

Guidance for appointed doctors on the Ionising Radiations Regulations 2017

Medical surveillance of classified persons

Introduction

1 This document provides guidance for appointed doctors on conducting medical surveillance of workers exposed to ionising radiation, for the purposes of the Ionising Radiations Regulations 2017 (IRR).¹ It replaces the previous version, which was based on the Ionising Radiations Regulations 1999 and published in 2011. The 2017 Regulations implement EU Basic Safety Standards Directive 2013/59/Euratom for protection against the dangers arising from exposure to ionising radiation.² Appointed doctors should also be familiar with the Approved Code of Practice and guidance: *Work with ionising radiation* (L121)³ and the Health and Safety Executive (HSE) appointed doctor website.⁴

Background

2 Ionising radiation (IR) is carcinogenic and the risk of cancer induction cannot be excluded even at low doses. There is no 'safe level' of radiation exposure. Practices involving exposure to IR must firstly be justified – the benefits to society and exposed individuals must outweigh the health risk. Secondly, the protection provided to control radiation exposures must be optimised. Thirdly, there must be a system for dose limitation for workers and the public. The principles and methods for restricting radiation exposures to as low as reasonably practicable (ALARP) are well established. For example, in relation to an external radiation hazard, they may involve:

- restriction of the length of time of exposure;
- introduction of distance to separate the individual from the source of exposure; and
- use of shielding.

3 Further information on IR and radiation protection is available on HSE's IR website⁵ and from Public Health England.⁶

General principles underlying medical surveillance

4 Under IRR, classified persons require medical surveillance by an appointed doctor or employment medical adviser. The purpose of medical surveillance is to confirm that an individual is fit or continues to be fit for the intended work with IR. Classified persons are defined as

those exposed workers likely to receive an effective dose of radiation greater than 6 mSv per year or an equivalent dose greater than 15 mSv per year to the lens of the eye or greater than 150 mSv per year to the skin and extremities. Employers must also arrange for adequate medical surveillance for any employee who has received an overexposure, whether or not they have been designated as a classified person.

5 The requirements of adequate medical surveillance comprise:

- a medical assessment before first being designated as a classified person in a role involving work with IR;
- periodic reviews of health at least once every year;
- special medical surveillance of an employee when a relevant dose limit has been exceeded;
- determining whether specific conditions for working with IR are necessary; and
- a review of health after ending work involving IR where this is necessary to safeguard a person's health.

6 The format of medical surveillance for each employee should take account of the nature of their work with IR and their state of health.

Roles and responsibilities

Employer

7 The responsibilities of the employer, with regard to medical surveillance, include:

- designating workers as classified persons;
- consulting with the radiation protection adviser (RPA) as required;
- arranging for medical surveillance of classified workers;
- maintaining a valid health record for each classified worker;
- ensuring that any conditions specified in the health record by the appointed doctor (eg no work with unsealed sources) are observed;
- providing the appointed doctor with relevant information before periodic reviews of health, the minimum being the health record, summaries of dose records, sickness absence records, any other medical concerns brought to their attention by the employee and any change in the employee's duties since the last review;
- permitting the appointed doctor to view the workplace;
- providing facilities for medical examinations or allowing workers to attend the appointed doctor's premises to be examined;
- notifying the appointed doctor of any suspected overexposure received by any of their employees arising as a result of their work; and
- cooperating with other employers as necessary, to ensure compliance with IRR.

Appointed doctor

8 To fulfil the requirements for adequate medical surveillance, as the appointed doctor you should:

- liaise with the employer to ensure you understand the nature of the work being done and the hazards/risks associated with exposure to IR in that work;
- assess the fitness of individuals to work with IR;
- inform an HSE medical adviser in the event of any known or suspected overexposure (see paragraph 42);
- provide counselling and advice to individuals regarding medical aspects of their work with IR;
- maintain adequate clinical records for the medical examinations completed;
- submit statistical returns on request; and
- undertake IR training at least once every five years (see Appendix 1) and maintain up-to-date knowledge.

Administrative arrangements

Health record

9 Employers may use any format for the health record, providing it contains the information listed in Schedule 6 of IRR. A suggested form for this purpose is provided on HSE's appointed doctor website (form F2067).⁷ The health record should not contain confidential clinical information (see paragraph 11). The record, or a copy of it, must be kept until the person it relates to has (or would have) reached the age of 75, but in any event for at least 30 years from the date of the last entry.

10 On completing the medical assessment before classification and after any periodic health review, you should record whether you consider the person:

- fit to work with IR;
- fit subject to conditions; or
- unfit.

Clinical records

11 You can use any suitable form for this purpose, such as FODMS101, available on HSE's appointed doctor website.⁸

Change of employment

12 When a classified person has changed employment and is to be classified by the new employer, a further medical examination may not be necessary. This applies if the individual has been certified as fit for that type of work with IR within the preceding 12 months and a copy of that certification is obtained and kept with the health record. Any conditions already imposed will continue to apply unless removed or varied at the next periodic health review.

13 If the change in employment entails a significant change of duties or work environment (eg a move from work involving sealed sources to work involving unsealed sources), the new employer should consult their own appointed doctor. If the medical records from previous medical surveillance are available to the appointed doctor, they should decide whether a further medical examination is necessary to determine whether the individual is fit to undertake their new duties. In the absence of previous medical records, the appointed doctor should review the worker before they start the new role. This would also apply when a classified person remains with the same employer but their duties or work environment change.

Appeals

14 IRR makes provision for a person who is aggrieved by a decision of an appointed doctor to apply for the decision to be reviewed by HSE. Such an application should be made in writing to HSE's Principal Medical Adviser within 28 days of being informed of the decision. Details of the appeals procedure are available on HSE's website.⁹

Examination before designation as a classified person

15 The main purpose of this examination is to establish the fitness of the individual to work with IR, including the wearing of respiratory protective equipment (RPE) or other personal protective equipment (PPE), if that is required.

Work environment and tasks

16 When conducting the examination, you should be familiar with the work environment where the classified person is to be employed and the type of work with IR. You should therefore visit the workplace, where practicable, so you can see the working conditions and the workers under medical surveillance.

17 You should enquire about and record the following (it will be necessary in most instances to obtain the information from the employer or RPA):

- What is the source of IR?
- Is the IR electrically generated or from sealed or unsealed radioactive materials?
- To what type of radiation could the employee be exposed (alpha/beta/gamma/neutrons/X-rays)?
- What are the risks of internal (inhalation, ingestion or through breaks in the skin) and external exposures, given the type of work being done?
- What is the likely annual dose that the classified person will receive and by which route will exposure occur?
- What methods will be used to assess the dose?
- What are the tasks involved?
- Is the work done in a purpose-built facility with appropriate

engineering controls and shielding to restrict exposures such as an enclosure/room with a maze entrance or interlocked doors?

- Is the work done on several different sites?
- Are large quantities of sealed or unsealed radioactive materials used?
- Is there potential for significant exposure or overexposure of the extremities, skin or eyes?
- Is the wearing of RPE or other PPE necessary?

General medical history

18 You should obtain a full medical history before the individual is designated as a classified person. Most of the information will be relevant to the general duties of the post but of particular importance to those aspects of work involving IR will be a history of:

- chronic skin disease;
- chronic pulmonary disease;
- psychiatric illness or personality disorder;
- blood disorder;
- inherited predisposition to malignancy;
- medical exposure to IR; and
- treatment with cytotoxic drugs.

19 However, they should not be regarded as reasons for automatically excluding an individual from work with IR. In deciding on fitness, you should adopt a risk-based approach in each case.

Previous occupational history

20 In addition to obtaining general information about previous employment, you should record any previous occupational exposures to IR or other known carcinogenic agents (eg asbestos).

21 For individuals who were classified by their previous employer, details of previous exposure to IR should be set out in the dosimetry termination record. The worker should receive a copy of this record from their previous employer. When such an individual is to be classified by a new employer, the prospective employer should ensure a copy of this record is made available to the appointed doctor. For individuals who have not previously been classified, but have worked in controlled areas and/or been subject to personal dose monitoring, the previous employer should be able to provide the individual with monitoring results or assessments for at least the past two years.

Previous medical exposure to ionising radiation

22 It is important to establish and document previous diagnostic and therapeutic exposures to IR. However, even though a significant previous occupational or other exposure to IR has occurred, this may not be of paramount importance in deciding on fitness of an applicant for employment as a classified person. To put the issue into perspective, a course of radiotherapy for carcinoma of the prostate commonly requires

a total dose of around 60 Gy to be delivered to the bladder over a 6-week period. In contrast, the lifetime occupational effective dose that a classified worker receives may be no more than several mSv.

Female workers

23 The employer must inform female employees engaged in work with IR of the possible risks to the foetus and nursing infant arising from exposure to IR and the importance of informing the employer in writing as soon as possible if they become pregnant or start breastfeeding.

24 When an employee has notified her employer in writing that she is pregnant or breastfeeding, the employer must ensure that:

- the equivalent dose to the foetus is not likely to exceed 1 mSv during the remainder of the pregnancy (ie a dose limit similar to that applying to members of the public); and
- in the case of an employee who is breastfeeding, the conditions of exposure are restricted to prevent significant bodily contamination of that employee.

25 More information is given in the HSE leaflet: *Working safely with ionising radiation: Guidelines for expectant or breastfeeding mothers*.¹⁰

Mental health

26 The way in which classified persons carry out their duties is often critical to their own safety and that of their colleagues. Therefore, you should be alert to the presence of any psychiatric illness or personality disorder inconsistent with the need for psychological stability and self-discipline in such workers.

Clinical examination

27 The precise format of the clinical examination will depend on the information obtained from the medical and occupational history.

Skin

28 Where work will be done using unsealed sources, you should examine exposed areas of the skin to identify lesions which could allow entry of radioactive materials into the body and be difficult to decontaminate. You should find out which protective measures may be implemented, for example appropriate use of PPE, and monitoring of PPE, clothing and skin for contamination.

29 Some people who suffer from a chronic skin condition (eg eczema or psoriasis) may be deemed unfit for work with unsealed sources. Others with less severe diseases may be found fit to work with unsealed sources subject to specific conditions such as more frequent clinical assessment. These specific conditions for working with IR should be entered in the health record.

Respiratory system

30 If there is a need to use breathing apparatus or impervious protective clothing, whether routinely or in an emergency, you should carefully assess the respiratory system. It might be inappropriate to deploy an individual with chronic respiratory disease (eg asthma) in such a workplace as the increased respiratory effort involved in using this apparatus may result in respiratory distress. If an episode occurs in a contaminated area, removal of the apparatus in an effort to gain relief or to administer first aid would inevitably result in internal contamination of the worker.

Blood test

31 There is no requirement for a full blood count either as part of the initial examination or at periodic review, unless clinically indicated.

Counselling

32 The stochastic effects (eg malignancy) which may result from exposure to IR can result in anxiety, particularly when any positive findings from new research are reported in the media. You should be prepared to address any such concerns which become apparent during medical surveillance, whether or not these arise directly from a clinical finding.

33 You should be familiar with basic information about radiation and its biological effects. You should also understand the comparative risks arising from other work activities and from activities in daily life, and be able to present and interpret these risks in the context of an individual worker's employment.

34 You should be familiar with the magnitude of the reproductive risks from exposure to IR and be able to put them into context alongside other risks associated with reproduction.

Periodic reviews of health

35 IRR requires the state of health of all classified persons to be reviewed by an appointed doctor every 12 months, or after a shorter period as may have been specified at the time of the last review. In practice, the review may be carried out from one month before to one month after the expiry date of the last entry on the health record. It will be treated as if carried out on that expiry date. The next periodic review would normally be due 12 months after that date. Where a period of more than 13 months has passed since the start of the current period of validity, the appointed doctor should carry out a medical examination.

36 The purpose of the periodic review is to reassess the general state of health of the classified person and confirm their continued medical fitness for the work in which they are employed. When conducting the review, you should take account of:

- recorded doses of radiation exposure;

- the sickness absence record and any medical concerns brought to your attention;
- matters requiring follow-up from an earlier review; and
- any change in duties since the last review.

37 Whether periodic review should include a face-to-face assessment with the worker is usually a matter of clinical judgement based on the issues referred to in paragraph 36 and an assessment of risk. Where there is a high risk of exposure (eg site radiography or people working in areas of significant surface or airborne contamination), the review will often include a face-to-face assessment. Even where the work environment is well controlled and low-risk, a face-to-face assessment at least once every five years should be considered. This would provide an opportunity for the classified worker to raise any concerns they may have about their health, work or work environment, with you.

38 It is recognised that in some cases, the radiation dose received by the extremities of workers may not be accurately reflected by whole-body dosimetry. Examples of such work include industrial radiography and interventional radiology. Where such a risk is identified, the employer should make arrangements with the Approved Dosimetry Service for routine monitoring of extremity doses.

39 Periodic review of classified persons at risk of high radiation doses to the extremities, for example site industrial radiographers, should include a clinical examination.

40 You should enter the fitness to work decision in the health record.

Counselling

41 At periodic review, counselling may be indicated where a significant cumulative dose of radiation has accrued or where an episode of ill health that could be caused by radiation has occurred.

Overexposure – special medical surveillance

42 When it is suspected that a classified person, or any other person, has been subjected to an overexposure, the employer must notify HSE as soon as practicable. Where the person in question is their employee, they must also notify the appointed doctor. Special medical surveillance may be necessary for any employee who has received an overexposure (and is subject to an investigation under regulation 26 of IRR). In these circumstances, the appointed doctor should contact an HSE medical adviser to discuss the case.⁴ They will work in consultation with the appointed doctor and others, as appropriate, to determine the content of special medical surveillance. It should include a medical assessment, counselling and detailing of possible restrictions on further exposure. Specific tests, such as chromosome aberration dosimetry, may be warranted to help establish the degree of any overexposure.

43 An essential first step is for the appointed doctor to establish, usually through discussions with the employer, employee and RPA, full details of the circumstances of the suspected overexposure. The form that any subsequent clinical examination takes will be dependent on this information. It may include looking for clinical evidence of radiation exposure and then taking appropriate action.

Whole-body overexposures exceeding 1 Sv

44 Where the overexposure is known or believed to have exceeded 1 Sv and to have been received over a brief period, the individual should be kept under careful observation in an appropriate hospital for signs of acute radiation syndrome.

Blood test

45 A full blood count and film should only be regarded as mandatory where it is believed the individual has received a radiation dose from X-rays, gamma rays or neutrons exceeding 250 mSv. However, apart from an early fall in the number of circulating lymphocytes, it is likely that several days will elapse before obvious abnormalities appear in the peripheral blood.

Chromosome aberration dosimetry

46 The presence of chromosome aberrations in peripheral blood lymphocytes may be used as a biological dosimeter following radiation overexposure. On a routine basis, the lower limit of detection is equivalent to a whole-body dose of about 100 mSv for gamma rays. Before requesting this test, you should discuss it with an HSE medical adviser (see paragraph 42).

47 This technique is relatively expensive and only available at a few specialist facilities. Structural aberrations arise as the result of discontinuities or breaks in the DNA and typically take the form of dicentric, ring and fragmented chromosomes. Dicentric aberration is almost unique to radiation, with a low frequency (about 1 per 100 000) in people exposed solely to background radiation.

48 It is advisable, particularly in the case of partial-body or non-uniform exposure, to wait 24 hours after radiation exposure before taking the blood sample. This will allow circulating and pooled lymphocytes to mix and equilibrate, ensuring the sample contains a representative proportion of irradiated cells.

49 If IR exposure has been less than 20% of total body area, chromosome aberration testing is unlikely to be helpful, even if there has been sufficient local irradiation to cause injury. When counselling the individual before the test, you should consider the psychological effect of a positive result.

Fluorescence in-situ hybridisation

50 Fluorescence in-situ hybridisation (FISH) is a test looking at chromosomal translocations that do not decline with time. It is appropriate for people who want to know their exposure to ionising radiation over preceding decades (eg when working abroad). It is rarely performed and expensive.

Decontamination

51 Decontamination is not a specific part of appointed doctor work. However, many appointed doctors have additional training in decontamination due to the nature of their roles within the nuclear industry. They should be familiar with the decontamination arrangements in the organisations where they provide appointed doctor services.

Counselling

52 Receiving an overexposure, or the suspicion of one, is inevitably a stressful experience. A face-to-face medical assessment of the worker is indicated, to address any anxieties resulting from the experience.

53 Once the immediate effects of overexposure have been managed, it will be possible to consider any longer-term consequences for the individual.

Dose limitation for overexposed employees

54 Under IRR, the employer must ensure they limit further exposure of an overexposed employee during the remainder of the dose limitation period. The employee must not receive a dose of IR greater than that proportion of any dose limit calculated by relating the remaining part of the dose limitation period to the whole of that period, as shown in the following example:

- A classified worker receives an effective dose of 32 mSv in the first 3 months of their dose limitation period (12 months in total). The annual dose limit is 20 mSv. For the rest of that dose limitation period, ie for the next 9 months, the worker must not receive a dose of IR greater than $20 \times (9/12) = 15$ mSv.

Working with ionising radiation following an overexposure

55 A classified worker who receives a significant overexposure should be kept under appropriate surveillance by the appointed doctor to identify early deterministic effects (eg skin erythema). You should consider the nature and extent of any such effects when deciding on return to work with IR. In general, it is not justifiable to restrict subsequent employment solely on the possibility of late stochastic effects. The additional doses of IR, which the individual will receive during the remainder of their working life, are likely to be comparatively small (see paragraphs 22 and 56). The only situation where it may not be appropriate for the individual to continue work with IR is if they remain distressed by the experience.

Risk estimates

56 Where the issue in question is accumulated dose, then an estimate of the lifetime risk of cancer can be made using risk factors which are widely published. For example, a worker who has a total occupational dose of radiation of 100 mSv has a lifetime risk of cancer (in addition to their background risk) of 0.4%, based on the current estimate of risk to an adult of 4% per Sv.¹¹ This information is not of great value until put into context. For example, approximately 1 in 2 people born after 1960 in the UK will develop some form of cancer during their lifetime.¹²

Cancer in a classified person

57 Where a case of cancer occurs in a classified person, there are two key issues – firstly, whether the cancer may have been caused by IR and, secondly, whether the individual can continue as a classified person. A formal calculation of the probability of causation can be made which forms the basis of the compensation scheme agreed between some nuclear employers and trade unions.

58 The decision about continuing employment as a classified person can only be taken in the light of full information about the disease and its treatment. Of equal importance to medical details will be the individual's psychological response to the illness.

Contingency planning and emergency preparedness

59 Under IRR, where the risk assessment shows a radiation accident is reasonably foreseeable, the employer must prepare a contingency plan to restrict exposure to IR of employees or others should such an event occur.

60 Radiation emergency preparedness and public information legislation provides a framework for protection of the public through emergency preparedness for radiation accidents. It requires employers to make arrangements for medical surveillance of employees who have been subject to emergency exposures. Further information is available on HSE's IR website.⁵

61 National arrangements for incidents involving radioactivity are the responsibility of Public Health England.⁶

Appendix 1 Ionising radiation training for appointed doctors

Doctors appointed under IRR are required to undertake specific training in IR and to refresh that training at least once every five years.⁴ The training should cover the following main topics:

- Introduction, legislation and the role and duties of the appointed doctor
- Radiation – its nature, biological effects and measurement
- Epidemiology of carcinogenesis and risk estimates
- Deterministic and other effects of radiation and radiation protection
- Assessment of fitness for work with IR
- Measuring personal exposure – personal dosimetry methods and techniques
- Medical methods for assessing exposures and their threshold of detection
- Response to overexposures, real or suspected, and emergencies
- Counselling of workers and maintenance of knowledge

References

- 1 *The Ionising Radiations Regulations 2017* SI 2017/1075 The Stationery Office www.legislation.gov.uk/uksi/2017/1075/contents/made
- 2 *Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation* Official Journal of the European Union L13 17/1/2014 1-73 ec.europa.eu/energy/sites/ener/files/documents/CELEX-32013L0059-EN-TXT.pdf
- 3 *Work with ionising radiation. Ionising Radiations Regulations 2017. Approved Code of Practice and guidance* L121 (Second edition) HSE Books 2018 www.hse.gov.uk/pubns/books/l121.htm
- 4 HSE's appointed doctor website: www.hse.gov.uk/doctors
- 5 HSE's ionising radiation website: www.hse.gov.uk/radiation/ionising
- 6 *Health Protection: Radiation*. Public Health England www.gov.uk/topic/health-protection/radiation
- 7 *Health record* F2067 HSE 2018 www.hse.gov.uk/doctors/forms.htm
- 8 *Clinical record* FODMS101 HSE 2018 www.hse.gov.uk/doctors/forms.htm
- 9 *Medical appeal: Ionising Radiations Regulations 2017* www.hse.gov.uk/radiation/ionising/appeals.htm
- 10 *Working safely with ionising radiation: Guidelines for expectant or breastfeeding mothers* INDG334(rev1) HSE 2015 www.hse.gov.uk/pubns/indg334.htm
- 11 Wrixon AD New ICRP recommendations *Journal of Radiological Protection* 2008 **28** 161-168 iopscience.iop.org
- 12 Cancer Research UK website: www.cancerresearchuk.org/health-professional/cancer-statistics/risk/lifetime-risk

Further information

For information about health and safety, or to report inconsistencies or inaccuracies in this guidance, visit www.hse.gov.uk/.

You can order HSE priced publications at <https://books.hse.gov.uk>.
HSE priced publications are also available from bookshops.

This publication is available at: www.hse.gov.uk/pubns/ms33.htm.

© Crown copyright If you wish to reuse this information visit www.hse.gov.uk/copyright.htm for details. First published 05/18.