patients and asymptomatic individuals as part of their diagnosis or treatment, carers and comforters and research volunteers. It is anticipated that aspects relating to these exposures, currently included in Regulation 32 (of IRR), and regulation of exposure to comforters and carers may be moved to new DoH regulations. Regulation of aspects relating to occupational and public exposure resulting from medical practices will be retained by HSENI.	**Amend regulation –** dependent on outcome of DH proposal
539 Reg 32(3)-(4)	The programme should specify the frequency of any testing (and other measurements) and appropriate action levels for equipment or apparatus which is subject to periodic testing. If these levels are found to have been exceeded the employer should assess what	**Amend regulation –** dependent on outcome of DH proposal

	remedial action is needed, including removal from service where necessary, taking into account the risk arising from its continued use for specified purposes. In establishing these levels, the employer should take into account guidance established by relevant professional bodies about criteria of acceptability for such equipment. <u>Department of Health (DoH)</u> are planning to implement all of the requirements of the BSSD's Chapter VII that pertain to medical exposure as defined within Article 4 ie exposure incurred by patients and asymptomatic individuals as part of their diagnosis or treatment, carers and comforters and research volunteers. It is anticipated that aspects relating to these exposures, currently included in Regulation 32 (of IRR), and regulation of exposure to comforters and carers may be moved to new DoH regulations. Regulation of aspects relating to occupational and public exposure resulting from medical practices will be retained by HSENI.	
540 Reg 32(3)-(4)	In devising a suitable quality assurance programme for equipment, employers should give special attention to equipment used for medical exposure: • of children; • as part of a health screening programme; • involving high doses to the patient such as interventional radiology, computed tomography or radiotherapy. <u>Department of Health (DoH)</u> are planning to implement all of the requirements of the BSSD's Chapter VII that pertain to medical exposure as defined within Article 4 ie exposure incurred by patients and asymptomatic individuals as part of their diagnosis or treatment, carers and comforters and research volunteers. It is anticipated that aspects relating to these exposures, currently included in Regulation 32 (of IRR), and regulation of exposure to comforters and carers may be moved to new DoH regulations. Regulation of aspects relating to occupational and public exposure resulting from medical practices will be retained by HSENI.	**Amend regulation –** dependent on outcome of DH proposal

COSTS AND BENEFITS

31. The GB Impact Assessment has been prepared detailing the costs associated with implementing the new occupational health and safety requirements of the Directive. Cost details have been provided by the various industries and sectors with whom HSE has engaged. The proposed approach will maintain existing health and safety protections and increase standards in some instances. HSENI is of the opinion that the analysis and considerations (except for the fees which HSENI do not propose charging and which are not included in the calculations) as set out in the GB Impact Assessment can be applied to Northern Ireland on a proportionate basis. HSENI estimates that the total net present value costs over a ten year period will be around £241,750 of which approximately £87,500 will be attributable to business with the remainder falling to the public sector.

EQUALITY IMPACT

32 The proposals have been screened for any possible impact on equality of opportunity affecting the groups listed in section 75 of the Northern Ireland Act 1998 and no adverse or, or, with the exception of age, differential impacts were identified 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.

33. . A copy of the screening document is at Annex 4.

INVITATION TO COMMENT

34 HSENI would welcome your comments on the proposals in this CD. Comments are particularly welcome on the assumptions relating to costs and benefits relevant to Northern Ireland, and the conclusion that the proposals would have no adverse effect on any section 75 groups.

35. Comments, in whatever format you choose to use, should be sent to: -

Mr David Beck
Health and Safety Executive for Northern Ireland
83 Ladas Drive
Belfast BT6 9FR
Tel: 028 9054 6871; Fax: 028 9054 5383;
Textphone: 028 9054 6896
E-mail: IRRConsultation@hseni.gov.uk

*so as to arrive no*t later than **noon on 05 October 2017.**

36 HSENI tries to make its consultation procedures as thorough and open as possible. Responses to this consultation will be kept at the office of HSENI at the above address after the close of this consultation period, where they can be inspected by members of the public or be copied to them. HSENI can only refuse to disclose information in exceptional circumstances. Before you submit your response, please read the paragraphs below on the confidentiality given by you in response to this consultation.

37 The Environmental Information Regulations 2004 and the Freedom of Information Act 2000 give the public rights of access to information held by a public authority, namely, HSENI in this case. These rights of access to information include information provided in response to a consultation. HSENI cannot automatically consider as confidential information supplied to it in response to a consultation. However, it does have the responsibility to decide whether any information provided by you in response to this consultation, including information about your identity, should be made public or be treated as confidential.

38 This means that information provided by you in response to the consultation is unlikely to be treated as confidential, except in very particular circumstances.

STATUTORY RULES OF NORTHERN IRELAND

2018 No. 000

HEALTH AND SAFETY

Ionising Radiations Regulations (Northern Ireland) 2018

Made - - - -	***
Coming into operation -	***

The Department for the Economy([a]), being the Department concerned([b]), makes the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972 ("the 1972 Act")([c]), and Articles 2(5), 17(1), (2), (3), (4), (5) and (6), 40(2) and (4), 54(1) and 55(2) of, and paragraphs 1(1) and (2), 2, 5, 6, 7, 8, 9, 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 ("the 1978 Order")([d]).

The Department was designated for the purposes of section 2(2) of the 1972 act in relation to measures relating to the basic safety standards for the protection of the general public and workers against the dangers of ionising radiation.

Apart from the modifications referred to in the next paragraph, the Regulations give effect without modifications to proposals submitted to the Department by the Health and Safety Executive for Northern Ireland under Article 13(1A)([e]) of the 1978 Order after the Executive had carried out consultations in accordance with Article 46(3)([f]).

It appears to the Department that—

([a]) Formerly the Department of Enterprise, Trade and Investment; *see* 2016 c.5, section 1(3); that Department was formerly the Department of Economic Development; *see* S.I. 1999/283 (N.I. 1), Article 3(5); that Department was formerly the Department of Manpower Services, *see* S.I. 1982/846 (N.I. 11), Article 3

([b]) *See* Article 2(2) of S.I. 1978/1039 (N.I. 9)

([c]) 1972 c. 68; the enabling powers conferred by section 2(2) were extended by virtue of section 1 of the European Economic Area Act 1993 (c. 51). Section 2(2) was further amended by section 27(1) of the Legislative and Regulatory Reform Act 2006 (c. 51)

([d]) S.I. 1978/1039 (N.I. 9): the general purposes of Part II referred to in Article 17(1) were extended by S.I. 1992/1728 (N.I. 17), Articles 3(1) and 4(1). Article 55(2) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraph 19

([e]) Article 13(1) was substituted by S.I. 1998/2795 (N.I. 18), Article 4

([f]) Article 46(3) was amended by S.I. 1998/2795 (N.I. 18), Article 6(1) and Schedule 1, paragraphs 8 and 18

(a) the amendments to secondary legislation referred to in Schedule 9; and

(b) the revocations in relation to the instruments referred to in regulation 43,

are expedient as set out in Article 54(1) of the 1978 Order.

PART 1

PRELIMINARY

Citation and commencement

1. These Regulations may be cited as the Ionising Radiations Regulations (Northern Ireland) 2018 and shall come into operation on xx xxxx 2018.

Interpretation

2.—(1) In these Regulations—

"the 1978 Order" means the Health and Safety at Work (Northern Ireland) Order 1978;

"accelerator" means an apparatus or installation in which particles are accelerated and which emits ionising radiation with an energy higher than 1MeV;

"appointed doctor" means a registered medical practitioner who meets recognition criteria as may from time to time be specified in writing by the Executive;

"approved" means approved for the time being in writing for the purposes of these Regulations by the Executive and published in such form as the Executive considers appropriate;

"approved dosimetry service" means a dosimetry service approved—

(a) in accordance with regulation 36; or

(b) by the Great Britain Executive under regulation 36 of the Great Britain Regulations;

"calendar year" means a period of 12 calendar months beginning with the 1st January;

"classified outside worker" means a classified person who carries out services in the controlled or supervised areas of any employer (other than the controlled or supervised areas of their own employer);

"classified person" means—

(a) a person designated as such pursuant to regulation 21(1); and

(b) in the case of an outside worker employed by an undertaking in Great Britain or in another member State, a person who has been designated as a Category A exposed worker within the meaning of Article 40 of the Directive;

"comforter and carer" means an individual who (other than as part of their occupation) knowingly and willingly incurs an exposure to ionising radiation resulting from the support and comfort of another person who is undergoing or who has undergone any medical exposure;

"contamination" means the unintended or undesirable presence of radioactive substances on surfaces or within solids, liquids or gases or on the human body and "contaminated" has the related meaning;

"controlled area" means—

(a) in the case of an area situated in Northern Ireland, an area which has been so designated in accordance with regulation 17(1); and

(b) in the case of an area situated in Great Britain or in another member State, an area subject to special rules for the purposes of protection against ionising radiation and to which access is controlled as specified in Article 37 of the Directive;

"the Directive" means Council Directive 2013/59/ Euratom laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom;

"dose" means, in relation to ionising radiation, any dose quantity or sum of dose quantities mentioned in Schedule 3;

"dose assessment" means the dose assessment made and recorded by an approved dosimetry service in accordance with regulation 22;

"dose constraint" means a constraint set on the prospective doses to individuals which may result from a given radiation source;

"dose limit" means, in relation to persons of a specified class, the limit on effective dose or equivalent dose specified in Schedule 3 in relation to a person of that class;

"dose rate" means, in relation to a place, the rate at which a person or part of a person would receive a dose of ionising radiation from external radiation if that person were at that place being a dose rate at that place averaged over one minute;

"dose record" means, in relation to a person, the record of the doses received by that person as a result of that person's exposure to ionising radiation, being the record made and maintained on behalf of the employer by the approved dosimetry service in accordance with regulation 22;

"employment medical adviser" means an employment medical adviser appointed under Article 48 of the 1978 Order;

"the Executive" means the Health and Safety Executive for Northern Ireland;

"external radiation" means, in relation to a person, ionising radiation coming from outside the body of that person;

"the Great Britain Executive" means the Health and Safety Executive established under section 10 of the Health and Safety at Work etc. Act 1974([a]);

"the Great Britain Regulations" means the Ionising Radiations Regulations 2018([b]);

"health record" means, in relation to an employee, the record of medical surveillance of that employee maintained by the employer in accordance with regulation 25(3);

"high-activity sealed source" means a sealed source for which the activity of the radionuclide is equal to or exceeds the relevant activity value set out in Part 5 of Schedule 7;

"industrial irradiation" means the use of ionising radiation to sterilise, process or alter the structure of products and materials;

"industrial radiography" means the use of ionising radiation for non-destructive testing purposes where the image of the item under test is formed;

"internal radiation" means, in relation to a person, ionising radiation coming from inside the body of that person;

"ionising radiation" means the transfer of energy in the form of particles or electromagnetic waves of a wavelength of 100 nanometres or less or a frequency of 3×10^{15} hertz or more capable of producing ions directly or indirectly;

"licensee" has the meaning assigned to it by section 26(1) of the Nuclear Installations Act 1965([c]);

"local rules" means rules made in accordance with regulation 18;

"maintained", where the reference is to maintaining plant, apparatus, equipment or facilities, means maintained in an efficient state, in efficient working order and good repair;

([a]) 1974 c.37
([b]) S.I. 2018/?
([c]) 1965 c.57

"medical exposure" means exposure of a person to ionising radiation for the purpose of that person's medical or dental examination or treatment which is conducted under the direction of a suitably qualified person and includes any such examination for legal purposes and any such examination or treatment conducted for the purposes of research;

"member State" means a member State of the European Union;

"non-classified outside worker" means a person who is not a classified person who carries out services in the supervised or controlled areas of any employer (other than the supervised or controlled areas of his own employer);

"outside worker" means both a classified outside worker and a non-classified outside worker;

"overexposure" means any exposure of a person to ionising radiation to the extent that the dose received by that person causes a dose limit relevant to that person to be exceeded or, in relation to regulation 27(2), causes a proportion of a dose limit relevant to any employee to be exceeded;

"practice" means work involving—

(a) the production, processing, handling, disposal, use, storage, holding or transport of radioactive substances; or

(b) 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 radiation from a radiation source;

"radiation accident" means an accident where immediate action would be required to prevent or reduce the exposure to ionising radiation of employees or any other persons;

"radiation passbook" means—

(a) in the case of an outside worker employed by an employer in Northern Ireland—

(i) a passbook approved by the Executive for the purpose of these Regulations;

(ii) a passbook approved by the Great Britain Executive for the purposes of the Great Britain Regulations; or

(iii) a passbook to which paragraph 15 of Schedule 8 (Transitional Provisions) applies; and

(b) in the case of an outside worker employed by an employer in Great Britain or in another member State, a passbook authorised by the competent authority for Great Britain or that member State, as the case may be;

"radiation protection adviser" means an individual who, or a body which, meets such criteria of competence as may from time to time be specified in writing by—

(a) the Executive; or

(b) the Great Britain Executive;

"radiation source" means an entity that may cause exposure to ionising radiation, such as by emitting ionising radiation or by releasing radioactive substances;

"radioactive source" means a radiation source incorporating a radioactive substance (or substances) for the purpose of utilising the radioactivity of that substance (or substances);

"radioactive substance" means any substance which contains one or more radionuclides whose activity cannot be disregarded for the purposes of radiation protection;

"sealed source" means a source containing any radioactive substance whose structure is such as to prevent, under normal conditions of use, any dispersion of radioactive substances into the environment, but it does not include any radioactive substance inside a nuclear reactor or any nuclear fuel element;

"supervised area" means an area which has been so designated by the employer in accordance with regulation 17(3);

"territorial sea" means the territorial sea of the United Kingdom adjacent to Northern Ireland and "within the territorial sea" includes on, over and under it;

"trainee" means a person aged 16 years or over (including a student) who is undergoing instruction or training which involves operations which would, in the case of an employee, be work with ionising radiation;

"transport" means, in relation to a radioactive substance, carriage of that substance on a road within the meaning of Article 2(2) of the Road Traffic (Northern Ireland) Order 1995([a]) or through another public place (whether on a conveyance or not), or by rail, inland waterway, sea or air and, in the case of transport on a conveyance, a substance is deemed as being transported from the time that it is loaded onto the conveyance for the purpose of transporting it until it is unloaded from that conveyance, but a substance is not to be considered as being transported if—

(a) it is transported by means of a pipeline or similar means; or

(b) it forms an integral part of a conveyance and is used in connection with the operation of that conveyance;

"woman of reproductive capacity" means a woman who is made subject to the additional dose limit for a woman of reproductive capacity specified in paragraphs 5 and 11 of Schedule 3 by an entry in that woman's health record made by an appointed doctor or employment medical adviser;

"work with ionising radiation" means work to which these Regulations apply by virtue of regulation 3(1).

(2) In these Regulations, any reference to—

(a) an employer includes a reference to a self-employed person and any duty imposed by these Regulations on an employer in respect of that employer's employee extends to a self-employed person in respect of themselves;

(b) an employee includes a reference to—

(i) a self-employed person, and

(ii) a trainee who but for the operation of this sub-paragraph and paragraph (3) would not be classed as an employee;

(c) exposure to ionising radiation is a reference to exposure to ionising radiation arising from work with ionising radiation;

(d) a person entering, remaining in or working in a controlled or supervised area includes a reference to any part of a person entering, remaining in or working in any such area.

(3) For the purposes of these Regulations and Part I of the 1978 Order—

(a) the word "work" is extended to include any instruction or training which a person undergoes as a trainee and the meaning of "at work" is extended accordingly; and

(b) a trainee, while undergoing instruction or training in respect of work with ionising radiation, is to be treated as the employee of the person whose undertaking (whether for profit or not) is providing that instruction or training and that person is to be treated as the employer of that trainee except that the duties to the trainee imposed upon the person providing instruction or training will only extend to matters under the control of that person.

(4) In these Regulations, where reference is made to a quantity specified in Schedule 7, that quantity is to be treated as being exceeded if—

(a) where only one radionuclide is involved, the quantity of that radionuclide exceeds the quantity specified in the appropriate entry in Schedule 7; or

(b) where more than one radionuclide is involved, the quantity ratio calculated in accordance with Part III of Schedule 7 exceeds one.

([a]) S.I. 1995/2994 (N.I.18)

(5) Nothing in these Regulations is to be construed as preventing a person from entering or remaining in a controlled area or a supervised area where that person enters or remains in any such area—

(a) in the due exercise of a power of entry conferred on that person by or under any statutory provision; or

(b) for the purpose of undergoing a medical exposure.

(6) In these Regulations—

(a) any reference to an effective dose means the sum of the effective dose to the whole body from external radiation and the committed effective dose from internal radiation; and

(b) any reference to equivalent dose to a human tissue or organ includes the committed equivalent dose to that tissue or organ from internal radiation.

(7) The Interpretation Act (Northern Ireland) 1954([a]) shall apply to these Regulations as it applies to an Act of the Northern Ireland Assembly.

Application

3.—(1) Subject to the provisions of this regulation and to regulation 5(1), these Regulations shall apply to—

(a) any practice;

(b) any work (other than a practice) carried out in an atmosphere containing radon 222 gas at an annual average activity concentration in air exceeding 300 Bq m-3; and

(c) any work (other than work referred to in sub-paragraphs (a) and (b)) with any radioactive substance containing naturally occurring radionuclides.

(2) The following regulations shall not apply where the only work being undertaken is that referred to in paragraph 1(b), namely regulations 24, 28 to 31, 33 and 34.

(3) The following regulations shall not apply in relation to persons undergoing medical exposures, namely regulations 8, 9, 12, 17 to 19, 24, 26, 32(1) and 35(1).

(4) Regulation 11 shall not apply in relation to any comforter and carer.

(5) In the case of a classified outside worker (working in a controlled area situated in Northern Ireland) employed by an employer established in Great Britain or in another member State, it shall be sufficient compliance with regulation 22 (dose assessment and recording) and regulation 25 (medical surveillance) if the employer complies with—

(a) where the employer is established in Great Britain, regulations 21 and 24 of the Great Britain Regulations; or

(b) where the employer is established in another member State, the legislation in that State implementing the relevant parts of Chapter VII of the Directive where such legislation exists.

Duties under the Regulations

4.—(1) Any duty imposed by these Regulations on an employer in respect of the exposure to ionising radiation of persons other than that employer's employees is imposed only in so far as the exposure of those persons to ionising radiation arises from work with ionising radiation undertaken by that employer.

(2) Duties under these Regulations imposed upon the employer shall also be imposed upon any person who is—

(a) the mine operator of a mine (within the meaning of regulation 2 of the Mines Regulations (Northern Ireland) 2016)([b]); and

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([a]) 1954 c.33 (N.I.)
([b]) S.R. 201 No 427

(b) the operator of a quarry (within the meaning of the Quarries Regulations (Northern Ireland) 2006([a])

in so far as those duties relate to the mine or part of the mine of which that person is the mine operator or the quarry of which that person is the operator and to matters within that person's control.

(3) Subject to regulation 5(1)(b), duties under these Regulations imposed upon the employer shall be imposed on the holder of a nuclear site licence under the Nuclear Installations Act 1965 in so far as those duties relate to the licensed site.

PART 2

General Principles and Procedures

Notification of specified work

5.—(1) This regulation applies to work with ionising radiation except—

(a) work specified in Schedule 1;

(b) work carried on at a site licensed under section 1 of the Nuclear Installations Act 1965;

(c) work arising from the carrying out of a registrable practice under regulation 6 or a licensable practice under regulation 7.

(2) Subject to paragraph (7) and to paragraph 9 of Schedule 8 (which relates to transitional provisions), an employer shall not for the first time since the coming into operation of this regulation carry out work with ionising radiation to which this regulation applies unless before commencing that work the employer has notified the Executive of its intention to carry out that work and has provided the Executive with such particulars relating to the work as the Executive may specify from time to time.

(3) Where an employer has notified work in accordance with paragraph (2), the Executive may, by notice in writing require that employer to provide such additional particulars of that work as it may reasonably require, and in such a case the employer shall provide those particulars by such time as is specified in the notice or by such other time as the Executive may subsequently agree.

(4) A notice under paragraph (3) may require the employer to notify the Executive of any of those additional particulars before each occasion on which the employer commences work with ionising radiation.

(5) Where an employer has notified work in accordance with paragraph (2) and subsequently makes a material change in that work which would affect the particulars so notified, the employer shall immediately notify the Executive of that change.

(6) Nothing in paragraph (5) is to be taken as requiring the cessation of the work to be notified in accordance with that paragraph except where the site or any part of the site in which the work was carried on has been or is to be vacated.

(7) Where the only work being undertaken is work referred to in regulation 3(1)(b) or (c), it shall be sufficient compliance with paragraph (2) if the employer having control of the premises where the work is carried on makes the notification required by that paragraph as soon as practicable after the work has commenced.

Registration of specified practices

6.—(1) The meaning set out in paragraph (2) applies for the purposes of this regulation.

(2) A "registrable practice" means a practice which is not a licensable practice (as defined in regulation 7) and which involves the operation of a radiation generator or a radioactive source.

([a]) S.R. 2006 No. 205

(3) An employer is permitted to carry out a registrable practice provided that—

(a) the employer completes a registration process in the manner specified by the Executive from time to time;

(b) the employer provides to the Executive any such additional particulars in relation to the practice requested by the Executive as the Executive may reasonably require for the purposes of registration;

(c) the practice is or is to be carried out in accordance with such conditions (which may include a limit of time) as the Executive may approve from time to time.

(4) The operation of a radioactive source is not a registrable practice if the activity concentration value of that source does not exceed the activity concentration value specified in column 4 of Part I of Schedule 7.

(5) Where a practice is registered pursuant to paragraph (3) and subsequently there occurs a material change to the circumstances relating to that practice, the employer responsible for that practice shall immediately notify the Executive of that change.

Licensing of specified practices

7.—(1) The meaning set out in paragraph (2) applies for the purposes of this regulation.

(2) A "licensable practice" means the occupational elements of any of the following practices—

(a) the deliberate administration of radioactive substances to persons and, in so far as the radiation protection of human beings is concerned, animals for the purpose of medical or veterinary diagnosis, treatment or research;

(b) the deliberate addition of radioactive substances in the production or manufacture of consumer products or other products, including medicinal products, and the import of such products;

(c) the operation of a accelerator (except an electron microscope);

(d) industrial radiography;

(e) industrial irradiation;

(f) any practice involving a high-activity sealed source (other than one within paragraph (d) or (e) above;

(g) the operation, decommissioning and closure of any facility for the long term storage or disposal of radioactive substances, including facilities managing radioactive substances for this purpose;

(h) practices discharging significant amounts of radioactive substances with airborne or liquid effluent into the environment.

(3) An employer is permitted to carry out a licensable practice provided that the employer is granted a licence for the practice by the Executive.

(4) A licence granted for a practice involving a high-activity sealed source shall include information regarding—

(a) responsibilities,

(b) minimum staff competencies, including information and training,

(c) minimum performance criteria for the high-activity sealed source, its container and any additional equipment,

(d) requirements for emergency procedures and communication links,

(e) work procedures that shall be followed,

(f) maintenance of equipment, high-activity sealed sources and containers,

(g) adequate management of disused high-activity sealed sources, including agreements regarding the transfer, if appropriate, of such sources to a manufacturer, supplier, another licensed employer or a waste disposal or storage facility.

(5) A licence granted under paragraph (3) may be granted subject to conditions and with or without limit of time and may be revoked in writing at any time.

(6) An employer applying for a licence under paragraph (3) shall provide—

(a) such information as is specified by the Executive from time to time having regard to the list of information in Schedule 2;

(b) any additional information requested by the Executive in writing which the Executive may reasonably require for the purposes of considering the licence application.

(7) An employer who is aggrieved by—

(a) a decision of the Executive—

(i) refusing to grant a licence under paragraph (3);

(ii) imposing a limit of time upon a licence granted under paragraph (3); or

(iii) revoking a licence under paragraph (5); or

(b) the terms of any conditions attached to a licence by the Executive under paragraph (5),

may appeal to the Department for the Economy.

(8) Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997([a]) shall apply to any appeal made under paragraph (7).

Prior risk assessment etc

8.—(1) An employer, before commencing a new activity involving work with ionising radiation in respect of which no risk assessment has been made by that employer, shall make a suitable and sufficient assessment of the risk to any employee and other person for the purpose of identifying the measures the employer needs to take to restrict the exposure of that employee or other person to ionising radiation.

(2) Without prejudice to paragraph (1), an employer shall not carry out work with ionising radiation unless it has made an assessment sufficient to demonstrate that—

(a) all hazards with the potential to cause a radiation accident have been identified; and

(b) the nature and magnitude of the risks to employees and other persons arising from those hazards have been evaluated.

(3) Where the assessment made for the purposes of this regulation shows that a radiation risk to employees or other persons exists from an identifiable radiation accident, the employer who made the assessment shall take all reasonably practicable steps to—

(a) prevent any such accident;

(b) limit the consequences of any such accident which does occur; and

(c) provide employees with the information, instruction and training, and with the equipment necessary, to restrict their exposure to ionising radiation.

(4) The requirements of this regulation are without prejudice to the requirements of regulation 3 (Risk assessment) of the Management of Health and Safety at Work Regulations (Northern Ireland) 2000([b]).

Restriction of exposure

9.—(1) Every employer shall, in relation to any work with ionising radiation that it undertakes, take all necessary steps to restrict so far as is reasonably practicable the extent to which its employees and other persons are exposed to ionising radiation.

([a]) S.R. 1997 No. 269
([b]) S.R. 2000 No. 388

(2) Without prejudice to the generality of paragraph (1), an employer in relation to any work with ionising radiation that it undertakes shall—

(a) so far as is reasonably practicable achieve the restriction of exposure to ionising radiation required under paragraph (1) by means of engineering controls and design features and in addition by the provision and use of safety features and warning devices; and

(b) in addition to sub-paragraph (a), provide such systems of work as will, so far as is reasonably practicable, restrict the exposure to ionising radiation of employees and other persons; and

(c) in addition to sub-paragraphs (a) and (b), where it is reasonably practicable to further restrict exposure to ionising radiation by means of personal protective equipment, provide employees or other persons with adequate and suitable personal protective equipment (including respiratory protective equipment) unless the use of personal protective equipment of a particular kind is not appropriate having regard to the nature of the work or the circumstances of the particular case.

(3) Where it is appropriate to do so at the planning stage of radiation protection, an employer, in relation to any work with ionising radiation that it undertakes, shall use dose constraints in restricting exposure to ionising radiation pursuant to paragraph (1).

(4) Such dose constraints shall be established by the employer in terms of individual effective or equivalent doses over a defined appropriate time period.

(5) An employer who provides any system of work or personal protective equipment pursuant to this regulation shall take all reasonable steps to ensure that it is properly used or applied as the case may be.

(6) Without prejudice to paragraph (1), an employer who undertakes work with ionising radiation shall ensure, that—

(a) in relation to an employee who is pregnant, the conditions of exposure are such that, after the employee's employer has been notified of the pregnancy, the equivalent dose to the foetus is as low as is reasonably practicable and is unlikely to exceed 1 mSv during at least the remainder of the pregnancy; and

(b) in relation to an employee who is breastfeeding, that employee shall not be engaged in any work involving a significant risk of intake of radionuclides or of bodily contamination.

(7) Nothing in paragraph (6) requires an employer to take any action in relation to an employee until that employee's employer has been notified by the employee that that employee is pregnant or breastfeeding and the employer to whom paragraph (6) relates has been made aware, or should reasonably have been expected to be aware, of that fact.

(8) Every employer shall, for the purpose of determining whether the requirements of paragraph (1) are being met, ensure that an investigation is carried out without delay when the effective dose of ionising radiation received by any of its employees for the first time in any calendar year exceeds 15 mSv or such other lower effective dose as the employer may specify, which dose shall be specified in writing in local rules made pursuant to regulation 18(1) or, where local rules are not required, by other suitable means.

Personal protective equipment

10.—(1) Any personal protective equipment provided by an employer pursuant to regulation 9 shall—

(a) comply with any provision of the Personal Protective Equipment Regulations 2002([a]) which is applicable to that item of personal protective equipment; or

([a]) S.I. 2002/1144

(b) in the case of respiratory protective equipment, where no provision referred to in sub-paragraph (a) applies, conform to any relevant guidance on respiratory protective equipment issued by the Executive.

(2) Every employer who provides personal protective equipment pursuant to regulation 9 shall ensure that adequate facilities are provided for the storage of that equipment.

Maintenance and examination of engineering controls etc and personal protective equipment

11.—(1) An employer who provides any engineering control, design feature, safety feature or warning device to meet the requirements of regulation 9(2)(a) shall ensure—

(a) that any such control, feature or device is properly maintained; and

(b) where appropriate, that thorough examinations and tests of such controls, features or devices are carried out at suitable intervals.

(2) Every employer shall ensure that all personal protective equipment provided pursuant to regulation 9 is, where appropriate, thoroughly examined at suitable intervals and is properly maintained and that, in the case of respiratory protective equipment, a suitable record of that examination is made and kept for at least two years from the date on which the examination was made and that the record includes a statement of the condition of the equipment at the time of the examination.

Dose limitation

12.—(1) Subject to paragraph (2) and to paragraph 5 of Schedule 3, every employer shall ensure that its employees and other persons within a class specified in Schedule 3 are not exposed to ionising radiation to an extent that any dose limit specified in Part I of that Schedule for such class of person is exceeded in any calendar year.

(2) Where an employer is able to demonstrate to the Executive that, in respect of an employee, the dose limit specified in paragraph 1 of Part I of Schedule 3 is impracticable having regard to the nature of the work undertaken by that employee, the Executive may in respect of that employee authorise the employer to apply the dose limits set out in paragraphs 9 to 11 of Schedule 3 and in such case the provisions of Part II of that Schedule will have effect.

(3) For the assessment of compliance with the dose limits relating to members of the public, every employer who carries out work with ionising radiation shall make realistic estimates of the average effective dose (and where relevant equivalent dose) to representative members of the appropriate reference group for the expected pathways of exposure.

Contingency plans

13.—(1) Where an assessment made in accordance with regulation 8 shows that a radiation accident is reasonably foreseeable (having regard to the steps taken by the employer under paragraph (3) of that regulation), the employer shall prepare a contingency plan designed to secure, so far as is reasonably practicable, the restriction of exposure to ionising radiation and the health and safety of persons who may be affected by such accident.

(2) An employer shall ensure that—

(a) where local rules are required for the purposes of regulation 18, a copy of the contingency plan made in pursuance of paragraph (1) is identified in those rules and incorporated into them by way of summary or reference;

(b) any employee under the employer's control who may be involved with or may be affected by arrangements in the plan has been given suitable and sufficient instructions and where appropriate issued with suitable dose meters or other devices obtained in either case from an approved dosimetry service;

(c) where appropriate, rehearsals of the arrangements in the plan are carried out at suitable intervals; and

(d) if circumstances arise where it is necessary for some or all of the arrangements in the plan to be carried out:

(i) the cause of those circumstances is analysed to determine, so far as is reasonably practicable, the measures, if any, required to prevent a recurrence of such circumstances;

(ii) a record of such analysis is made and kept for at least 2 years from the date on which it was made; and

(iii) any accidental exposure which occurs due to the above circumstances is noted on any relevant dose record.

PART 3

Arrangements for the Management of Radiation Protection

Radiation protection adviser

14.—(1) Subject to paragraph (3), every employer that is engaged in work with ionising radiation shall consult such suitable radiation protection advisers as are necessary for the purpose of advising the employer as to the observance of these Regulations and shall, in any event, consult one or more suitable radiation protection advisers with regard to those matters which are set out in Schedule 4.

(2) Where an employer consults a radiation protection adviser pursuant to the requirements of paragraph (1) (other than in respect of the observance of that paragraph), the employer shall appoint that radiation protection adviser in writing and shall include in that appointment the scope of the advice which the radiation protection adviser is required to give.

(3) Nothing in paragraph (1) requires an employer to consult a radiation protection adviser where the only work with ionising radiation undertaken by that employer is work specified in Schedule 1.

(4) The employer shall provide any radiation protection adviser appointed by it with adequate information and facilities for the performance of the radiation protection adviser's functions.

Information, instruction and training

15.—(1) Every employer shall ensure that—

(a) those of its employees who are engaged in work with ionising radiation are given appropriate training in the field of radiation protection and receive such information and instruction as is suitable and sufficient for them to know—

(i) the risks to health created by exposure to ionising radiation;

(ii) the general radiation protection procedures and precautions which should be taken and the specific radiation protection procedures and precautions in connection with the operational and working conditions of the work with ionising radiation to which they may be assigned; and

(iii) the importance of complying with the medical, technical and administrative requirements of these Regulations;

(b) adequate information is given to other persons who are directly concerned with the work with ionising radiation carried on by the employer to ensure their health and safety so far as is reasonably practicable; and

(c) those female employees of that employer who are engaged in work with ionising radiation are informed of the possible risk arising from ionising radiation to the foetus and to a nursing infant and of the importance of those employees informing the employer in writing as soon as possible—

(i) after becoming aware of their pregnancy; or

(ii) if they intend to breast feed an infant;

(d) any employees or outside workers engaged in work in a controlled area (as designated under regulation 17) are given specific training in connection with the characteristics of the workplace and the activities within it;

(e) the giving of training and information under this regulation is repeated at appropriate intervals and documented by the employer.

(2) In addition to the requirements in paragraph (1), employers engaged in work with ionising radiation involving a high-activity sealed source shall ensure that the information and training given to employees includes:

(a) specific requirements for the safe management and control of high-activity sealed sources for the purpose of preparing such employees for any events which may affect their radiation protection;

(b) particular emphasis on the necessary safety requirements in connection with high-activity sealed sources;

(c) specific information on the possible consequences of the loss of adequate control of high-activity sealed sources.

Co-operation between employers and others

16.—(1) Where work with ionising radiation undertaken by one employer is likely to give rise to the exposure to ionising radiation of the employee of another employer, the employers concerned shall co-operate by the exchange of information or otherwise to the extent necessary to ensure that each such employer—

(a) has access to information on the possible exposure of their employees to ionising radiation, and

(b) is enabled to comply with the requirements of these Regulations in so far as their ability to comply depends upon such co-operation.

(2) The persons and bodies listed in paragraph (3) shall co-operate with each other as appropriate regarding the exchange of all relevant information on the doses received by an employee in connection with—

(a) the medical examination prior to employment or classification of the employee pursuant to regulation 25, and

(b) the control of further exposure of employees to ionising radiation.

(3) The persons and bodies referred to in paragraph (2) are—

(a) the employer of the employee in respect of whom the information relates;

(b) the Executive;

(c) occupational health services;

(d) radiation protection advisers;

(e) dosimetry services.

PART 4

Designated Areas

Designation of controlled or supervised areas

17.—(1) Every employer shall designate as a controlled area any area under its control which has been identified by an assessment made by that employer (whether pursuant to regulation 8 or otherwise) as an area in which—

(a) it is necessary for any person who enters or works in the area to follow special procedures designed to restrict significant exposure to ionising radiation in that area or prevent or limit the probability and magnitude of radiation accidents or their effects; or

(b) any person working in the area is likely to receive an effective dose greater than 6 mSv a year or an equivalent dose greater than 15mSv a year for the lens of the eye or 150 mSv a year for the skin and the hands, forearms, feet and ankles.

(2) An employer shall not intentionally create in any area conditions which would require that area to be designated as a controlled area unless that area is for the time being under the control of that employer.

(3) An employer shall designate as a supervised area any area under its control, not being an area designated as a controlled area—

(a) where it is necessary to keep the conditions of the area under review to determine whether the area should be designated as a controlled area; or

(b) in which any person is likely to receive an effective dose greater than 1 mSv a year or an equivalent dose greater than 5 mSv a year for the lens of the eye or 50 mSv a year for the skin and the hands, forearms, feet and ankles.

Local rules and radiation protection supervisors

18.—(1) For the purposes of enabling work with ionising radiation to be carried on in accordance with the requirements of these Regulations, every employer that is engaged in work with ionising radiation shall, in respect of any controlled area or, where appropriate having regard to the nature of the work carried out there, any supervised area, make and set down in writing such local rules as are appropriate to the radiation risk and the nature of the operations undertaken in that area.

(2) Local rules shall identify the main working instructions intended to restrict any exposure in that controlled or supervised area.

(3) An employer shall take all reasonable steps to ensure that any local rules made pursuant to paragraph (1) and which are relevant to the work being carried out are observed.

(4) An employer shall ensure that such of those rules made pursuant to paragraph (1) as are relevant are brought to the attention of those employees and other persons who may be affected by them.

(5) An employer shall—

(a) appoint one or more suitable radiation protection supervisors for the purpose of securing compliance with these Regulations in respect of work carried out in any area made subject to local rules pursuant to paragraph (1);

(b) set down in the local rules the names of such individuals so appointed; and

(c) provide the means necessary for the radiation protection supervisor to perform their role.

Additional requirements for designated areas

19.—(1) Every employer who designates any area as a controlled or supervised area shall ensure that any such designated area is adequately described in local rules and that—

(a) in the case of any controlled area—

(i) the area is physically demarcated or, where this is not reasonably practicable, delineated by some other suitable means; and

(ii) suitable and sufficient signs are displayed in suitable positions indicating that the area is a controlled area, the nature of the radiation sources in that area and the risks arising from such sources; and

(b) in the case of any supervised area, suitable and sufficient signs giving warning of the supervised area are displayed, where appropriate, in suitable positions indicating the nature of the radiation sources and the risks arising from such sources.

(2) The employer who has designated an area as a controlled area shall not permit any employee or other person to enter or remain in such an area unless that employee or other person—

(a) being a person other than a classified outside worker, is a classified person;

(b) being a classified outside worker, is a person in respect of whom the employer who has so designated an area as a controlled area has taken all reasonable steps to ensure that the person—

(i) is subject to individual dose assessment pursuant to regulation 22;

(ii) has been provided with and has been trained to use any personal protective equipment that may be necessary pursuant to regulation 9(2)(c);

(iii) has received any specific training required pursuant to regulation 15; and

(iv) has been certified fit for the work with ionising radiation which the person is to carry out pursuant to regulation 25; or

(c) not being a classified person, enters or remains in the area in accordance with suitable written arrangements for the purpose of ensuring that—

(i) in the case of an employee or a non-classified outside worker aged 18 years or over, that person does not receive in any calendar year a cumulative dose of ionising radiation which would require that person to be designated as a classified person; or

(ii) in the case of any other person, he does not receive in any calendar year a dose of ionising radiation exceeding any relevant dose limit.

(3) A non-classified outside worker is not permitted to enter or remain in a controlled area pursuant to paragraph 2(c)(i) unless paragraphs 2(b)(ii) (personal protective equipment) and 2(b)(iii) (specific training) have been observed in relation to that non-classified outside worker.

(4) An employer who has designated an area as a controlled area shall not permit a person to enter or remain in such area in accordance with the written arrangements under paragraph (2)(c), unless that employer can demonstrate, by personal dose monitoring or other suitable measurements, that the doses are restricted in accordance with that sub-paragraph.

(5) An employer who has designated an area as a controlled area shall, in relation to a classified outside worker, ensure that—

(a) the classified outside worker is subject to arrangements for estimating the dose of ionising radiation received by that worker whilst in the controlled area;

(b) as soon as is reasonably practicable after the services carried out by that classified outside worker in that controlled area are completed, an estimate of the dose received by that worker is entered into that worker's radiation passbook; and

(c) when the radiation passbook of the classified outside worker is in the possession of that employer, the passbook is made available to that worker upon request.

(6) The employer who carries out the monitoring or measurements pursuant to paragraph (4) shall keep the results of the monitoring or measurements referred to in that paragraph for a period of 2 years from the date they were recorded and shall, at the request of the person to whom the monitoring or measurements relate and on reasonable notice being given make the results available to that person.

(7) In any case where there is a significant risk of the spread of radioactive contamination from a controlled area, the employer who has designated that area as a controlled area shall make adequate arrangements to restrict, so far as is reasonably practicable, the spread of such contamination.

(8) Without prejudice to the generality of paragraph (7), the arrangements required by that paragraph shall, where appropriate, include—

(a) the provision of suitable and sufficient washing and changing facilities for persons who enter or leave any controlled or supervised area;

(b) the proper maintenance of such washing and changing facilities;

(c) the prohibition of eating, drinking or smoking or similar activity to result in the ingestion, inhalation or absorption of a radioactive substance by any employee or outside worker in a controlled area; and

(d) the means for monitoring contamination—

(i) on any person, article or goods leaving a controlled area;

(ii) within the controlled area and, where appropriate, in the adjacent area.

Monitoring of designated areas

20.—(1) Every employer who designates an area as a controlled or supervised area shall take such steps as are necessary (otherwise than by use of assessed doses of individuals), having regard to the nature and extent of the risks resulting from exposure to ionising radiation, to ensure that levels of ionising radiation are adequately monitored for each such area and that working conditions in those areas are kept under review.

(2) In relation to areas designated on the basis of—

(a) external radiation, adequate monitoring shall include measurement of dose rates (averaged over a suitable period if necessary);

(b) internal radiation, adequate monitoring shall include measurements of air activity and surface contamination where appropriate, taking into account the physical and chemical states of the radioactive contamination;

(3) The employer upon whom a duty is imposed by paragraph (1) shall provide suitable and sufficient equipment for carrying out the monitoring required by that paragraph, which equipment shall—

(a) be properly maintained so that it remains fit for the purpose for which it was intended; and

(b) be adequately tested and examined at appropriate intervals.

(4) Equipment provided pursuant to paragraph (3) shall not be or remain suitable unless—

(a) the performance of the equipment has been established by adequate tests before it has first been used; and

(b) the tests and examinations carried out pursuant to paragraph (3) and sub-paragraph (a) have been carried out by or under the supervision of a qualified person.

(5) The employer upon whom a duty is imposed by paragraph (1) shall—

(a) make suitable records of the results of the monitoring carried out in accordance with paragraph (1) and of the tests carried out in accordance with paragraphs (3) and (4);

(b) ensure that the records of the tests carried out pursuant to sub-paragraph (a) are authorised by a qualified person; and

(c) keep the records referred to in sub-paragraph (a), or copies of those records, for at least 2 years from the respective dates on which they were made.

(6) For areas designated on the basis of—

(a) external radiation, suitable records shall include an indication of the nature and quality of the radiation in question;

(b) internal radiation, suitable records shall include, where appropriate, an indication of the nature and physical and chemical states of the radioactive contamination.

PART 5

Classification and Monitoring of Persons

Designation of classified persons

21.—(1) Subject to paragraph (2), the employer shall designate as classified persons those of its employees who are likely to receive an effective dose in excess of 6 mSv per year or an equivalent dose which exceeds 15 mSv per year for the lens of the eye or 150 mSv per year for the skin and the hands, forearms, feet and ankles and shall immediately inform those employees that they have been so designated.

(2) The employer shall not designate an employee as a classified person unless—

(a) that employee is aged 18 years or over; and

(b) an appointed doctor or employment medical adviser has certified in the health record that that employee is fit for the work with ionising radiation which that employee is to carry out.

(3) The employer may cease to treat an employee as a classified person only at the end of a calendar year except where—

(a) an appointed doctor or employment medical adviser so requires; or

(b) the employee is no longer employed by the same employer in a capacity which is likely to result in significant exposure to ionising radiation during the remainder of the relevant calendar year.

Dose assessment and recording

22.—(1) Every employer shall ensure that—

(a) in respect of each of its employees who is designated as a classified person, an assessment is made of all doses of ionising radiation received by such employee which are likely to be significant; and

(b) such assessments are recorded.

(2) For the purposes of paragraph (1), the employer shall make suitable arrangements with one or more approved dosimetry service for—

(a) the making of systematic assessments of such doses by the use of suitable individual measurement for appropriate periods or, where individual measurement is inappropriate, by means of other suitable measurements; and

(b) the making and maintenance of dose records relating to each classified person.

(3) For the purposes of paragraph (2)(b), the arrangements that the employer makes with the approved dosimetry service shall include requirements for that service—

(a) to keep the records made and maintained pursuant to the arrangements, or a copy of those records, until the person to whom the record relates has or would have attained the age of 75 years but in any event for at least 30 years from when they were made;

(b) to provide the employer at appropriate intervals with suitable summaries of the dose records maintained in accordance with sub-paragraph (a);

(c) when required by the employer, to provide the employer with such copies of the dose record relating to any of its employees as the employer may require;

(d) when required by the employer, to make a record of the information concerning the dose assessment relating to a classified person who ceases to be an employee of the employer, and to send that record to the Executive and a copy of the record to the employer as soon as possible, and a record so made is referred to in this regulation as a "termination record";

(e) within 3 months, or such longer period as the Executive may agree, of the end of each calendar year to send to the Executive summaries of all current dose records relating to that year;

(f) when required by the Executive, to provide it with copies of any dose records;

(g) where a dose is estimated pursuant to regulation 23, to make an entry in a dose record and retain the summary of the information used to estimate that dose;

(h) where the employer employs a classified outside worker, to provide, where appropriate, a current radiation passbook in respect of that classified outside worker; and

(i) where the employer employs a classified outside worker who works in Great Britain or another member State, to maintain a continuing record of the assessment of the dose received by that classified outside worker when working in such place.

(4) The employer shall provide the approved dosimetry service with such information concerning its employees as is necessary for the approved dosimetry service to comply with the arrangements made for the purposes of paragraph (2).

(5) An employer shall—

(a) ensure that each classified outside worker employed by it is provided with a current individual radiation passbook which shall not be transferable to any other worker and in which shall be entered the particulars set out in Schedule 5; and

(b) make suitable arrangements to ensure that the particulars entered in the radiation passbook are kept up-to-date during the continuance of the employment of the classified outside worker by that employer.

(6) The employer shall—

(a) at the request of a classified person employed by the employer (or of a person formerly employed by the employer as a classified person) and on reasonable notice being given, obtain (where necessary) from the approved dosimetry service and make available to that person—

(i) a copy of the dose summary provided for the purpose of paragraph (3)(b) relating to that person and made within a period of 2 years preceding the request; and

(ii) a copy of the dose record of that person; and

(b) when a classified person ceases to be employed by the employer, take all reasonable steps to provide to that person a copy of that person's termination record.

(7) The employer shall keep a copy of the summary of the dose record received from the approved dosimetry service for at least 2 years from the end of the calendar year to which the summary relates.

Estimated doses and special entries

23.—(1) Where a dosemeter or other device is used to make any individual measurement under regulation 22(2) and that dosemeter or device is lost, damaged or destroyed or it is not practicable to assess the dose received by a classified person over any period, the employer shall make an adequate investigation of the circumstances of the case with a view to estimating the dose received by that person during that period and either—

(a) in a case where there is adequate information to estimate the dose received by that person, shall send to the approved dosimetry service an adequate summary of the information used to estimate that dose and shall arrange for the approved dosimetry service to enter the estimated dose in the dose record of that person; or

(b) in a case where there is inadequate information to estimate the dose received by the classified person, shall arrange for the approved dosimetry service to enter a notional dose in the dose record of that person which shall be the proportion of the total annual dose limit for the relevant period,

and in either case the employer shall take reasonable steps to inform the classified person of that entry and arrange for the approved dosimetry service to identify the entry in the dose record as an estimated dose or a notional dose as the case may be.

(2) The employer shall, at the request of the classified person (or a person formerly employed by that employer as a classified person) to whom the investigation made under paragraph (1) relates and on reasonable notice being given, make available to that person a copy of the summary sent to the approved dosimetry service under sub-paragraph (a) of paragraph (1).

(3) Subject to paragraphs (5) and (8), where an employer has reasonable cause to believe that the dose received by a classified person is much greater or much less than that shown in the relevant entry of the dose record, the employer shall make an adequate investigation of the circumstances of the exposure of that person to ionising radiation and, if that investigation confirms the employer's belief, the employer shall, where there is adequate information to estimate the dose received by the employee—

(a) send to the approved dosimetry service an adequate summary of the information used to estimate that dose;

(b) arrange for the approved dosimetry service to enter that estimated dose in the dose record of that person and for the approved dosimetry service to identify the estimated dose in the dose record as a special entry; and

(c) notify the classified person accordingly.

(4) The employer shall make a report of any investigation carried out under paragraph (3) and shall preserve a copy of that report for a period of 2 years from the date it was made.

(5) Paragraph (3) shall not apply—

(a) in respect of a classified person subject only to an annual dose limit, more than 12 months after the original entry was made in the record; and

(b) in any other case, more than 5 years after the original entry was made in the record.

(6) Where a classified person is aggrieved by a decision to replace a recorded dose by an estimated dose pursuant to paragraph (3) that person may, by an application in writing to the Executive made within 3 months of the date on which that person was notified of the decision, apply for that decision to be reviewed.

(7) Where the Executive concludes (whether as a result of a review carried out pursuant to paragraph (6) or otherwise) that—

(a) there is reasonable cause to believe the investigation carried out pursuant to paragraph (3) was inadequate; or

(b) a reasonable estimated dose has not been established,

the employer shall, if so directed by the Executive, re-instate the original entry in the dose record.

(8) The employer shall not, without the consent of the Executive, require the approved dosimetry service to enter an estimated dose in the dose record in any case where—

(a) the cumulative recorded effective dose is 20 mSv or more in one calendar year; or

(b) the cumulative recorded equivalent dose for the calendar year exceeds a relevant dose limit.

Dosimetry for accidents etc

24.—(1) Where any accident or other occurrence takes place which is likely to result in a person receiving an effective dose of ionising radiation exceeding 6 mSv or an equivalent dose greater than 15 mSv for the lens of an eye or 150 mSv for the skin and the hands, forearms, feet and ankles, the employer shall—

(a) in the case of a classified person, arrange for a dose assessment to be made by the approved dosimetry service as soon as possible;

(b) in the case of an employee to whom a dosemeter or other device has been issued in accordance with regulation 13(2), arrange for that dosemeter or device to be examined

and for the dose received to be assessed by the approved dosimetry service as soon as possible;

(c) in any other case, arrange for the dose to be assessed by an appropriate means as soon as possible, having regard to the advice of the radiation protection adviser.

(2) In such a case, the employer shall—

(a) take all reasonably practicable steps to inform each person for whom a dose assessment has been made of the result of that assessment; and

(b) keep a record of the assessment or a copy thereof until the person to whom the record relates has or would have attained the age of 75 years but in any event for at least 30 years from the date of the relevant accident.

Medical surveillance

25.—(1) This regulation shall apply in relation to—

(a) classified persons and persons whom an employer intends to designate as classified persons;

(b) employees who have received an overexposure and are not classified persons;

(c) employees who are engaged in work with ionising radiation subject to conditions imposed by an appointed doctor or employment medical adviser under paragraph (8).

(2) The employer shall ensure that each of its employees to whom this regulation relates is under adequate medical surveillance by an appointed doctor or employment medical adviser for the purpose of determining the fitness of each employee for the work with ionising radiation which that employee is to carry out.

(3) Adequate medical surveillance shall include—

(a) a medical examination before first being designated as a classified person in a post involving work with ionising radiation;

(b) periodic reviews of health at least once a year;

(c) special medical surveillance of an employee when a relevant dose limit has been exceeded;

(d) a determination of whether any specific conditions are necessary; and

(e) a review of health after cessation of work where this is necessary to safeguard the health of the employee.

(4) The nature of the medical surveillance for each employee shall take account of the nature of their work with ionising radiation and their state of health.

(5) The employer shall ensure that a health record, containing the particulars referred to in Schedule 6, in respect of each of its employees to whom this regulation relates is made and maintained and that that record or a copy of the record is kept until the person to whom the record relates has or would have attained the age of 75 years but in any event for at least 30 years from the date of the last entry made in it.

(6) Subject to paragraph (7), the employer shall ensure that there is a valid entry in the health record of each of its employees to whom this regulation relates (other than employees who have received an overexposure and who are not classified persons) made by an appointed doctor or employment medical adviser and an entry in the health record shall be valid—

(a) for 12 months from the date it was made or treated as made by virtue of paragraph (7);

(b) for such shorter period as is specified in the entry by the appointed doctor or employment medical adviser; or

(c) until cancelled by an appointed doctor or employment medical adviser by a further entry in the record.

(7) For the purposes of paragraph (6)(a), a further entry in the health record of the same employee, where made not less than 11 months nor more than 13 months after the start of the current period of validity, is to be treated as if made at the end of that period.

(8) Where the appointed doctor or employment medical adviser has certified in the health record of an employee to whom this regulation relates that in his professional opinion that employee should not be engaged in work with ionising radiation or that the employee should only be so engaged under conditions specified by the appointed doctor or employment medical adviser in the health record, the employer shall not permit that employee to be engaged in the work with ionising radiation except in accordance with the conditions, if any, so specified.

(9) Where an appointed doctor or employment medical adviser, for the purpose of carrying out their functions under these Regulations, requires to inspect any workplace the employer shall permit them to do so.

(10) The employer shall make available to the appointed doctor or employment medical adviser the summary of the dose record kept by the employer pursuant to regulation 22(7) and such other records kept for the purposes of these Regulations as the appointed doctor or employment medical adviser may reasonably require.

(11) Where an employee is aggrieved by a decision recorded in the health record by an appointed doctor or employment medical adviser the employee may, by an application in writing to the Executive made within [28 days] of the date on which the employee was notified of the decision, apply for that decision to be reviewed in accordance with a procedure approved for the purposes of this paragraph by the Executive, and the result of that review shall be notified to the employee and entered in that employee's health record in accordance with the approved procedure.

Investigation and notification of overexposure

26.—(1) Where an employer suspects or has been informed that any person is likely to have received an overexposure as a result of work with ionising radiation carried out by that employer, that employer shall make an immediate investigation to determine whether there are circumstances which show beyond reasonable doubt that no overexposure could have occurred and, unless this is shown, the employer shall—

(a) as soon as practicable notify the suspected overexposure to—

(i) the Executive;

(ii) in the case of an employee of some other employer, that other employer; and

(iii) in the case of the employer's own employee, the appointed doctor or employment medical adviser;

(b) as soon as practicable take reasonable steps to notify the suspected overexposure to the person affected; and

(c) make or arrange for such investigation of the circumstances of the exposure and an assessment of any relevant dose received as is necessary to determine, so far as is reasonably practicable, the measures, if any, required to be taken to prevent a recurrence of such overexposure and shall immediately notify the results of that investigation and assessment to the persons and authorities mentioned in sub-paragraph (a) and shall—

(i) in the case of the employer's employee, immediately notify that employee of the results of the investigation and assessment, or

(ii) in the case of a person who is not the employer's employee, where the investigation has shown that that person has received an overexposure, take all reasonable steps to notify that person of their overexposure.

(2) An employer who makes any investigation pursuant to paragraph (1) shall make a report of that investigation and shall—

(a) in respect of an immediate investigation, keep that report or a copy of the report for at least 2 years from the date on which it was made; and

(b) in respect of an investigation made pursuant to sub-paragraph (c) of paragraph (1), keep that report or a copy of the report until the person to whom the record relates has or would have attained the age of 75 years but in any event for at least 30 years from the date on which it was made.

(3) Where the person who received the overexposure is an employee who has a dose record, the employee's employer shall arrange for the assessment of the dose received to be entered into that dose record.

Dose limitation for overexposed employees

27.—(1) Without prejudice to other requirements of these Regulations and in particular regulation 25(6), where an employee has been subjected to an overexposure paragraph (2) applies in relation to the employment of that employee on work with ionising radiation during the remainder of the dose limitation period commencing at the end of the personal dose assessment period in which that employee was subjected to the overexposure.

(2) The employer shall ensure that an employee to whom this regulation relates does not, during the remainder of the dose limitation period, receive a dose of ionising radiation greater than that proportion of any dose limit which is equal to the proportion that the remaining part of the dose limitation period bears to the whole of that period.

(3) The employer shall inform an employee who has been subjected to an overexposure of the dose limit which is applicable to that employee for the remainder of the relevant dose limitation period.

(4) In this regulation, "dose limitation period" means, as appropriate, a calendar year or the period of five consecutive calendar years.

PART 6

Arrangements for the Control of Radioactive Substances, Articles and Equipment

Sealed sources and articles containing or embodying radioactive substances

28.—(1) Where a radioactive substance is used as a source of ionising radiation in work with ionising radiation, the employer shall ensure that, whenever reasonably practicable, the substance is in the form of a sealed source.

(2) The employer shall ensure that the design, construction and maintenance of any article containing or embodying a radioactive substance, including its bonding, immediate container or other mechanical protection, is such as to prevent the leakage of any radioactive substance—

(a) in the case of a sealed source, so far as is practicable; or

(b) in the case of any other article, so far as is reasonably practicable.

(3) Where appropriate, the employer shall ensure that suitable tests are carried out at suitable intervals to detect leakage of radioactive substances from any article to which paragraph (2) applies and the employer shall make a suitable record of each such test and shall retain that record for at least 2 years after the article is disposed of or until a further record is made following a subsequent test to that article.

Accounting for radioactive substances

29. Every employer, for the purpose of controlling radioactive substances which are involved in work with ionising radiation undertaken by that employer, shall take such steps as are appropriate to account for and keep records of the quantity and location of those substances and shall keep those records or a copy thereof for at least 2 years from the date on which they were made and, in addition, for at least 2 years from the date of disposal of that radioactive substance.

Keeping and moving of radioactive substances

30.—(1) Every employer shall ensure, so far as is reasonably practicable, that any radioactive substance under its control which is not for the time being in use or being moved, transported or disposed of—

(a) is kept in a suitable receptacle; and

(b) is kept in a suitable store.

(2) Every employer who causes or permits a radioactive substance to be moved (otherwise than by transporting it) shall ensure that, so far as is reasonably practicable, the substance is kept in a suitable receptacle, suitably labelled, while it is being moved.

(3) Nothing in paragraphs (1) or (2) applies in relation to a radioactive substance while it is in or on the live body or corpse of a human being.

Notification of certain occurrences

31.—(1) Every employer shall immediately notify the Executive in any case where a quantity of a radioactive substance which was under its control and which exceeds the quantity specified for that substance in column 4 of Schedule 7—

(a) has been released or is likely to have been released into the atmosphere as a gas, aerosol or dust; or

(b) has been spilled or otherwise released in such a manner as to give rise to significant contamination.

(2) Paragraph (1) shall not apply where such release—

(a) was in accordance with a registration under section 10 of the Radioactive Substances Act 1993([a]) or which was exempt from such registration by virtue of section 11 of that Act; or

(b) was in a manner specified in an authorisation to dispose of radioactive waste under section 13 of the said Act or which was exempt from such authorisation by virtue of section 15 of that Act.

(3) Where an employer has reasonable cause to believe that a quantity of radioactive substance which exceeds the quantity for that substance specified in column 5 of Schedule 7 and which was under its control is lost or has been stolen, the employer shall immediately notify the Executive of that loss or theft, as the case may be.

(4) Where an employer suspects or has been informed that an occurrence notifiable under paragraph (1) or (3) may have occurred, it shall make an immediate investigation and, unless that investigation shows that no such occurrence has occurred, it shall immediately make a notification in accordance with the relevant paragraph.

(5) An employer who makes any investigation in accordance with paragraph (4) shall make a report of that investigation and shall, unless the investigation showed that no such occurrence occurred, keep that report or a copy thereof for at least 50 years from the date on which it was made or, in any other case, for at least 2 years from the date on which it was made.

Duties of manufacturers etc of articles for use in work with ionising radiation

32.—(1) In the case of articles for use at work, where that work is work with ionising radiation, Article 7(1) of the 1978 Order([b]) (which imposes general duties on manufacturers etc as regards articles and substances for use at work) is modified so that any duty imposed on any person by that subsection includes a duty to ensure that any such article is so designed and constructed as to restrict so far as is reasonably practicable the extent to which employees and other persons are or are likely to be exposed to ionising radiation.

(2) Where a person erects or installs an article for use at work, being work with ionising radiation, that person shall—

([a]) 1993 c.12

([b]) S.I. 1978/1039 (N.I. 9); Article 7 was amended by the Consumer Protection (Northern Ireland) Order 1987 (S.I. 1987/2049 (N.I. 20)), Article 28 and Schedule 2

(a) undertake a critical examination of the way in which the article was erected or installed for the purpose of ensuring, in particular, that—

(i) any safety features and warning devices operate correctly; and

(ii) there is sufficient protection for persons from exposure to ionising radiation;

(b) consult with the radiation protection adviser that they appointed, or that the employer engaged in work with ionising radiation appointed, with regard to the nature and extent of any critical examination and the results of that examination; and

(c) provide the employer engaged in work with ionising radiation with adequate information about proper use, testing and maintenance of the article.

Equipment used for medical exposure [Note: This regulation may be subject to change – see consultation document]

33.—(1) Every employer who has to any extent control of any equipment or apparatus which is used in connection with a medical exposure shall, having regard to the extent of his control over the equipment, ensure that such equipment is of such design or construction and is so installed and maintained as to be capable of restricting so far as is reasonably practicable the exposure to ionising radiation of any person who is undergoing a medical exposure to the extent that this is compatible with the intended clinical purpose or research objective.

(2) An employer who has to any extent control of any radiation equipment which is used for the purpose of diagnosis and which is installed after the date of the coming into operation of these Regulations shall, having regard to the extent of the employer's control over the equipment, ensure that such equipment is provided, where practicable, with suitable means for informing the user of that equipment of the quantity of radiation produced by that equipment during a radiological procedure.

(3) Every employer in respect of whom a duty is imposed by paragraph (1) shall, to the extent that it is reasonable for the employer to do so having regard to the extent of the employer's control over the equipment, make arrangements for a suitable quality assurance programme to be provided in respect of the equipment or apparatus for the purpose of ensuring that it remains capable of restricting so far as is reasonably practicable exposure to the extent that this is compatible with the intended clinical purpose or research objective.

(4) Without prejudice to the generality of paragraph (3), the quality assurance programme required by that paragraph shall require the carrying out of—

(a) in respect of equipment or apparatus first used after the coming into operation of this regulation, adequate testing of that equipment or apparatus before it is first used for clinical purposes;

(b) adequate testing of the performance of the equipment or apparatus at appropriate intervals and after any major maintenance procedure to that equipment or apparatus;

(c) where appropriate, such measurements at suitable intervals as are necessary to enable the assessment of representative doses from any radiation equipment to persons undergoing medical exposures.

(5) Every employer who has to any extent control of any radiation equipment shall take all such steps as are reasonably practicable to prevent the failure of any such equipment where such failure could result in an exposure to ionising radiation greater than that intended and to limit the consequences of any such failure.

(6) Where an employer suspects or has been informed that an incident may have occurred in which a person while undergoing a medical exposure was, as the result of a malfunction of, or defect in, radiation equipment under the control of that employer, exposed to ionising radiation to an extent much greater than that intended, the employer shall make an immediate investigation of the suspected incident and, unless that investigation shows beyond reasonable doubt that no such incident has occurred, shall immediately notify the Executive of the incident and make or arrange for a detailed investigation of the circumstances of the exposure and an assessment of the dose received.

(7) An employer who makes any investigation in accordance with paragraph (6) shall make a report of that investigation and shall—

(a) in respect of an immediate report, keep that report or a copy of the report for a period of at least 2 years from the date on which it was made; and

(b) in respect of a detailed report, keep that report or a copy of the report for a period of at least 50 years from the date on which it was made.

(8) In this regulation, "radiation equipment" means equipment which delivers ionising radiation to the person undergoing a medical exposure and equipment which directly controls the extent of the exposure.

Misuse of or interference with sources of ionising radiation

34. No person may intentionally or recklessly misuse or without reasonable excuse interfere with any radioactive substance or any electrical equipment to which these Regulations apply.

PART 7

Duties of employees and Miscellaneous

Duties of employees

35.—(1) An employee who is engaged in work with ionising radiation shall not knowingly expose themselves or any other person to ionising radiation to an extent greater than is reasonably necessary for the purposes of their work, and shall exercise reasonable care while carrying out such work.

(2) Every employer or outside worker for whom personal protective equipment is provided pursuant to regulation 9(2)(c) shall—

(a) make full and proper use of any such personal protective equipment;

(b) immediately report to the employer who provided any such personal protective equipment any defect they discover in that equipment; and

(c) take all reasonable steps to ensure that any such personal protective equipment is returned after use to the accommodation provided for it.

(3) It is the duty of every classified outside worker not to misuse the radiation passbook issued to that worker or falsify or attempt to falsify any of the information contained in it.

(4) Any employee to whom regulation 22(1) or regulation 13(2)(b) relates shall comply with any reasonable requirement imposed on that person by that person's employer for the purposes of making the measurements and assessments required under regulation 22(1) and regulation 24(1).

(5) An employee who is subject to medical surveillance under regulation 25 shall, when required by his employer and at the cost of the employer, present themselves during their working hours for such medical examination and tests as may be required for the purposes of paragraph (2) of that regulation and shall provide the appointed doctor or employment medical adviser with such information concerning their health as the appointed doctor or employment medical adviser may reasonably require.

(6) Where an employee has reasonable cause to believe that—

(a) they or some other person has received an overexposure;

(b) an occurrence mentioned in paragraph (1) or (3) of regulation 31 has occurred; or

(c) an incident mentioned in regulation 33(6) has occurred,

they shall immediately notify their employer of that belief.

Approval of dosimetry services

36.—(1) The Executive (or such other person as may from time to time be specified in writing by the Executive) may, by a certificate in writing, approve (in accordance with such criteria as may from time to time be specified by the Executive) a suitable dosimetry service for such of the purposes of these Regulations or of the Radiation (Emergency Preparedness and Public Information) Regulations (Northern Ireland) 2001 as are specified in the certificate.

(2) A certificate made pursuant to paragraph (1) may be subject to conditions and may be revoked in writing at any time.

(3) The Executive (or such other person as may from time to time be specified in writing by the Executive) may at such suitable periods as it considers appropriate carry out a re-assessment of any approval granted pursuant to paragraph (1).

Enforcement

37. Insofar as any provision of regulation 22 is made under section 2(2) of the European Communities Act 1972, Articles—

(a) 18 to 24 (approval of codes of practice and enforcement);

(b) 25 (provisions supplementary to sections 23 and 24) and 26 (appeal against improvement or prohibition notice), so far as they relate to an improvement notice;

(c) 28 (power to indemnify inspectors); and

(d) 31 to 39 (provisions as to offences),

of the 1978 Order apply to that provision as if that provision had been made under Article 17 of that Order.

Defence on contravention

38.—(1) In any proceedings against an employer for an offence under regulation 5(2) (notification), or under regulation 6(3)(a) (registration) in connection with the use or operation of a radioactive source, it is a defence for that employer to prove that—

(a) it neither knew nor had reasonable cause to believe that it had carried out or might be required to carry out work subject to notification or registration under the relevant regulation mentioned in paragraph (1); and

(b) in a case where it discovered that it had carried out or was carrying out work subject to notification under regulation 5(2), it had immediately notified the Executive of the information required by that regulation; or

(c) in a case where it discovered that it had carried out or was carrying out work involving the use or operation of a radioactive source which is subject to registration under the relevant regulation mentioned above, it had immediately—

(i) ceased carrying out that work, and

(ii) communicated the circumstances of the use or operation of the radioactive source to the Executive.

(2) In any proceedings against an employer for an offence under regulation 8, it is a defence for that employer to prove that—

(a) it neither knew nor had reasonable cause to believe that it had commenced a new activity involving work with ionising radiation; and

(b) in a case where it had discovered that it had commenced a new activity involving work with ionising radiation, it had as soon as practicable made an assessment as required by regulation 8.

(3) In any proceedings against an employer for an offence under regulation 28(2) it is a defence for that employer to prove that—

(a) it had received and reasonably relied on a written undertaking from the supplier of the article concerned that the article complied with the requirements of that paragraph; and

(b) it had complied with the requirements of paragraph (3) of that regulation.

(4) In any proceedings against an employer of an outside worker for a breach of a duty under these Regulations it is a defence for that employer to show that—

(a) it had entered into a contract in writing with the employer who had designated an area as a controlled area and in which the outside worker was working or was to work for that employer to perform that duty on its behalf; and

(b) the breach of duty was a result of the failure of the employer referred to in sub-paragraph (a) to fulfil that contract.

(5) In any proceedings against any employer who has designated a controlled area in which any outside worker is working or is to work for a breach of a duty under these Regulations it is a defence for that employer to show that—

(a) it had entered into a contract in writing with the employer of an outside worker for that employer to perform that duty on its behalf; and

(b) the breach of duty was a result of the failure of the employer referred to in sub-paragraph (a) to fulfil that contract.

(6) The person charged is not, without leave of the court, entitled to rely on the defence referred to in paragraph (4) or (5) unless, within a period ending seven clear days before the hearing, that person has served on the prosecutor a notice in writing of that person's intention to rely on the defence and this notice shall be accompanied by a copy of the contract on which that person intends to rely and, if that contract is not in English, an accurate translation of that contract into English.

(7) Where a contravention of these Regulations by any person is due to the act or default of some other person, that other person will be guilty of the offence which would, but for any defence under this regulation available to the first-mentioned person, be constituted by the act or default.

Exemption certificates

39.—(1) Subject to paragraph (2), the Executive may, by a certificate in writing, exempt—

(a) any person or class of persons;

(b) any premises or class of premises; or

(c) any equipment, apparatus or substance or class of equipment, apparatus or substance,

from any requirement or prohibition imposed by these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked by a certificate in writing at any time.

(2) The Executive shall not grant an exemption unless, having regard to the circumstances of the case and in particular to—

(a) the conditions, if any, which it proposes to attach to the exemption; and

(b) any other requirements imposed by or under any enactments which apply to the case,

it is satisfied that—

(c) the health and safety of persons who are likely to be affected by the exemption will not be prejudiced in consequence of it; and

(d) compliance with the fundamental radiation protection provisions underlying regulations 9(1) and (2)(a), 12, 13(1), 17(1) and (3), 20(1), 21(1), 22(1), 25(2) and 33(1) will be achieved.

(3) Where the only work being undertaken is that referred to in regulation 3(1)(b), paragraph 2(d) is to be read and applied as if the references to regulations 13(1), 17(1) and (3), 20(1), 21(1), 22(1), 25(2) and 33(1) were omitted.

Application within the territorial sea

40.—(1) Subject to paragraph (2), within the territorial sea these Regulations shall apply only to or in relation to the premises and activities to which any of paragraphs 2 to 9 of Schedule 10 applies.

(2) For the purposes of paragraph (1), in any case where it is not reasonably practicable for an employer to comply with the requirements of these Regulations in so far as they relate to functions being performed by an appointed doctor or employment medical adviser or by an approved dosimetry service, it is sufficient compliance with any such requirements if the employer makes arrangements affording an equivalent standard of protection for its employees and those arrangements are set out in local rules.

Modifications relating to the Ministry of Defence etc.

41.—(1) In this regulation, any reference to—

(a) "visiting forces" is a reference to visiting forces within the meaning of any provision of Part 1 of the Visiting Forces Act 1952; and

(b) "headquarters or organisation" is a reference to a headquarters or organisation designated for the purposes of the International Headquarters and Defence Organisations Act 1964.

(2) The Secretary of State for Defence may, in the interests of national security, by a certificate in writing exempt—

(a) Her Majesty's Forces;

(b) visiting forces;

(c) any member of a visiting force working in or attached to any headquarters or organisation; or

(d) any person engaged in work with ionising radiation for, or on behalf of, the Secretary of State for Defence,

from all or any of the requirements or prohibitions imposed by these Regulations and any such exemption may be granted subject to conditions and to a limit of time and may be revoked at any time by a certificate in writing, except that, where any such exemption is granted, suitable arrangements shall be made for the assessment and recording of doses of ionising radiation received by persons to whom the exemption relates.

(3) Sub-paragraph (i) of regulation 22(3) does not apply in relation to a practice carried out—

(a) by or on behalf of the Secretary of State for Defence;

(b) by a visiting force; or

(c) by any member of a visiting force in or attached to any headquarters or organisation.

(4) Regulations 5 (notification), 6 (registration) and 7 (licensing) do not apply in relation to work carried out by visiting forces or any headquarters or organisation on premises under the control of such visiting force, headquarters or organisation, as the case may be, or on premises under the control of the Secretary of State for Defence.

(5) The requirement of regulation 5(2) to notify the particulars specified by the Executive only applies in relation to the particulars (if so specified by the Executive) set out in paragraph (9), and the requirement in regulation 5(3) does not apply at all, in any case where the Secretary of State for Defence decides that not to so restrict the application of those regulations would be against the interests of national security or where suitable alternative arrangements have been agreed with the Executive.

(6) Regulation 5(4) does not apply to an employer in relation to work with ionising radiation undertaken for or on behalf of the Secretary of State for Defence, visiting forces or any headquarters or organisation.

(7) Regulations 23(6), (7) and (8) and regulation 25(9) do not apply in relation to visiting forces or any member of a visiting force working in or attached to any headquarters or organisation.

(8) In regulation 26(1) the requirement to notify the Executive of a suspected overexposure and the results of the consequent investigation and assessment do not apply in relation to the exposure of—

(a) a member of a visiting force; or

(b) a member of a visiting force working in or attached to a headquarters or organisation.

(9) The particulars referred to in paragraph (5) are—

(a) the name and address of the employer and a contact telephone or fax number or email address;

(b) the address of the premises where or from where the work activity is to be carried out and a telephone or fax number or email address at such premises;

(c) the nature of the business of the employer;

(d) dates of notification and commencement of the work activity.

Transitional provisions and savings

42. Schedule 8, which makes transitional provisions and savings, has effect.

Consequential amendments and revocation

43.—(1) Schedule 9, which contains consequential amendments to primary legislation and secondary legislation, has effect.

(2) The Ionising Radiations Regulations (Northern Ireland) 2000 are revoked.

SCHEDULE 1

Work not required to be notified under regulation 5

1. Work with ionising radiation is not required to be notified in accordance with regulation 5 when the only such work being carried out is in one or more of the following categories—

(a) where the concentration of activity per unit mass of a radioactive substance does not exceed the concentration specified in column 2 of Part 1 of Schedule 7;

(b) where the quantity of radioactive substance involved does not exceed the quantity specified in column 3 of Part 1 of Schedule 7;

(c) higher values than set out in subparagraphs (a) and (b) that, for specific applications, are approved by the Executive and satisfy the general exemption and clearance criteria set out in Part IV of Schedule 7;

(d) where apparatus contains radioactive substances in a quantity exceeding the values specified in sub-paragraphs (a) and (b) provided that—

(i) the apparatus is of a type approved—

(aa) by the Executive; or

(bb) by the Great Britain Executive in accordance with paragraph 1(d) of Schedule 1 to the Great Britain Regulations;

(ii) the apparatus is constructed in the form of a sealed source;

(iii) the apparatus does not under normal operating conditions cause a dose rate of more that $1\mu Svh^{-1}$ at a distance of 0.1m from any accessible surface; and

(iv) conditions for the disposal of the apparatus have been specified by the chief inspector;

(e) the operation of any electrical apparatus to which these Regulations apply other than apparatus referred to in sub-paragraph (f) provided that—

(i) the apparatus is of a type approved—

(aa) by the Executive; or

(bb) by the Great Britain Executive in accordance with paragraph 1(e) of Schedule 1 to the Great Britain Regulations; and

(ii) the apparatus does not under normal operating conditions cause a dose rate of more than $1\mu Svh^{-1}$ at a distance of 0.1m from any accessible surface;

(f) the operation of—

(i) any cathode ray tube intended for the display of visual images; or

(ii) any other electrical apparatus operating at a potential difference not exceeding 30kv,

provided that the operation of the tube or apparatus does not under normal operating conditions cause a dose rate of more than 1 μSvh^{-1} at a distance of 0.1m from any accessible surface;

(g) where the work involves material contaminated with radioactive substances resulting from authorised releases which the chief inspector has declared not to be subject to further control;

(h) specific types of practices in respect of which the Executive acting in accordance with the general exemption criteria set out in Part IV of Schedule 7 assesses that exemption from notification is appropriate.

2. In this Schedule, "the chief inspector" has the meaning assigned to it by section 47(1) of the Radioactive Substances Act 1993([a]).

([a]) 1993 c.12

SCHEDULE 2

Information for licensing: matters to which the Executive shall have regard

1. Responsibilities and organisational arrangements for protection and safety.

2.Staff competences, including information and training.

3.Design features of the facility and of radiation sources.

4.Anticipated occupational and public exposures in normal operation.

5.Safety assessment of the activities and the facility in order to:

(a) identify ways in which potential exposures or accidental and unintended medical exposures could occur;

(b) estimate, to the extent practicable, the probabilities and magnitude of potential exposures;

(c) assess the quality and extent of protection and safety provisions, including engineering features, as well as administrative procedures;

(d) define the operational limits and conditions of operation.

6. Emergency procedures.

7.Maintenance, testing, inspection and servicing so as to ensure that the radiation source and the facility continue to meet the design requirements, operational limits and conditions of operation throughout their lifetime.

8.Management of [radioactive waste] and arrangements for the disposal of such waste, in accordance with applicable regulatory requirements.

9.Management of disused sources.

10. Quality assurance.

SCHEDULE 3

Dose limits

PART I

Classes of Persons to whom Dose Limits Apply

Employees and trainees of 18 years of age or above

1.For the purposes of regulation 12(1), the limit on effective dose for any employee or trainee, being of 18 years of age or above, is 20 mSv in any calendar year.

2.Without prejudice to paragraph 1—

(a) the limit on equivalent dose for the lens of the eye is—

(i) 20 mSv in a calendar year; or

(ii) in accordance with conditions specified by the Executive from time to time, 100 mSv in any five consecutive calendar years subject to a maximum equivalent dose of 50 mSv in any single calendar year;

(b) the limit on equivalent dose for the skin is 500 mSv in a calendar year as applied to the dose averaged over any area of 1 cm^2 regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles is 500 mSv in a calendar year.

Trainees aged under 18 years

3.For the purposes of regulation 12(1), the limit on effective dose for any trainee under 18 years of age is 6 mSv in any calendar year.

4.Without prejudice to paragraph 3—

(a) the limit on equivalent dose for the lens of the eye is 15 mSv in a calendar year;

(b) the limit on equivalent dose for the skin is 150 mSv in a calendar year as applied to the dose averaged over any area of 1 cm^2 regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles is 150 mSv in a calendar year.

Women of reproductive capacity

5.Without prejudice to paragraphs 1 and 3, the limit on equivalent dose for the abdomen of a woman of reproductive capacity who is at work, being the equivalent dose from external radiation resulting from exposure to ionising radiation averaged throughout the abdomen, is 13 mSv in any consecutive period of three months.

Other persons

6.Subject to paragraph 7, for the purposes of regulation 12(1) the limit on effective dose for any person other than an employee or trainee referred to in paragraphs 1 or 3, including any person below the age of 16, is 1 mSv in any calendar year.

7.Paragraph 6 does not apply in relation to any person (not being a comforter or carer) who may be exposed to ionising radiation resulting from the medical exposure of another and in such a case the limit on effective dose for any such person is 5 mSv in any period of 5 consecutive calendar years.

8.Without prejudice to paragraphs 6 and 7—

(a) the limit on equivalent dose for the lens of the eye is 15 mSv in any calendar year;

(b) the limit on equivalent dose for the skin is 50 mSv in any calendar year averaged over any 1 cm^2 area regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles is 50 mSv in a calendar year.

PART II

9. For the purposes of regulation 12(2), the limit on effective dose for employees or trainees of 18 years or above is 100 mSv in any period of five consecutive calendar years subject to a maximum effective dose of 50 mSv in any single calendar year.

10. Without prejudice to paragraph 9—

(a) the limit on equivalent dose for the lens of the eye is—

(i) 20 mSv in a calendar year; or

(ii) in accordance with conditions specified by the Executive from time to time, 100 mSv in any five consecutive calendar years subject to a maximum equivalent dose of 50 mSv in any single calendar year;

(b) the limit on equivalent dose for the skin is 500 mSv in a calendar year as applied to the dose averaged over any area of 1 cm^2 regardless of the area exposed;

(c) the limit on equivalent dose for the hands, forearms, feet and ankles is 500 mSv in a calendar year.

11. Without prejudice to paragraph 9, the limit on equivalent dose for the abdomen of a woman of reproductive capacity who is at work, being the equivalent dose from external radiation resulting from exposure to ionising radiation averaged throughout the abdomen, is 13 mSv in any consecutive period of three months.

12. The employer shall ensure that any employee in respect of whom regulation 12(2) applies is not exposed to ionising radiation to an extent that any dose limit specified in paragraphs 9 to 11 is exceeded.

13. An employer shall not put into effect a system of dose limitation pursuant to regulation 12(2) unless—

(a) the radiation protection adviser and any employees who are affected have been consulted;

(b) any employees affected and the approved dosimetry service have been informed in writing of the decision and of the reasons for that decision; and

(c) notice has been given to the Executive at least 28 days (or such shorter period as the Executive may allow) before the decision is put into effect giving the reasons for the decision

14. Where there is reasonable cause to believe that any employee has been exposed to an effective dose greater than 20 mSv in any calendar year, the employer shall, as soon as is practicable—

(a) undertake an investigation into the circumstances of the exposure for the purpose of determining whether the dose limit referred to in paragraph 9 is likely to be complied with; and

(b) notify the Executive of that suspected exposure.

15. An employer shall review the decision to put into effect a system of dose limitation pursuant to regulation 12(2) at appropriate intervals and in any event not less than once every five years.

16. Where as a result of a review undertaken pursuant to paragraph 15 an employer proposes to revert to a system of annual dose limitation pursuant to regulation 12(1), the provisions of paragraph 13 apply as if the reference in that paragraph to regulation 12(2) was a reference to regulation 12(1).

17. Where an employer puts into effect a system of dose limitation in pursuance of regulation 12(2), that employer shall record the reasons for that decision and shall ensure that the record is preserved for a period of 50 years from the date of its making.

18. In any case where—

(a) the dose limits specified in paragraph 9 are being applied by an employer in respect of an employee; and

(b) the Executive is not satisfied that it is impracticable for that employee to be subject to the dose limit specified in paragraph 1 of Part 1 of this Schedule,

the Executive may require the employer to apply the dose limit specified in paragraph 1 of Part I with effect from such time as the Executive may consider appropriate having regard to the interests of the employee concerned.

19. In any case where, as a result of a review undertaken pursuant to paragraph 15, an employer proposes to revert to an annual dose limitation in accordance with regulation 12(1), the Executive may require the employer to defer the implementation of that decision to such time as the Executive may consider appropriate having regard to the interests of the employee concerned.

20. Any person who is aggrieved by the decision of the Executive taken pursuant to paragraphs 18 or 19 may appeal to the Department for the Economy.

21. Chapter I of the Schedule to the Deregulation (Model Appeal Provisions) Order (Northern Ireland) 1997 shall apply to any appeal under paragraph 20.

SCHEDULE 4

Matters in respect of which a radiation protection adviser shall be consulted

1. The implementation of requirements as to controlled and supervised areas.

2.The prior examination of plans for installations and the acceptance into service of new or modified sources of ionising radiation in relation to any engineering controls, design features, safety features and warning devices provided to restrict exposure to ionising radiation.

3.The regular calibration of equipment provided for monitoring levels of ionising radiation and the regular checking that such equipment is serviceable and correctly used.

4.The periodic examination and testing of engineering controls, design features, safety features and warning devices and regular checking of systems of work provided to restrict exposure to ionising radiation.

SCHEDULE 5

Particulars to be entered in the radiation passbook

1. Individual serial number of the passbook.

2.A statement that the passbook has been approved by the Executive for the purpose of these Regulations.

3.Date of issue of the passbook by the approved dosimetry service.

4.The name, telephone number and mark of endorsement of the issuing approved dosimetry service.

5.The name, address, telephone number and e-mail address of the employer.

6.Full name (surname, forenames) date of birth, gender and national insurance number of the outside worker to whom the passbook has been issued.

7.Date of the last medical review of the outside worker and the relevant classification in the health record maintained under regulation 25 as fit, fit subject to conditions (which shall be specified) or unfit.

8.The relevant dose limits applicable to the outside worker to whom the passbook has been issued.

9.The cumulative dose assessment in mSv for the year to date for the outside worker, external (whole body, organ or tissue) and/or internal as appropriate and the date of the end of the last assessment period.

10. In respect of services performed by the outside worker—

(a) the name and address of the employer responsible for the controlled area;

(b) the period covered by the performance of the services;

(c) the following estimated dose information, as appropriate—

(i) an estimate of any whole body effective dose in mSv received by the outside worker;

(ii) in the event of non-uniform exposure, an estimate of the equivalent dose in mSv to organs and tissues as appropriate; and

(iii) in the event of internal contamination, an estimate of the activity taken in or the committed dose.

SCHEDULE 6

Particulars to be contained in a health record

The following particulars shall be contained in a health record made for the purposes of regulation 25(3)—

(a) the employee's—

(i) full name;

(ii) sex

(iii) date of birth

(iv) permanent address; and

(v) National Insurance number;

(b) the date of the employee's commencement as a classified person in present employment;

(c) the nature of the employee's employment;

(d) in the case of a female employee, a statement as to whether that employee is likely to receive in any consecutive period of three months an equivalent dose of ionising radiation for the abdomen exceeding 13 mSv;

(e) the date of last medical examination or health review carried out in respect of the employee;

(f) the type of the last medical examination or health review carried out in respect of the employee;

(g) a statement by the appointed doctor or employment medical adviser made as a result of the latest medical examination or health review carried out in respect of the employee classifying the employee as fit, fit subject to conditions (which should be specified) or unfit;

(h) in the case of a female employee in respect of whom a statement has been made under paragraph (d) to the effect that that employee is likely to receive in any consecutive period of three months an equivalent dose of ionising radiation for the abdomen exceeding 13 mSv, a statement by the appointed doctor or employment medical adviser certifying whether in their professional opinion the employee should be subject to the additional dose limit specified in paragraphs 5 and 11 of Schedule 3;

(i) in relation to each medical examination and health review, the name and signature of the appointed doctor or employment medical adviser;

(j) the name and address of the approved dosimetry service with whom arrangements have been made for maintaining the dose record in accordance with regulation 22.

SCHEDULE 7

Quantities and Concentrations of radionuclides

Part I

Table of Radionuclides

1	*2*	*3*	*4*	*5*	*6*
Radionuclide name, symbol, isotope	*Concentration for notification*	*Quantity for notification*	*Concentration for registration*	*Quantity for notification of occurrence*	*Quantity for notification of occurrences*
	Regulation 5 (Bq/g)	*Regulation 5 (Bq)*	*Regulation 6 (Bq/g)*	*Regulation 30(1) Bq*	*Regulation 30(3) Bq*
Hydrogen					
H-3 (Tritiated compounds)	10^2	10^9	10^6	10^{12}	10^{10}
Beryllium					
Be-7	10	10^7	10^3	10^{12}	10^8
Carbon					
C-14	10	10^7	10^4	10^{11}	10^8
Oxygen					
O-15		10^9	10^2	10^{10}	
Fluorine					
F-18	1	10^6	10^1	10^{13}	10^7
Sodium					
Na-22	0.1	10^6	10^1	10^{10}	10^7
Na-24	0.1	10^5	10^1	10^{11}	10^6
Silicon					
Si-31	10^3	10^6	10^3	10^{13}	10^7
Phosphorus					
P-32	10^3	10^5	10^3	10^{10}	10^6
P-33	10^3	10^8	10^5	10^{11}	10^9
Sulphur					
S-35	10^2	10^8	10^5	10^{11}	10^9
Argon					
Ar-37		10^8	10^6	10^{13}	
Ar-41		10^9	10^2	10^9	
Chlorine					
Cl-36	1	10^6	10^4	10^{10}	10^7
Cl-38	10	10^5	10^1	10^{13}	10^6

Potassium					
K-40		10^{6}	10^{2}	10^{10}	10^{7}
K-42	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
K-43	10	10^{6}	10^{1}	10^{11}	10^{7}
Calcium					
Ca-45	10^{2}	10^{7}	10^{4}	10^{10}	10^{8}
Ca-47	10	10^{6}	10^{1}	10^{11}	10^{7}
Scandium					
Sc-46	0.1	10^{6}	10^{1}	10^{10}	10^{7}
Sc-47	10^{2}	10^{6}	10^{2}	10^{11}	10^{7}
Sc-48	1	10^{5}	10^{1}	10^{11}	10^{6}
Vanadium					
V-48	1	10^{5}	10^{1}	10^{10}	10^{6}
Chromium					
Cr-51	10^{2}	10^{7}	10^{3}	10^{12}	10^{8}
Manganese					
Mn-51	10	10^{5}	10^{1}	10^{13}	10^{6}
Mn-52	1	10^{5}	10^{1}	10^{10}	10^{6}
Mn-52m	10	10^{5}	10^{1}	10^{13}	10^{6}
Mn-53	10^{2}	10^{9}	10^{4}	10^{12}	10^{10}
Mn-54	0.1	10^{6}	10^{1}	10^{11}	10^{7}
Mn-56	10	10^{5}	10^{1}	10^{12}	10^{6}
Iron					
Fe-52+	10	10^{6}	10^{1}	10^{12}	10^{7}
Fe-55	10^{3}	10^{6}	10^{4}	10^{11}	10^{7}
Fe59	1	10^{6}	10^{1}	10^{10}	10^{7}
Cobalt					
Co-55	10	10^{6}	10^{1}	10^{11}	10^{7}
Co-56	0.1	10^{5}	10^{1}	10^{10}	10^{6}
Co-57	1	10^{6}	10^{2}	10^{11}	10^{7}
Co-58	1	10^{6}	10^{1}	10^{10}	10^{7}
Co-58m	10^{4}	10^{7}	10^{4}	10^{13}	10^{8}
Co-60	0.1	10^{5}	10^{1}	10^{10}	10^{6}
Co-60m	10^{3}	10^{6}	10^{3}	10^{16}	10^{7}
Co-61	10^{2}	10^{6}	10^{2}	10^{13}	10^{7}
Co-62m	10	10^{5}	10^{1}	10^{13}	10^{6}
Nickel					
Ni-59	10^{2}	10^{8}	10^{4}	10^{11}	10^{9}
Ni-63	10^{2}	10^{8}	10^{5}	10^{11}	10^{9}
Ni-65	10	10^{6}	10^{1}	10^{13}	10^{7}
Copper					
Cu-64	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
Zinc					
Zn-65	0.1	10^{6}	10^{1}	10^{10}	10^{7}
Zn-69	10^{3}	10^{6}	10^{4}	10^{14}	10^{7}
Zn-69m+	10	10^{6}	10^{2}	10^{12}	10^{7}

Gallium					
Ga-72	10	10^5	10^1	10^{11}	10^6
Germanium					
Ge-71	10^4	10^8	10^4	10^{13}	10^9
Arsenic					
As-73	10^3	10^7	10^3	10^{11}	10^8
As-74	10	10^6	10^1	10^{11}	10^7
As-76	10	10^5	10^2	10^{11}	10^6
As-77	10^3	10^6	10^3	10^{12}	10^7
Selenium					
Se-75	1	10^6	10^2	10^{11}	10^7
Bromine					
Br-82	1	10^6	10^1	10^{11}	10^7
Krypton					
Kr-74		10^9	10^2	10^9	
Kr-76		10^9	10^2	10^{10}	
Kr-77		10^9	10^2	10^9	
Kr-79		10^5	10^3	10^{10}	
Kr-81		10^7	10^4	10^{11}	
Kr-83m		10^{12}	10^5	10^{12}	
Kr-85		10^4	10^5	10^{12}	
Kr-85m		10^{10}	10^3	10^{10}	
Kr-87		10^9	10^2	10^9	
Kr-88		10^9	10^2	10^9	
Strontium					
Sr-85	1	10^6	10^2	10^{11}	10^7
Sr-85m	10^2	10^7	10^2	10^{13}	10^8
Sr-87m	10^2	10^6	10^2	10^{13}	10^7
Sr-89	10^3	10^6	10^3	10^{10}	10^7
Sr-90+	1	10^4	10^2	10^9	10^5
Sr-91+	10	10^5	10^1	10^{12}	10^7
Sr-92	10	10^6	10^1	10^{12}	10^7
Rubidium					
Rb-86	10^2	10^5	10^2	10^{11}	10^6
Yttrium					
Y-90	10^3	10^5	10^3	10^{11}	10^6
Y-91	10^2	10^6	10^3	10^{10}	10^7
Y-91m	10^2	10^6	10^2	10^{13}	10^7
Y-92	10^2	10^5	10^2	10^{12}	10^6
Y-93	10^2	10^5	10^2	10^{12}	10^6
Zirconium					
Zr-93	10	10^7	10^3	10^9	10^8
Zr-95+	1	10^6	10^1	10^{10}	10^7
Zr-97+	10	10^5	10^1	10^{11}	10^6
Niobium					
Nb-93m	10	10^7	10^4	10^{11}	10^8

Nb-94	0.1	10^{6}	10^{1}	10^{9}	10^{7}
Nb-95	1	10^{6}	10^{1}	10^{11}	10^{7}
Nb-97+	10	10^{6}	10^{1}	10^{13}	10^{7}
Nb-98	10	10^{5}	10^{1}	10^{13}	10^{6}
Molybdenum					
Mo-90	10	10^{6}	10^{1}	10^{12}	10^{7}
Mo-93	10	10^{8}	10^{3}	10^{11}	10^{9}
Mo-99	10	10^{6}	10^{2}	10^{11}	10^{7}
Mo-101	10	10^{6}	10^{1}	10^{13}	10^{7}
Technetium					
Tc-96	1	10^{6}	10^{1}	10^{11}	10^{7}
Tc-96m	10^{3}	10^{7}	10^{3}	10^{14}	10^{8}
Tc-97	10	10^{8}	10^{3}	10^{12}	10^{9}
Tc-97m	10^{2}	10^{7}	10^{3}	10^{10}	10^{8}
Tc-99	1	10^{7}	10^{4}	10^{10}	10^{8}
Tc-99m	10^{2}	10^{7}	10^{2}	10^{13}	10^{8}
Ruthenium					
Ru-97	10	10^{7}	10^{2}	10^{12}	10^{8}
Ru-103	1	10^{6}	10^{2}	10^{10}	10^{7}
Ru-105	10	10^{6}	10^{1}	10^{12}	10^{7}
Ru-106+	0.1	10^{5}	10^{2}	10^{9}	10^{6}
Rhodium					
Rh-103m	10^{4}	10^{8}	10^{4}	10^{15}	10^{9}
Rh-105	10^{2}	10^{7}	10^{2}	10^{12}	10^{8}
Palladium					
Pd-103+	10^{3}	10^{8}	10^{3}	10^{11}	10^{9}
Pd-109+	10^{2}	10^{6}	10^{3}	10^{12}	10^{7}
Silver					
Ag-105	1	10^{6}	10^{2}	10^{11}	10^{7}
Ag-108m+		10^{6}	10^{1}	10^{10}	10^{7}
Ag-110m	0.1	10^{6}	10^{1}	10^{10}	10^{7}
Ag-111	10^{2}	10^{6}	10^{3}	10^{11}	10^{7}
Cadmium					
Cd-109+	1	10^{6}	10^{4}	10^{10}	10^{7}
Cd-115+	10	10^{6}	10^{2}	10^{11}	10^{7}
Cd-115m+	10^{2}	10^{6}	10^{3}	10^{10}	10^{7}
Indium					
In-111	10	10^{6}	10^{2}	10^{11}	10^{7}
In-113m	10^{2}	10^{6}	10^{2}	10^{13}	10^{7}
In-114m+	10	10^{6}	10^{2}	10^{10}	10^{6}
In-115m	10^{2}	10^{6}	10^{2}	10^{13}	10^{7}
Tin					
Sn-113+	1	10^{7}	10^{3}	10^{11}	10^{8}
Sn-125	10	10^{5}	10^{2}	10^{10}	10^{6}
Antimony					
Sb-122	10	10^{4}	10^{2}	10^{11}	10^{5}
Sb-124	1	10^{6}	10	10^{10}	10^{7}

Sb-125+	0.1	10^6	10^2	10^{10}	10^7
Tellurium					
Te-123m	1	10^7	10^2	10^{10}	10^8
Te-125m	10^3	10^7	10^3	10^{10}	10^8
Te-127	10^3	10^6	10^3	10^{12}	10^7
Te-127+	10	10^7	10^3	10^{10}	10^8
Te-129	10^2	10^6	10^2	10^{14}	10^7
Te-129m	10	10^6	10^3	10^{10}	10^7
Te-131	10^2	10^5	10^2	10^{14}	10^6
Te-131m	10	10^6	10	10^{11}	10^7
Te-132+	1	10^7	10^2	10^{11}	10^7
Te-133	10	10^5	10	10^{14}	10^6
Te-133m	10	10^5	10	10^{13}	10^6
Te-134	10	10^6	10	10^{13}	10^7
Iodine					
I-123	10^2	10^7	10^2		
I-125	10^2	10^6	10^3	10^{10}	10^7
I-126	10	10^6	10^2		
I-129	0.01	10^5	10^2	10^9	10^6
I-130	10	10^6	10	10^{11}	10^7
I-131+	10	10^6	10^2	10^{10}	10^7
I-132	10	10^5	10	10^{12}	10^6
I-133	10	10^6	10	10^{11}	10^7
I-134	10	10^6	10	10^{13}	10^6
I-135	10	10^6	10	10^{12}	10^7
Xenon					
Xe-131m		10^4	10^4	10^{11}	
Xe-133		10^4	10^3	10^{11}	
Xe135		10^{10}	10^3	10^{10}	
Caesium					
Cs-129	10	10^5	10^2	10^{12}	10^6
Cs-131	10^3	10^6	10^3	10^{12}	10^7
Cs-132	10	10^5	10	10^{11}	10^6
Cs-134	0.1	10^4	10		
Cs-134m	10^3	10^5	10^3	10^{13}	10^6
Cs-135	10^2	10^7	10^4	10^{13}	10^7
Cs-136	1	10^5	10	10^{10}	10^6
Cs-137+	1	10^4	10	10^{10}	10^5
Cs-138	10	10^4	10	10^{13}	10^5
Barium					
Ba-131	10	10^6	10^2	10^{15}	10^7
Ba-140+	1	10^5	10		
Lanthanum					
La-140	1	10^5	10	10^{11}	10^6
Cerium					
Ce-139	1	10^6	10^2	10^{11}	10^7
Ce-141	10^2	10^7	10^2	10^{10}	10^8
Ce-143	10	10^6	10^2	10^{11}	10^7
Ce-144+	10	10^5	10^2	10^9	10^6
Praseodymium					
Pr-142	10^2	10^5	10^2	10^{12}	10^6
Pr-143	10^3	10^6	10^4	10^{11}	10^7

Neodymium					
Nd-147	10^{2}	10^{6}	10^{2}	10^{11}	10^{7}
Nd-149	10^{2}	10^{6}	10^{2}	10^{13}	10^{7}
Promethium					
Pm-147	10^{3}	10^{7}	10^{4}	10^{10}	10^{8}
Pm-149	10^{3}	10^{6}	10^{3}	10^{11}	10^{7}
Samarium					
Sm-151	10^{3}	10^{8}	10^{4}	10^{10}	10^{9}
Sm-153	10^{2}	10^{6}	10^{2}	10^{11}	10^{7}
Europium					
Eu-152	0.1	10^{6}	10	10^{9}	10^{7}
Eu-152m	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
Eu-154	0.1	10^{6}	10	10^{9}	10^{7}
Eu-155	1	10^{7}	10^{2}	10^{10}	10^{8}
Gadolinium					
Gd-153	10	10^{7}	10^{2}	10^{10}	10^{8}
Gd-159	10^{2}	10^{6}	10^{3}	10^{12}	10^{7}
Terbium					
Tb-160	1	10^{6}	10	10^{10}	10^{7}
Dysprosium					
Dy-165	10^{3}	10^{6}	10^{3}	10^{13}	10^{7}
Dy-166	10^{2}	10^{6}	10^{3}	10^{11}	10^{7}
Holmium					
Ho-166	10^{2}	10^{5}	10^{3}	10^{11}	10^{6}
Erbium					
Er-169	10^{3}	10^{7}	10^{4}	10^{11}	10^{8}
Er-171	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
Thulium					
Tm-170	10^{2}	10^{6}	10^{3}	10^{10}	10^{7}
Tm-171	10^{3}	10^{8}	10^{4}	10^{11}	10^{9}
Ytterbium					
Yb-175	10^{2}	10^{7}	10^{3}	10^{11}	10^{8}
Lutetium					
Lu-177	10^{2}	10^{7}	10^{3}	10^{11}	10^{8}
Hafnium					
Hf-181	1	10^{6}	10^{1}	10^{10}	10^{7}
Tantalum					
Ta-182	0.1	10^{4}	10	10^{10}	10^{5}
Tungsten					
W-181	10	10^{7}	10^{3}	10^{12}	10^{8}
W-185	10^{3}	10^{7}	10^{4}	10^{11}	10^{8}
W-187	10	10^{6}	10^{2}	10^{12}	10^{7}
Rhenium					
Re-186	10^{3}	10^{6}	10^{3}	10^{11}	10^{7}

Re-188	10^{2}	10^{5}	10^{2}	10^{12}	10^{6}
Osmium					
Os-185	1	10^{6}	10	10^{11}	10^{7}
Os-191	10^{2}	10^{7}	10^{2}	10^{11}	10^{8}
Os-191m	10^{3}	10^{7}	10^{3}	10^{12}	10^{8}
Os-193	10^{2}	10^{6}	10^{2}	10^{11}	10^{7}
Iridium					
Ir-190	1	10^{6}	10	10^{10}	10^{7}
Ir-192	1	10^{4}	10	10^{10}	10^{5}
Ir-194	10^{2}	10^{5}	10^{2}	10^{11}	10^{6}
Platinum					
Pt-191	10	10^{6}	10^{2}	10^{11}	10^{7}
Pt-193m	10^{3}	10^{7}	10^{3}	10^{12}	10^{8}
Pt-197	10^{3}	10^{6}	10^{3}	10^{12}	10^{7}
Pt-197m	10^{2}	10^{6}	10^{2}	10^{14}	10^{7}
Gold					
Au-198	10	10^{6}	10^{2}	10^{11}	10^{7}
Au-199	10^{2}	10^{6}	10^{2}	10^{11}	10^{7}
Mercury					
Hg-197	10^{2}	10^{7}	10^{2}	10^{12}	10^{8}
Hg-197m	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
Hg-203	10	10^{5}	10^{2}	10^{11}	10^{6}
Thallium					
Tl-200	10	10^{6}	10	10^{11}	10^{7}
Tl-201	10^{2}	10^{6}	10^{2}	10^{12}	10^{7}
Tl-202	10	10^{6}	10^{2}	10^{11}	10^{7}
Tl-204	1	10^{4}	10^{4}	10^{11}	10^{5}
Lead					
Pb-203	10	10^{6}	10^{2}	10^{12}	10^{7}
Pb-210+		10^{4}	10	10^{8}	10^{5}
Pb-212+		10^{5}	10	10^{10}	10^{6}
Bismuth					
Bi-206	1	10^{5}	10	10^{10}	10^{6}
Bi-207	0.1	10^{6}	10	10^{10}	10^{7}
Bi-210		10^{6}	10^{3}	10^{9}	10^{7}
Bi-212+		10^{5}	10	10^{11}	10^{6}
Polonium					
Po-203	10	10^{6}	10	10^{13}	10^{7}
Po-205	10	10^{6}	10	10^{12}	10^{7}
Po-207	10	10^{6}	10	10^{12}	10^{7}
Po-210		10^{4}	10	10^{7}	10^{5}
Astatine					
At-211	10^{3}	10^{7}	10^{3}	10^{10}	10^{8}
Radon:					
Rn-220+		10^{7}	10^{4}	10^{8}	10^{8}
Rn-222+-		10^{8}	10	10^{9}	10^{9}
Radium					
Ra-223+		10^{5}	10^{2}	10^{7}	10^{6}

Ra-224+		10^5	10	10^8	10^6
Ra-225	10	10^5	10^2	10^7	10^6
Ra-226+	0.1	10^4	10	10^7	10^5
Ra-227	10^2	10^6	10^2	10^{13}	10^7
Ra-228+		10^5	10	10^8	10^6
Actinium					
Ac-228		10^6	10	10^{10}	10^7
Thorium					
Th-226+	10^3	10^7	10^3	10^{11}	10^8
Th-227		10^4	10	10^7	10^5
Th-228+		10^4	1	10^6	10^5
Th-229+	0.1	10^3	1	10^6	10^4
Th-230		10^4	1	10^6	10^5
Th-231		10^7	10^3	10^{12}	10^8
Th-234+		10^5	10^3	10^{10}	10^6
Protactinium					
Pa-230	10	10^6	10	10^8	10^7
Pa-231		10^3	1	10^6	10^4
Pa-233	10	10^7	10^2	10^{10}	10^8
Uranium					
U-230+	10	10^5	10	10^7	10^6
U-231	10^2	10^7	10^2	10^{11}	10^8
U-232+	0.1	10^3	1	10^6	10^4
U-233	1	10^4	10	10^7	10^5
U-234		10^4	10	10^7	10^5
U-235+		10^4	10	10^7	10^5
U-236	10	10^4	10	10^7	10^5
U-237	10^2	10^6	10^2	10^{11}	10^7
U-238+		10^4	10	10^7	10^5
U-239	10^2	10^7	10^2	10^{14}	10^7
U-240		10^6	10^3	10^{12}	10^8
U-240+	10^2	10^6	10	10^{11}	10^7
Neptunium					
Np-237+	1	10^3	1	10^7	10^4
Np-239	10^2	10^7	10^2	10^{11}	10^7
Np-240	10	10^6	10	10^{13}	10^7
Plutonium					
Pu-234	10^2	10^7	10^2	10^{10}	10^8
Pu-235	10^2	10^7	10^2	10^{14}	10^8
Pu-236	1	10^4	10	10^7	10^5
Pu-237	10^2	10^7	10^3	10^{11}	10^8
Pu-238	0.1	10^4	1	10^6	10^5
Pu-239	0.1	10^4	1	10^6	10^5
Pu-240	0.1	10^3	1	10^6	10^4
Pu-241	10	10^5	10^2	10^8	10^6
Pu-242	0.1	10^4	1	10^6	10^5
Pu-243	10^3	10^7	10^3	10^{13}	10^8
Pu-244	0.1	10^4	1	10^6	10^5
Americium					
Am-241	0.1	10^4	1	10^6	10^5
Am-242	10^3	10^6	10^3	10^{10}	10^7

Am-242m+	0.1	10^4	1	10^6	10^5
Am-242+	0.1	10^3	1		
Curium					
Cm-242	10	10^5	10^2	10^7	10^6
Cm-243	1	10^4	1	10^7	10^5
Cm-244	1	10^4	10	10^7	10^5
Cm-245	0.1	10^3	1	10^6	10^4
Cm-246	0.1	10^3	1	10^6	10^4
Cm-247	0.1	10^4	1	10^6	10^5
Cm-248	0.1	10^3	1	10^6	10^4
Berkelium					
Bk-249	10^2	10^6	10^3	10^9	10^7
Californium					
Cf-246	10^3	10^6	10^3	10^9	10^7
Cf-248	1	10^4	10	10^7	10^5
Cf-249	0.1	10^3	1	10^6	10^4
Cf-250	1	10^4	10	10^6	10^5
Cf-251	0.1	10^3	1	10^6	10^4
Cf-252	1	10^4	10	10^7	10^5
Cf-253	10^2	10^5	10^2	10^8	10^6
Cf-254	1	10^3	1	10^7	10^4
Einsteinium					
Es-253	10^2	10^5	10^2	10^8	10^6
Es-254+	0.1	10^4	10	10^7	10^5
Es-254m+	10	10^6	10^2	10^9	10^7
Fermium					
Fm-254	10^4	10^7	10^4	10^{10}	10^8
Fm-255	10^2	10^6	10^3	10^9	10^7

[(a)] Parent radionuclides, and their progeny whose dose contributions are taken into account in the dose calculation (thus requiring only the exemption level of the parent radionuclide to be considered) are listed below

Parent radionuclide	*Progeny*	*Parent radionuclide*	*Progeny*
Fe-52	**Mn52m**	**Sn-113**	**In-113m**
Zn-69m	**Zn-69**	**Sb-125**	**Te-125m**
Sr-90	**Y-90**	**Te-127m**	**Te-127**
Sr-91	**Y-91m**	**Te-129m**	**Te-129**
Zr-95	**Nb-95**	**Te-131m**	**Te-131**
Zr-97	**Nb-97m, Nb-97**	**Te132**	**I-132**
Nb-97	**Nb-97m**	**Cs-137**	**Ba-137m**
Mo-99	**Tc-99m**	**Ce-144**	**Pr-144, Pr-144m**
Mo-101	**Tc-101**	**U-232**	**Th-228, Ra-224**
Ru-103	**Rh-103m**		**Rn-220, Po-216, Pb-212, Bi-212, Ti-208**
Ru-105	**Rh-105m**	**U-240**	**Np-240m, Np-240**
Ru-106	**Rh-106**	**Np237**	**Pa-233**
Pd-103	**Rh103m**	**Pu-244**	**U-240, Np-240m, Np-240**
Pd-109	**Ag-109m**	**Am-242m**	**Np-238**

Ag-110m	**Ag-110**	**Am-243**	**Np-239**
Cd-109	**Ag-109m**		
Cd-115	**In-115m**	**Cm-247**	**Pu-243**
Cd-115m	**In-115m**	**Es-254**	**Bk-250**
In-114m	**In-114**	**Es-254m**	**Fm-254**

PART II

Table of naturally occurring radionuclides

Values for exemption or clearance for naturally occurring radionuclides in solid materials in secular equilibrium with their progeny

Radionuclide: *Name, symbol and isotope*	*Concentration for notification* *Regulation 5* *(Bq/g)*
K-40	**10**
All other radionuclides of natural origin	**1**

PART III

Quantity ratios for more than one radionuclide

1. For the purpose of Regulation 2(4), the quantity ratio for more than one radionuclide is the sum of the quotients of the quantity of a radionuclide present Q_p divided by the quantity of that radionuclide specified in the appropriate column of Part I of this Schedule Q_{lim}, namely—

[diagram]

2. In any case where the isotopic composition of a radioactive substance is not known or is only partially known, the quantity ratio for that substance is to be calculated by using the values specified in the appropriate column in Part I for 'other radionuclides not listed above' for any radionuclide that has not been identified or where the quantity of a radionuclide is uncertain, unless the employer can show that the use of some other value is appropriate in the circumstances of a particular case, when the employer may use that value.

PART IV

General exemption and clearance criteria

3. The general criteria for the exemption of practices from notification are as follows:

(a) the radiological risks to individuals caused by the practice are sufficiently low, as to be of no regulatory concern; and

(b) the type of practice has been determined to be justified; and

(c) the practice is inherently safe.

4. Practices involving small amounts of radioactive substances or low activity concentrations, comparable to the exemption values laid down in columns 2, 3 or 4 of Part I of Schedule 7 are deemed to fulfil criterion (c).

5. Practices involving amounts of radioactive substances or activity concentrations below the exemption values laid down in columns 2, 3 or 4 of Part I of Schedule 7, are deemed to comply with criterion (a) without further consideration. This is also the case for the values in [BSSD Annex VII, Table A, Part 2 (NORMS) – not yet included in the draft regulations], with the

exception of the recycling of residues in building materials or the case of specific exposure pathways, for instance, drinking water.

PART V

Activity values defining high-activity sealed sources

For radionuclides not listed in the table below, the relevant activity is the same as the D-value defined in the IAEA publication: Dangerous quantities of radioactive material (D-values), (EPR-D-VALUES 2006)

Radionuclide	*Activity (TBq)*
Am-241	6 × 10 –2
Am-241/Be-9*	6 × 10 –2
Cf-252	2 × 10 –2
Cm-244	5 × 10 –2
Co-60	3 × 10 –2
Cs-137	1 × 10 –1
Gd-153	1 × 10 0
Ir-192	8 × 10 –2
Pm-147	4 × 10 1
Pu-238	6 × 10 –2
Pu-239/Be-9*	6 × 10 –2
Ra-226	4 × 10 –2
Se-75	2 × 10 –1
Sr-90 (Y-90)	1 × 10 0
Tm-170	2 × 10 1
Yb-169	3 × 10 –1

(*) The activity given is that of the alpha-emitting radionuclide.

SCHEDULE 8

Transitional provisions and savings

PART I

Interpretation and general transitional provisions

1. In this Schedule—

"the 2000 Regulations" means the Ionising Radiations Regulations (Northern Ireland) 2000;

"restated provision" means any provision of these Regulations so far as it corresponds (with or without modification) to a provision of the 2000 Regulations;

"superseded provision" means any provision of the 2000 Regulations as it has effect immediately before 1st January 2018 so far as it corresponds (with or without modification) to a provision of these Regulations.

2. In this Schedule references to things done include references to things omitted to be done.

3.Any thing done, or having effect as if done, under or for the purposes of any superseded provision, if effective immediately before 1st January 2018, has effect, so far as is required for continuing its effect on and after that date, as if done under or for the purposes of the corresponding restated provision.

4.Where any superseded provision—

(a) prescribed a penalty for an offence of any kind, that penalty continues to apply to offences of that kind committed before 1st January 2018;

(b) provides a defence to a contravention, the superseded provision continues to have effect on and after 1st January 2018 to the extent necessary to enable the defence to be available in relation to a contravention that took place before that date.

5. Any proceedings in connection with an offence or alleged offence which have been commenced under a superseded provision before 1st January 2018 may be continued and completed as if the superseded provision continued to have effect on and after 1st January 2018.

6.Where—

(a) an offence has been, or is alleged to have been, committed under a superseded provision before 1st January 2018, but

(b) proceedings have not been commenced before that date in connection with that offence, or alleged offence,

proceedings in connection with the offence or alleged offence under the superseded provision may be commenced under the relevant superseded provision as if the superseded provision continued to have effect on and after 1st January 2018.

7. Sub-paragraph (1) does not apply in any case where it was determined before 1st January 2018 not to commence proceedings in connection with the offence or alleged offence.

8.This Part of this Schedule is subject to any provision made in these Regulations.

9.Any specific provision in Part 2 of this Schedule is not to be taken to affect the generality of the provisions of this Part.

PART II

Specific Matters

10. Where on or before 5th February 2018 an employer commences for the first time since the coming into operation of these Regulations work in respect of which a notification is required under regulation 5(2), it will be sufficient compliance with that regulation if the employer notifies the Executive in respect of that work and provides the particulars required under regulation 5(2) before 5th February 2018.

11. Where on or before 5th February 2018 a person carries out a registrable practice under regulation 6(3) it will be sufficient compliance with that regulation if the person completes the registration process under regulation 6(3) on or before 5th February 2018.

12.A person who carried out a licensable practice under regulation 7 on or before 5th February 2018 is deemed to hold a licence for that practice under regulation 7(3) until 5th February 2018.

13. Where an employer has, in respect of an employee, applied the dose limits set out in paragraphs 9 to 11 of Schedule 4 to the 2000 Regulations in accordance with the requirements of regulation 11(2) of those Regulations and those dose limits have effect immediately before 1st January 2018, the Executive is deemed to have approved, for the purposes of regulation 12(2) of these Regulations, the application of the dose limits, in respect of that employee, set out in paragraphs 9 to 11 of Schedule 3 to these Regulations.

14. The deemed approval granted in paragraph 11 is valid until 5th February 2018.

15.A radiation passbook approved for the purposes of the 2000 Regulations and issued prior to [30th April 2018] in respect of an outside worker employed by an employer in Northern Ireland and which was at that date valid remains valid for such time as the worker to whom the passbook relates continues to be employed by the same employer.

16. Where a superseded provision provides a period of time within which an aggrieved person may apply for a decision to be reviewed, that period of time continues to apply on and after 1st January 2018 in relation to any decision notified to the aggrieved person before 1st January 2018.

SCHEDULE 9

Consequential Amendments

SCHEDULE 10

PREMISES AND ACTIVITIES WITHIN THE TERRITORIAL SEA OR A DESIGNATED AREA

Interpretation

1.—(1) In this Schedule—

"activity" includes a diving project and standing a vessel by;

"diving project" has the meaning assigned to it by regulation 2(1) of the Diving at Work Regulations (Northern Ireland) 2005([a]) save that it includes an activity in which a person takes part as a diver wearing an atmospheric pressure suit and without breathing in air or other gas at a pressure greater than atmospheric pressure;

"offshore installation" shall be construed in accordance with paragraph 2(2) and (3);

"supplementary unit" means a fixed or floating structure, other than a vessel, for providing energy, information or substances to an offshore installation;

"vessel" includes a hovercraft and any floating structure which is capable of being navigated.

(2) For the purposes of this Schedule, any structures and devices on top of a well shall be treated as forming part of the well.

(3) Any reference in this Schedule to premises and activities includes a reference to any person, article or substance on those premises or engaged in, or, as the case may be, used or for use in connection with any such activity, but does not include a reference to an aircraft which is airborne.

Offshore installations

2.—(1) This paragraph shall apply within the territorial sea or a designated area to and in relation to—

(a) any offshore installation and any activity on it;

(b) any activity in connection with, or any activity immediately preparatory to an activity in connection with, an offshore installation, whether carried on from the installation itself, in or from a vessel or in any manner, other than an activity falling within sub-paragraph (4);

(c) a diving project involving—

(i) the survey and preparation of the sea bed for an offshore installation;

(ii) the survey and restoration of the sea bed consequent on the removal of an offshore installation.

(2) Subject to sub-paragraph (3), in this Schedule, "offshore installation" means a structure which is, or is to be, or has been, used while standing or stationed in water, or on the foreshore or other land intermittently covered with water—

(a) for the exploitation, or exploration with a view to exploitation, of mineral resources by means of a well;

(b) for undertaking activities falling within paragraph 6(2);

(c) for the conveyance of things by means of a pipe;

(d) for undertaking activities that involve mechanically entering the pressure containment boundary of a well; or

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([a]) S.R. 2005 No. 45, as amended by S.R. 2007 No. 247

(e) primarily for the provision of accommodation for persons who work on or from a structure falling within any of the provisions of heads (a) to (d),

together with any supplementary unit which is ordinarily connected to it, and all the connections.

(3) Any reference in sub-paragraph (2) to a structure or supplementary unit does not include—

(a) a structure which is connected with dry land by a permanent structure providing access at all times and for all purposes;

(b) a well;

(c) a mobile structure which has been taken out of use and is not yet being moved with a view to its being used for any of the purposes specified in sub-paragraph (2);

(d) any part of a pipeline; and

(e) a structure falling within paragraph 8(c).

(4) Subject to sub-paragraph (5), the following activities fall within this paragraph—

(a) transporting, towing or navigating an installation;

(b) any of the following activities carried on in or from a vessel—

(i) giving assistance in the event of an emergency;

(ii) training in relation to the giving of assistance in the event of an emergency;

(iii) testing equipment for use in giving assistance in the event of an emergency;

(iv) putting or maintaining a vessel on stand-by ready for an activity referred to in any of sub-heads (i) to (iii).

(5) Sub-paragraph (4)(b) does not apply in respect of a vessel in or from which an activity is carried on in connection with, or any activity that is immediately preparatory to an activity in connection with, an offshore installation other than an activity falling within sub-paragraph 4(b).

Wells

3.—(1) Subject to sub-paragraph (2), this paragraph applies within the territorial sea or a designated area to and in relation to—

(a) a well and any activity in connection with it; and

(b) an activity which is immediately preparatory to any activity in head (a).

(2) Sub-paragraph (1) includes keeping a vessel on station for the purpose of working on a well but otherwise does not include navigation or an activity connected with navigation.

Pipelines

4.—(1) This paragraph applies within the territorial sea or a designated area to and in relation to—

(a) any pipeline;

(b) any pipeline works;

(c) the following activities in connection with pipeline works—

(i) the loading, unloading, fuelling or provisioning of a vessel;

(ii) the loading, unloading, fuelling, repair and maintenance of an aircraft on a vessel,

being in either case a vessel which is engaged in pipeline works; or

(iii) the moving, supporting, laying or retrieving of anchors attached to a pipe-laying vessel including the supervision of those activities and giving of instruction in connection with them.

(2) In this paragraph—

"pipeline" means a pipe or system of pipes for the conveyance of any thing, together with—

(a) any apparatus for inducing or facilitating the flow of any thing through, or through part of, the pipe or system;

(b) any apparatus for treating or cooling any thing which is to flow through, or through part of, the pipe or system;

(c) valves, valve chambers and similar works which are annexed to, or incorporated in the course of, the pipe or system;

(d) apparatus for supplying energy for the operation of any such apparatus or works as are mentioned in heads (a) to (c);

(e) apparatus for the transmission of information for the operation of the pipe or system;

(f) apparatus for the cathodic protection of the pipe or system; and

(g) a structure used or to be used solely for the support of a part of the pipe or system;

but not including a pipeline of which no initial or terminal point is situated in the United Kingdom, within the territorial sea adjacent to the United Kingdom, or within a designated area;

"pipeline works" means—

(h) assembling or placing a pipeline or length of pipeline including the provision of internal or external protection for it;

(i) inspecting, testing, maintaining, adjusting, repairing, altering or renewing a pipeline or length of pipeline;

(j) changing the position of or dismantling or removing a pipeline or length of pipeline;

(k) opening the bed of the sea for the purposes of the works mentioned in heads (a) to (c), and tunnelling or boring for those purposes;

(l) any activities incidental to the activities described in heads (a) to (d);

(m) a diving project in connection with any of the works mentioned in heads (a) to (e) or for the purpose of determining whether a place is suitable as part of the site of a proposed pipeline and the carrying out of surveying operations for settling the route of a proposed pipeline.

Mines

5.—(1) This paragraph applies to and in relation to a mine within the territorial sea, and any activity in connection with it, while it is being worked.

(2) In this paragraph "mine" has the same meaning as in the Mines Act (Northern Ireland) 1969([a]).

Gas Importation and Storage

6.—(1) Subject to sub-paragraph (3), this paragraph applies within the territorial sea to and in relation to any activities connected with or immediately preparatory to the activities set out in sub-paragraph (2).

(2) The activities are—

(a) the unloading of gas to an installation or pipeline;

(b) the storage of gas, whether temporary or permanent, in or under the shore or bed of any water;

(c) the conversion of any natural feature for the purpose of storing gas, whether temporarily or permanently;

(d) the recovery of gas stored;

([a]) 1969 c. 6 (N.I.)

(e) exploration with a view to, or in connection with, the carrying on of activities within heads (a) to (d).

(3) Sub-paragraph (1) does not apply to an activity falling within sub-paragraph (2) if the provisions of this Schedule apply to or in relation to that activity by virtue of paragraph 2(1).

(4) In this paragraph—

"gas" means any substance which is gaseous at a temperature of 15°C and a pressure of 101.325 kPa (1013.25 mb); and

"installation" includes any floating structure or device maintained on a station by whatever means.

(5) For the purposes of sub-paragraphs (2) and (4), references to gas include any substance which consists wholly or mainly of gas.

Production of Energy from Water or Wind

7.—(1) This paragraph applies within the territorial sea to and in relation to any energy structure or activities connected with or preparatory to—

(a) the exploitation of those areas for the production of energy from water or wind,

(b) the exploration of such areas with a view to, or in connection with, the production of energy from water or wind, or

(c) the operation of a cable for transmitting electricity from an energy structure.

(2) In this paragraph "energy structure" means a fixed or floating structure or machine, other than a vessel, which is, or is to be, or has been, used for producing energy from water or wind.

Underground Coal Gasification

8. This paragraph applies within the territorial sea or a designated area to and in relation to—

(a) underground coal gasification and any activity in connection with it;

(b) any activity which is immediately preparatory to any activity in sub-paragraph (a); and

(c) any fixed or floating structure which is, or is to be, or has been, used in connection with the carrying on of activities within sub-paragraphs (a) and (b).

Other activities

9.—(1) Subject to sub-paragraph (2), this paragraph applies within the territorial sea to and in relation to—

(a) the construction, reconstruction, alteration, repair, maintenance, cleaning, use, operation, demolition and dismantling of any building, or other structure, not being in any case a vessel, or any preparation for any such activity;

(b) the transfer of people or goods between a vessel or aircraft and a structure (including a building) mentioned in head (a);

(c) the loading, unloading, fuelling or provisioning of a vessel;

(d) a diving project;

(e) the laying, installation, inspection, maintenance, operation, recovery or repair of a cable;

(f) the construction, reconstruction, finishing, refitting, repair, maintenance, cleaning or breaking up of a vessel except when carried out by the master or any officer or member of the crew of that vessel;

(g) the maintaining on a station of a vessel which would be an offshore installation were it not a structure to which paragraph 2(3)(c) applies;

(h) the transfer of people or goods between a vessel or aircraft and a structure mentioned in head (g).

(2) This paragraph does not apply—

(a) to a case where paragraph 2, 3, 4, 5, 6, 7 or 8 applies; or

(b) to vessels which are registered outside the United Kingdom and are on passage through the territorial sea.

ANNEX 2

Revised ACOP text

1	2	3	4	5
Guidance Paragraph and Current/new Regulation reference	**Current ACOP**	**New and revised ACOP**	**Decision on status**	**Rationale for decision**
9 Reg 2(1)/3(1)	**For a substance used in a practice, its activity should never be disregarded for the purposes of radiation protection where that activity exceeds the values set out in column 2 of Schedule 8, subject to the quantity of the substance also exceeding the values set out in column 3 of Schedule 8.**	**No change.**	**Retain as ACOP**	This will ensure consistency with Other Government Departments legislation such as Environmental Permitting Regulations
11 Reg 2(1)/3(1)	**In the special case of substances containing naturally occurring radionuclides used in work other than a practice, their activity cannot be disregarded for the purposes of radiation protection where their use is likely to lead to employees or other people receiving an effective dose of ionising radiations in excess of 1 millisievert in a year.**	**No change.**	**Retain as ACOP –** more work required	More work required on the identification of Naturally Occurring Radioactive Materials (NORM) has been discussed – identified industries using NORM listed in BSSD should be considered as a new schedule in IRR. This list is not exhaustive so further numerical quantification of NORM to help industry is required.
44 Reg 7/8	**Where a radiation employer is required to undertake a prior risk assessment, the following matters must be**	**No change.**	**Retain as ACOP**	Clarifies the content of the risk assessment specific to ionising radiation and adds to both IRRs

	considered, where they are relevant: (a) **the nature of the sources of ionising radiation to be used, or likely to be present, including accumulation of radon in the working environment;** (b) **estimated radiation dose rates to which anyone can be exposed;** (c) **the likelihood of contamination arising and being spread;** (d) **the results of any previous personal dosimetry or area monitoring relevant to the proposed work;** (e) **advice from the manufacturer or supplier of equipment about its safe use and maintenance;** (f) **engineering control measures and design features already in place or planned;** (g) **any planned systems of work;** (h) **estimated levels of airborne and surface contamination likely to be encountered;** (i) **the effectiveness and the suitability of personal protective equipment to be provided;** (j) **the extent of unrestricted access to working areas where dose rates or contamination levels are likely to be significant;** (k) **possible accident situations, their likelihood and potential severity;** (l) **the consequences of possible failures of control measures – such as electrical interlocks,**			and MHSWR obligations.

	ventilation systems and warning devices – or systems of work; (m) **steps to prevent identified accidents situations, or limit their consequences.**			
45 Reg 7/8	**This prior risk assessment should enable the employer to determine:** **(p) what action is needed to ensure that the radiation exposure of all persons is kept as low as reasonably practicable (regulation 8(1))** **(q) what steps are necessary to achieve this control of exposure by the use of engineering controls, design features, safety devices and warning devices (regulation 8(2)(a)) and, in addition, by the development of systems of work (regulation 8(2)(b));** **(r) whether it is appropriate to provide personal protective equipment and if so what type would be adequate and suitable (regulation 8(2)(c));** **(s) whether it is appropriate to establish any dose constraints for planning or design purposes, and if so what values should be used (regulation 8(3));** **(t) the need to alter the working conditions of any female employee who declares she is pregnant or is breastfeeding (regulation 8(5));** **(u) an appropriate investigation level to check that exposures are being restricted as far as reasonably practicable (regulation 8(7));** **(v) what maintenance and testing schedules are**	**This prior risk assessment should enable the employer to determine:** **(a) what action is needed to ensure that the radiation exposure of all persons is kept as low as reasonably practicable (regulation 8(1))** **(b) what steps are necessary to achieve this control of exposure by the use of engineering controls, design features, safety devices and warning devices (regulation 8(2)(a)) and, in addition, by the development of systems of work (regulation 8(2)(b));** **(c) whether it is appropriate to provide personal protective equipment and if so what type would be adequate and suitable (regulation 8(2)(c));** **(d) whether it is appropriate to establish any dose constraints for planning or design purposes, and if so what values should be used**	**Retain as ACOP –** add specific content	Clarifies the content of the risk assessment specific to ionising radiation and adds to both IRRs and MHSWR obligations. To clarify that prior risk assessment will also help to determine leak testing, a bullet point will be added – this will be deleted from ACOP paragraph 283.

	required for the control measures selected (regulation 10); **(w) what contingency plans are necessary to address reasonably foreseeable accidents (regulation 12);** **(x) the training needs of classified and non-classified employees (regulation 14);** **(y) the need to designate specific areas as controlled or supervised areas and to specify local rules (regulations 16 and 17);** **(z) the actions needed to ensure restriction of access and other specific measures in controlled or supervised areas (regulation 18);** **(aa) the need to designate certain employees as classified persons (regulation 20);** **(bb) the content of a suitable programme of dose assessment for employees designated as classified persons and for others who enter controlled areas (regulations 18 and 21);** **(cc) the responsibilities of managers for ensuring compliance with these Regulations; and** **(dd) an appropriate programme of monitoring or auditing of arrangements to check that the requirements of these Regulations are being met.**	**(regulation 8(3));** **(e) the need to alter the working conditions of any female employee who declares she is pregnant or is breastfeeding (regulation 8(5));** **(f) an appropriate investigation level to check that exposures are being restricted as far as reasonably practicable (regulation 8(7));** **(g) what maintenance and testing schedules are required for the control measures selected (regulation 10);** **(h) what contingency plans are necessary to address reasonably foreseeable accidents (regulation 12);** **(i) the training needs of classified and non-classified employees (regulation 14);** **(j) the need to designate specific areas as controlled or supervised areas and to specify local rules (regulations 16 and 17);** **(k) the actions needed to ensure restriction of access**		

		and other specific measures in controlled or supervised areas (regulation 18); **(l) the need to designate certain employees as classified persons (regulation 20);** **(m) the content of a suitable programme of dose assessment for employees designated as classified persons and for others who enter controlled areas (regulations 18 and 21);** **(n) the requirements for the leak testing of radioactive sources (regulation 27)** **(o) the responsibilities of managers for ensuring compliance with these Regulations; and** **(p) an appropriate programme of monitoring or auditing of arrangements to check that the requirements of these Regulations are being met.**		
59 Reg 8(1)/9(1)	**Dose sharing should not be used as a primary means of keeping exposures below the dose limits. Rather, the radiation employer should give priority to improving engineering controls and adopting other means of restricting exposure, including changing the**	**Dose sharing should not be used as a primary means of keeping exposures below the dose limits.**	**Partial deletion** – keep first sentence as ACOP, the remaining text	The first sentence gives clear instruction on compliance. The text following is guidance rather than ACOP.

	methods of work. However, if a choice has to be made between restricting doses to individuals and restricting doses to a group of persons, priority should be given to keeping individual doses as far below dose limits as is reasonably practicable.		redraft and move to guidance.	
60 Reg 8(1)/9(1)	**Radiation employers should take particular steps to restrict the exposure of any employees who would not normally be exposed to ionising radiation in the course of their work. The dose control measures should make it unlikely that such persons would receive an effective dose greater than 1 millisievert per year or an equivalent dose which exceeds that specified as a dose limit for any other person in Schedule 4.**	**Employers must restrict the exposure of any employees who would not normally be exposed to ionising radiation in the course of their work. The dose control measures must make it unlikely that such persons would receive an effective dose greater than 1 millisievert per year or an equivalent dose which exceeds that specified as a dose limit for any other person in Schedule 4.**	**Retain as ACOP**	ACOP makes it clear that for employees not normally exposed to ionising radiation, exposure must not exceed 1mSv per year. The Regulation only refers to employees without further clarification. This is consistent with the principle of dose limitation set out in the directive.
71 Reg 8(1)/9(1)	**Radioactive materials, including those in the form of sealed sources, should not be held or directly manipulated in the hand (or close to the hand) if it is practicable for the task to be completed by other means, unless the skin of the hand is unlikely to receive a significant dose and the employee is unlikely to become significantly contaminated with radioactive substances.**	No ACOP required	**Full deletion –** move to guidance	This reflects the general overarching principles of risk limitation so this does not add anything to the Regulation
79 Reg 8(2)/9(2)	**Where reasonably practicable, work involving exposure to external radiation must be done in a room, enclosure, cabinet or purpose-made structure which is provided with adequate shielding. In other cases, adequate local shielding should be used as far as reasonably practicable. Shielding, including beam collimation, will normally be adequate if designed to**	**Where reasonably practicable, work involving exposure to external radiation must be done in a room, enclosure, cabinet or purpose-made structure which is provided with adequate shielding.**	**Retain as ACOP Redraft and streamline**	This paragraph provides additional detail on the adequacy of the measures described in the regulations. Paragraph needed to be redrafted to focus on key information, as stakeholders have fed back that this is unclear..

	reduce dose rates below 7.5 microsieverts per hour in specific locations where persons will be working. If the device is designed for use in public areas or where there is continuous access to the working area by employees or other persons not directly involved in the work, the shielding should be designed to reduce dose rates to the lowest level that is reasonably practicable. In this case, the dose rate should be so low that it is unnecessary to designate the area around the device as a supervised area.	**Shielding will be adequate if it is not necessary to designate the area around the room, enclosure, cabinet, radiation store or purpose-made structure as a supervised area.**		Radiation store included in 2nd paragraph to make it clear that radiation stores must not present a risk.
81 Reg 8(2)/9(2)	**Fluoroscopic devices should be provided with viewing facilities which do not permit direct vision of the fluoroscopy screen.**		**Possible full deletion**	HSE is checking with stakeholders over the validity of this paragraph in current operations.
83 Reg 8(2)/9(2)	**Radiation employers should give priority to the containment of radioactive substances as a means of preventing dispersal or contamination. Where such containment alone is not sufficient to give the required protection, ventilation should be provided. A building, room or enclosure being built or modified for work with unsealed radioactive material should incorporate design features which take into account the risk of contamination likely to arise from the work. In particular, radiation employers should take steps to ensure ease of cleaning and decontamination of worktops, floors, etc. There should also be provision for safe decommissioning or dismantling of equipment which may have become internally contaminated.**	**Radiation employers must give priority to the containment of radioactive substances as a means of preventing dispersal or contamination. Where such containment alone is not sufficient to give the required protection, ventilation should be provided.**	**Partial deletion** – keep first 2 sentences as ACOP, rest move to guidance	The first two sentences of this section are relevant to how to comply. The text that follows this is guidance.
87 Reg 8(2)/9(2)	**Where control systems permit, interlocks or trapped key systems should be provided and properly used where they can prevent access to high dose rate**	**Where control systems permit, interlocks or trapped key systems should be provided**	Retain	The original example which was included in brackets is in practice used by dutyholders to define what a high-dose rate is.

	enclosures (for example in which employed persons could receive an effective dose greater than 20 millisieverts or an equivalent dose in excess of a dose limit within several minutes when radiation emission is under way). They should be fitted so that the control system will ensure an exposure: **a) cannot commence while the access door, access hatch, cover or appropriate barrier to the enclosure is open;** **b) is interrupted if the access door, access hatch, cover or barrier is opened; and** c) **does not recommence on the mere act of closing a door, access hatch, cover or barrier.**	**and properly used where they can prevent access to high dose rate enclosures in which employed persons could receive an effective dose greater than 20 millisieverts or an equivalent dose in excess of a dose limit within several minutes when radiation emission is under way. They should be fitted so that the control system will ensure an exposure:** **(a) cannot commence while the access door, access hatch, cover or appropriate barrier to the enclosure is open;** **(b) is interrupted if the access door, access hatch, cover or barrier is opened; and** **(c) does not recommence on the mere act of closing a door, access hatch, cover or barrier.**		
96 Reg 8(2)/9(2)	**Where there is a risk of significant exposure arising from unauthorised or malicious operation of X-ray generators or radioactive source containers, radiation employers should make use of equipment which has been fitted with locking-off arrangements to prevent its uncontrolled use.**	**No change**	**Retain as ACOP** – on the basis of legal advice and specialist expertise.	Legal advice was sought by HSE to clarify the position with respect to this, as Policy and specialists differed in opinion regarding retention of ACOP. Lawyers are of the opinion that this is a good example of the ACOP to help with compliance.

97 Reg 8(2)/9(2)	**The initiation of exposures should be under key control, or by some equally effective means, so as to prevent unintended or accidental emission of a radiation beam or exposure of a source. This is particularly important where the control point is remote from the equipment which will be activated or there is general access to equipment by members of the public or personnel who are not undertaking the work with ionising radiation.**	**No change**	**Retain as ACOP.**	Lawyers feel this is similar to the paragraph above. This paragraph gives practical measures to avoid a breach in the regulation.
99 Reg 8(2)/9(2)	**Sources of ionising radiation which can give rise to significant exposure in a very short time should be fitted with suitable warning devices which:** **(a) indicate for a radioactive source whether it is in or out of its shielding (or the exposure shutter is open or closed);** **(b) indicate for an X-ray generator when the tube is in a state of readiness to emit radiation and, except for diagnostic radiology, give a signal when the useful beam is about to be emitted and a distinguishable signal when the emission is under way unless this is impracticable;** **(c) for X-ray generators other than those used for diagnostic radiology, are designed to be automatic and fail-safe, ie if the warning device itself fails the exposure will not proceed.**	**Sources of ionising radiation which can cause significant exposure in a very short time must be fitted with suitable warning devices which:** **a) indicate for a radioactive source whether it is in or out of its shielding ~~(~~and/or the exposure shutter is open or closed~~)~~;** **b) indicate for an X-ray generator when the tube is ready to emit radiation;** **c) for X-ray generators other than those used for diagnostic radiology, give a signal when the beam is about to be emitted and; a signal which is clearly different when the emission is under way;** **d) for X-ray generators**	**Retain as ACOP**	Warning devices are included as a design feature mainly on the basis of this ACOP paragraph, retention will ensure this is upheld. An extra paragraph has been added to clarify the text for readability.

		other than those used for diagnostic radiology, are designed to be automatic and fail-safe, ie if the warning device itself fails the exposure will not proceed.		
100 Reg 8(2)/9(2)	**The radiation employer should make sure that warning signals can be seen or heard by all those people who need to know the status of the radiation equipment for protection purposes.**	**Employers must make sure that warning signals can be seen or heard by all those people who need to know the status of the radiation equipment for protection purposes.**	**Retain as ACOP**	This paragraph and the ACOP paragraph above have similar themes. This ACOP is required as it has been cited in a number of enforcement actions. This is particularly important for industrial radiography which is a sector priority.
111 Reg 8(2)/9(2)	**The radiation employer should require a check to be made with a suitable radiation monitoring instrument after each exposure using high dose rate sealed source equipment (such as that generally used for industrial radiography or processing of products) unless reliance can be placed on effective devices to ensure that the equipment has been restored to a safe state. The purpose is to establish that the sealed source has fully retracted to its shielded position and that the area is safe to enter.**	**Employers working with ionising radiation must make sure that a check is made with a suitable radiation monitoring instrument after each exposure using high dose rate sealed source equipment (such as that generally used for industrial radiography or processing of products). The purpose is to establish that the sealed source has fully retracted to its shielded position and that the area is safe to enter.** **In addition, all employees engaged in the work must**	**Retain as ACOP** – redraft to clarify and fit in with guidance paragraph 112.	This text does add to compliance with reg 8(2) with respect to systems of work regarding sealed sources. Personal dosemeters with an alarm triggered by high dose rates are now an industry standard as a control measure to restrict exposure, at the time the 1999 regulations were drafted the dosemeters were relatively new.

		wear a dosemeter which gives an audible alarm when high doses are detected.		
114 Reg 8(2)/9(2)	**The term 'adequate' in regulation 8(2)(c) refers to the ability of the equipment to protect the wearer. The term 'suitable' refers to the correct matching of the equipment to the job and the person. To be considered 'adequate and suitable' personal protective equipment should be correctly selected and used.**	**No ACOP required**	**Full deletion** – move into guidance	HSE already has advice available on PPE. This should be referred/linked to in guidance. The directive only states that "appropriate" PPE is required
126 Reg 8(3)/9(3)	**It should always be appropriate to use dose constraints in restricting exposure for carers and comforters**	Under review with Department of Health	**Needs discussion:** Article 6.1 of the BSSD requires dose constraints to be established for carers and comforters – however this area may move over to DH and therefore could come under IRMER	HSE have had prolonged discussions with the Department of Health regarding the division of the responsibilities regarding medical exposure, these discussions are ongoing but may result in this moving to the new Ionising Radiation (Medical Exposures) Regulations (IRMER).
165 Reg 10(1)/11(1)	**All active engineering controls and design features (eg local exhaust ventilation systems), safety features (eg electromechanical interlocks) and warning devices should be subjected to a regime of examination and test at suitable intervals.**	**No ACOP required**	**Full deletion**	This repeats the regulation and does not add or clarify the regulation to help with compliance.
175 Reg	**Sufficient records must be kept of these**	**No change**	**Retain ACOP**	PUWER regs are too general for

10(1)/11(1)	**examinations and tests to enable radiation employers to identify which controls, features or devices have been examined or tested, what action is required to maintain them and when the next examination or test is due.**			this to be deleted. Also, need to avoid end user having to go to alternative regs.
181 Reg 11(1)/12(1)	**Assessments of effective dose and equivalent dose from external radiation for the purpose of comparison with the dose limits specified in Schedule 4 of the Regulations should be made using the values and relationships in Annex II of Council Directive 96/29/Euratom[3].**	**Assessments of effective dose and equivalent dose from external radiation for the purpose of comparison with the dose limits specified in Schedule 4 of the Regulations must be made using the values and relationships in Annex II of Council Directive 2013/59/EURATOM.**	**Retain ACOP**	Any move to delete this and rely on the definition provided by the Directive would restrict the services that measure dose to using agreed methodologies and not offer flexibility as to innovative approaches to calculate dose where the agreed methodologies may not be suitable.
182 Reg 11(1)/12(1)	**Assessments of committed effective dose and committed equivalent dose following intakes of radionuclides into the body should take account of the dose likely to accrue over a period of 50 years following the intake (up to age 70 for children) and should be attributed to the calendar year of the intake for the purpose of comparison with dose limits.**	**No change**	**Retain ACOP**	Timescales are set out within the definition of committed effective dose – however enforcement action cannot be taken against a definition so retention of this paragraph allows this.
183 Reg 11(1)/12(1)	**For the assessment of compliance with the dose limits relating to members of the public, realistic estimates should be made of the average effective dose (and where relevant equivalent dose) to representative members of the appropriate reference group for the expected pathways of exposure.**	**No ACOP required**	**Full deletion** – move text to regulations to meet new requirement	This is a new requirement of BSSD.
216 Reg 13(1)-(3)/14(1)-(3)	**To be suitable, a radiation protection adviser will need to possess the specific knowledge, experience and competence required for giving advice on the particular working conditions or circumstances for**	**No ACOP required**	**Full deletion** possible guidance text required	This text will be covered in guidance, and it is also to additive to the management regulations. Additionally, the definition of a

	which the employer is making the appointment.			radiation protection adviser which will be in the regulations means that it is inherent that these qualities are met.
217 Reg 13(1)-(3)/14(1)-(3)	**In addition to the specific matters set out in Schedule 5, radiation employers must consult a radiation protection adviser where advice is necessary for the observance of the Regulations. This should normally include:** **a) the risk assessment required by regulation 7;** **b) the designation of controlled and supervised areas as required by regulation 16, except where there is good reason to consider that such areas are not required, for example based on advice from the supplier of the radiation source or written guidance from an authoritative body;** **c) the handling of the various investigations required by the Regulations;** **d) the drawing up of contingency plans required by regulation 12;** **e) the dose assessment and recording required by regulation 21; and** **f) the quality assurance programme in respect of medical equipment or apparatus required by regulation 32.**	**No change**	**Retain as ACOP**	Legal advice has suggested that this should be kept as ACOP to support the Directive.
232 Reg 13(4)/14(4)	**Radiation employers who need advice in relation to plans for off- site emergencies should provide, or may arrange to share, a specialised radiation protection unit. Such units should be distinct from production and operational units and authorised to perform**	**No ACOP required**	**Full deletion**	IRR and REPPIR were not developed in parallel so this is now not needed in IRR

	radiation protection tasks.			
248 Reg 16(1)/15(1)	**Special procedures should always be necessary to restrict the possibility of significant exposure, and therefore employers should designate controlled areas, in cases where:** **(f) the external dose rate in the area exceeds 7.5 microsieverts per hour when averaged over the working day;** **(g) the hands of an employee can enter an area and the 8-hour time average dose rate in that area exceeds 75 microsieverts per hour;** **(h) there is a significant risk of spreading radioactive contamination outside the working area;** **(i) it is necessary to prevent, or closely supervise, access to the area by employees who are unconnected with the work with ionising radiation while that work is under way; or** **(j) employees are liable to work in the area for a period sufficient to receive an effective dose in excess of 6 millisieverts a year.**	**Employers must designate controlled areas, in cases where:** **a) the external dose rate in the area exceeds 7.5 microsieverts per hour;** **b) the hands of an employee can enter an area and the dose rate in that area exceeds 75 microsieverts per hour;** **c) there is a risk of spreading significant radioactive contamination outside the working area;** **d) it is necessary to prevent, or closely supervise, access to the area by employees who are unconnected with the work with ionising radiation and other processes while that work is under way; or** **e) employees are liable to work in the area for a period sufficient to receive an effective dose in excess of 6 millisieverts a year.; or** **f) employees untrained in radiation protection are likely to enter that area, unless the only work**	**Retain as ACOP**	The text supports the Articles of the Directive – however the 7.5 µSv rate is not specified in the Directive. Specialists advise that it would be a major change for industry if this were to be removed and it gives limits for dutyholders to aid designation. .

		with radiation involves a radioactive substance dispersed in a human body, where the dose rate exceeds 7.5 microsieverts per hour		
249 Reg 16(1)/17(1)	**In addition, an area should be designated as a controlled area if the dose rate (averaged over a minute) exceeds 7.5 microsieverts per hour and:** **(c) the work being undertaken is site radiography; or** **(d) employees untrained in radiation protection are likely to enter that area, unless the only work with ionising radiation involves a radioactive substance dispersed in a human body and none of the conditions in the previous paragraph apply.** **In this context, site radiography means any radiography of inanimate objects other than that which is carried out in an enclosure or cabinet that restricts the dose rate (averaged over a minute) outside the enclosure to 7.5 microsieverts per hour.**	**No ACOP required**	**Delete and move part of this to 248 (above)**	The majority of this paragraph is unnecessary now with the exception of (b) which overlaps with the paragraph above so can be rolled into this.
272 Reg 17(1)/18(1)	**Written local rules must identify the key working instructions intended to restrict any exposure in that controlled or supervised area. The details given in these rules should be appropriate to the nature and degree of the risk of exposure to ionising radiations. The rules must cover work in normal circumstances and also the particular steps to be taken to control exposure in the event of a radiation accident, as set out in the contingency plan required by regulation 12. Local rules for a controlled area should include a summary of the arrangements for restricting access**	**No ACOP required**	**Full deletion** move first sentence to regulation, rest to guidance	Full analysis of the regulation suggests that the first sentence should be moved to regulation in line with the Directive. The rest of the paragraph either replicates the regulation or is only appropriate for guidance.

	into that area, including the written arrangements covering those who are not classified persons.			
339 Reg 19(1)/20(1)	**For areas designated on the basis of external radiation, adequate monitoring must include measurement of dose rates (averaged over a suitable period if necessary). For areas designated on the basis of internal radiation, adequate monitoring should include measurements of air activity and surface contamination where appropriate, taking into account the physical and chemical states of the radioactive contamination. In either case, the monitoring must be sufficient to indicate whether levels of radiation and contamination are satisfactory for continuing work with ionising radiation.**	**No ACOP required**	**Full deletion** final sentence to go into guidance, rest into regs to meet new requirement	Elements of this are consistent with the Directive and relevant text from the Directive will be placed in regulation to implement.
340 Reg 19(1)/20(1)	**Monitoring should be designed to indicate breakdowns in controls or systems and to detect changes in radiation or contamination levels. In order to check the continued correct designation of areas, monitoring will be necessary both inside and outside the boundaries of controlled and supervised areas.**	**No change**	**Retain as ACOP**	The text adds to the regulation and clarifies compliance.
341 Reg 19(1)/20(1)	**Employees carrying out the monitoring should be familiar with the proper use of the instruments and know how to interpret and record the results correctly.**	**No ACOP required**	**Full deletion** move to guidance	This is guidance rather than ACOP.
347 Reg 19(2)/20(2)	**Monitoring instruments used for measuring external radiation should be suitable for the nature and quality of the radiation concerned. Instrumentation used for measurements of air activity and surface contamination should be suitable for the physical and chemical state of the radioactive materials present.**	**No ACOP required**	**Full deletion**	This will be partly covered by moving of ACOP para 339 to regulation and the rest is repetition of the regulation.

348 Reg 19(2)/20(2)	**Monitoring equipment should normally be tested and thoroughly examined at least once every year.**	Text still to be clarified, suggested text: **Monitoring equipment must be tested and thoroughly examined at least once every year, prior risk assessment (regulation 7) will help to determine if this is the correct frequency of retesting and examination**	**Retain as ACOP**	This text adds a timescale to the regulation However, equipment may require testing more or less. To take account of this it will be suggested that this should be determined by risk assessment and included in guidance in the relevant regulation.
355 Reg 19(3)/20(3)	**All instruments should be individually calibrated before first use and as part of the annual examination and test.**	**No ACOP required**	**Full deletion – m**ove to guidance	This is not in the Directive; suggest that this is placed in guidance).
356 Reg 19(3)/20(3)	**Qualified persons should possess the necessary expertise in instrumentation, theory and practice appropriate to the type of instrument to be tested.**	**No ACOP required**	**Full deletion** – move to guidance	This is does not add to the regulation or provide agreed methodology, move to guidance. The industry already has a certified competence scheme in place RPA 2000
362 Reg 19(4)/20(4)	**Suitable monitoring records should include the date, time and place of monitoring and confirm that controlled and supervised areas are correctly designated and show where levels are being approached which may require investigatory or remedial action to be taken. For areas designated on the basis of external radiation there should be an indication of the nature and quality of the radiation in question. For areas designated on the basis of internal radiation the results should indicate the nature and physical and chemical states of radioactive contamination unless this is**	**No ACOP required**	**Full deletion** Move first sentence to guidance. The text from the second sentence onwards will be escalated into regulation via copy out from the Directive.	The first.sentence does not reflect the Directive and will be added to guidance as good practice, as how areas are designated is covered elsewhere. The second sentence onwards is a requirement of the Directive and will be moved to regulation.

	inappropriate.			
363 Reg 19(4)/20(4)	**Any records of instrument tests carried out for the purposes of regulations 19(2) and (3) should be signed by a qualified person. The name and contact details of that person should be stated in the record.**	**No change**	**Retain as ACOP**	This would be expected to be made available on request to an inspector and by association also means that Para 356 of ACOP is not necessary as a qualified person is required to sign this off.
367 Reg 20(1)- (2)/21(1)-(2)	**In deciding whether a person should be classified, the employer should take account of the potential for exposure to ionising radiation (including the possibility of accidents etc which are likely to occur) as a result of the work the individual is required to undertake.**	**No change**	**Retain as ACOP**	This adds clarity to the regulation as to what exposure should be considered.
368 Reg 20 (1)- (2)/21(1)-(2)	**An employer should designate as a classified person any employee who works with any source of ionising radiation which is capable of giving rise to a dose rate such that it is reasonably foreseeable an employee could receive an effective dose greater than 20 millisieverts or an equivalent dose in excess of a dose limit within several minutes.**	**No change**	**Retain as ACOP –** supplement guidance .	This is included due to the likelihood of a potential exposure such as this happening on a nuclear site. This designation as a classified worker due to the potential of this occurrence should continue in ONRs opinion.
376 Reg 20(3)/21(3)	**Exposure is significant if the employee is likely to receive an effective dose at a rate exceeding 1 millisievert per year as a result of work in the new post.**	**No change**	**Retain as ACOP** – context needs to be explained.	Clarifies what “significant” means in context of the regulation – possible rewording may help clarify; along the lines of exposure in a new post would still result in classification

				based on cumulative levels of exposure.
409 Reg 21(5)/22(5)	**Entries in passbooks should only be made by people who have been authorised by the approved dosimetry services or the appropriate employer to make such entries. Suitable arrangement should include written instructions, specifying who does what and when, unless this would clearly be inappropriate in the circumstances.**	**Entries in passbooks must only be made by people who have been authorised by the approved dosimetry services or the appropriate employer to make such entries.**	**Partial deletion –** keep first sentence as ACOP, rewrite second sentence as guidance	This should be part of the suitable arrangements specified already within the regulations. As such, this would be repetition.
415 Reg 22(1)-(2)/23(1)-(2)	**The employer's investigation should take account of the following where relevant:** **(e) details of the pattern of work of the individual such as the time spent in particular controlled and supervised areas;** **(f) measurements from any additional dosemeter or direct reading device worn by the person concerned;** **(g) individual measurements made on other employees carrying out the same work with ionising radiations; and** **(h) the results of monitoring for controlled and supervised areas carried out in accordance with regulation 19.**	**No ACOP required**	**Full deletion** Move to guidance	Paragraph is not a definitive list of measures to be assessed, so should be moved to guidance. This can be combined with paragraph 421.
420 Reg 23(3)-(8)/24(3)-(8)	**An estimate of the dose received should be regarded as much greater than or much less than the original entry in the dose record for a particular period if:** **(d) the dose received differs from the original entry in the dose record by at least 1 millisievert for**	**An estimate of the dose received should be regarded as much greater than or much less than the original entry in the dose record for a particular period, if:**	**Retain ACOP**	This is not covered in the BSSD Specialists are redrafting as this paragraph is not well understood. This could be used in enforcement action.

	recorded doses of 1 millisievert or less; or **(e) the dose received differs from the original entry in the dose record by a factor of 2 or more for recorded doses in excess of 1 millisievert but less than the relevant dose limit; or** **(f) the dose received differs from the original entry in the dose record by a factor of 1.5 or more for recorded doses above the relevant dose limit.**	**a) for recorded doses of 1 millisievert or less the dose received differs from the original entry in the dose record by at least 1 millisievert; or** **b) for recorded doses in excess of 1 millisievert but less than the relevant dose limit the dose received differs from the original entry in the dose record by a factor of 2 or more or** **c) for recorded doses above the relevant dose limit the dose received differs from the original entry in the dose record by a factor of 1.5 or more**		
421 Reg 23(3)-(8)/24(3)-(8	**The employer's investigation into the circumstances of the exposure should take account of:** **(a) relevant information provided by the approved dosimetry service;** **(b) details of the pattern of work of the individual such as the time spent in particular controlled and supervised areas;** **(c) measurements from any additional dosemeter or direct reading device worn by the person concerned;** **(d) individual measurements made on other employees carrying out the same work with**	**No ACOP required**	**Full Deletion – move to guidance**	This does not provide a comprehensive list of what should be taken account of in the investigation by the dutyholder, so does not provide clear direction on what to do to comply. This can be combined with paragraph 421 in guidance.

	ionising radiations; and **(e) the results of monitoring for controlled and supervised areas carried out in accordance with regulation 19.**			
422 Reg 23(3)-(8)/24(3)-(8	**The information used to estimate the dose received will be adequate if it:** **(c) shows that there is reasonable cause to believe that the dose received by the classified person was much greater than or much less than the dose recorded in the dose record; and** **(d) includes sufficient information to permit a reliable reconstruction of the exposure conditions for the person during the relevant dose assessment period.** **The investigation report should at least include the information in (a) and (b).**	**No ACOP required**	**Full Deletion** move to guidance .	The text gives an outline but no detail on some of the terminology used so the dutyholder is unable to know if they will be compliant. This also overlaps with Para 420 which is being retained so is not necessary.
446 Reg 24(2)/25(2)	**Adequate medical surveillance should include:** **(f) a medical examination before first being designated as a classified person in a post involving work with ionising radiations;** **(g) periodic reviews of health at least once every year;** **(h) special medical surveillance of an employee when a relevant dose limit has been exceeded;**	**No ACOP required**	**Full deletion**	To comply with the Directive, all of this text now moves to regulation

	(i) determining whether specific conditions are necessary; and **(j) a review of health after cessation of work where this is necessary to safeguard the health of the individual.**			
447 Reg 24(2)/25(2)	**The nature of the medical surveillance for each individual should take account of the nature of the work with ionising radiation and that individual's state of health.**	**No ACOP required**	**Full deletion** .	This is now a requirement of the Directive, so the paragraph moves to regulation.
448 Reg 24(2)/25(2)	**Medical surveillance carried out following an investigation under regulation 25 should include a special medical examination of the individual if that person has received an effective dose of ionising radiation in excess of 100 millisieverts in a year or an equivalent dose of at least twice any relevant annual dose limit.**	**No ACOP required**	**Full Deletion**	This ACOP is not required due to the previous ACOP paragraph 446 being moved to regulation. This will require surveillance when a dose limit is exceeded so further clarification with respect to an overexposure is not necessary as this will be carried out anyway.
466 Reg 24(7)- (8)/25(7)-(8)	**The records made available to the appointed doctor or employment medical adviser before the periodic review of health is carried out should always include any relevant records of sickness absence for the person as well as the health record and copies of the summaries of the dose record provided by the approved dosimetry service and retained in accordance with regulation 21 (7).**	**No ACOP required**	**Full deletion** move to guidance	The text is too similar to the regulation with the exception of "relevant records of sickness absence" which can be inferred as a record that an Appointed Doctor may reasonably require. Guidance infers this is seen automatically so suggest that this text is moved to guidance as it seems to be captured already.
483 Reg 27(3)/28(3)	**The purpose of a leak test is to show that the mechanisms for preventing dispersal of radioactive**	**Where testing is appropriate under normal operating**	**Partial deletion** final sentence	The first sentence of the paragraph is not ACOP and seems to define a

	substances are functioning as intended. The assessment required by regulation 7 should identify potential ways in which containment could be lost and their likelihood of occurring. A test method and a frequency of testing should then be chosen that is capable of detecting leakage of radioactivity from the source or article before a radiation risk arises. Where testing is appropriate under normal operating conditions, the interval between tests should not exceed two years.	**conditions, the interval between tests should not exceed two years.**	ACOP, rest redraft into guidance	leak test so can be placed in guidance. The rest of the text, apart from the final sentence adds little and could be integrated in the ACOP paragraph 45 (risk assessment). The final sentence remains as ACOP as the two year period is historically based on industry standards and manufacturers guidelines, but must be kept to uphold protection. .
493 Reg 28/29	**The procedures for accounting should ensure that the location of radioactive substances is known and, as a consequence, losses of significant quantities can quickly be identified. A frequency for checking the location of the source should be determined, taking account of the likely movement of the source, its potential for being displaced and its susceptibility to damage. For portable sources, such as radiography sources and portable gauges, the check should be at least on each working day.**	**The procedures for accounting must ensure that the location of radioactive substances is known and, as a consequence, losses or theft of significant quantities can quickly be identified. A frequency for checking the location of the source must be determined, taking account of the likely movement of the source, its potential for being displaced and its susceptibility to damage. For portable sources, such as radiography sources and portable gauges, the check should be at least on each working day.**	**Retain as ACOP** – text added to reflect theft	This clarifies the regulation – specialists have asked, (based on regulatory experience), to include theft in the accounting requirements
494 Reg 28/29	**Other examples of intervals at which the location of a source should be updated are:** **(c) for static sources securely attached to machines**	**No ACOP required**	**Full deletion** move to guidance	The text gives examples of circumstances which are not exhaustive so do not clarify the regulation generically.

	the interval between checks may be up to one month, providing that additional checks are carried out following any maintenance or repair which could have affected the source; and **(d) for sources located within patients, the interval between checks should be compatible with the clinical treatment of that patient.**			
522 Reg 31(2)/32(2)	**It is appropriate to carry out a critical examination if there may be radiation protection implications arising from the way in which an article is being or has been erected or installed.**	**No ACOP required**	**Full deletion** move to regs	Legal advice is that a slight change to the regulations removes the ambiguity created by the regulation that requires the ACOP – this will be actioned in draft regulations.
523 Reg 31(2)/32(2)	**Matters on which the radiation protection adviser should be consulted include the plans for installing the equipment, the nature and extent of any tests undertaken as part of the critical examination and the acceptability of any test results.**	**No ACOP required**	**Full deletion** explain in guidance (link back to reg 13)	This already covered in the regulations and is repetition..
538 Reg 32(3)-(4)/33(3)-(4)	**A suitable quality assurance programme establishes those planned and systematic actions necessary to provide adequate confidence that equipment will satisfy the requirements of regulation *32(1)*. The extent of the programme will depend on the nature and range of equipment in use. In drawing up a quality assurance programme make it clear:** • **who has responsibility for organising the various elements,** • **who will carry out testing or dose assessment and** • **who has responsibility for acting on any**		Depends on Department of Health (DH) proposal to have Reg 32 vires. If remains with HSE re – write with DH agreement.	Under review with Department of Health

	adverse findings.			
539 Reg 32(3)-(4)/33(3)-(4)	**The programme should specify the frequency of any testing (and other measurements) and appropriate action levels for equipment or apparatus which is subject to periodic testing. If these levels are found to have been exceeded the employer should assess what remedial action is needed, including removal from service where necessary, taking into account the risk arising from its continued use for specified purposes. In establishing these levels, the employer should take into account guidance established by relevant professional bodies about criteria of acceptability for such equipment.**		Depends on Department of Health (DH) proposal to have Reg 32 vires. If remains with HSE re – write with DH agreement.	Under review with Department of Health
540 Reg 32(3)-(4)/33(3)-(4)	**In devising a suitable quality assurance programme for equipment, employers should give special attention to equipment used for medical exposure:** • **of children;** • **as part of a health screening programme;** • **involving high doses to the patient such as interventional radiology, computed tomography or radiotherapy.**		Depends on Department of Health (DH) proposal to have Reg 32 vires. If remains with HSE re – write with DH agreement.	Under review with Department of Health

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 **Other departments or agencies:** **269** Business, Energy, and Industrial Strategy (BEIS)	**Impact Assessment (IA)** **Date:** 26/10/2016 **Stage:** Consultation **Source of intervention:** EU **Type of measure:** Secondary Legislation **Contact for enquiries:** Julia.Laverty@hse.gov.uk Michael.Zand@hse.gov.uk

Summary: Intervention and Options

RPC Opinion: GREEN

Cost of Preferred (or more likely) Option				
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**
-£9.77m	-£3.70m	£0.4m (£0.1m in scope of BIT)	Qualifying Provision	In Scope

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.Where possible, we will use copy out, unless doing so decreases clarity in a way that has an adverse impact on health and safety or unless it leads to higher costs to business.

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: Do Minimum

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:** -8.24

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	4.4		0.5	**8.2**

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 84% of the total costs, or £7.0 million. £5.3 million of these are costs to the medical sector. A new notification, registration, and licencing regime (the graded approach) leads to around 11% of total costs, or £0.94 million. These are costs to a range of sectors (including medical, nuclear, industrial, and research); however, the regime is risk-based, so the costs are proportionate to the risks.

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

- It is expected that the 'graded approach' would include a fee for the higher risk activities requiring registration and licencing. The fee is still unknown, but overall costs are likely to be higher.
- Familiarisation costs have not been quantified for this consultation stage IA.

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

- The current levels of exposures to the lens of the eye in the medical sector are uncertain. This determines the number of additional controls required and classifications of workers, and has a large impact on costs.
- The fees that HSE intends to charge for registration and licencing are currently not known. Once monetised these will increase the overall costs.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: N/A
Costs: 0.3	**Benefits: 0**	**Net: -0.3**	

Summary: Analysis & Evidence

Policy Option 2

Description: Option 1 + Renewal of Registrations and Licences

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:** -9.77

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	4.4		0.6	**9.8**

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

The additional costs in Option 2, compared to Option 1, are from the renewals of registrations and licences under the graded approach. These account for an additional £1.5 million over the appraisal period.
Changes to requirements for doses to the lens of the eye still account for the greatest proportion of costs (71%), or £7.0 million. The graded approach, including renewals, now accounts for 25% of total costs, or £2.5 million.

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

- It is expected that the 'graded approach' would include a fee for the higher risk activities requiring registration and licencing. The fee is still unknown, but overall costs are likely to be higher.
- Familiarisation costs have not been quantified for this consultation stage IA.

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

- The current levels of exposures to the lens of the eye in the medical sector are uncertain. This determines the number of additional controls required and classifications of workers, and has a large impact on costs.
- The fees that HSE intends to charge for registration and licencing are currently not known. Once monetised these will increase the overall costs.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: 0.5
Costs:0.4	**Benefits: 0**	**Net: -0.4**	

Summary: Analysis & Evidence

Policy Option 3

Description: Option 2 + Extension of Licences

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:** -9.67

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	4.4		0.6	**9.8**

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

The additional costs in Option 3, compared to Option 2, are from the extension of licencing requirements to cover other high-risk practices, under the graded approach. These account for around an additional £0.07 million over the appraisal period. Changes to requirements for doses to the lens of the eye still account for the greatest proportion of costs (71%), or £7.0 million. The graded approach, including renewals and extensions, now accounts for 26% of total costs, or £2.5 million.

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

- It is expected that the 'graded approach' would include a fee for the higher risk activities requiring registration and licencing. The fee is still unknown, but overall costs are likely to be higher.
- Familiarisation costs have not been fully quantified for this consultation stage IA.

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	0		0	**0.2**

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

The extension of licences introduces a cost saving to business in the industrial radiography sector as businesses would no longer need to submit notifications for certain work. The total cost saving over the appraisal period is around £0.2 million. However, this might change depending on the structure of the fees for registration and licensing, which have not yet been quantified.

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

- The current levels of exposures to the lens of the eye in the medical sector are uncertain. This determines the number of additional controls required and classifications of workers, and has a large impact on costs.
- The fees that HSE intends to charge for registration and licencing are currently not known. Once monetised these will increase the overall costs, and, depending on their structure, they might result in lower or no savings for this option as compared to the other options.

BUSINESS ASSESSMENT (Option 3)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m: 0.5
Costs:0.4	**Benefits: 0**	**Net: -0.4**	

• Glossary

ACOP	Approved Code of Practice
ADS	An Approved Dosimetry Service is approved by HSE to provide services that produce, maintain and summarise radiation dose records
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
CDG	Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009
CE	European conformity marking
CIDI	Central Index of Dose Information (HSE)
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
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
PPE	Personal Protective Equipment
REPPIR	Radiation (Emergency Preparedness and Public Information) Regulations
RPA	Radiation Protection Adviser
RPS	Radiation Protection Supervisor
RSA	Radioactive Substances Act 1993

• Contents

• Chapter 1: Introduction

270 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 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 new Basic Safety Standards Directive (BSSD 2013) consolidates and updates existing Euratom provisions for protection against the harmful effects of ionising radiation by replacing five existing Directives and a Commission Recommendation. It covers occupational, medical and public exposure. 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. HSE has two sets of regulations which implement those aspects of the Directives in scope of HSE's area of responsibility: the Ionising Radiations Regulations 1999 (IRR 1999), which regulates occupational exposures; and the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR 2001)[1], which establishes a framework for emergency preparedness for certain radiation emergencies. For the reasons described in paragraph 10, the scope of this impact assessment is limited to changes to the Ionising Radiations Regulations only. Changes to REPPIR will be subject to a separate impact assessment.

[1] The IA submitted by HSE to the RPC for an opinion covered proposals for implementation of the BSSD for the Ionising Radiations Regulations (IRR) 2009 and the Radiation (Emergency Preparedness and Public Information) Regulations (REPPIR) 2001 in order to get feedback on the level of analysis conducted for both proposals. This IA however only covers proposed changes to IRR 1999, this is explained further in Chapter 1, paragraph 10.

6. It should be noted that Section 18 of HSWA has been amended so the Office for Nuclear Regulation 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 the Office for Nuclear Regulation.

7. The Euratom Treaty does not apply to defence activities. However, the Health and Safety at Work Act applies to all employers including MoD and, as such, any changes to IRR 1999 apply to MoD sites. The Secretary of State for Defence will retain the power to exempt HM Forces from aspects of IRR at any time. The Defence Nuclear Safety Regulator works very closely with the statutory regulator and provides assurance to the Secretary of State for Defence that standards of nuclear and radiological safety throughout the defence nuclear programmes produce outcomes that are, so far as reasonably practicable, at least as good as those which would have been required by legislation had there been no exemption for the MoD.

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. HSE will implement the Directive through changes to the appropriate health and safety legislation: Ionising Radiations Regulations 1999 (IRR99). 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. BEIS have overall policy responsibility for civil nuclear sites in England and Wales and their emergency preparedness and as such they are leading the transposition of the BSSD for these areas. Close liaison is required for the devolved administration to assess the impact on them. In addition, as BEIS have policy responsibility for the transport of radioactive substances they will prepare and submit a separate impact assessment

10. HSE has considered what changes may also be required to an additional set of regulations: the Radiation (Emergency Preparedness and Public Information) Regulations 2001 (REPPIR). However, because REPPIR is cross-cutting legislation which extends into policy areas that are the responsibility of other government departments, to ensure a common approach, HSE is continuing to working closely with these government departments to consider all aspects of emergency preparedness and response for the UK. A separate consultation for REPPIR will therefore take place at a later date and at the same or similar time period as the other government departments involved.

11. On 23 June, 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.

Ionising radiation

12. 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.

13. 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. An estimated 50,000 dutyholders in the UK will be affected by some or all of the changes required in IRR 1999 and REPPIR 2001 as a consequence of the Directive.

14. 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. There is no "safe" level of exposure to ionising radiation and high doses, such as those expected in an uncontrolled exposure, can kill within a short period of time.

15. 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 limits to the eye be substantially reduced. This change is discussed further in Section 0 (Chapter 2).

The Ionising Radiations Regulations 1999 (IRR 1999)

16. IRR 1999 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.[2] ACOPs are not law but do have a special legal status; if the advice in ACOP material is followed in relevant circumstances dutyholders can be confident they are complying with the law.

17. The key measures set out in IRR 1999 to reduce exposure are:
- carrying out of 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[3], 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.

[2] This can be found in HSE publication "L121 working with ionising radiations". See www.hse.gov.uk/pUbns/priced/l121.pdf

[3] 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.

Rationale for intervention

18. 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 five 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. Three 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;

- a new requirement to renew registrations and licences to maintain and improve existing levels of protection ('Graded Approach' Option 2 – see Section 0)

- the extension of the requirement to license to cover certain 'high-risk' practices, which would otherwise need to register ('Graded Approach' Option 3 – see Section 0). Due to the way HSE intends to implement this requirement, we expect it could reduce costs to business.

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

- application of dose limits to work with Naturally Occurring Radioactive Materials (NORM) 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 0 (Chapter 2).

Implementation date

19. 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.

20. However, the UK 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 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 0 (Chapter 2).

21. 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.

Policy objectives

22. 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.

Description of options considered

Do nothing

23. 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 impact assessment only as the notional baseline against which the other options are assessed.

Option 1: Do minimum – Update the Ionising Radiations Regulations 1999

24. Option 1 is presented as the 'do minimum' option, which demonstrates the costs and benefits of implementing the Directive in a way that does not introduce new requirements which go beyond the scope of the Directive. In this option, HSE would implement the Directive by updating ('repeal and replace') IRR.

25. Implementing the Directive in this way would not result in extensive changes to existing arrangements, so this option is the least burdensome to dutyholders who are already familiar with current requirements and legislative framework. Although this option meets the requirement to implement the Directive and is achievable within the implementation timescale, because it maintains two sets of regulations it does not fully conform to the Government's better regulation framework.

26. This 'do minimum' option includes the early implementation of the regulations described above in Section 0, as this reduces burdens on businesses from the regulatory change. It also includes the maintenance of existing standards associated with Naturally Occurring Radioactive Materials (NORM) and requirements around the immediate notification of radon in the workplace above specified limits (also discussed in Section 0), which do not introduce new burdens on businesses.

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

Option 2: As per Option 1 but with a requirement for the renewal of licences and registrations under the 'Graded Approach'

27. Option 2 implements the Directive in the way described for Option 1 but contains an additional requirement for licences and registrations under the 'Graded Approach' to be renewed periodically. This goes beyond the scope of the Directive and results in additional costs to business. However, as

described and justified further in Section 0, this is necessary to provide up-to-date information on dutyholders and ensure the effective operation of the Graded Approach system.

Option 2 only differs for the Graded Approach; all other changes to IRR are as per Option 1. Therefore, Option 2 is only assessed in Section 0 on the Graded Approach.

Option 3: As per Option 2 but with an extension to licencing requirements to cover certain high-risk practices to ensure consistency in the regulatory approach

28. Option 3 contains all of the same provisions as Option 2 but extends the requirements for licencing under the 'Graded Approach' to cover certain high-risk practices, which would need to register under Option 2. While licencing is a more stringent requirement than registration, extending licences in this way may reduce costs to business compared with Option 2 (which does not extend licences), and the rationale and the detail of how this is to be implemented is covered in Section 0.

29. Option 3 only differs for the Graded Approach, so is only assessed in Section 0.

Option considered but not being taken forward

Merge the Ionising Radiation Regulations and the Radiation (Emergency Preparedness and Public Information) Regulations

30. HSE considered the option to merge IRR and REPPIR to form a newly combined piece of legislation, which would be in line with the Government's policy to reduce legislation. This approach would only be advantageous for only a few dutyholders who have to comply with the requirements of both IRR and REPPIR, as they would only have to refer to one set of regulations, ACOP and guidance.

31. However in the main, the audiences for the two sets of regulations are very different, and merging the regulations would make it more challenging for the majority of dutyholders who would need to fully consider and understand which requirements apply to them. This could lead to dutyholders taking inappropriate or unnecessary actions thereby increasing the burden on UK businesses. This option can also be discounted now due to necessity to coordinate any REPPIR activity with BEIS, to ensure systems and definitions are aligned. This has resulted in different timescales for IRR and REPPIR implementation.

32. For these reasons merging existing legislation has been ruled out as a viable policy option and is not considered further in this IA.

HSE's preferred Option

33. Option 1 is not HSE's preferred option, as it does not gather necessary information HSE considers essential to ensuring the effective operation of the Graded Approach system. Options 2 and 3 would both ensure that the requirements of the Directive are met, whilst not reducing radiological protection measures or placing unnecessary burdens on business. HSE will use information gathered during the consultation period to determine which of these options best meets the policy objectives.

34. In considering these options, 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.

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

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

Proposed Legislation

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

• Chapter 2: Impact Assessment on Changes to IRR

Summary of requirements

38. The Ionising Radiations Regulations 1999 (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.

39. To ensure that exposure is kept as low as reasonably practicable, IRR99 sets out a number of measures, such as:

- carrying out of a prior risk assessment to consider potential doses;
- taking steps to restrict exposure using the hierarchy of control, and use of administrative arrangements to ensure that exposure is controlled;
- designation of areas where high exposures are possible and control of access into these areas, as well as 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 in relation to that particular type of work.

40. IRR also sets out dose limits, measured in millisieverts (mSv),[1] 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 20mSv or 100mSv in any 5 consecutive years, with no more than 50 mSv in a single year);
- for the skin, 500mSv in a calendar year;
- for the extremities, 500mSv in a calendar year.

41. 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.

Application of IRR99

42. 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) carried out in a radon containing atmosphere, where the concentration of radon exceeds a specified limit;

[1] 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 is 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.

- any work, not specified above, with Naturally Occurring Radioactive Materials (NORM).

43. 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).

44. HSE enforces IRR99 at all premises except Nuclear Licenced Sites and certain Authorised sites where the Office for Nuclear Regulation (ONR) enforces. A detailed breakdown of numbers of dutyholders can be found at Annex 1.

Summary of work undertaken to inform the consultation stage IA

45. 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 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.

46. 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.

47. Engagement through working groups means that HSE has had direct contact with an estimated 178 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 480 stakeholders are members of an on-line Community of Interest, where meeting minutes and notes and BSSD updates are posted.

48. 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 IRR. 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.

49. 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), and intends to talk at three conferences organised by the Society for Radiological Protection conferences prior to/during the formal consultation phase. HSE will continue to consult with other stakeholders during this stage.

50. Section 0 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.

New requirements in the proposed Ionising Radiations Regulations 2017

51. 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.

52. The new key requirements are:

- Eye Dose: A reduction in the eye dose limit and changes to classification levels (Section 0);
- Graded Approach: Introduction of a risk-based approach to regulatory control of practices using ionising radiation (Section 0);
- Outside Workers: Change in the definition that widens the scope of the regulations (Section 0);
- Weighting Factors: Introduction of new weighting factors for dosimetry (Section 0);
- Public Dose Estimation: A requirement to estimate doses to members of the public (Section 0);
- Other changes that lead to no additional cost (**Table 4**);
- Other changes which could be viewed as potentially going beyond the minimum requirements of the directive (Section 0).

General assumptions for the cost and benefits assessment

53. This section summarises general assumptions made in the costs and benefits assessment.

In accordance with the HM Treasury Green Book guidance on cost-benefit analysis, the discount rate applied is 3.5%.[2]

In accordance with the impact assessment toolkit in the Better Regulation Framework Manual, the analysis uses a 10-year appraisal period for regulatory changes with no identifiable end point. The appraisal period begins in 2018, the year of implementation.[3] There is a potential argument for using a longer appraisal period, given the potential longer-term health benefits that arise from the proposals. However, we are not able to quantify these at this stage. See Section 0 and 0 for further information.

In the analysis, we estimate the cost of business time based on a valuation of the workers' opportunity cost of time, which is assumed to be equal to their wage, plus the additional costs of employing them, such as pensions, National Insurance contributions and other overheads. We have used figures provided by stakeholders, wherever possible. Where not possible, we have based the cost of time on the mean hourly wage for relevant professions obtained from the

[2] HM Treasury guidance for public sector bodies on how to appraise proposals before committing funds to a policy, programme or project. See www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

[3] The Better Regulation Framework Manual is a guide for government officials covering all aspects of the UK Government's better regulation framework.

Annual Survey of Hourly Earnings (ASHE).[4] The mean wages have then been uprated by 19.8% to account for non-wage costs of labour.[5] The specific wage rates applied are described in further detail in the relevant sections that follow.

Prices are presented in 2016 prices. Where the source of the prices was in a different price year, these have been inflated using the relevant price index.

All estimates derived in this assessment are presented in rounded form, to two significant figures, in order to avoid spurious accuracy. As a consequence, readers may observe rounding error when following calculations based on these rounded figures. Underlying calculations have been undertaken using unrounded values.

Changes to requirements on doses to the lens of the eye

Background – Change to dose limit for the lens of the eye

54. In June 2011, the ICRP recommended that the dose limit for ionising radiation exposure to the lens of the eye be reduced to 20mSv 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.

55. Based on the ICRP recommendation, the BSSD 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 to 20 mSv.
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.

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 50mSv in any single year.

56. 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 0 discusses the potential for impacts in other sectors.

Summary of research on impacts of changes to eye dose limit

Stakeholder engagement

57. As discussed in Section 0, HSE has undertaken a large amount of research and engagement with stakeholders to understand the potential impacts of the proposed regulatory changes. This section provides more information on research and engagement specifically regarding the change in eye dose requirements.

58. 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.

[4] The 2015 provisional data was used, available on the ONS website
[5] This is based on data on labour costs available from Eurostat (http://ec.europa.eu/eurostat/web/labour-market/labour-costs/main-tables)

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]

59. HSE 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.

60. 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.

61. A key uncertainty during these discussions was the existing level of eye doses received by workers in the medical sector. There is very little data available with regard to eye doses in the medical sector; discussions with stakeholders suggest that the NHS has not routinely monitored eye doses, given the current higher eye dose limit of 150 mSv (which was not expected to be exceeded in most cases). If current exposures are higher than the proposed dose limit or classification level, medical sector employers will need to take a number of actions to classify workers and control doses, incurring potentially large costs. The cost of actions required to comply will depend how high the current doses are in comparison with the new dose limit.

62. 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.

Dosimetry research

63. To gather further information on current exposures, HSE commissioned Public Health England 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.

[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.

64. 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 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. Additionally, there may be some self-selection bias given that participants volunteered to take part, and fewer than half of the questionnaires were returned with full information.

65. Subsequent to this research, on HSE's request, an Approved Dosimetry Service (ADS)[7] undertook an ad-hoc analysis of doses in its own 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. These two sources of data (which are related) suggest that at least some workers in the medical sector have current eye doses in excess of the proposed classification level and dose limit.

66. In 2016, HSE held further discussions with medical sector stakeholders in an attempt to reconcile the conflicting evidence and to test some of the key assumptions made during the negotiation phase of the Directive. These discussions provided some useful further information to refine cost assumptions but were not conclusive about existing exposures, the potential need for classification and additional control measures, so considerable uncertainty remains. We anticipate that further monitoring information may become available and HSE will engage with medical sector representatives during consultation to determine whether this information can be used to inform the final stage impact assessment.

Research into the effectiveness of personal protective equipment (PPE)

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

68. Given the level of uncertainty regarding existing exposures and the potential for impacts on the medical sector, HSE has based this assessment on information provided by the sector (primarily during the negotiation phase of the Directive, with refinement based on information gathered since). Most notably, this includes: assumptions regarding the number of additional workers in the medical sector who will need to be classified (Section 0) and associated costs; the number of additional controls required to reduce doses to the lens of the eye (Section 0) and associated costs; and costs arising from the process of revising risk assessments, raising awareness of the change in requirements, and providing training and advice (Section 0).

69. The iterative way that these estimates have been developed means they have a degree of validation from the stakeholders HSE has engaged with so far. However, as these were the views of an engaged stakeholder group, HSE cannot be sure at this stage that it is representative of the wider medical sector. We will seek further information at consultation to reduce the level of uncertainty in these estimates.

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

Medical sector – affected groups and costs of time

Affected groups

70. Clinicians and support staff can receive doses of ionising radiation to the lens of the eye (herein referred to as 'eye dose') 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.[8] Radioactive substances used in nuclear medicine, such as Positron Emission Tomography (PET), can also cause radiation exposures to the eye.[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.

71. 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 for private hospitals. As a consequence, we have identified some limited costs to the employers of newly classified (based on eye-dose) 'outside workers' (see Section 0). Aside from this, we assume that the costs in this assessment for the medical sector are borne by the public sector; primarily the NHS. HSE will gather further information in the formal consultation period to determine whether there are any additional impacts to the private medical sector (see **Table 4**, Chapter 3).

Affected sites

72. 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).

73. This gives 232 sites in the medical sector where workers are most likely to be affected by the revised dose limit for the lens of the eye.

Affected workers

74. Monitoring data and reports from medical stakeholders suggests that workers most likely to be affected by the change in requirements are interventional radiologists and interventional cardiologists. These workers spend most time in close proximity to ionising radiation sources undertaking complex

[8] 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.
[9] Positron emission tomography (PET) is a nuclear medicine, functional imaging technique that is used to observe metabolic processes in the body
[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

surgical procedures and are therefore most likely to receive high cumulative doses to the lens of the eye. Data gathered suggests that in the UK 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).

75. Therefore, there are total of between 1,235 and 1,385 of these workers who 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 impact assessment, we categorise these as 'higher risk' workers, i.e. those likely to receive the highest doses.

76. 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;
- gastroenterologists;
- radiopharmacy technicians;
- cyclotron engineers;
- nurses and other support staff assisting in interventional procedures, working close to the patient and radiation source.

77. 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).

78. 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 0). Including these gives a (rounded) estimate of 10,500 affected workers in the medical sector (including MoD medics).

79. 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.

Costs of time

80. 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 around £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;

[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.

- 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.

81. The roles of these workers and how they are affected by the regulatory changes are described in the sections that follow.

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

Revising risk assessments

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

83. 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. 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; recent 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.

84. Ras should be reviewed as a matter of course under the requirements of MHSW Regulations. Information provided by Radiation Protection Advisors (RPAs) in the medical sector in recent discussions was that Ras are reviewed on a rolling three-year basis – that is, 1/3 of Ras are reviewed each year under the baseline on average anyway. This leaves two-thirds, or around 620, additional Ras reviewed because of the change in eye dose limit.

85. Information provided by stakeholders and discussions with HSE 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;
- an RPA;
- a Radiation Protection Supervisor (RPS).[14]

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[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).

[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.

86. 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 0 gives an average total cost of time per RA of around £120.

87. 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.

88. HSE has based this estimate regarding time spent on revising risk assessments on feedback from medical sector stakeholders. HSE believes that the time taken to revise such risk assessments is likely to have been overestimated, as existing risk assessments should already take account of eye doses and revision should not be an onerous task. Additionally, in a number of cases, the Operational Manager and RPS may be the same worker, so there is potential for double counting. We will revise these assumptions based on information received during the formal consultation.

Raising awareness, providing advice & training

89. Medical sector employers will need to ensure that affected workers are aware of the change in eye dose requirements. Employers will also need to communicate the results of Ras, and provide advice and training to employees where action is required to reduce eye doses.

90. The views of medical sector stakeholders and HSE specialist inspectors indicate there is variation in which employee(s) will be responsible for providing this information at each site. RPAs will primarily provide advice to employers on reducing doses, though it may be the role of a RPS, or an operational/departmental manager with responsibility for health and safety, to communicate advice to employees and provide training.

91. Overall, information provided by NHS representatives suggests that up to 30 hours of staff time per site may be required in preparing and communicating advice, including any training, regarding the change in dose limit and any actions required. In the absence of reliable information on how this time is split between an RPA, RPS, and operational/departmental manager, we assume each spends equal time (one-third each), giving a weighted average cost per hour of around £41, a total cost per site of £1,200, and a total one-off cost across all 232 sites of around £290,000 in the first year.

92. Staff will need to spend time engaging with communications, advice and training. We assume that all affected staff (higher risk and lower risk workers) will receive communications about the change in eye dose limit. This could range from an email circulation to a short presentation during routine health and safety briefings. Discussions with stakeholders suggest that each worker may spend an average of 5-10 minutes of additional time to engage with these communications. Valued at the cost of time for a clinician (around £51 per hour), and multiplied across all 10,500 affected workers, gives an estimated cost of staff time of £67,000.

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.

93. Those routinely involved in interventional procedures (higher-risk workers) are most likely to need further advice and training. According to medical stakeholders, this may require between 30 minutes to an hour of staff time. Taking the midpoint (45 minutes), multiplying by the total number of higher-risk workers (1,300), and multiplying by the cost of time for a clinician (£51 per hour), gives a total cost of this staff time of around £50,000.

94. Adding the estimates above gives a total one-off cost of staff time in raising awareness and providing advice & training of around £400,000 in the first year.

95. HSE believes that the estimates of time likely to be taken on raising awareness will be less than that indicated by stakeholders as the change will only affect those staff who will now need to be classified. To avoid underestimating costs at this stage, we have based our estimates on stakeholder feedback and will seek to test assumptions at consultation.

Medical sector – classifying workers and monitoring non-classified workers

Newly classified workers

96. Under the proposed regulatory change, 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 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.

97. As discussed in Section 0, there is considerable uncertainty over the current level of exposures in the medical sector. Research undertaken by PHE for HSE found no doses exceeding the new classification level, suggesting that very few, if any; additional workers would need to be classified. Therefore, we would estimate no costs due to the change in classification level, based on this evidence alone.

98. However, representatives from the medical sector have reported potentially large costs from newly classifying workers. Limited monitoring data provided by the medical sector provides some support for this, although, as discussed above, relatively little monitoring data is available and it is difficult to validate.

99. Given this uncertainty, this assessment of classification costs is based on information provided by medical sector stakeholders about the number of workers they may need to classify and the associated costs. Based on the evidence, HSE expects that this may overestimate costs and we will seek to gather further evidence during the consultation period on exposures and additional classifications to refine estimates for the final stage assessment.

100. At the 2013 Medical Stakeholder event, representatives from the medical sector estimated that around 20% to 25% of the 1,300 'high risk' employees may need to be classified. Taking the midpoint, this gives around 300 additional classified workers. These workers would require an initial medical upon classification, plus an annual medical thereafter. They would also require eye dosimetry and keeping of dose records.

101. 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 (particularly given the uncertainty over the current level of exposures), or the types of procedures that may be involved, but HSE will incorporate any substantive information provided during formal consultation about future impacts into the final stage assessment.

Initial medicals for classified workers

102. 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.

103. 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 0, this gives a cost of time per medical of around £130.

104. 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.

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

105. 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 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.

106. We expect the cost of 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 £19,000, starting in the second year.

107. 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.

108. As with the face-to-face medicals, it would take an RPA 5-10 minutes per worker to request dose reports from the Approved Dosimetry Service 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 provide additional information beyond that collated by the RPA/employer.

109. 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 following the enactment of the Regulations.

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

Dosimetry and record keeping costs for additional classified workers

110. 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.

111. Each newly classified worker would require an eye dosemeter supplied by an Approved Dosimetry Service (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.

112. Across all 300 newly classified workers, this gives a total annual cost for monitoring classified workers of around £34,000 (from the first year). There are some potential costs which have not been quantified, as they are expected to be minimal:

There may be additional costs involved in RPAs reviewing doses and estimating doses for lost or damaged dosemeters. These are difficult to quantify and are not expected to be large, so have not been calculated here.

There will also be 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 personal protective equipment (PPE) worn, which is necessary for accurately estimating dose to the lens of the eye where two dosemeters are worn. This leads to a very small cost and it is not proportionate to quantify this further.

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 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) on average, we expect any additional costs to be negligible.

Additional monitoring of non-classified workers

113. 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; although the requirement to undertake monitoring has not changed, 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.

114. 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.

[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.

115. 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.

116. To reflect this, and to give an estimate of potential costs, we assume that 25% of non-classified high-risk workers (around 250) would require additional eye dosimetry. Non-classified workers may be monitored less frequently than classified workers. For these workers we assume a new dosemeter is issued every 2 months (6 times a year), at a cost of around £48 per year. The total estimated annual cost across all non-classified workers requiring additional monitoring is around £12,000 (from the first year).

Additional Classified Outside Workers

117. A Classified Outside Worker, for the purposes of IRR99, is classified person who carries out services in a controlled area for another organisation who is not their employer, for example, a contractor employed by a private hospital brought in to cover staff shortages in an NHS hospital. The employer of the classified outside workers is required to ensure that these workers have a radiation passbook. The passbook records doses incurred during work in controlled areas of other employers to ensure that total cumulative doses can be monitored. Medical sector stakeholders anticipate an increase in the number of classified outside workers, as defined above, with associated costs, caused by the expected increase in the number of workers classified due to eye doses.

118. In the medical sector, clinicians who are contracted to carry out interventional work for someone else other than their own employer are most likely to be Classified Outside Workers. For example, a practitioner employed by a private hospital may be asked by their employer to carry out work for an NHS Trust. This will involve them undertaking procedures as an Outside Worker, in the supervised or controlled area of another organisation which is not their actual employer. A clinician carrying out work in any building within their own employer's estate would not be considered to be an Outside Worker.

119. 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 employers who are not their employer. The number of such workers is uncertain; information provided by medical sector stakeholders suggests it could be around 25% of the total number of adult cardiologists. 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.

120. 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.

121. 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.

122. Based on discussions with medical sector stakeholders, Outside Workers will work for between 1 and 3 other organisations. As a conservative assumption, we assume for the purposes of this assessment that, on average, 2 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.

123. 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.

Medical sector – additional controls to reduce eye doses

124. 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. HSE inspectors also concur with these findings. This is contrary to representations by NHS stakeholders that the medical sector may incur considerable costs in complying with the new eye dose limit, and the limited monitoring data available, which suggests at least some workers in the NHS currently receive eye doses above the proposed new dose limit.

125. To represent potential costs, the analysis is based on information provided by NHS representatives; HSE expects that this may overestimate costs and will seek to refine estimates for the final stage assessment.

126. In the medical sector, there is a range of engineering controls and personal protective equipment in use to protect against radiation doses. The main source of radiation to the lens of the eye is secondary radiation 'scattered' from other objects, often the patient's body. 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.

127. HSE's discussions with representatives from the NHS have confirmed that leaded glass screens and eyewear are the primary control measures. However, medical sector employers believe 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. The following sections assess the potential costs of supplying this equipment.

Cost of supplying additional protective leaded eyewear

128. Employers, as part of the risk assessment (RA) process, will need to assess the adequacy of the provision of existing eye protection. NHS representatives believe that some current designs in use may not offer sufficient side protection to avoid 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 high permitted eye dose limit in the past). 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.

129. 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. Furthermore, recent discussions with RPAs in the NHS, and an HSE Specialist Inspector with experience working in the medical sector, suggests that there will be variation in the practice of issuing eyewear. Some employers may supply protective eyewear primarily to interventional rooms,

where they are pooled for use by clinicians and support staff working in the room, while others may supply eyewear mostly to individuals. Individuals with corrective prescription glasses will require individual protective eyewear tailored to their prescription.

130. A plausible 'typical' scenario is that senior clinicians most commonly involved in complex interventional procedures 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 analysis makes the following assumptions, based on information from NHS representatives and discussions with HSE 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, of course, the 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 assume that 25% of these workers will receive new eyewear, giving an estimate of 250 pairs. Better monitoring data from the NHS showing the distribution of eye doses around the classification level would enable HSE to improve this estimate – HSE will investigate whether it is possible to obtain additional monitoring data during the consultation period.

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 1,200 across all 232 sites. 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; however we have assumed that around half will be. This gives approximate 1,500 pairs of eyewear issued to interventional rooms.

131. This gives a total of 2,100 pairs of eyewear issued across the medical sector in the first year. 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 £870,000 in the first year.

132. 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 £170,000 (from the second year).

Ceiling-mounted lead glass screens

133. 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).

134. As with protective eyewear, the number of additional mounted screens that would need to be installed to allow work on both sides of the patient is uncertain. The number per site would depend on the number of interventional rooms per site and the specification of existing screens installed.

135. Information provided by stakeholders during and after the March 2013 Medical Stakeholder event was that around two-thirds of the 232 affected sites (140) may need to have some screens replaced, with 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 (three), this gives an estimate of around 410 screens replaced in total.

136. The cost of a new screen is estimated 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).

137. Multiplying across all 410 screens requiring replacement gives a total estimated one-off cost (in the first year) of around £1.7 million across the medical sector.

138. There may also be some ongoing maintenance and replacement costs for lead glass screens, which have not been included in the current cost estimates. These will depend in particular on the typical service life of lead screens. HSE will include these costs for the final stage assessment. We will also seek to gather further information from the medical sector regarding the number of interventional rooms needing replacement lead glass screening to refine the cost estimate.

Total costs to the medical sector

139. Total one-off costs to the medical sector estimated in the preceding sections amount to around £3.1 million, occurring in the first year.

140. 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 £250,000.

141. The total present value of costs to the medical sector, applying a 3.5% discount rate, is £5.3 million over the 10-year appraisal period.

142. All costs at this stage are assumed to fall to the public sector (NHS).

Nuclear sector – numbers affected and costs of time

Numbers affected

143. In GB there are estimated to be around seven nuclear sector employers, including the Ministry of Defence, who are likely to be affected by the proposed dose limit for the lens of the eye.

144. According to HSE's Central Index of Dose Information (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 eye doses. Taking the middle of this range (7.5%) gives around 1,500 affected classified workers.

145. 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 be 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.

146. 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.

Cost of time

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

A decommissioning glovebox worker 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.[17]

A Radiation Protection Supervisor (RPS) has an FEC of £31.20 per hour

A health and safety manager has an FEC of £31.20 per hour[18]

148. In addition, certain workers' activities are instead costed at the amount charged to the employer. These are activities carried out by parties brought in and who charge an hourly or daily rate, rather than employees. These are as follows:

A Radiation Protection Advisor (RPA) charges around £106 per hour, as estimated by stakeholders

Nuclear sector – communicating the change in requirement and determining any further action needed

Cost of revising Risk Assessments (Ras)

149. 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 during the negotiation phase of the Directive suggested that this is a reasonable assumption. Multiplying this across all 45 nuclear sites regulated or authorised by the Office for Nuclear Regulation (ONR) gives a total of around 2,000 hours of staff time to revise Ras across the nuclear sector.

150. 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;

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

[18] Hourly rates for RPS and health and safety manager are taken from ASHE 2015(p): Production managers and directors in mining and energy (1123). The rate has been uprated by 19.8% to account for non-wage costs and inflated to 2016 prices using ONS seasonally-adjusted weekly average earning index.

One sixth will be undertaken by a Radiation Protection Supervisor (RPS);

One sixth will be undertaken by the decommissioning and glovebox workers.

151. This gives a weighted average cost of time per hour of around £60 (taking the midpoint of ranges). Multiplying by the estimate of 2,000 hours across the nuclear sector gives a total one-off cost of revising Ras of around £120,000.

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

152. Nuclear sector employers will need to ensure that affected workers are aware of the change in eye dose requirements. Employers will also need to communicate the results of Ras, and provide advice and training to employees where action is required to reduce eye doses.

153. Information provided by stakeholders suggests around 10 to 15 hours of staff time will be required per site to prepare and provide communications, advice and training on the change in requirements. This time is less than for medical sites, as discussions with nuclear industry stakeholders are that such information is provided routinely to staff. Practices are likely to vary across nuclear sites, though it is expected that an RPA, RPS and health and safety manager will be involved in providing communications, advice and training. We assume that each will spend an equal amount of time – one-third each – giving a weighted average cost of staff time of around £56 per hour, or £700 per site. Multiplying this across all 45 nuclear sites gives a one-off cost of providing communications, advice and training of around £32,000.

154. Affected workers will need to spend time engaging with communications and receiving advice and training. Discussions with nuclear sector stakeholders suggests much of this could be done during 'tool box talks' or other routine health and safety briefings, so the additional time may be limited. To account for the potential for training for workers, we apply an estimate of one hour per affected worker in total provided by industry sector stakeholders. We value this time at the average rate of glovebox worker's time (£55 per hour). Multiplying this across all 1,800 affected workers gives a total estimated cost of workers' time of £98,000.

155. Adding the estimates in this section gives total one-off costs of around £130,000 in the first year from communications, advice and training regarding the change in eye dose requirements.

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

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

156. 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 will need eye dosimetry.

157. Each would require eye dosemeters. It is estimated by stakeholders and HSE that these would cost around £95 per worker per year (see paragraph 111), 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.

158. 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 ADS of the type of PPE worn. Charged at £106 per hour, this gives a total cost of RPA time of around £9,300.

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

160. 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.

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

161. As per Section 0, information provided by the nuclear sector suggests that around 250 non-classified staff may require routine monitoring for eye dose.

162. Each would require a dosemeter to measure the dose to the eye. 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.[19] 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.

163. 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 classified worker, which is important for accurately estimating dose to the lens of the eye. Charged at £106 per hour, this gives a total cost of RPA time of around £1,500.

164. The total annual cost of this routine monitoring for non-classified workers is therefore estimated to be £9,500.

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

165. 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.[20] 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).

166. 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.

Total costs to the nuclear sector

167. 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 £310,000 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 £1.7 million. While these will include some costs to the MoD, these are expected to be a relatively small proportion, and so all costs at this stage are assumed to fall to the private nuclear sector. HSE will improve the estimate of the public/private split of costs for the final stage impact assessment.

[19] 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.

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

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

168. 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.

169. Expert advice from HSE Specialist Inspectors suggests there will no impact on dentists, since they 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.

170. 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.

171. 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.

172. 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.

173. 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. HSE has included a member of the British Veterinary Association in membership of the Occupational Exposures Working Group; however, we need to explore this with a number of representatives from the sector at the formal consultation.

174. 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. The view of HSE specialist inspectors is that the change in the eye dose limit will not impact the education sector, as they do not carry out practices that have a significant eye dose risk.

175. HSE will seek to gather further information during the formal consultation on potential impacts to other sectors.

Eye dose – other impacts not costed

Provisions to account for eye doses over five years

176. HSE will implement a provision in the BSSD which will allow 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.

177. The Directive requires that five-year averaging is to be “as specified in national legislation”. HSE will set out the conditions in national legislation (see paragraph 181 below) that dutyholders must comply with to adopt five- year averaging. In complying with these conditions, dutyholders may incur some costs.

178. 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.

179. 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 seems to indicate 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.

180. 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 the 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.

181. The likely 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.

Additional approvals for Approved Dosimetry Services

182. 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.

183. The number of applications and associated costs depends to a large extent on the number of additional classifications, particularly in the medical sector, which, as described throughout this assessment, is highly uncertain.

184. 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).

185. Initial 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. If HSE receives evidence during the formal consultation period that this will be a more significant (indirect) impact, we will attempt to quantify it for the final stage assessment.

Eye Dose – Health benefits

186. Long term exposure of the lens of the eye to ionising radiation can cause eye lens opacities (a 'clouding' of the lens, which obstructs the passage of light). In the early stages, ionising radiation-induced opacities usually do not have an effect on vision; therefore, the individual is not aware of them. The identification of early changes in the lens due to ionising radiation would require an assessment by a specialist eye doctor. Usually, opacities which cause visual impairment are called cataracts; therefore a change in the number of cataracts due to exposure to ionising radiation is the relevant health outcome to measure health benefits.

187. Cataracts are common in the general population. A number of risk factors contribute to the development of the various types of cataract, such as aging, smoking, diabetes, exposure to sunlight, certain medication and other sources of ionising radiation. 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 reduction in ionising radiation exposures; further hinders an assessment.

188. The key document in respect of the reduction in eye dose limit from 150 mSv to 20 mSv adopted into the Basic Safety Standards Directive comes from ICRP Publication 118.[21] 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. Therefore, the reduction of cataracts which could be linked to the decreased dose limit, even if we had better data on the current level of exposures, is highly uncertain.

189. Advice from HSE medical advisers is that, while the reduction in the eye dose limit should reduce opacities, a similar reduction in cataracts is more uncertain. HSE will use any additional data gathered during the consultation period (e.g. monitoring data, the costs of cataract operations to the NHS, and the impacts on quality of life of reduced vision due to cataracts prior to operation) to improve the analysis of health benefits where possible, although a quantitative analysis of the expected change in cataracts will be difficult, due to the reasons described above.

Graded Approach (notification, registration, and licencing)

190. The Directive introduces a risk-based approach to regulatory control of practices using ionising radiation. This approach to regulatory control comprises of informing the competent authority (HSE)

[21] ICRP (2012) statement on Tissue Reactions and Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context

about work with ionising radiation and 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 licencing (for practices with the highest risks).

191. 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 focus 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.

192. HSE is considering three options for the implementation of the graded approach. Option 1 is a 'do minimum' option. Option 2 would introduce renewals of registration and licences, in addition to the 'do minimum'. Option 3 would extend the licencing requirement in Option 2 to higher-risk practices to ensure a consistent approach to the regulation of risks from exposure to ionising radiation.

Graded Approach Option 1

Notifications of low-risk practices

193. Notification applies to the practices with least risk. That includes work with small quantities of radioactive material, naturally occurring 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.

194. Firstly, however, the Directive requires all existing notified practices to be re-notified under the regulations. It is difficult to estimate how many existing notified practices would simply re-notify, as a number of these will either be registering or applying for a licence under the changes (see sections 0 and 0, below). However, the unit cost of one notification will be negligible, as described in paragraph 196.

195. 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 additional number of practices that may need to notify, so we cannot quantify the number of dutyholders affected at this stage but it is likely to be small.

196. The unit cost of one notification will be negligible. Notification would be via an online process that would require responses to no more than 10 questions. The information required to answer these questions is expected to be readily known by the business notifying and to be of such a nature that they would not need to undertake any information-gathering or analysis to be able to respond. Thus, we estimate that it would take a dutyholder no longer than 20 minutes to complete the form. No fee will be charged to notify HSE, and the dutyholder would not be expected to renew the notification. At an average full economic cost of time of £27.72 per hour[22], we estimate that it would cost an organisation

[22] 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.

around £9.00 to submit a notification to HSE. Given the low unit cost per notification, we estimate that there will be minimal costs to business from the requirement to notify low risk practices.

Registration

197. 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 radiation specialists estimate that this applies to around 27,000 practices of which around 40% are public sector practices (particularly in health care).[23]

198. HSE will set up an online system to facilitate registrations. We estimate that it will take businesses around half an hour to collate the information they require to submit, and 10 minutes to submit the information on the online portal, responding to no more than 17 questions. Thus at the cost of time of £27.72 per hour (see paragraph 195), the cost per registration would be £18.48. In addition to this, HSE intends to charge a fee to recover the costs of setting up the IT system and its continued operation. However, the fee has not yet been determined and is not included in this assessment. As explained in section 0 we expect that the information on fees will be available before the final-stage IA, and will incorporate it into our analysis at that stage.

199. To simplify the costs assessment we assume that all 27,000 practices register in the first year of implementation. We also assume that there will be around 12% new applications from businesses each year (or around 1,900 of the approximately 16,000 private practices who register in the first year).[24] Thus, we estimate a cost in the first year of around £490,000 (excluding fees), and an annual cost from the second year onwards of around £36,000. Over the 10-year appraisal period, this is a present value cost of £770,000 (excluding fees).

Licencing

200. The Directive lists the highest-risk practices that would require the highest tier of approval. It also lists the information needed so that a licence can be granted.

201. The unit cost of one licencing application is higher than the unit cost for registration as more detailed information would be required. The application would have around 30 questions, which fulfil the needs of the Directive. We estimate that it would take a dutyholder around 80 minutes to gather information for the application and around 15 minutes to complete it. At a full economic cost of time of £27.72 per hour (see paragraph 194), the unit cost per application is therefore £43.89. A fee, that covers the costs of setting up the IT system and its continuation, would also be charged. However, the fee has not yet been determined and is not included in this assessment. As explained in section 0, we expect that the information on fees will be available before the final stage IA, and will incorporate it into our analysis at that stage.

202. HSE has estimated that in 2018 around 2,400 applications will be received, of which around 67% are from business, and 33% from the NHS.[25] We also assume that there will be around 12% new applications from businesses each year (or around 190).[26] Therefore, around 2,400 applications for a licence will be received in the first year, and around 190 each year following that. It would cost

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[23] Annex 1 provides the estimated number of IRR dutyholders by sector, therefore providing an overview of the kind of businesses that may need to register.
[24] This is based on ONS Business Demography data
[25] The number of licence applications are based on type of practice (for example, the discharge of radioactive material into the environment) rather than on sector. Therefore, the estimate 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.
[26] This is based on ONS Business Demography data

dutyholders around £44 to submit each of these applications, though this does not account for the fee charged by HSE. Thus, we estimate a cost in the first year of around £100,000, and an annual cost from the second year onwards of around £8,300. Over the 10-year appraisal period, this is a present value cost of £170,000 (excluding fees).

Registration and Licencing Fees

203. As mentioned in paragraphs 198 and 201, HSE intends to charge a fee for registration and licencing to cost-recover for the design, operation and maintenance of the graded approach, including the IT system. HSE currently estimates that the IT system may cost in the region of several hundreds of thousands of pounds. However, this estimate is still highly uncertain as the IT system is still in an early stage of development, and costs are likely to change. It is therefore not possible to provide an estimate of fees per licence or registration at this stage. Estimates that are more accurate will be available for the Final Stage Impact Assessment and the additional costs from these fees will therefore be monetised at that stage.

Notification of material changes

204. 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; IRR already require this for the notifications received under the current regulations. However, the 'graded approach' is broader in scope than our current requirements so more dutyholders may have to notify us of material changes.

205. It is not possible to estimate the number of practices that would need to notify HSE about these material changes. Therefore, we cannot estimate the costs to business at this stage. However, we estimate that the unit cost would be about the time required to submit a notification, or no more than £9 (see paragraph 196).

Summary of costs from the graded approach – Option 1

Table 1 Present Value Costs from the Graded Approach, Option 1, in millions of £

	Total	**Business**	**Public Sector**
Notification	Not quantified		
Registration	£0.77	£0.56	£0.20
Licencing	£0.17	£0.13	£0.03
Notification of material changes	Not quantified		
Total	**£0.94**	**£0.70**	**£0.24**

Note that totals may not sum due to rounding

Graded Approach Option 2

206. Option 2 is identical to Option 1, only it introduces a renewal requirement for registrations and licences.

Renewals of Registrations and Licences

207. HSE may be going beyond the minimum requirements of the Directive by requesting renewals of registrations and licences. The Directive is silent on the details of implementing the registration and licencing systems. The implicit requirement of the Directive is to implement a system that is robust, can hold organisations to account and has longevity. HSE has considered these needs and, although the timescales for renewals have not been finalised, the proposal is that registrations would require a

renewal every 5 years, whereas licences would require an annual renewal to be effective. The proposed renewal periods are proportionate to the risks associated with registered and licenced practices respectively. Whilst this may gold-plate the Directive, having up-to-date information forms the basis of any functional licencing system, and would enable HSE to target inspections to those areas where they will have most impact. Requiring periodic renewal of registrations and licences, in addition to the notification of material changes, provides assurance that HSE will receive this information.

208. In paragraph 198, we state that the cost per registration is £18.48 (excluding fees). We assume that 27,000 practices (i.e. the same as in Year 1) renew their registration five and 10 years later (in Year 5 and Year 10). This is a simplifying assumption, as some of those practices would no longer be operating. We are assuming here that any new practices registering are exactly offset by those practices that are no longer being carried out.

209. At a cost of £18.48 per application, the cost in year 5 and year 10 is around £490,000. Over the appraisal period, this is equivalent to a present value cost of £790,000. Around 60% of these costs fall on businesses, approximately £470,000. The other 40% (£330,000) fall on the NHS and some research, education, and training institutions.

210. In paragraph 201, we state that the cost per licence is £43.89 (excluding fees). We assume that around 2,200 renewals are received each year between Year 2 and Year 10 of the appraisal period. This means that we are assuming that the number of applications for licences remains constant over the 10-year appraisal period (combining the new licences from paragraph 202, and the renewals in this paragraph). Therefore, any new practices applying for a licence are exactly offset by practices that are no longer being carried out, and therefore not having their licences renewed.

211. At a cost of £43.89 per application, the cost each year is around £96,000. Over the appraisal period, this is equivalent to a present value cost of £730,000. Around two-thirds of these costs fall on businesses, approximately £470,000, and the other one-third (£260,000) fall on the NHS.

Summary of the costs from the graded approach – Option 2

212. The total costs from this option are around £2.5 million in present value terms. Registration will cost around £1.6 million, whereas licencing will cost around £0.90 million. However, these costs exclude any fees that would be charged as these are not yet known. **Table 2** summarises costs.

Table 2: Present Value Costs from the Graded Approach, Option 2, in millions of £

	Total	Business	Public Sector
Minimum Requirements			
Notification	Not quantified		
Registration	£0.77	£0.56	£0.20
Licencing	£0.17	£0.13	£0.03
Notification of material changes	Not quantified		
Sub-total	*£0.94*	*£0.70*	*£0.24*
Renewals			
Renewing Registrations	£0.79	£0.47	£0.33
Renewing Licences	£0.73	£0.47	£0.26
Sub-Total	*£1.5*	*£0.94*	*£0.59*
Total	**£2.5**	**£1.6**	**£0.82**

Note that totals may not sum due to rounding

Graded Approach Option 3

213. Option 3 is identical to Option 2, only it extends licencing requirements to high-risk practices to ensure consistency in the regulatory approach.

Extension of licences under the Graded Approach

214. Strictly implementing the requirements set out in the Directive (that is, as described in Sections 0 to 0), would result in certain work activities within GB (industrial radiography and industrial irradiation) requiring both a licence and a registration for the different types of practice carried out. Specifically, the use of a High Activity Sealed Source (HASS) would require a licence, whereas the use of a radiation generator would require registration, but these pieces of equipment would be used for the same work activity.

215. HSE radiation specialists 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 be licenced. Therefore, HSE is considering using the flexibility allowed within the Directive to require the overall work activity to be licenced for these practices, which would cover work with both HASS and radiation generators. Doing so would create two new licensable practices, “Industrial Radiography” and “Industrial Irradiation”, and affect an estimated 165 Industrial radiography dutyholders and 8 industrial irradiation dutyholders.

216. Extending the scope of licences in this way goes beyond the minimum requirements of the Directive, by requiring the use of radiation generators to be licenced 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 additional costs to the dutyholders above those described in Section 0, for the reasons described below.

217. Firstly, without this extension of licencing, some dutyholders would need to make two applications: a licence for the use of HASS, and to register the use of a radiation generator. If licences were extended as above, they would only need to apply for one licence (under the appropriate licensable 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 £18.50 administrative costs plus fee).

218. There may be a small number of dutyholders who use radiation generators only. These would experience an increase in costs, as under this option they would need to apply for a licence, rather than register. Advice from radiation specialists 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.

219. Therefore, the number of dutyholders registering a work practice under this approach to implementation is slightly lower (by around 173 businesses) than the number (27,000) described in paragraph 197 (Option 1 and 2). However, the estimated number of registrations is uncertain so a reduction of around 173 businesses is within the margin of error. So the costs from registration are no different to those described in Options 1 and 2.

220. Secondly, HSE would receive additional information when extending licencing for the industrial radiography sector as a whole, which could provide assurance that suitable levels of risk assessment and management are being employed by the applicants. HSE is proposing to use the licencing 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 could place restrictions on site radiography practices within specific conditions in any licence documentation issued, enabling us to remove the existing requirement to notify HSE seven days in advance of every instance of site radiography.

221. There are an average of 5,000 seven-day notifications sent to HSE each year, and 70 waiver applications. Businesses could save around £4.00 for every notification not required (assuming each application takes 10 minutes to complete, at a cost of time of £24.29 per hour).[27] On average, an estimated 5,070 applications would not be required per year, meaning businesses would incur savings against the baseline of around £21,000 per annum. This results in savings over the appraisal period of £180,000.

222. HSE is also considering using the flexibility allowed within the Directive to require another extension to licencing – 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 licencing by the Directive. HSE estimates that this extension to licencing would capture around 20 commercial/academic dutyholders and around 175 NHS Trusts. As these practices are not part-captured by existing licencing requirements (see section 0 above), there would be costs associated with this proposal.

223. Therefore, HSE expects to receive around 2,600 applications for licences (around 200 more than in Option 2). Adopting the same assumptions as in paragraphs 201, 202, 210, and 211, we estimate that the costs (compared to the baseline) are around £110,000 per annum, equivalent to around £970,000 in

[27] 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.

present value terms over the appraisal period. The additional costs, compared to Option 2, are around £9,000 per annum, or £74,000 over the appraisal period.

224. Therefore, Option 3, to extend licencing under the graded approach, would lead to total net costs under the graded approach of £2.4 million, compared to £2.5 million under Option 2, and £0.94 million under Option 1.

Summary of the costs from the graded approach

225. A summary of the costs from Option 3 are provided in Table 3 below. Table 3 also compares the costs with Option 2 and Option 1. As explained in the text above, these cost estimates do not include the costs from fees, though we will determine these ahead of the final stage IA.

226. Costs arising from Options 2 and 3 gold-plate the Directive (requiring renewals of registrations and licences, and extending the scope of licences) and are therefore in scope of the Business Impact Target (BIT). The equivalent annual net costs to business from the gold-plated aspect of Option 2 are £0.1 million, in 2014 prices. The equivalent annual net costs to business from the gold plated aspects of Option 3 are £0.1 million in 2014 prices. The net costs from Option 3 are lower than those in Option 2 because Option 3 introduces cost savings of around £0.02 million per annum.

Table 3: Present Value Costs from the Graded Approach, comparing all Options, in millions of £

	Total	**Business**	**Public Sector**
Option 1			
Notification	Not quantified		
Registration	0.77	0.56	0.20
Licencing	0.17	0.13	0.03
Notification of material changes	Not quantified		
Total Costs – Option 1	**0.94**	**0.70**	**0.24**
Option 2			
Option 1 costs	0.94	0.70	0.24
Renewing Registrations	0.79	0.47	0.33
Renewing Licences	0.73	0.47	0.26
Total Costs – Option 2	**2.5**	**1.6**	**0.82**
Option 3			
Option 1 and Option 2 costs	2.5	1.6	0.82
Additional cost from Extension of Licences	0.07	0.01	0.07
Total Costs – Option 3	**2.5**	**1.7**	**0.89**
Savings Option 3			
Removal of 7-day notification	(0.18)	(0.18)	Nil
Net Costs – Option 3	**2.4**	**1.5**	**0.89**

Note that totals may not sum due to rounding

Graded Approach – Health benefits

227. 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 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.

Outside workers

228. An outside worker is someone 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 0.

229. HSE will adopt a new definition of outside workers to comply with the Directive. This extends the definition of outside workers from 'classified workers carrying out services in the controlled area of another employer' to 'any worker who carries out services in the controlled or supervised area of another employer'. Under the current regulations, arrangements for outside workers are set out in the regulations but only apply to classified outside workers. 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 that work for the employer undertaking the work with radiation) relating to training, instruction, protective equipment, dose monitoring and entering of controlled and supervised areas.

230. Current arrangements require the employers of outside workers to ensure their workers are correctly classified regarding the dose of radiation they receive from work. Their employers also need to provide training, protective equipment and passbooks to record doses to their workers while working in other employer's premises.

231. The employer responsible for the controlled area must have suitable arrangements in place for entry into that area and must agree arrangements for dose monitoring with 'people who enter that area who are not their employees '. They must also ensure adequate information is given to persons directly concerned with the work carried out by the employer to ensure their health and safety, so far as reasonably practicable. Additionally, there is also a current requirement for all employers to cooperate if work with ionising radiation undertaken by one employer is likely to expose the employee of another employer to radiation. This means that employers of outside workers will find out details of the services to be performed, the estimate of the dose likely to arise from this, work procedures to be followed and any additional training required. Employers are also required to exchange information to ensure that they can comply with the requirements of the current regulations.

232. When HSE engaged with stakeholders from the medical, nuclear, non-destructive testing, education and oil and gas sectors on these changes, the consensus was that they already treat outside workers in the same way as employees. This implies that there is also no difference in how non-classified outside workers and ordinary non-classified workers are treated. Based on this early consultation with stakeholders we concluded that any additional costs from the change would be one-off and minimal.

233. We also asked specific questions about associated costs in a questionnaire circulated to stakeholders in August 2016. The stakeholders were from a range of industries including nuclear, non-destructive testing, and the medical sector. Twelve of the twenty-four respondents stated that there would be no additional costs to their organisation. One could not respond, and another two could not answer with certainty. The remaining nine respondents stated that there may be additional costs to their business. However, five of these stated that costs would only arise if HSE would require the same arrangements for non-classified outside workers as those for classified workers (that is, the provision of passbooks to record doses). As HSE does not intend to replicate these arrangements for non-classified outside workers, there would be no additional costs for these stakeholders. Another three respondents

could not provide sufficient details for us to be able to estimate costs. The other respondent, from an NHS Trust, stated that there may be a one-off cost to clerical staff tasked with determining specific contractual arrangements; however, given the information provided, it is difficult to determine what the costs may be.

234. Therefore, at this stage we are unable to monetise the additional costs arising from this change. However, from the information provided we anticipate that there would be no significant ongoing costs to businesses, and any costs incurred would be one-off costs where organisations assess their compliance with the change. We will test this conclusion with a wider group of stakeholders at consultation. These costs will be monetised if proportionate to do so for the final stage IA.

Outside workers – Health benefits

235. Currently, although arrangements exist which do protect outside workers who are not classified, these are not fully captured in regulation; putting this in regulation would ensure that their exposure is controlled.

236. Extension of provisions to other areas where work is carried out which could cause higher levels of exposure (supervised areas) increases the protection to outside workers, and ensures that radiological protection is equal between all workers undertaking the practice. However, any benefits are likely to be minimal, given employer's views that they already treat outside workers in the same way as employees, as discussed above.

Weighting Factors

237. HSE will adopt new radiation and tissue weighting factors set out in the Directive. These weighting factors allow Approved Dosimetry Services (ADS) to estimate the effective and equivalent doses from external and internal radiation.[28] Applying the new tissue weighting factors will take account of the latest scientific data to calculate radiation dose. This will ensure that the calculation of the actual dose is as accurate as possible taking account of all the possible exposures, and that classification is or isn't warranted on this basis meaning that workers are given adequate protection dependent on the dose received.

238. This update will trigger a series of changes described below, mainly relating to the change in tissue weighting factors. HSE discussed this issue in two dosimetry working groups in 2015. In this, we gathered feedback from one ADS that they would have to update specialist software that they use, which in some cases is shared with other ADSs. They estimate that it may cost around £250,000 to update this software. This cost will be passed on to ADSs when they purchase the update. Additionally ADS's databases will also require updating to reflect the new weighting factors. There are 33 ADSs across the UK that may have to do this. However, it is not possible to estimate the cost of database updates at this stage; HSE will seek to gather information about these costs during formal consultation.

239. The updated factors may lead to an increase or decrease in the number of classified workers, if the weighting factors change the estimates of effective doses such that the worker moves above or below the classification threshold. However, it is not yet possible to say what the effect on the number of classified workers might be, and if so whether it would lead an increase or decrease in costs to

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[28] **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').

business, in advance of changes to ADS software and databases. HSE will engage with ADSs during the consultation period to determine whether an assessment can be undertaken for the final stage IA.

240. The change in weighting factors will therefore introduce one-off costs of at least £250,000, though further costs may arise which cannot be quantified at this stage.

Public Dose Estimation

241. Upon implementation, there will be a new requirement on employers to estimate ionising radiation doses to members of the public, arising from work activities they undertake using ionising radiation. However, the majority of stakeholders already carry out this 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. HSE expects that the businesses affected are mainly those in the non-destructive testing sector, and any business using X-ray detection devices, and XRF analysers. There are around 1,200 such businesses across GB. HSE will seek to gather information on whether other sectors are affected during formal consultation.

242. Initial responses to a questionnaire indicate that it would take stakeholders between 1 and 6 hours to make the calculation in the first year of implementation. At the cost of time of £24.29, as used in paragraph 221, this is estimated at a cost of between £24 and £146 per assessment, with a best estimate of £85. Across the 1,200 businesses affected, this is a one-off cost to businesses in the first year of between £29,000 and £174,000, with a best estimate of £102,000. Businesses may review this estimate when practices have changed. However, it is not possible at this stage to estimate how many businesses will review it and how frequently they would review it over the appraisal period.

243. There is potential for some small but unknown public health benefits arising from this change. Ensuring that businesses who 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 1mSv.

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

244. 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" and to ensure that accidental exposures and doses[29] are recorded in the dose record. 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.

245. 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.

246. 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. HSE proposes to add to this, so that employers would

[29] 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 "

also be required to record and analyse any event which causes, or potentially causes, the enactment of a contingency plan.

247. We asked about the potential costs from this requirement in the questionnaire circulated in July 2016 (see Section 0). Of the 21 respondents who could respond 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 are 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, it appears that the majority of stakeholders already meet the proposed requirement and that this requirement is actually considered standard practice. However, whilst there may be some additional costs to some businesses it is not possible to quantify or monetise them at this stage and we would have to explore the costs further during consultation.

248. Secondly, dutyholders would be required to record any accidental exposure from enactment of the contingency plan on dose records. Discussions with industry stakeholders suggest that there is scope to do this in the 'free text' part of a data entry in existing databases. We expect the cost of recording one accidental exposure is not large, as ADSs would choose the easiest way to record it, requiring no structural changes in databases, or one-off changes in processes. However, it has not been possible with current information to estimate how many accidental exposures there would be over the appraisal period, so we cannot quantify the cost of this change at this stage.

Accidental exposures and 'significant events' – Health benefits

249. 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.

Changes to regulation with no significant costs to business expected

250. There are several proposed changes to the regulations required to implement the Directive, which HSE believes should not lead to significant additional costs to businesses, based on consultations with stakeholders to date. Table 4 (next page) summarises these changes and the reasons why these are not expected to give rise to significant costs. HSE will seek views about whether the assessment of no significant costs for these changes is valid in the formal consultation period.

Table 4 Ionising Radiations Regulations: Summary table of changes to regulation 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. HSE will seek to validate whether this is representative of other sectors and businesses during the consultation period.

Short description	What is the change?	Why are there no costs to business?
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 Regulations. This value has now changed to an annual average concentration greater than 300 Bq m^{-3}.	Calculations carried out by Public Health England 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, IRRs 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.
Equipment used for medical exposure	Department of Health (DH) have proposed a transfer of responsibilities covered in existing provisions in IRR99 into their new Ionising Radiation (Medical Exposure) Regulations 2018.This has been agreed in principle with discussions ongoing to establish if DH regulators have necessary enforcement powers and competences to carry out this work.	No further burden will be placed on businesses from this change, as we do not expect the requirements on dutyholders to alter. Any changes to requirements introduced by the ionising Radiation (Medical Exposure) Regulations 2018 would be assessed in the impact assessment for those regulations.
Estimation of dose via calculation methodology approved by the Competent Authority	The current regulations 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, stakeholders could not think of any circumstances for which this is required. 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 but will consult wider stakeholder views in the formal consultation.

Changes which potentially go beyond the scope of the Directive

251. 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.

Under Option 1

Cost saving – early implementation of the regulations

252. To meet EU obligations, new Ionising Radiations Regulations must be UK law by February 2018. Current dose recording arrangements under IRR 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.

253. 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 Approved Dosimetry Services – 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.

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 date. HSE consulted with members of the Occupational Exposure Working Group (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 previous 1996 Directive was 5 months earlier than the transposition deadline for similar reasons.

Maintaining existing standards of radiological protection:

254. 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 additional costs to businesses compared with the 'do nothing' baseline:

Current regulations apply dose limits for exposure to radiation to all work including work with Naturally Occurring Radioactive Materials (NORM). HSE is aware that NORM work can give rise to exposures close to or exceeding the limit for classification of workers. The Directive proposes that dose limits do not apply to such work; this means that there will be no limits to restrict exposure to workers or the public. HSE feels this is lessening the standards of radiological protection and propose that we keep the current regulatory position where dose limits apply to work with NORM.

Existing arrangements state that if radon is detected in the workplace above a certain level then the employer must notify HSE immediately. The proposal outlined by the Directive would mean that notification was only required once the dutyholder had detected that radon was present above the specified level and tried and failed to remediate below this level. HSE feels 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 they are not required to notify. Therefore, HSE think this provision is confusing and lessens radiological protection significantly and we propose that current arrangements are maintained.

255. HSE will seek to gather information during the formal consultation period to estimate the costs of maintaining these standards above the minimum requirements of the Directive and present these for the final stage impact assessment.

Under Option 2

256. As discussed in Section 0, HSE proposes to require the renewal of registrations and licences. Legal advice is that, because the Directive does not explicitly require renewals, doing so would 'gold-plate' the Directive. However, having up-to-date information forms the basis of any functional licencing system, and would enable HSE to target inspections to those areas of highest risk in order to uphold standards of radiological protection. The additional costs of requiring the renewal of registrations and licences are £1.5 million. Of those, the additional costs to business are £0.94 million, and the equivalent annual net cost to business in 2016 prices is £0.11 million. These costs would be in scope of the Business Impact Target as they arise from gold-plating.

Under Option 3

257. As discussed in Section 0, HSE is considering an option to extend the scope of licences to include practices that would otherwise be registered. Implementing this option goes beyond the minimum requirements of the Directive and so is potentially gold-plating. While it may increase costs in some instances, HSE expects these to be outweighed by savings to dutyholders, relative to Option 2, due to the way this would be implemented (see paragraphs 214 to 221).

258. The total additional costs of extending the scope of licences compared with Option 2 (i.e. not extending the scope of licences) are £0.07 million over the appraisal period, of which the additional costs to business are £0.01 million. The change also introduces a saving of £0.18 million over the same period, meaning that implementing this change could result in net savings of £0.17 million, relative to Option 2.

259. Therefore, the gold-plated aspects of Option 3 (including renewals from Option 2 and the extension of licences) lead to additional net costs relative to the 'do nothing' baseline of £1.4 million, of which £0.77 million are additional net costs to business over the appraisal period. The equivalent annual net cost to business in 2016 prices is £0.09 million.

260. The Business Impact Target (BIT) score as estimated using the IA calculator is £0.5 million for both Option 2 and Option 3. This incorporates all net costs arising from gold-plating. However, the BIT at the final stage impact assessment is likely to be higher as it will include fees, which have not been estimated at this stage (as explained in section 0).

Summary of costs from changes to Ionising Radiations Regulations

Table 5 Present Value Costs from the Implementation of IRR, comparing all options, in millions of £

	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	£5.3	£3.1	£0.25	Not Quantified			£5.3	£3.1	£0.25
Eye Dose – Nuclear Sector	£1.7	£0.31	£0.16	£1.7	£0.31	£0.16	Nil	Nil	Nil
Graded Approach	£0.94	£0.60	£0.04	£0.70	£0.36	£0.04	£0.24	£0.24	Nil
Outside Workers	Not Quantified			Not Quantified			Not Quantified		
Weighting Factors	£0.25	£0.25	Nil	£0.25	£0.25	Nil	Nil		
Public Dose Estimation	£0.10	£0.10	Nil	£0.10	£0.10	Nil	Nil		
Accidental Exposures	Not Quantified			Not Quantified			Not Quantified		
Total Costs – Option 1	£8.2	£4.4	£0.45	£2.8	£1.0	£0.20	£5.5	£3.4	£0.25
Option 2									
Option 1 Costs	£8.2	£4.4	£0.45	£2.8	£1.0	£0.20	£5.5	£3.4	£0.25
Graded Approach Renewals	£1.5	Nil	£0.18	£0.94	Nil	£0.11	£0.59	Nil	£0.07
Total Costs – Option 2	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Option 3									
Option 2 Costs	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Graded Approach Extension	£0.07	Nil	£0.01	£0.01	Nil	£0.00	£0.07	Nil	£0.01
Total Costs – Option 3	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Option 3 Savings	£0.18	Nil	£0.02	£0.18	Nil	£0.02	Nil		
Net Costs – Option 3	£9.7	£4.4	£0.61	£3.5	£1.0	£0.29	£6.1	£3.4	£0.32

Note that totals may not sum due to rounding

• Chapter 3: Other Impacts and Summary

Overall impacts

Familiarisation

261. There will be costs to affected dutyholders who spend time familiarising with the changes in regulatory requirements 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.

262. It has not been possible to quantify familiarisation costs arising from changes to IRR at this stage, except for actions relating to the change in eye dose requirements, described in the next paragraph. IRR is wide in scope, ranging from secondary schools, which may use small amounts of ionising radiation sources for practical purposes, to large nuclear operators. Due to the reasons described in the previous paragraph, the extent to which dutyholders such as these will need to familiarise with the changes will vary greatly. During the consultation period, HSE will gather information on how dutyholders in different sectors will gather information on the changes, and the likely staff time involved in familiarising, in order to estimate these costs for the final stage assessment.

263. However, a number of additional actions costed under the changes to the eye dose limit do account for the costs of time spent on activities which can be termed 'familiarisation': raising awareness of changes within an organisation, providing advice and training regarding the new requirements, and revising risk assessments (see Sections 0 and 0). The total costs associated with these activities are around £750,000 in the first year.

Wider impacts

Health impacts

264. Sections 0, 0, 0, and 0 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 0. It has not been possible to quantify the associated improvement in health outcomes at this stage for the reasons described in that section.

Small business impacts

265. 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. Exempting small businesses from 'gold-plated' requirements presented in Options 2 and 3 would not be appropriate due to the nature of the risks, as above.

266. Of the changes to IRR assessed in Chapter 2, implementation of the 'Graded Approach' (Section 0) is likely to lead to the highest costs to small businesses. At this stage, it has not been possible for HSE to assess costs of the Graded Approach to small businesses. Changes to eye dose requirements (Section 0) are expected to mainly affect the NHS and nuclear sector, so are unlikely to lead to significant costs to small businesses. The impact of other changes to IRR on small businesses is more

uncertain but because the extent of these changes is much smaller, they are also not expected to lead to substantial costs to small businesses.

267. HSE will undertake a full assessment of impacts to small businesses for the final stage assessment.

Other wider impacts

268. 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 BSS Directive is being implemented across Europe and so it is not anticipated there will be any competition impacts);
- Environmental; and
- Sustainable development.

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

Table 6 Present Value Costs from the Implementation of IRR, comparing all options, in millions of £

	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	£7.0	£3.4	£0.41	£1.7	£0.31	£0.16	£5.3	£3.1	£0.25
Graded Approach	£0.94	£0.60	£0.04	£0.70	£0.36	£0.04	£0.24	£0.24	Nil
Weighting Factors	£0.25	£0.25	Nil	£0.25	£0.25	Nil	Nil		
Public Dose Estimation	£0.10	£0.10	Nil	£0.10	£0.10	Nil	Nil		
Other Changes	Not Quantified or Nil			Not Quantified or Nil			Not Quantified or Nil		
Total Costs – Option 1	£8.2	£4.4	£0.45	£2.8	£1.0	£0.20	£5.5	£3.4	£0.25
Option 2									
Option 1 Costs	£8.2	£4.4	£0.45	£2.8	£1.0	£0.20	£5.5	£3.4	£0.25
Graded Approach Renewals	£1.5	Nil	£0.18	£0.94	Nil	£0.11	£0.59	Nil	£0.07
Total Costs – Option 2	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Option 3									
Option 2 Costs	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Graded Approach Extension	£0.07	Nil	£0.01	£0.01	Nil	£0.00	£0.07	Nil	£0.01
Total Costs – Option 3	£9.8	£4.4	£0.63	£3.7	£1.0	£0.31	£6.1	£3.4	£0.32
Option 3 Savings	£0.18	Nil	£0.02	£0.18	Nil	£0.02	Nil	Nil	Nil
Net Costs – Option 3	£9.7	£4.4	£0.61	£3.5	£1.0	£0.29	£6.1	£3.4	£0.32

Note that totals may not sum due to rounding

269. **Table 6** summarises the monetised costs and benefits to dutyholders from changes to IRR under Options 1, 2 and 3.

Proportionality approach

270. Sections 0 and 0 explain the considerable level of evidence gathering undertaken to inform this impact assessment, prioritised on those areas expected to lead to the greatest additional costs to business. 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. On the basis of this evidence, HSE has been able to quantify and monetise many of the impacts associated with the regulatory proposals.

271. There are some impacts which HSE has not been able to quantify, or are uncertain. These are discussed in Section 0 below. HSE believes that the approach to the research and analysis is proportionate to the changes proposed, at this stage of policy development.

Risks and assumptions

272. The extensive consultation and research to inform the policy approach and impact assessment means HSE is confident that it has identified the key impacts and has minimised the risk of unintended consequences. However, a number of uncertainties remain. The key uncertainties in the assessment are summarised in the table below:

Table 7

Source of uncertainty	Expected effect	Scale	Plans to refine
Changes to requirements on doses to the lens of the eye (Section 0)			
1. The current level of exposures to the lens of the eye in the medical sector, as discussed in Section 0.	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.	(Applies to uncertainty 1, 2, and 3) We will discuss with NHS representatives about the best way to collect information, including dosimetry data. One approach may be to survey a sample of NHS Trusts on the number of additional workers they expect to classify, and the number of additional controls they will require.

Source of uncertainty	Expected effect	Scale	Plans to refine
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. As discussed in Section 0, 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. As discussed in Section 0, 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.	
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 will seek to engage with private medical sector representatives during the formal consultation period, including the Association of Private Medical Practices.

Source of uncertainty	Expected effect	Scale	Plans to refine
Graded Approach (notification, registration and licencing) (Section 0)			
5. Estimate of the number of dutyholders that need to complete a one-off notification	The unit cost is small so the cost is not expected to be large	The unit cost is small so the cost is not expected to be large	Further attempts to refine estimates together with operational colleagues
6. The fees that HSE intends to charge for registration and licencing 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	We expect that the information will be available internally ahead of the Final Stage IA
7. The time taken to complete notification, registration and licencing are estimates based on internal expert judgement	This could increase or decrease costs	The effect is not expected to be large	The online system may be subject to user-testing and, if undertaken before the final stage impact assessment, we could use the user-testing to triangulate our time estimates
Outside Workers (Section 0)			
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 will consult on this change during formal consultation
Weighting Factors (Section 0)			
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 will gather further information on the costs of updating databases during the formal consultation. HSE will engage further with ADSs to understand the potential implications of the change in weighting factors for the number of classified workers. However, it may not be possible to fully quantify the impacts for the final stage IA, as this can only be known once ADS software and database systems have been updated, and it is unlikely this will happen in time.
Public Dose Estimation (Section 0)			

Source of uncertainty	Expected effect	Scale	Plans to refine
10.We do not currently know how frequently dutyholders will review their public dose estimates	This is expected to be small because it only applies to 1200 stakeholders	Small impact on 1200 stakeholders	HSE will seek to gather further information on this impact via the stakeholder consultation.
Accidental Exposures and the Recording and Analysis of 'Significant' Events (Section 0)			
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 will seek to gather further information on this impact via the stakeholder consultation.

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

273. Under Option 1, the do minimum option, the total net present value (NPV) to society (including businesses and the public sector) is -£8.24 million. However, only 34% of the costs are costs to business, so the business NPV is -£2.76 million, and the net direct cost to business per year (EANDCB) is £0.3 million, in 2014 prices and 2015 present values. The largest costs are from the impacts to the NHS from changes to the eye dose limit. These account for 64% of the total costs, or £5.3 million, and they are all costs to the public sector. Option 1 does not go beyond the requirements of the Directive so is out of scope of the Business Impact Target.

274. Option 2 is identical to Option 1 except for the introduction of renewals for registrations and licences under the graded approach. This goes beyond the requirements of the Directive and therefore introduces gold-plating. Under Option 2, the total NPV to both business and public sector is -£9.77 million. However, only 38% of costs are costs to business, so that the total business NPV is -£3.70 million, and the EANDCB (2014 prices, 2015 present values) is £0.4 million. As under Option 1,

the greatest costs are from the impacts to the NHS from changes to the eye dose limit (accounting for 54% of total costs). The graded approach, including renewals, accounts for 25% of total costs, or £2.5 million. The costs from the graded approach fall to business (for example, in the industrial radiography sector) and the public sector (in health, defence, and education). The business NPV from the renewals of registration and licences (the gold plated aspect of Option 2) is -£0.94 million, the EANDCB (in 2014 prices and 2015 present values) is £0.1 million, and the BIT score is £0.5 million, as calculated by the Business Impact Target Assessment Calculator.[a]

275. Option 3 is identical to Option 2, except for extending the licencing requirement in Option 2 to higher-risk practices to ensure a consistent approach to the regulation of risks from exposure to ionising radiation. This extension goes beyond the requirements of the Directive and therefore introduces gold plating. Under Option 3, the total NPV to both business and public sector is -£9.67 million. However, the business NPV is -£3.53 million, and the EANDCB (2014 prices, 2015 present values) is £0.4 million. As under Option 2, the highest costs are from the impacts to the NHS from changes to the eye dose limit, and from the graded approach. The business NPV from the renewals of registration and licences and from the extension of licences to higher-risk practices (that is, the gold plated aspects of Option 3) is -£0.77 million, the EANDCB (2014 prices, 2015 present values) is £0.1 million. Therefore the BIT score is £0.5 million, as calculated by the Business Impact Target Assessment Calculator.

Summary and preferred option with description of implementation plan

276. HSE will consider which of Options 2 and 3 best meet the policy objectives, which are to implement the Directive in a way that 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 protection. Where possible, the UK will use copy-out from the Directive, except where doing so would adversely affect UK interests. The five areas where proposed implementation goes beyond the Directive are summarised in Sections 0 and 0.

277. HSE will undertake a formal consultation with stakeholders to further understand the impacts of implementation. Information received will be used to refine the approach to implementation and to update the final stage IA.

278. It is estimated that the total quantified net present value (NPV) of the costs of the proposed Ionising Radiations Regulations 2017 is -£9.77 million over 10 years under Option 2, and -£9.67 million under Option 3.

279. The estimated Equivalent Annual Direct Net Cost to Business (EANDCB) is estimated to be about £0.4 million in 2014 prices under both Option 2 and Option 3. However, the EANCB in scope of the Business Impact Target is £0.1 million in 2014 prices (under both Option 2 and Option 3). .

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[a] October 2016 Version, accessed at: https://www.gov.uk/government/publications/impact-assessment-calculator--3

• Annex 1: Estimated number of IRR dutyholders by sector

Nuclear:

Including all civil nuclear operators and Ministry of Defence (MoD) sites, there are approximately 45 nuclear sites in scope of IRR.

Medical/veterinary:

There are approximately 175 acute NHS trusts which will have to comply with IRR. Additionally, there are 20 mental health trusts and 10 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 500 private health care providers 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 13,000 dentists 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 4,500 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, which may use radiation sources for practical and research purposes.

Some secondary school will have radioactive sources for teaching and practical use. There are around 1,900 secondary schools in England, Wales and Scotland that may use and hold sources.

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 4,500 dutyholders.

Other practices such as electron beam welders (10 estimated practices), ion implanters (5 estimated practices), industrial irradiators (10 estimated practices), XRF analysers (1000 estimated practices), 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, and an estimated 20 docks and ports of entry dutyholders.

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.

The amount of NORM practices in the UK is currently unknown – we expect that the new notification arrangements may help to gather correct data on this.

• Annex 2: Occupational Exposure Working Group membership

AMEC
Association of University Radiation Protection Officers (AURPO)
Atomic Weapons Establishment (AWE)
Association of Healthcare Technology Providers for Imaging, Radiotherapy and Care (AXREM)
Babcock
Blue Lights Working Group (BLWG)
British Aviation Preservation Council
British Institute of Non-Destructive Testing (BINDT)
British Institute of Radiology
British Nuclear Medicine Society
British Veterinary Association
Cast Metals Federation
Confederation of British Industry (CBI)
Consortium of Local Education Authorities for the Provision of Science Services (CLEAPSS)
Business, Energy, and Industrial Strategy (BEIS)
Department Of Environment Northern Ireland (DOENI)
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 (LAWG)
Magnox sites
National Farmers Union
Natural Resources Wales
NHS (various trusts)
NPV Diagnostics
Northern Ireland Environment Agency
Nuclear Emergency Arrangements Forum (NEAF)
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

DfE EQUALITY SCREENING FORM

Part 1. Policy scoping

The first stage of the screening process involves scoping the policy under consideration. The purpose of policy scoping is to help prepare the background and context and set out the aims and objectives for the policy, being screened. At this stage, scoping the policy will help identify potential constraints as well as opportunities and will help the policy maker work through the screening process on a step by step basis.

Public authorities should remember that the Section 75 statutory duties apply to internal policies (relating to people who work for the authority), as well as external policies (relating to those who are, or could be, served by the authority).

Information about the policy

Name of the policy

Proposals on the transposition of Directive 2013/59/EURATOM which lays down basic safety standards for protection against the dangers arising from exposure to ionising radiation.

Is this an existing, revised or a new policy?

New. Directive 2013/59/EURATOM (BSS Directive) will be implemented by the introduction of new health and safety Regulations.

What is it trying to achieve? (intended aims/outcomes)

To implement the BSS Directive in Northern Ireland. The main aim of the Directive is to ensure that basic safety standards for protection against the dangers arising from exposure to ionising radiation are in place. The proposed Regulations 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

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arise from exposure to ionising radiation.

The proposal also covers the approval in Northern Ireland of the revised Approved Code of Practice (ACOP) 'Working with Ionising Radiation' published by the Health and Safety Executive in Great Britain (HSE).

Are there any Section 75 categories which might be expected to benefit from the intended policy?
If so, explain how.

The provisions of the proposed Regulations will have a justified differential impact in respect of age as they relate primarily to workplaces and 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.

Who initiated or wrote the policy?

The BSS Directive provides for the policy changes to be made by all Member States. HSENI is responsible for devising and delivering the proposals for the NI implementing legislation to DfE. If DfE accepts the proposals, it is responsible for enacting the legislation.

Who owns and who implements the policy?

HSENI

Implementation factors

Are there any factors which could contribute to/detract from the intended aim/outcome of the policy/decision?

If yes, are they

☐ financial

☒ legislative

☐ other, please specify _____

Main stakeholders affected

Who are the internal and external stakeholders (actual or potential) that the policy will impact upon?

☐ staff

☐ service users

☐ other public sector organisations

☐ voluntary/community/trade unions

☒ other, please specify – staff in industries where workers may be exposed to ionising radiation such as dentists, vets, hospitals, and other businesses that use any form of x-ray equipment and members of the public.

Other policies with a bearing on this policy

• what are they?

The BSS Directive will also be implemented by the introduction of new Radiation (Emergency Preparedness and Public Information) Regulations

• who owns them?

HSENI

Available evidence

Evidence to help inform the screening process may take many forms. Public authorities should ensure that their screening decision is informed by relevant data.

What evidence/information (both qualitative and quantitative) have you gathered to inform this policy? Specify details for each of the Section 75 categories.

Section 75 category	**Details of evidence/information**
Religious belief	Although there is no available data the policy changes apply equally beneficially to all religious beliefs.
Political opinion	Although there is no available data the policy changes apply equally beneficially to all political opinions.
Racial group	Although there is no available data the policy changes apply equally beneficially to all racial groups.
Age	As the proposals relate primarily to workplaces they will have a justified *differential* impact on those of working age. The proposals are anticipated to increase safety standards for protection of employees (and others) against the dangers arising from exposure to ionising radiation.
Marital status	Although there is no available data the policy changes apply equally beneficially irrespective of marital status
Sexual orientation	Although there is no available data the policy changes apply equally beneficially irrespective of sexual orientation
Men and women generally	Although there is no available data the policy changes apply equally beneficially to men and women generally. The revised wording at regulation 9 (6) in relation to pregnant and breastfeeding employees reflects the wording of the Directive and provides clarification. No practical implications are anticipated.
Disability	Although there is no available data the policy changes apply equally beneficially to those with and without a disability.

Dependants	Although there is no available data the policy changes apply equally beneficially to those with and without dependents.

Needs, experiences and priorities

Taking into account the information referred to above, what are the different needs, experiences and priorities of each of the following categories, in relation to the particular policy/decision? Specify details for each of the Section 75 categories

Section 75 category	**Details of needs/experiences/priorities**
Religious belief	Although there is no available data the policy changes apply equally beneficially to all religious beliefs.
Political opinion	Although there is no available data the policy changes apply equally beneficially to all political opinions
Racial group	Although there is no available data the policy changes apply equally beneficially to all racial groups
Age	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.
Marital status	Although there is no available data the policy changes apply equally beneficially irrespective of marital status.
Sexual orientation	Although there is no available data the policy changes apply equally beneficially irrespective of sexual orientation.
Men and women generally	Although there is no available data the policy changes apply equally beneficially to men and women generally. The revised wording at regulation 9 (6) in relation to pregnant and breastfeeding employees reflects the wording of the Directive and provides clarification. No practical implications are anticipated.
Disability	Although there is no available data the policy changes apply equally beneficially to those with and without a disability.
Dependants	Although there is no available data the policy changes apply equally beneficially to those with and without dependents.

Part 2. Screening questions

Introduction

In making a decision as to whether or not there is a need to carry out an equality impact assessment, the public authority should consider its answers to the questions 1-4 detailed below.

If the public authority's conclusion is **none** in respect of all of the Section 75 equality of opportunity and/or good relations categories, then the public authority may decide to screen the policy out. If a policy is 'screened out' as having no relevance to equality of opportunity or good relations, a public authority should give details of the reasons for the decision taken.

If the public authority's conclusion is **major** in respect of one or more of the Section 75 equality of opportunity and/or good relations categories, then consideration should be given to subjecting the policy to the equality impact assessment procedure.

If the public authority's conclusion is **minor** in respect of one or more of the Section 75 equality categories and/or good relations categories, then consideration should still be given to proceeding with an equality impact assessment, or to:

- measures to mitigate the adverse impact; or
- the introduction of an alternative policy to better promote equality of opportunity and/or good relations.

In favour of a 'major' impact

a) The policy is significant in terms of its strategic importance;
b) Potential equality impacts are unknown, because, for example, there is insufficient data upon which to make an assessment or because they are complex, and it would be appropriate to conduct an equality impact assessment in order to better assess them;
c) Potential equality and/or good relations impacts are likely to be adverse or are likely to be experienced disproportionately by groups of people including those who are marginalised or disadvantaged;
d) Further assessment offers a valuable way to examine the evidence and develop recommendations in respect of a policy about which there are concerns amongst affected individuals

and representative groups, for example in respect of multiple identities;
e) The policy is likely to be challenged by way of judicial review;
f) The policy is significant in terms of expenditure.

In favour of 'minor' impact

a) The policy is not unlawfully discriminatory and any residual potential impacts on people are judged to be negligible;
b) The policy, or certain proposals within it, are potentially unlawfully discriminatory, but this possibility can readily and easily be eliminated by making appropriate changes to the policy or by adopting appropriate mitigating measures;
c) Any asymmetrical equality impacts caused by the policy are intentional because they are specifically designed to promote equality of opportunity for particular groups of disadvantaged people;
d) By amending the policy there are better opportunities to better promote equality of opportunity and/or good relations.

In favour of none

a) The policy has no relevance to equality of opportunity or good relations.
b) The policy is purely technical in nature and will have no bearing in terms of its likely impact on equality of opportunity or good relations for people within the equality and good relations categories.

Taking into account the evidence presented above, consider and comment on the likely impact on equality of opportunity and good relations for those affected by this policy, in any way, for each of the equality and good relations categories, by applying the screening questions detailed below and indicate the level of impact on the group i.e. minor, major or none.

Screening questions

1 What is the likely impact on equality of opportunity for those affected by this policy, for each of the Section 75 equality categories? Minor/major/none		
Section 75 Category	Details of policy impact	Level of impact? Minor/major/none
Religious belief	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to all religious beliefs	None.
Political opinion	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to all political opinions	As above
Racial group	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to all racial groups	As above
Age	As the proposals relate primarily to workplaces they will have a justified *differential* impact on those of working age.	The proposals are anticipated to increase safety standards for protection of employees (and others) against the dangers arising from exposure to ionising radiation.
Marital status	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally irrespective of marital status	None
Sexual orientation	No impact on equality of opportunity. The proposals are	As above

	specifically designed to implement the BSS Directive in Northern Ireland and will apply equally irrespective of sexual orientation.	
Men and women generally	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to men and women generally. The revised wording at regulation 9 (6) in relation to pregnant and breastfeeding employees reflects the wording of the Directive and provides clarification. No practical implications are anticipated.	As above
Disability	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to those with and without a disability.	As above
Dependants	No impact on equality of opportunity. The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will apply equally to those with and without dependents.	As above

2 Are there opportunities to better promote equality of opportunity for people within the Section 75 equalities categories?		
Section 75 category	If **Yes**, provide details	If **No**, provide reasons
Religious		No adverse impact to

belief		any of the Section 75 Groups is anticipated and the policy has no relevance to the promotion of equality of opportunity.
Political opinion		As above
Racial group		As above
Age		As above
Marital status		As above
Sexual orientation		As above
Men and women generally		As above
Disability		As above
Dependants		As above

3 To what extent is the policy likely to impact on good relations between people of different religious belief, political opinion or racial group?		
Section 75 category	Details of policy impact	Level of impact minor/major/none
Religious belief	The proposals are specifically designed to implement the BSS Directive in Northern Ireland and will not impact on good relations.	None.
Political opinion	As above	As above
Racial group	As above	As above

4 Are there opportunities to better promote good relations between people of different religious belief, political opinion or racial group?		
Good relations category	If **Yes**, provide details	If **No**, provide reasons
Religious belief		The policy will apply equally beneficially to all of the Section 75 Groups and to other groups and has no relevance to the promotion of good relations between people of different religious belief, political opinion or racial group.
Political opinion		As above
Racial group		As above

Additional considerations

Multiple identity

Generally speaking, people can fall into more than one Section 75 category. Taking this into consideration, are there any potential impacts of the policy/decision on people with multiple identities? (*For example; disabled minority ethnic people; disabled women; young Protestant men; and young lesbians, gay and bisexual people).*

Provide details of data on the impact of the policy on people with multiple identities. Specify relevant Section 75 categories concerned.

The policy has been designed to implement a European Directive into Northern Ireland law to take account of health and safety of workers regarding exposure to ionising radiation. No adverse impact to any of the section 75 groups is anticipated including people with multiple identities.

Part 3. Screening decision

If the decision is not to conduct an equality impact assessment, please provide details of the reasons.

The policy change is necessary to transpose a European Directive into Northern Ireland law. It will apply equally to all businesses to which workers may be exposed to ionising radiation. There is no evidence to suggest that any Section 75 group will be adversely affected by the proposals.

If the decision is not to conduct an equality impact assessment the public authority should consider if the policy should be mitigated or an alternative policy be introduced.

The provisions of the proposed Regulations would be expected to benefit, rather than adversely impact, all of the Section 75 groups . There are therefore no grounds for mitigation or alternative policies.

If the decision is to subject the policy to an equality impact assessment, please provide details of the reasons.

All public authorities' equality schemes must state the authority's arrangements for assessing and consulting on the likely impact of policies adopted or proposed to be adopted by the authority on the promotion of equality of opportunity. The Commission recommends screening and equality impact assessment as the tools to be utilised for such assessments. Further advice on equality impact assessment may be found in a separate Commission publication: Practical Guidance on Equality Impact Assessment.

Mitigation

When the public authority concludes that the likely impact is ‘minor’ and an equality impact assessment is not to be conducted, the public authority may consider mitigation to lessen the severity of any equality impact, or the introduction of an alternative policy to better promote equality of opportunity or good relations.

Can the policy/decision be amended or changed or an alternative policy introduced to better promote equality of opportunity and/or good relations?

If so, give the **reasons** to support your decision, together with the proposed changes/amendments or alternative policy.

Timetabling and prioritising

Factors to be considered in timetabling and prioritising policies for equality impact assessment.

If the policy has been **'screened in'** for equality impact assessment, then please answer the following questions to determine its priority for timetabling the equality impact assessment.

On a scale of 1-3, with 1 being the lowest priority and 3 being the highest, assess the policy in terms of its priority for equality impact assessment.

Priority criterion	**Rating (1-3)**
Effect on equality of opportunity and good relations	
Social need	
Effect on people's daily lives	
Relevance to a public authority's functions	

Note: The Total Rating Score should be used to prioritise the policy in rank order with other policies screened in for equality impact assessment. This list of priorities will assist the public authority in timetabling. Details of the Public Authority's Equality Impact Assessment Timetable should be included in the quarterly Screening Report.

Is the policy affected by timetables established by other relevant public authorities?

If yes, please provide details

Part 4. Monitoring

Public authorities should consider the guidance contained in the Commission's Monitoring Guidance for Use by Public Authorities (July 2007).

The Commission recommends that where the policy has been amended or an alternative policy introduced, the public authority should monitor more broadly than for adverse impact (See Benefits, P.9-10, paras 2.13 – 2.20 of the Monitoring Guidance).

Effective monitoring will help the public authority identify any future adverse impact arising from the policy which may lead the public authority to conduct an equality impact assessment, as well as help with future planning and policy development.

Part 5. Disability Duties

Under the Disability Discrimination Act 1995 (as amended by the Disability Discrimination (Northern Ireland) Order 2006), public authorities, when exercising their functions, are required to have due regard to the need:

- **to promote positive attitudes towards disabled people; and**

- **to encourage participation by disabled people in public life.**

5. Does this policy/legislation have any potential to contribute towards promoting positive attitudes towards disabled people or towards encouraging participation by disabled people in public life? If yes, please give brief details.

Names of Consultees

Action for Children
Action on Hearing Loss (AHL)
Action Mental Health (AMH)
Advice NI
AE Global (Allpipe Engineering Ltd.)
AES
AFBI
Age NI
Age Sector Platform
Agency for the Legal Deposit Libraries
Alliance Party
An Munia Tober
Archbishop of Armagh and Primate of all Ireland
Ards Business Centre Ltd.
Argyle Business Centre Ltd.
Armagh Business Centre Ltd.
Aspergers Network NI
Attorney General (NI)
Autism NI
Ballymena Business Centre Ltd.
Banbridge Enterprise Centre
Bar Council
Barnardos
Belfast Butterfly Club
Belfast Centre for the Unemployed
Belfast City Centre Management
Belfast Harbour Commissioners
Belfast Health and Social Care Trust
Belfast Hebrew Congregation
Belfast Islamic Centre
Belfast Jewish Community
Belfast MET
Belfast Solicitors Association
Bishop of Down and Connor
Board of Deputies of British Jews
BOC
Bombardier
British Council
British Veterinary Nurse Association
Bryson House
Bryson Intercultural
Buildhealth NI
Business in the Community
Calor Gas (NI) Ltd.
Cancer Focus NI
Cara Friend
Carers NI
Carrickfergus Enterprise Agency Ltd.

Catholic Bishops of NI
Causeway Enterprise Agency Ltd
Cedar Foundation
Chartered Institute of Environmental Health NI
Chemical Business Association
Chief Constable, PSNI
Chief Officers 3rd Sector (CO3)
Children in Northern Ireland (CINI) *(inc. Participation Network)*
Children's Law Centre
Chinese Chamber of Commerce
Chinese Welfare Association
Church of Ireland
Citizens Advice
Commission for Victims and Survivors
Commissioner for Older People NI
Committee on the Administration of Justice
Communication Workers Union (CWU)
Community Foundation NI
Community NI
Community Relations Council
Construction Employers' Federation (CEF)
Construction Industry Training Board NI (CITB)
Cookstown Enterprise Centre Ltd.
Co-Operation Ireland
Council for Catholic Maintained Schools
Council of District Judges (NI)
Countryside Services
Craigavon Industrial Development Organisation Ltd.
Creggan Enterprises Ltd.
Democratic Unionist Party (DUP)
Disability Action
Disability Equality NI
District Councils in NI (11)
Dr Canice McGivern (Regional Medical Physics Service, RVH)
Dr Ian Gillan (Regional Medical Physics Service, Forster Green Hospital)
Drinking Water Inspectorate (NIEA)
Driver and Vehicle Testing Agency
Du Pont (UK) Industrial Ltd.
Dungannon Enterprise Centre Ltd.
East Belfast Community Development Agency
East Belfast Enterprise Park Ltd.
East Belfast Partnership Board
Education Authority
Employers for Disability NI
Engineering Employers' Federation NI (EEF)
Equality Coalition
Equality Commission NI
European Commission Office in NI
Evangelical Alliance
Executive Council of the Inn of Court of NI
Falls Community Council

Federation of Small Businesses
Fermanagh Enterprise Ltd.
Fire Brigades Union
Focus: Identity Trust
Food Standards Agency NI
Forensic Science Agency of NI
Foyle Women's Information Network
Freight Transport Association
GEDA Construction
General Consumer Council for NI
General Dental Council
Gingerbread NI
GMB
Grand Orange Order
Gray & Adams (Ireland) Ltd
Greater Shankill Partnership
Green Party
Guide Dogs
Harland and Wolff Heavy Industries Ltd.
Health and Safety Executive
Health and Social Care Board (inc Central Services Agency)
Heron Brothers Ltd.
HM Council of County Court Judges
HM Revenue and Customers
Home Retail Group
Include Youth
Inclusive Mobility and Transport Advisory Committee (IMTAC)
INCORE Conflict Resolutions Ltd.
Indian Community Centre
Information Commissioner's Office
Institute of Directors (NI Division)
Invest NI
Irish National Teachers' Organisation (INTO)
Kesh Development Association
Labour Relations Agency
Larne Development Forum
Law Centre (NI)
Law Society of NI
Local Government Staff Commission for NI
Lonmin (NI) Ltd
Lord Chief Justice Office
Magherafelt Womens Group
Mallusk Enterprise Park
Maritime and Coastguard Agency
McClay Library, QUB
Mr John Collings (Education Authority)
MENCAP
Mens Health Forum
MEPs for NI (3)
Methodist Church
Mindwise

Ministry of Defence
MPs for NI (18)
Multi-Cultural Resource Centre
Musicians Union
Mutual Energy Ltd.
NASUWT
National Library of Ireland
Newry and Mourne Enterprise Agency
NI Assembly – Clerk of the Economy Committee
NI Assembly - Library
NI Assembly – MLAs (90)
NI Assembly – The Speaker
NI Association for the Care and Resettlement of Offenders (NIACRO)
NI Association for Mental Health (NIAMH)
NI Audit Office
NI Authority for Utility Regulation
NI Centre for Competitiveness
NI Chamber of Commerce & Industry
NI Commissioner for Children and Young People (NICCY)
NI Committee/Irish Congress of Trade Unions (NIC/ICTU)
NI Council for Ethnic Minorities (NICEM)
NI Council for Voluntary Action (NICVA)
NI Court Service
NI Courts and Tribunal Service
NI Electricity
NI Environment Link
NI Executive Ministers (12) *(c/o Private Offices)*
NI Fire and Rescue Service (NIFRS)
NI Gay Rights Association (NIGRA)
NI Government Departments (9)
NI Housing Executive (NIHE)
NI Human Rights Commission
NI Judicial Appointments Commission
NI Law Commission
NI Local Government Association (NILGA)
NI Prison Service
NI Public Service Alliance (NIPSA)
NI Public Service Ombudsman (NIPSO)
NI Rural Womens Network
NI Safety Group (NISG)
NI Statistics and Research Agency (NISRA)
NI Water
NI Women's European Platform (NIWEP)
North Belfast Partnership Board
North City Business Centre Ltd.
North Down Development Organisation Ltd.
North / South Ministerial Council (NSMC)
North West Community Network
North West Regional College
Northern Group
Northern Health and Social Care Trust

Northern Ireland Office (NIO)
Northern Regional College
NSPCC, Northern Ireland Regional Office
NUS/USI (NI Student Centre)
Occupational Health Service (OHS)
Office of Industrial Tribunals & Fair Employment Tribunal
Omagh Enterprise Co. Ltd.
Onephoton Ltd.
Open University
Ormeau Enterprises Ltd.
Oyster (Transgender NI)
Participation and the Practice of Rights (PPR)
PCM Associates – Training & Consultancy Services
People Before Profit Alliance (PBPA)
Pharmaceutical Society of NI
POBAL
Police Federation for NI
Police Service of Northern Ireland (PSNI)
PRAXIS
Presbyterian Church
Prince's Trust
Progressive Unionist Party (PUP)
Prospect
Quarry Products Association NI
Queen's University
Rainbow Project
Relate
Roy Coulter Consulting Ltd.
Royal College of Midwives
Royal Institution of Chartered Surveyors (RICS)
Royal National Institute for the Blind (NI) (RNIB)
Rural Community Network
Rural Development Council
St. Marys University College
St. John Ambulance NI
Save the Children
Scotia Gas Networks (SGN)
Scotts Electrical
Seagate Technology (Ireland)
Sense
Services Industrial Professional Technical Union (SIPTU)
Sinn Fein (SF)
Social Democratic & Labour Party (SDLP)
South Belfast Partnership Board
South Eastern College
South Eastern Health and Social Care Trust
South West Fermanagh Development Organisation
South Western College
Southern Health and Social Care Trust
Southern Regional College
SSE Airtricity Energy Supply (NI) Ltd

Strabane Industrial Properties Ltd.
Stranmillis University College
Tennants Textile Colours Ltd.
Tourism NI
Townsend Enterprise Park Ltd.
Traditional Unionist Voice (TUV)
Training for Women Network
Trans Forum
Translink
Transport Salaried Staff Association
UK Independence Party (UKIP)
UK National Committee of UN Women
Ulster Farmers' Union (UFU)
Ulster Scots Agency
Ulster Teachers' Union
Ulster Unionist Party (UUP)
Union of Construction, Allied Trades and Technicians (UCATT)
UNISON
Unite the Union
University & College Union
University of Ulster
Visual Access NI
Volunteer Now
West Belfast Development Trust Ltd.
West Belfast Partnership Board
Western Health and Social Care Trust
Westlink Enterprise Ltd.
William Keown Trust
Women's Forum
Women's Information Group
Women's Resource and Development Agency
Women's Support Network
Women's Training, Enterprise and Childcare
Workers' Party
Workspace