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Report by the Industrial Injuries Advisory Council in accordance with Section 171 of the Social Security Administration Act 1992 reviewing the terms of prescription for cancers due to ionising radiation under the Industrial Injuries Scheme

Presented to Parliament by the Secretary of State for Work and Pensions
By Command of Her Majesty
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Dear Secretary of State

REVIEW OF THE TERMS OF PRESCRIPTION FOR CANCERS DUE TO IONISING RADIATION

The carcinogenic potential of ionising radiation is recognised within the Industrial Injuries Scheme in the terms set out for Prescribed Disease (PD) A1. These currently provide coverage in relation to five cancers, leukaemia (other than chronic lymphatic leukaemia), and cancers of the bone, female breast, testis, and thyroid, provided that occupational exposures are sufficient to double the risk of the condition (the threshold at which a disease can be attributed to a person's work on the balance of probabilities). These terms were set in 1999.

Over time, however, new international evidence has accrued on the health effects of chronic exposure to ionising radiation and the sensitivity of body tissues to cancer induction. The Industrial Injuries Advisory Council has therefore reviewed whether the terms of PD A1 should be updated. Evidence has been taken, in particular, from the Centre for Radiation, Chemical and Environmental Hazards of Public Health England, the Government's official expert advisors on radiation risks.

The evidence is now such that the Council recommends that the terms of PD A1 be extended to cover six more cancers: of the colon, liver, lung, stomach, ovary and bladder. Additionally, the Council recommends that coverage for breast cancer be extended to permit claims in men, as well as in women. Finally, it recommends two minor changes to the wording of PD A1 which update and clarify its meaning and also provide improved advice to the Department on claims assessment.

Although the tumours proposed for addition are common in the population at large, the qualifying exposures are exceptionally high by modern standards. As such, the impact on claims activity is likely to be small and to relate to industrial circumstances where exposure conditions historically were very different from recent decades.

Yours sincerely

Professor Keith Palmer
Chairman
Industrial Injuries Advisory Council 23 February 2016

Summary

1. Five cancers are currently prescribed within the Industrial Injuries Scheme in relation to occupational exposures to ionising radiation: leukaemia (other than chronic lymphatic leukaemia), and cancers of the bone, female breast, testis and thyroid (Prescribed Disease (PD) A1).

2. Because of the technical complexities of the subject, and also the greater scope to assess workers' exposures case by case, the scheduled exposure in PD A1 is defined broadly, as: "Exposure to electromagnetic radiations (other than radiant heat) or to ionising particles where the dose is sufficient to double the risk of the occurrence of the condition".

3. These terms were last amended in 1999. With the passage of time, however, and the accrual of long-term follow-up data in exposed populations, it has become possible to model the chronic effects of ionising radiation on cancer induction more accurately. A review has therefore been undertaken to assess whether the prescription should now be updated.

4. Evidence has been taken principally from the Centre for Radiation, Chemical and Environmental Hazards of Public Health England (PHE), the Government's official advisors on radiation risks.

5. PHE has highlighted the potential to recognise six new cancers under the Scheme, arising from tissues thought now to be more radiosensitive than in 1999. These are tumours of the colon, liver, lung, stomach, ovary and bladder. By contrast, PHE advised that the link between testicular cancer and ionising radiation appears to be less well established than previously advised.

6. Following a careful examination of the evidence, the Council recommends that the terms of PD A1 be extended to cover the six additional cancers identified by PHE; it further recommends that the existing coverage in respect of "female breast cancer" should be extended to allow claims in affected men. However, it does not recommend the withdrawal of prescription for cancer of the testis. The reasoning behind this advice is set out in detail below.

7. Opportunity is also being taken to propose two minor alterations to the prescription's wording (detailed in paragraphs 65 and 66). These reflect, on the one hand, a change in medical terminology and, on the other, a need to clarify that the health effects in question relate to ionising radiation, and not to non-ionising radiation.

This report contains some technical terms, the meanings of which are explained in a concluding glossary.

Introduction

8. The present terms of Prescribed Disease (PD) A1 (cancers arising from occupational exposure to ionising radiation) were last amended in 1999 in the Command Paper *Conditions induced by Ionising and Non-Ionising Radiation*, Cm 4280.

9. Since then, however, many authoritative reviews have been published that have updated risk models for cancers caused by ionising radiation (e.g. Advisory Group on Ionising Radiation (AGIR), 2003; Biological Effects of Ionising Radiation (BEIR) VII phase 2, 2006; AGIR, 2011; United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) 2012; International Agency for Research on Cancer (IARC), 2012). In consequence, a revised international expert consensus has emerged on the sensitivity of body tissues to chronic doses of ionising radiation, potentially allowing a wider range of tumours to be recognised for prescription and for award of Industrial Injuries Disablement Benefit (IIDB).

10. This report reviews the current basis of prescription and its rationale, describes the further evidence taken by the Industrial Injuries Advisory Council (IIAC) on cancers caused by ionising radiation, and proposes amendments to the terms of prescription for PD A1. Further general information on the considered cancers is provided in Appendix 1.

The Industrial Injuries Disablement Benefit Scheme

11. The Scheme provides a benefit that can be paid to employed earners because of an occupational accident or prescribed disease. The benefit is no-fault, tax-free, non-contributory and administered by the Department for Work and Pensions. It is paid in addition to other incapacity and disability benefits, but is taken into account when determining the level of payment for income-related benefits.

The Industrial Injuries Advisory Council

12. IIAC is an independent statutory body established in 1946 to advise the Secretary of State for Work and Pensions and the Department for Social Development in Northern Ireland. IIAC advises on the prescription of occupational diseases; matters referred by the Secretary of State; draft regulations or proposals concerning the IIDB Scheme; and any other matter relating to the Scheme or its administration.

13. IIAC is a non-departmental public body and has no power or authority to become involved in individual cases or in their decision making processes.

Prescribed Disease provisions of the IIDB Scheme

14. The Social Security Contributions and Benefits Act 1992 states that the Secretary of State may prescribe a disease where he or she is satisfied that the disease:

    a) Ought to be treated, having regard to its causes and incidence and any other considerations, as a risk of the occupation and not as a risk common to all persons; and

    b) Is such that, in the absence of special circumstances, the attribution of particular cases to the nature of employment can be established or presumed with reasonable certainty.

15. In other words, a disease may only be prescribed if there is a recognised risk to workers in an occupation, and the link between disease and occupation can be established or reasonably presumed in individual cases. This is the framework in which IIAC must work when considering the prescription of occupational diseases.

16. Some occupational diseases are relatively simple to verify, as the link with occupation is clear-cut. For example, the proof that an individual's dermatitis is caused by their occupation may lie in its improvement when they are on holiday and regression when they return to work, and in the demonstration that they are allergic to a specific substance with which they come into contact only at work. It can be that a disease only occurs as a result of an occupational hazard (e.g. coal workers' pneumoconiosis) or rarely outside work (e.g. mesothelioma).

17. Other diseases are not uniquely occupational, and when caused by occupation, are indistinguishable from the same disease occurring in someone who has not been exposed to a hazard at work. In these circumstances, attribution to occupation on the balance of probabilities depends on epidemiological evidence that work in the prescribed job, or with the prescribed occupational exposure, increases the risk of developing the disease by a factor of two or more.

18. The requirement for, at least, a doubling of risk follows from the fact that if a hazardous material doubles risk, for every 50 cases that would normally occur in an unexposed population, an additional 50 would be expected if the population were exposed to the hazard. Thus, out of every 100 cases that occurred in an exposed population, 50 would only do so as a consequence of their exposure while the other 50 would have been expected to develop the disease, even in the absence of the exposure. Therefore, for an individual case occurring in the exposed population, there would be a 50% chance that it would have occurred even without the exposure. Below the threshold of a doubling of risk only a minority of cases in an exposed population would be caused by the hazard and individual cases therefore could not be attributed to exposure on the balance of probabilities; above it, they may be. The epidemiological evidence required should ideally be drawn from several independent studies, and be sufficiently robust that further research at a later date would be unlikely to overturn it.

19. The cancers considered in this report are not exclusively occupational and do not have unique clinical features when they occur in the occupational context. The case for prescription of cancers listed in PD A1, therefore, rests on a reliable determination that a claimant has had sufficient exposure to ionising radiation to have more than doubled their risk of the cancer occurring.

20. Accidental exposures at work are separately catered for within the IIDB Scheme. This report focuses on risks from occupational exposure in the absence of an identifiable accident.

Ionising Radiation

21. Radiation is the transfer of energy by particles or waves that can travel across a vacuum. Ionising radiation comprises of those forms of radiation that have sufficient energy to displace electrons from atoms. These include alpha particles, beta particles, gamma rays, X-rays and neutrons.

22. Occupational exposures to ionising radiation may occur from natural sources (such as radon gas present in underground mines or cosmic radiation from flying at high altitudes) or from man-made sources (such as radioactive sources in the nuclear industry, X-ray machines in healthcare, and X-rays in the non-destructive testing of metals).

23. Ionising radiation can cause cancerous changes in the body's cells by damaging its DNA (deoxyribonucleic acid), which in turn upsets its mechanisms for repair and cell growth. In consequence, cancer cells continue to grow out of control, forming new, abnormal cells and invading other tissues.

24. The various types of radiation differ in their propensity to damage DNA and these differences are characterised by so-called "quality factors", numerical scaling factors that allow these differences to be captured in dose assessment and the units of radiation dose used for radiological protection purposes. The SI unit of dose for ionising radiation is the Sievert (Sv), which represents the amount of energy deposited in a defined mass of human tissue. As the Sievert is a large value, doses are usually represented in milliSieverts (mSv).

25. Under the 1999 Ionising Radiation Regulations every employer must restrict so far as is reasonably practicable the extent to which people are exposed to ionising radiation, the current limit on equivalent dose (for those aged 18 or over) being 20 mSv in any calendar year.

26. In 2004, according to the Central Index of Dose Information (CIDI, 2004) there were around 39,000 classified workers, receiving on average an annual occupational dose of 0.5 mSv. Only four workers exceeded the annual dose limit in that year. However, there is evidence, for example, that exposures in certain parts of the nuclear industry were very much higher in the past than they are today (Douglas *et al.*, 1994) (as detailed in paragraph 50).

27. The health effects of ionising radiation fall into two broad categories. Deterministic effects are those whose **severity** varies according to the dose received, such that there may be a threshold dose below which the effect does not occur or is never apparent. Probabilistic or stochastic effects are those which occur with a **probability** that is dose dependent, there being no threshold below which the risk can be considered to be zero; however, the severity of a stochastic effect does not depend on dose, only the likelihood of it occurring.

28. Stochastic effects include cancer and heritable genetic damage. Body tissues vary in their sensitivity to ionising radiation and certain types of cancer are more readily induced than others. Risks depend not only on the radiation dose received but also on sex, age at first exposure and time since first exposure (attained age at disease onset).

Current terms of PD A1

29. Five cancers are presently prescribed in relation to ionising radiation: leukaemia (other than chronic lymphatic leukaemia), and cancers of the bone, female breast, testis, and thyroid.

30. The assessment of risks in relation to these tumours is technically complicated, as the doubling dose depends on multiple factors (paragraph 28). Thus, in scheduling PD A1, Command Paper Cm 4280 recommended defining the qualifying exposure not in terms of particular work for particular periods, or in terms of stipulated doses, but more broadly, as: "Exposure to electromagnetic radiations (other than radiant heat) or to ionising particles where the dose is sufficient to double the risk of the occurrence of the condition". Current terms of prescription reflect this recommendation.

31. It was intended that claims for PD A1 would be referred to a competent authority (previously the National Radiological Protection Board (NRPB), currently, Public Health England (PHE)) for advice on whether the qualifying levels of exposure had been met or exceeded. To ensure appropriate use of a scarce specialist resource, the NRPB developed a table, framed conservatively in terms of 'threshold' doses below which risks for certain diseases could be discounted as unable to double risks of diseases, to screen out before referral those applications with no possibility of award (Table 1).

Table 1: Minimum Doubling Doses

Cancer	Minimum doubling dose estimated to double a person's risk of cancer (Sv)
Leukaemia	0.23
Bone	0.56
Female breast	0.74
Testis	0.81
Thyroid	0.51

32. The five qualifying cancers were identified by NRPB as ones which potentially might arise from occupational exposures during the course of ordinary employment and in the absence of an accidental over-exposure event.

33. It was recognised that a much longer list of cancers can be caused by ionising radiation at very high doses, likely only to be encountered in the event of an accident (many tumours have been linked with exposures in atomic bomb survivors of the Second World War and in patients receiving large doses of therapeutic radiation); but for these it was noted the Scheme's accident provisions could potentially allow access to benefit, depending on the individual circumstances of a claim. This camp included cancers of the colon, liver, lung, stomach, ovary and bladder.

34. In constructing the terms of PD A1, assumptions were required about how high occupational exposures could be (in the absence of an accident), and about the sensitivity of body tissues to the stochastic effects of ionising radiation. Since the NRPB's advice was received and implemented, a number of authoritative reviews have been published. In particular, respected international authorities have updated their risk models for cancers arising from ionising radiation (e.g. AGIR, 2003; BEIR VII phase 2, 2006; AGIR, 2011; UNSCEAR, 2012; IARC, 2012) as data from atomic bomb survivors and other groups have accumulated. The Council has, therefore, undertaken a review of the continuing appropriateness of the terms of PD A1 and the dose values used in

the filter table for referral to PHE for exposure assessment. Additionally, opportunity was taken to review the wording of the prescription as a whole, which in some respects bears updating.

Methods of inquiry

35. For this review, evidence has been taken from experts on radiological protection within the Centre for Radiation, Chemical and Environmental Hazards at PHE. In particular, a representative of that body attended two meetings of the Council's Research Working Group, furnished the Council with written advice and a presentation, and performed relevant risk calculations upon the Council's request. Further evidence was taken from a representative of the University of Manchester. A list of consultees is given in Appendix 2.

36. Additionally, a review was undertaken of reports of AGIR on leukaemia and solid cancers; evidence was taken from the Health and Safety Executive (HSE) on patterns of occupational exposure to ionising radiation in the UK; and peer-reviewed scientific papers were checked for similar historical data on exposure.

Consideration of the evidence

37. The first question the Council addressed was whether the list of cancers in the current prescription should be updated; the second concerned the exposure values serving as a filter to rule out claims.

38. In relation to solid cancers (i.e. cancers other than of the haematopoietic system), the advice received from PHE was based on the summary of evidence contained in the report of the independent AGIR, 2011; that for leukaemia came from its 2003 report (AGIR, 2003). According to current dose risk models, the colon, liver, lung, stomach, ovary and bladder are now considered more sensitive to ionising radiation than believed earlier when the NRPB formulated its advice to the Council. Accordingly, PHE advised giving consideration to the addition of six new cancer sites to those listed in PD A1. By contrast, the link between testicular cancer and ionising radiation was considered less well established than previously advised. Below the Council lists, in brief, the studies that weighed in the AGIR's considerations and considers the potentially qualifying doses in relation to exposure patterns in the UK in light of the new evidence received from PHE.

Sources of evidence

39. The data considered by the AGIR and PHE came from a number of sources, including data on Japanese atomic bomb survivors, registries of radiation workers in the nuclear industry, and records of patients treated with radiotherapy (for cancer and a number of other diseases) or undergoing radio-imaging.

40. Increasingly, over time, risk models based on the pooling of epidemiological data have become less reliant on investigations of acute high level exposures (e.g. Japanese atomic bomb survivors, patients given large single therapeutic doses of radiation source) and somewhat more representative of chronic exposures accumulated in occupational circumstances.

41. Nonetheless, tables of risk by exposure level, and by sex, age at first exposure and attained age are typically constructed under the assumption that a given total dose is received at a single point in time. More complex calculations are required to simulate chronic exposures accumulated gradually over a working lifetime and these need to be established on a case by case basis.

Testicular cancer

42. The AGIR's report on solid tumours identified five main studies on testicular cancer and ionising radiation: three on disease incidence (the Stockholm Skin Haemangioma study (Lundell and Holm, 1995), the Canadian National Dose Registry study (Sont *et al.*, 2001) and the UK National Registry for Radiation Workers (Muirhead *et al.*, 2009)); one on mortality in which data from nuclear workers in the '15 countries' study (Cardis *et al.*, 2005; Cardis *et al.*, 2007) were compared with those in the UK's national registry for radiation workers; and a further report on British nuclear industry workers who had been monitored for exposure to plutonium (Carpenter *et al.*, 1998).

43. Relative risks (RR) at 1 Sv were more than doubled in all but one of these investigations. In the UK National Registry for Radiation Workers, the RR for incident disease was 2.02 (116 cases) and that for mortality was 4.29 (13 deaths); in British nuclear industry workers monitored for exposure to plutonium, the RR for mortality was 3.36 (although based on only four observed cases). However, findings were statistically significant ($P<0.05$) in only some of the studies and, given this uncertainty regarding the role of chance in findings, the AGIR concluded that "It is currently unclear whether radiation causes testicular cancer – more information is needed before final conclusions can be drawn".

44. In principle, a disease can be removed from the prescription list recognised for benefit if there is sufficient evidence for this course of action. (The last such disease removed from the list was miners' nystagmus in 2007.) However, the Council believes that somewhat different considerations apply to the removal of a prescribed disease from the criteria applied currently in extending the list.

45. Specifically, although many diseases are newly recommended for prescription only when there is sufficient robust scientific evidence that their risks are more than doubled under occupational exposure circumstances that can be scheduled, in deciding to remove a disease that is already prescribed, the Council requires sufficient evidence that the current prescription is wrong and that the balance of evidence lies against prescription.

46. While current evidence that ionising radiation causes testicular cancer has certain limitations (paragraph 43), it points if anything towards an elevation in risk and, in the Council's judgement, does not provide sufficient grounds to recommend that the existing prescription of testicular cancer in PD A1 should be withdrawn.

Other cancers identified by Public Health England

47. While many cancers can be caused by occupational exposure to ionising radiation, for most the dose required to double risk is very high, especially in relation to modern circumstances of exposure. In this situation, the accident provisions of the Scheme can be used to support a claim and prescription is unnecessary.

48. Regarding occupational exposures outwith the extremes of accidental over-exposure, the Council proposes that risk assessments should be based on cancer sites for which the doubling dose does not exceed an arbitrary lifetime value of 2 Sv (the rationale for this choice is given below).

49. It should be noted that the chosen cut-point is exceptionally high by modern standards. A total accumulated dose of 1 Sv would correspond to a worker receiving the current annual dose limit of 20 mSv in each of 50 years of employment or 50 mSv (2.5-times the exposure limit) in each of 20 years. According to the data from the CIDI (2004) maintained by PHE on behalf of HSE, the mean annual dose among classified workers in 2010-2012 was 0.4 to 0.5 mSv and only 0.4 to 0.5% of doses were >6 mSv (3/10th of the annual dose limit); during 1990-1996, just 1 to 7 classified workers received more than 50 mSv in a given year (one 20th to one 200th of 1%).

50. Historically, however, in the 1950s through to the 1970s, cumulative exposures in the nuclear industry were substantially higher, for example, at the Sellafield nuclear plant (Douglas *et al.*, 1994). Even then, average radiation doses at the Sellafield plant did not reach 20 mSv per year. But for 5.6% of the workforce (577 people) the total cumulative dose over the study period (1947–1986) reached 500 mSv or more; for 54 more people (0.5%) it reached 1 Sv or more, and the highest recorded accumulated dose in any individual was of 1.8 Sv. Moreover, some reports from overseas have indicated much higher lifetime doses (e.g. Vano *et al.*, 2010), albeit in circumstances whose relevance to workers' experiences in the UK is rather uncertain. The Council has therefore decided to apply a high cut-point, both in considering the case for prescription of additional cancers and in updating the filter table available for claims assessment of PD A1.

51. Tables 2 and 3 provide sample calculations supplied to the Council by PHE. Represented for a range of cancers are the parameters used in risk modelling (the assumed age at first exposure and attained age at diagnosis), and separately for men and women the dose in Sv required to double the risk of a given cancer assuming an age at exposure of 18 years (Table 2) or 30 years (Table 3). The other assumptions applied by PHE are also given.

Table 2: Dose of ionising radiation estimated to double the risks of certain cancers, assuming that it is received at 18 years of age (Source: PHE) (Cancers that are already prescribed, excepting testicular cancer, are identified in bold)

Cancer	Assumptions in the model		Doubling dose in men (Sv)	Doubling dose in women (Sv)	Model used
	Age at exposure (years)	Age at diagnosis (years)			
Leukaemia	18	20	0.05	0.04	BEIR VII
Breast	18	23	-	0.30	BEIR VII
Thyroid	18	Any	0.70	0.35	BEIR VII
Bone	18	23	0.14	0.14	UNSCEAR
Colon	18	23	0.30	0.43	BEIR VII
Liver	18	23	0.58	0.58	BEIR VII
Lung	18	23	0.58	0.13	BEIR VII
Stomach	18	23	0.87	0.38	BEIR VII
Ovary	18	23	-	0.48	BEIR VII
Bladder	18	23	0.37	0.11	BEIR VII

Table 3: Dose of ionising radiation estimated to double the risks of certain cancers, assuming that it is received at 30 years of age Source: PHE) (Cancers that are already prescribed, excepting testicular cancer, are identified in bold)

Cancer	Assumptions in the model		Doubling dose in men (Sv)	Doubling dose in women (Sv)	Model used
	Age at exposure (years)	Age at diagnosis (years)			
Leukaemia	30	32	0.23	0.21	BEIR VII
Breast	30	35	-	0.67	BEIR VII
Thyroid	30	Any	1.89	0.95	BEIR VII
Bone	30	35	0.34	0.34	UNSCEAR
Colon	30	35	0.75	1.10	BEIR VII
Liver	30	35	1.47	1.47	BEIR VII
Lung	30	35	1.50	0.34	BEIR VII
Stomach	30	35	2.25	0.97	BEIR VII
Ovary	30	35	-	1.24	BEIR VII
Bladder	30	35	0.95	0.29	BEIR VII

52. The doubling dose of ionising radiation can be seen to be lower at younger ages (Table 2) than at older ages (Table 3), implying that RRs for a given dose are higher. This pattern exists not because the excess risk attributable to radiation declines with age (it remains roughly constant) but because the background risk of cancer in the population at large increases with age. Thus, a dose that may double risks at a younger age at diagnosis may no longer do so at a later age of diagnosis. In terms of prescription this poses a potential constraint: by virtue of their shorter work histories, young workers may not have sufficient time to accumulate a qualifying level of exposure (other than through an accident); but for older workers, the doubling dose may be so great as to be unobtainable in practice. The data in Tables 2 and 3 (and other similar tables prepared for the Council by PHE, for other assumed ages of first exposure) seek to test the plausibility of prescription, against a cut-point of total exposure which, though extreme by modern standards, has nonetheless been encountered in practice historically by British workers.

53. As an example, taking Table 3 and breast cancer in women, PHE figures indicate that a dose of 0.67 Sv at age 30 is estimated to double the risks of the tumour for women diagnosed with the disease at age 35.

54. The tables give an indication of the radiosensitivity of different tissues to tumour induction. It may be seen that estimated doubling doses for the currently prescribed tumours, and also for those highlighted by PHE during inquiries, are, according to current risk models, essentially below the highest lifetime dose incurred in Douglas's Sellafield study (Douglas *et al.*, 1994). Thus, an evidential basis exists for extending the list of cancers for which benefit may be payable under PD A1 to include those drawn to the Council's attention by PHE.

55. PHE also offered estimates for several other tumours that are potentially inducible by radiation (cancers of the salivary gland, oesophagus, rectum, skin and brain). However, the Council has been advised that, in lieu of direct evidence of acceptable quality with which to model risks, average values were chosen by PHE, based on an overall appraisal of risk of solid cancers in the AGIR report. Because of PHE's relative lack of confidence in the risk estimates, the Council feels that prescription is precluded on present evidence.

56. Primary carcinoma of the lung is already prescribed in relation to work underground in a tin mine (PD D10(a)), the relevant exposure being that to radon gas, which is a source of ionising radiation. Average annual exposures in Cornish tin mines may have reached as much as 0.25 Sv historically, while high levels have also been found in some haematite mines (Duggan *et al.*, 1970). However, exposures in coal mines appear to have been considerably lower (Duggan *et al.*, 1970) and, according to reports of the time, death rates of UK coal miners from lung cancer were appreciably lower than similarly aged men nationally (e.g. Goldman, 1965).

Breast cancer in men – equality and diversity issues

57. The Council has resolved to seek to avoid unjustified discrimination on equality grounds, including age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, gender and sexual orientation.

58. During the course of this review one matter related to diversity and equality became apparent: the current prescription for PD A1 provides for coverage of women who develop breast cancer from ionising radiation but not for men. The current terms were added in 1999 (Cm 4280) on the advice of the NRPB. Updated evidence was taken on the matter from PHE and other parties.

59. Breast cancer is considerably rarer in men than women, probably because hormonal differences cause female breast tissue to be more active, with a higher cell turnover, and therefore more opportunities exist for cell damage, repair and cancer induction. However, breast cancer does occur in men, in whom its histology is essentially the same as for women.

60. Because of the rarity of male breast cancer, its relationship to ionising radiation is much less well established than for female breast cancer. However, ionising radiation is an established cause of male breast cancer.

61. In the Life Span Study of Japanese atomic bomb survivors, nine cases were observed amongst some 45,880 exposed men after 40 years of follow up, all arising 25 or more years after exposure (Ron *et al.*, 2005). It was estimated, but with a large degree of uncertainty, that the average doubling dose was 0.125 Sv (with implied 95% confidence limits of 0.02 Sv to 0.56 Sv). Equivalently, at 1 Sv the relative risk of male breast cancer was estimated to be elevated nine-fold. The implied doubling dose is below that for women in Tables 2 and 3 above.

62. In summary then, ionising radiation can cause male breast cancer. There is greater uncertainty over the dose required to double risks of the tumour in men. However, such evidence as exists does not indicate that it is likely to be markedly higher for men than for women, and indeed the reverse could apply.

63. In the absence of evidence to the contrary, the Council has decided that it would be reasonable to prescribe for breast cancer in men, and therefore to remove the adjective "female" from the definition of this prescribed disease. Claims in men are likely to be very rare. In processing them, it would be open to PHE to use its expertise to define a suitable doubling dose. One possibility, in the absence of evidence to the contrary, could be to base risk estimates on the totality of evidence across exposed populations, and therefore on estimates derived very largely from affected women.

Wording of the prescription PD A1

64. As well as considering which tumours should be covered by PD A1, the Council has taken the opportunity to consider the prescription's terms, two other aspects of which could be usefully updated.

65. The current prescription excludes from coverage of leukaemia, "chronic lymphatic leukaemia"; more modern terminology (as used in recent versions of the International Classification of Diseases) refers instead to "chronic lymphocytic leukaemia".

66. Prescription also refers to "exposure to electromagnetic radiations (other than radiant heat) or to ionising particles" whereas, in fact, the risk conferring exposures arises from ionising radiation alone and not from non-ionising forms of radiation, such as radiant heat; more exact and simpler then would be to refer to "exposure to ionising radiation".

Conclusions and recommendations

67. The Council accepts the PHE's advice and recommends that the following six cancers be added to the list of tumours for which benefit should be payable under PD A1: cancers of the colon, liver, lung, stomach, ovary and bladder.

68. It advises that cancer of the testis should remain prescribed under PD A1, as at present; and that prescription of breast cancer should be extended to men by omitting the adjective "female" in that part of the prescription.

69. It is further recommended that the terms of prescription of PD A1 be amended in line with paragraphs 65 and 66. Below, the Council sets out the current terms of prescription of PD A1 and the full changes envisaged.

Current terms

Prescribed disease	Occupation
A1. Leukaemia (other than chronic lymphatic leukaemia) or cancer of the bone, female breast, testis or thyroid	**Any occupation involving:** Exposure to electromagnetic radiations (other than radiant heat) or to ionising particles where the dose is sufficient to double the risk of the occurrence of the condition.

Suggested new terms

Prescribed disease	Occupation
A1. Leukaemia (other than chronic lymphocytic leukaemia) or primary cancer of the bone, bladder, breast, colon, liver, lung, ovary, stomach, testis or thyroid	**Any occupation involving:** Exposure to ionising radiation where the dose is sufficient to double the risk of the occurrence of the condition.

70. Separately, PHE has supplied the Department with new filter tables with which to process claims and to decide when further expert opinion should be sought. (The new PHE guidelines are similar to tables 2 and 3, but represent the doubling doses at 40, 50, and 60 years of age.)

71. The Council has considered the potential impact of its recommendations on claims assessment activity. In March 2010 (with rounding to the nearest multiple of 10), 20 cases of PD A1 were in payment, while between April 2002 and December 2010, some 70 new claims were made and 10 assessments performed (about 8 claims and 1 assessment per year). This low caseload reflects the exceptional nature of qualifying exposures, the improved safety record of radiation practice in modern times and, to an extent, the availability of alternative occupational schemes for compensation of

affected workers, such as the Compensation Scheme for Radiation Linked Diseases. Although the tumours proposed for addition to PD A1 are common in the population at large, the qualifying exposures will be very uncommon and probably historic; as such, claimants are likely to be few in number, elderly, and from industries where exposure conditions were very different in the past when compared with the last few decades. In these circumstances, the impact on claims activity is likely to be small.

Prevention

72. Work with ionising radiation should be controlled to minimise the additional cancer risk from any increases in exposure. Health and safety legislation applies to routine work and accidents where radioactive substances and electrical radiation generators are used, as well as to work with natural radiation, including work in which people are exposed to naturally occurring radon gas and its decay products. The general requirements of health and safety regulation apply to such work including The Health & Safety at Work etc. Act 1974 and The Management of Health & Safety at Work Regulations 1999 (MHSWR). There are also specific regulations for routine work, including reasonably foreseeable accidents: The Ionising Radiations Regulations 1999 (IRR99).

73. All employers must carry out a risk assessment to satisfy the requirements of MHSWR. This general requirement is extended under IRR99 to undertake a specific risk assessment relating to activity with ionising radiation and implement the findings. IRR99 applies maximum exposure limits to workers and members of the public, but also requires that all exposures to ionising radiations be restricted so far as reasonably practicable (even below the dose limits). Restriction of exposure should be achieved first by means of engineering control and design features. Where this is not reasonably practicable, employers should introduce safe systems of work and only rely on the provision of personal protective equipment or administrative controls as a last resort.

74. Workers likely to be exposed to the highest doses from routine work or reasonably foreseeable accidents are subject to personal radiation monitoring, dose record keeping and annual health reviews. The annual radiation doses to these workers and any suspected over-exposures must be reported to the HSE and emergency dose levels for major radiation emergencies must be authorised by the HSE.

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Appendix 1
Cancers considered in this report

Breast Cancer

Around 49,900 women and some 350 men are diagnosed with breast cancer in the UK each year. Breast cancer is now the most common cancer in the UK (excluding non-melanoma skin cancer) and by far the most common cancer in women. 1 in 8 women in the UK develop the disease during their lifetime. Known or suspected risk factors include: increasing age, having a close female relative diagnosed with the disease, previous breast cancer, having cancer other than breast cancer, sex hormones and other hormones such as diethylstilbesterol, hormone replacement therapy, the contraceptive pill, not having children or having them later in life, age commencing and ceasing menarche, ethnicity, carcinoma in situ, benign breast disease, having dense breast tissue, alcohol intake, smoking, height, weight, X-rays or radiotherapy, other medical conditions such as diabetes or benign thyroid conditions, certain medicines, dietary fat, and shift work. Cancer of the female breast is currently prescribed within the IIDB Scheme in relation only to ionising radiation (PD A1).

Lung cancer

Lung cancer is the second commonest cancer in the UK (excluding non-melanoma skin cancer). Around 43,500 people are diagnosed each year. By far the main cause of lung cancer is tobacco smoking. Other potential risk factors include: exposure to radon gas, exposure to certain chemicals, air pollution, previous lung disease, a family history of lung cancer, past cancer treatment, previous smoking-related cancers and lowered immunity. Cancer of the lung is currently prescribed within the IIDB Scheme in relation to exposure to arsenic (PD C4), nickel refining (C22b), asbestos (PD D8 and PD D8A), tin mining, bis(chloromethyl)ether, certain chromates, coke oven work and silica[1].

Colon cancer

Bowel cancer is the fourth most common cancer in the UK. Potential risk factors include: age, family history, inherited condition such as familial adenomatous polyposis, ethnicity, benign polyps in the bowel, ulcerative colitis and Crohn's disease, having previously been diagnosed with another cancer, being diabetic and exposure to ionising radiation. Cancer of the colon is not currently prescribed within the IIDB Scheme.

1 Full terms of prescription can be viewed at www.gov.uk/government/publications/ industrial-injuries-disablement-benefits-technical-guidance/industrial-injuries-disablement-benefits-technical-guidance#appendix-1-list-of-diseases-covered-by-industrial-injuries-disablement-benefit

Bladder Cancer

Around 10,400 people are diagnosed with bladder cancer each year in the UK. The causes of bladder cancer may include: smoking, various workplace chemicals, water disinfectant chemicals, treatment for other cancers, prostate surgery, diabetes, repeated bladder infection, bladder stones, previous bladder cancer, family history, early menopause, extrophy and hair dye. Cancer of the bladder is prescribed within the IIDB Scheme in relation to exposure to certain napthylamines, benzidine, auramine, magenta, 4-aminophenyl, methylene-bis-orthochloroaniline, orthtoluidine, 4-chloro-2-methylaniline and coal tar pitch volatiles (PD C23)[2].

Leukaemia

In the UK around 8,600 people are diagnosed each year with leukaemia. The causes may include: ionising radiation including radon exposure, exposure to benzene, smoking, genetic factors, past chemotherapy, blood disorders, auto-immune conditions, alcohol during pregnancy, and being overweight. Leukaemia is currently prescribed within the IIDB Scheme in relation to ionising radiation (PD A1) and exposure to benzene (PD C7, acute non-lymphatic leukaemia)[3].

Stomach cancer

Stomach cancer is now the fifteenth most common cancer amongst adults in the UK. Around 7,100 cases are diagnosed each year. Out of every 100 cancers diagnosed, 2 are cancer of the stomach. Almost twice as many cases are diagnosed in men as in women. Potential risk factors include: age, diet, *helicobacter pylori* infection, cigarette smoking, alcohol consumption, medical conditions affecting acid reflux, pernicious anaemia, family history of the disease, having other cancers, ionising radiation exposure, reduced immunity, hormone replacement therapy and blood group. Cancer of the stomach is not currently prescribed within the IIDB Scheme.

Ovarian cancer

Around 7,100 women are diagnosed with ovarian cancer in the UK each year and it is the fifth most common cancer in women. Its potential risk factors include: increasing age, inherited faulty genes, previous breast cancer, infertility, hormone replacement therapy, being overweight, being tall, endometriosis, and smoking. Cancer of the ovary is not currently prescribed within the IIDB Scheme.

2 Full terms of prescription can be viewed at www.gov.uk/government/publications/ industrial-injuries-disablement-benefits-technical-guidance/industrial-injuries-disablement-benefits-technical-guidance#appendix-1-list-of-diseases-covered-by-industrial-injuries-disablement-benefit

3 *Ibid*.

Liver cancer

Primary liver cancer is rare in the UK, but its incidence is rising, with around 4,300 primary liver cancers diagnosed each year in the UK. Potential risk factors include: liver cirrhosis, alcohol consumption, non-alcoholic fatty liver disease, viral hepatitis, smoking, low immunity, family history, diabetes, gall bladder removal, radiation from X-rays or CT scans, obesity, chewing betel quid, aflatoxins, and exposure to chemicals such as vinyl chloride. Cancer of the liver is prescribed within the IIDB Scheme in relation to exposure to vinyl chloride monomer (PD C24)[4].

Thyroid cancer

Thyroid cancer is quite a rare cancer with around 2,700 people diagnosed each year in the UK and it is 2-3 times more common in women than men. Potential risk factors include: benign thyroid disease, exposure to ionising radiation, family history of thyroid cancer, familial adenomatous polyposis, obesity, acromegaly and diabetes. Thyroid cancer is currently prescribed within the IIDB Scheme in respect of exposure to ionising radiation (PD A1).

Testicular cancer

Testicular cancer is a relatively rare disease with around 2,200 men diagnosed each year in the UK. Potential risk factors include: cryptorchidism, carcinoma in situ of the testicle, fertility problems, previous cancer, family history of the disease, other medical conditions such as hypospadias or inguinal hernia, having HIV or AIDS, and ethnicity. Testicular cancer is currently prescribed within the IIDB Scheme in respect of exposure to ionising radiation (PD A1).

Salivary gland cancer

Salivary gland cancer is rare with around 690 people in the UK diagnosed each year. Potential risk factors include: age, ionising radiation, previous skin cancer, smoking tobacco, family history of the disease and human papilloma virus. Salivary gland cancer is not currently prescribed within the IIDB Scheme.

Bone cancer

Bone cancer is rare, with around 550 cases diagnosed each year in the UK. Potential risk factors include: age, cancer treatments from radiotherapy and chemotherapy, certain bone diseases, and genetic factors. Bone cancer is currently prescribed within the IIDB Scheme in respect of exposures to ionising radiation (PD A1).

4 Full terms of prescription can be viewed at www.gov.uk/government/publications/ industrial-injuries-disablement-benefits-technical-guidance/industrial-injuries-disablement-benefits-technical-guidance#appendix-1-list-of-diseases-covered-by-industrial-injuries-disablement-benefit

Appendix 2
Experts consulted

The Council would like to thank the following experts for contributing evidence and thoughts to this review:

- Doctors Wei Zhang and Giovanni Leonardi, Public Health England.
- Professor Richard Wakeford, University of Manchester.

Appendix 3
Glossary of terms used in this report

Types of study

Case control study: A study which compares people who have a given disease (cases) with people who do not (non-cases, also called controls) in terms of exposure to one or more risk factors of interest. Have cases been exposed more than non-cases? The outcome is expressed as an **Odds Ratio**, a form of **Relative Risk**.

Measures of association

Statistical significance and P values: Statistical significance refers to the probability that a result as large as that observed, or more extreme still, could have arisen simply by chance. The smaller the probability, the less likely it is that the findings arise by chance alone and the more likely they are to be 'true'. A 'statistically significant' result is one for which the chance alone probability is suitably small, as judged by reference to a pre-defined cut-point. (Conventionally, this is often less than 5% ($P<0.05$)).

Relative Risk (RR): A measure of the strength of association between exposure and disease. RR is the ratio of the risk of disease in one group to that in another. Often the first group is exposed and the second unexposed or less exposed. *A value greater than 1.0 indicates a positive association between exposure and disease.* (This may be causal, or have other explanations, such as bias, chance or **confounding**.)

Other technical terms

Radiation dose

Absorbed dose describes the intensity of the energy deposited in any small amount of tissue located anywhere in the body. For ionising radiation, the unit of absorbed dose is the milligray (mGy). The effective dose is a calculated value, measured in mSv that takes into account the absorbed dose to all organs of the body, the relative harm level of the radiation and the sensitivities of each organ to radiation.

The Sievert (and mSv): A derived unit of ionising radiation dose in the international system of units. It is a measure of the health effects of external radiation from sources outside the body and the effect of internal irradiation due to inhaled or ingested radioactive substances. (A milliSievert (mSv) is one thousandth of a SV and so 1 Sv is equal to 1,000 mSv.)

Stochastic: Probabilistic or stochastic effects are those which occur with a probability that is dose dependent, there being no threshold below which the risk can be considered to be zero; however, the severity of a stochastic effect does not depend on dose, only the likelihood of it occurring.

Deterministic: Deterministic effects are those whose severity varies according to the dose received, such that there may be a threshold dose below which the effect does not occur or is never apparent.

This publication can be accessed online at:
https://www.gov.uk/government/publications/cancers-due-to-ionising-radiation-iiac-report

For more information about this publication, email: **iiac@dwp.gsi.gov.uk**

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