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THE INDUSTRIAL INJURIES ADVISORY COUNCIL

POSITION PAPER 36

**Interventional cardiology,
interventional radiology and cataract**

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Interventional cardiology, interventional radiology and cataract: Position Paper 36

Summary

1. In this paper the Council sets out evidence on cataracts and work with sources of ionising radiation.
2. The review has been prompted by growing concern that the lens of the eye is more susceptible to the hazardous effects of ionising radiation than formerly supposed, and by new investigations in workers previously not considered to be at important risk of developing radiation-related eye disease. A particular focus is on healthcare staff engaged in interventional procedures which may expose them to radiation.
3. Evidence has been taken from a number of sources, including experts from Public Health England's Centre for Radiation, Chemical and Environmental Hazards and a specialist in ophthalmology and ophthalmic epidemiology (listed later).
4. In the event, however, only a few studies of limited quality have been found, mostly focussing on the non-disabling end point of lens clouding without limitation of vision. The identified studies all come from overseas and the exposures reported in them appear to be of limited relevance to exposure circumstances in the UK.
5. The Council has concluded on balance that the case for prescription has not yet been made. However, it would encourage further research in occupations exposed to ionising radiation and would welcome the submission of further evidence as it emerges.

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

What is a cataract?

6. The lens of the eye is an optically transparent, bloodless biconvex protein fibre structure which refracts light and focuses it to form a sharp image on the retina. It is enclosed by a lens capsule, while its substance comprises an outer layer called the cortex and a central portion called the nucleus.
7. The main pathology of the lens is a clouding (opacification) which has the potential to prevent passage of light to the retina and thus to limit vision. Clouding of some degree is extremely common at older ages; in most instances, this does not affect vision, but advanced opacification is the leading cause of blindness worldwide. The term 'cataract' is normally used to describe clinically significant opacification with loss of vision, cloudiness of the lens before this stage being called 'lens opacity'. However, there is no clear cut-off point and the distinction in terms of prevalence and aetiological epidemiological research is somewhat arbitrary and inconsistently applied. (In this report 'cataract' refers to sight-limiting opacification of the lens.)
8. Cataracts may be classified broadly according to the part of the lens they affect – cortical (affecting the cortex), nuclear (affecting the nucleus), or posterior subcapsular (lying beneath the capsule at the back of the lens) (see Figures 1 and 2).

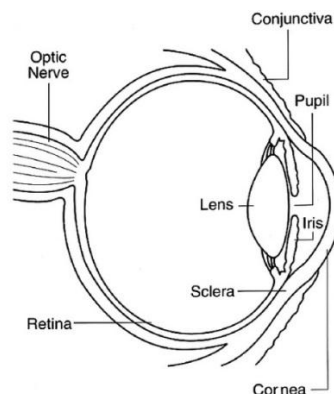


Figure 1: Schematic representation of the eye, showing position of the lens (We acknowledge the source of the diagram as the National Eye Institute Photos and Images Catalog).

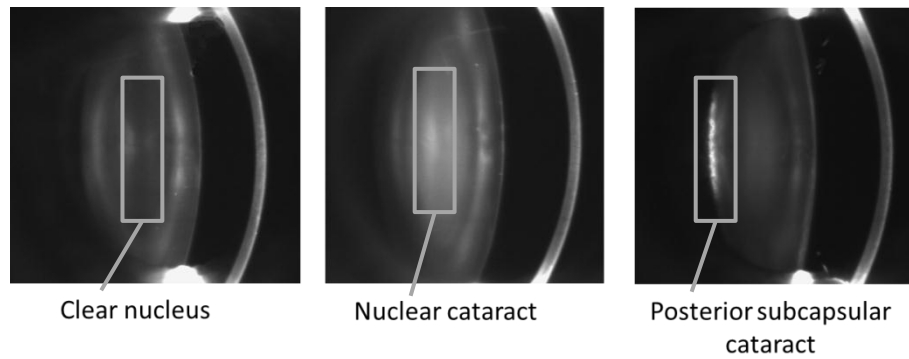


Figure 2: Cross-sectional photograph of the eye showing different patterns of cataract (photographs kindly provided by Professor C Hammond) (side on view, with the front of the eye to the right)

9. Opacities lying along the main visual axis of the eye (e.g. posterior subcapsular ones) are more sight-limiting than peripheral opacities, affecting clarity of vision and also causing glare.

10. Although several opacification-cataract severity grading systems have been developed, there is no single system for grading the severity of lens opacification which is widely accepted and consistently applied in research and clinical practice; rather, approaches both to diagnosis and to grading vary between studies.

11. Cataract is treatable by surgery and is often recommended when a person's loss of vision has a significant effect on their daily activities. Almost everyone who has such surgery experiences an improvement in their vision, although subsequently they may need to wear glasses. Success rates of surgery are high and complication rates are relatively low, although not all disability is necessarily removed by surgery in every case. In principle, sight-limiting cataract, if occupationally-caused, might give rise to disablement within the meaning given this term in the Industrial Injuries Scheme, unless and until successfully treated.

Non-occupational risk factors for cataract

12. The main risk factor for development of cataract is increasing age. However, there are many other recognised causes of lens opacification, including

steroid treatment, diabetes, cigarette smoking, various chronic eye pathologies, trauma or chemical injury to the eye, and various metabolic and nutritional diseases. Currently, claimants with cataract are potentially eligible for Industrial Injuries Disablement Benefit following “frequent or prolonged exposure to radiation from red-hot or white-hot material” (Prescribed Disease (PD) A2).

13. Additionally, lens opacification may be caused by ultraviolet, infrared and ionising radiation. In fact, the lens is one of the most radiosensitive tissues in the body, and well-documented instances of radiation-induced cataract have been described in atomic bomb survivors, residents of radiation-contaminated buildings, victims of the Chernobyl nuclear accident, patients undergoing radiotherapy and computer tomography scanning, and astronauts (International Committee for Radiological Protection (ICRP), 2012). Many mechanistic experiments in laboratory animals have also confirmed effects. More recently, reports have emerged on cataracts in those potentially exposed to ionising radiation in the workplace (see below). This review considered whether there was evidence to warrant extending the prescription of PD A2 to include cataracts arising from ionising radiation.

Radiation-induced cataract

14. Cataracts which are radiation-induced are said to develop and progress in a characteristic sequence. The earliest detectable effect is thought to be an opalescent sheen on the posterior lens capsule, observed by slit-lamp examination; subsequently, small vacuoles and punctate opacities appear, often centred around the posterior lens. Posterior subcapsular cataracts are believed to be the main clinical endpoint, although cortical cataracts have also been associated with ionising radiation. Furthermore, posterior subcapsular cataract has other causes than ionising radiation (e.g. steroid treatment, chronic uveitis, diabetes), so clinical appearances are not pathognomonic or cause-specific.

15. Radiation is the transfer of energy by particles or waves that can travel across a vacuum. Ionising radiation comprises those forms of radiation with sufficient

energy to displace electrons from atoms. These include alpha particles, beta particles, gamma rays, X-rays and neutrons.

16. The mechanism by which ionising radiation causes cataract is not generally agreed. The rate at which radiation-related changes progress depends on dose, age, sex, types of radiation and many other factors. The lens epithelium appears to be more sensitive to ionising radiation in infancy while the rate of progression of opacification at low doses may be greater in older people. In general, lower dose exposures are associated with a longer latency or interval from exposure to disease manifestation.

17. A matter of current debate is whether minor changes inevitably progress to cause visual disability given a long enough follow-up time. Early studies in the field were limited by poor measurements at lower doses and relatively short follow-up intervals and such evidence as now exists is somewhat conflicting on this issue, although the balance of evidence may be in favour of progression.

Threshold effects for cataract development following exposure to ionising radiation

18. Until relatively recently, the International Committee for Radiological Protection (ICRP) and the National Council on Radiation Protection and Measurements (NCRP) have estimated the threshold radiation dose for development of detectable lens opacities to be 5 Sieverts (Sv) for chronic exposures and 0.2-2.0 Sv for acute exposures (ICRP, 2007). Higher doses would be required before visually disabling cataracts develop, estimated to be of the order of 2-10 Sv for single brief exposures and more than 8 Sv for protracted ones (ICRP, 2007, NCRP, 1989).

19. In recent years, however, a number of new studies in occupational and non-occupational groups, including extended follow-up of previously reported cohorts and animal experiments, have led the ICRP to conclude that the lens is more radiosensitive than formerly assumed and to revise downwards the threshold values for detectable opacification to 0.5 Sv for chronic exposures,

some 10-fold lower (Ainsbury *et al.*, 2009). The occupational exposure limit for protection of the lens was recommended to be reduced from 150 mSv to 20 mSv per year (averaged over a five year period, with no single year exceeding 50 mSv), a 7.5-fold reduction (ICRP 2011). The ICRP's estimates and recommendations have since been endorsed in the UK by the Health Protection Agency's Centre for Radiation, Chemical and Environmental Hazards, now part of Public Health England (Bouffler *et al.*, 2012).

20. Although not fully established, the ICRP assumes that cataract induction is a 'deterministic' rather than a 'stochastic' event. The deterministic paradigm implies that there is a threshold dose below which the effect does not occur or is never clinically apparent. However, if cataracts are stochastic by nature, there would be no threshold below which the risk could be considered to be zero and the probability of manifestation of cataracts would increase with increased dose.

Occupations at potential risk

21. The downwardly revised risk estimates suggest a potential for exposures in some occupational groups to exceed the protection limits. Research in these occupations has both contributed to the evidence on risks at lower levels of total dose and created a research momentum of its own.

22. In this report, we consider findings in healthcare workers involved in interventional cardiology and radiology, as well as radiological technicians and allied workers in radiation protection zones, these being the occupational groups featuring most often in the published research reports.

23. In recent years an exponential increase has occurred in the use of fluoroscopy, an imaging technique that uses X-rays to obtain real-time moving images of the interior of an object (United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR), 2000). This method has been widely adopted in medical diagnosis and treatment, with applications in general radiology, interventional radiology, and image-guided surgery and cardiology. In its simplest form, a fluoroscope consists of an X-ray source and a

fluorescent screen, between which a patient is placed. However, since the 1950s most fluoroscopes have incorporated X-ray image intensifiers and cameras to improve the image's visibility and display it on a remote screen.

24. Workers may be exposed to scattered X-rays during interventional procedures, since they are in the controlled radiation area outside the protective screen. The dose received per procedure by staff members depends on the radiation delivered to the patient, the proximity and location of the worker and patient relative to the X-ray tube, and the duration of the procedure. Since such procedures tend to be quite lengthy, healthcare staff working close to patients can potentially accumulate relatively high ocular doses over a working lifetime, especially if eye protection is not worn. Interventional cardiologists, in particular, are frequent and intensive users of the technique. Eye protection has been recommended in the UK for radiation workers, including for radiologists. However, such use has not always been routine, especially in other parts of the world, as indicated by several research reports described below.

25. The Health and Safety Executive (HSE) has estimated that in excess of 200 medical facilities in the UK are likely to have been affected by the revised dose limit for the lens of the eye, employing some 1,300 potentially exposed workers.

26. A survey, commissioned by HSE and conducted by Public Health England, involving hospitals in central London, Manchester and Oxford, found that projected annual cumulative doses in 61 participants seldom approached 20 mSv (Ainsbury *et al.*, 2014), while use of protective equipment was described as generally 'good'.

27. These major centres may have been more representative of best practice than of usual practice. However, unpublished data, presented by Higgins to the 2015 Society of Radiological Protection Conference, also indicated a low dose to the eye as assessed in a small sample of interventional radiologists from Leeds (mean annual dose <5 mSv, A Higgins, personal communication),

as did measurements in a few radiopharmacists and nuclear imaging technicians from Scotland, presented by researchers to the same meeting (estimated annual dose <1.7 mSv for both occupational groups, C Stewart, personal communication).

28. However, the same unpublished study by Stewart identified two workers in an interventional radiology facility whose estimated annual doses to the eye reached 22-23 mSv (C Stewart, personal communication). Other published data, collated by Martin and Magee (2013) and by O'Connor *et al.* (2014) in Ireland, also indicate a potential for the 20 mSv dose limit to be exceeded in some hospitals around the UK.
29. Moreover, a few surveys in overseas cardiac catheterisation laboratories have estimated that very much higher risk-conferring levels of exposure can sometimes arise. In one survey of interventional cardiologists and technicians from Latin America, which combined selected field measurements with estimates of workers' occupational workload (lifetime numbers and kinds of procedure), the mean cumulative occupational dose to the lens was put at 6 Sv (range 0.1 to 27 Sv) in the physicians and 1.5 Sv (range, 0.2 to 4.5 Sv) in the nurses and technicians (Vano *et al.*, 2010). Film badges were seldom worn, however, and so these exposures had to be estimated.
30. In Serbian healthcare workers from a radiation protection zone, the estimated mean annual absorbed dose was lower, at 7.6 mSv per 5 years (range, 2.6 to 48.1 mSv per 5 years), which might equate at the upper limit to about 0.4 Sv over a 40 year career (Milacic, 2009).
31. In a multicentre study of cardiac suites from France, exposures per procedure were estimated to range from about 0.05 to 0.24 mSv; one worker averaged 1,267 procedures per year and the overall mean lifetime workload was put at more than 11,000 procedures (Jacob *et al.*, 2013). The estimated cumulative doses in those studied (129 interventional cardiologists, mean age of 51) ranged from 25 mSv to 1.66 Sv, with a mean of just over 0.4 Sv (Jacob *et al.*, 2013b).

32. In a large survey of radiological technicians from the US, the median lifetime dose to the lens was comparatively low, at 28.1 mSv, and averaged 60.1 mSv in the highest exposure band (Chodick *et al.*, 2008).
33. In the ORAMED (Optimization of Radiation Protection of Medical Staff) project some 13,000 procedures were assessed in 34 European hospitals. In general, estimated doses to the eye did not exceed 150 mSv (Vanhavare et al, 2011).
34. The range of exposure estimates in interventional cardiology and radiology is therefore wide and disparate. The relevance of high estimates in some of these studies to working practices in the UK is doubtful on present evidence (being far above the British and Irish surveys described in paragraphs 26-28, the European ORAMED study, and even published values for British nuclear workers with known extremely high lifetime levels of exposure historically (Douglas *et al.*, 1994)).

Studies of lens opacification and cataract in healthcare professionals

35. Surveys of cataract in healthcare workers have varied considerably in their case definitions, methods of assessment, and grading of disease severity.
36. A study from Serbia involved healthcare workers from a radiation protection zone and a comparison group from outwith the zone (Milacic, 2009). Cataracts (lens opacities with impaired visual acuity) in the former group were identified through annual preventive check-ups, including ophthalmic examination. Sampling methods were not clearly stated (for example, whether all cases were included among radiation workers or a sub-sample, and how the unexposed controls were selected). Analysis mostly compared the profile of people with cataracts from each zone, and incidence rates for each setting were not given; nor did analysis allow for age or other risk factors for cataract development. However, the relative risk (RR) of crystalline lens cataract was said to be elevated 4.6-fold in the radiation workers (probability (P) <0.01). Mean absorbed annual doses were similar in radiation workers with and without cataracts (1.59 mSv per year vs. 1.63 mSv per year). No distinction

was drawn between posterior subcapsular, cortical and nuclear cataracts.

37. A more detailed study by Vano *et al.* (2010) recruited delegates of two conferences of the Latin American Society of Interventional Cardiology, in Bogota and Montevideo, to undergo comprehensive slit lamp examination and retrospective dose assessment. Across the two conferences, 58 interventional cardiologists, 52 nurses and technicians working in catheterisation suites and 93 unexposed controls were screened. No details were given on how the study was advertised, or on response rates among the volunteers, or on how the controls were sampled and the backgrounds from which they came. Both groups were examined for "characteristic radiation-induced lens morphology"—changes in the posterior lens scored using a system developed originally for the assessment of radiation cataracts. No information was given on whether assessments were performed without knowledge of subjects' work histories.
38. The exposed group seldom wore personal dosimeters. However, from experimental measurements of scatter radiation doses in certain catheterisation laboratories, a dose to lens of 2 mSv per procedure was assumed and individuals' lifetime doses estimated from their occupational history. The total estimated in interventional cardiologists, 6 Sv (range 0.1 to 27 Sv) implies a lifetime average of 3,000 unprotected procedures over an average of 14 years, or about 214 procedures per year. Eye protection was rarely used.
39. Lens opacities were mostly graded as minor (unlikely to affect sight). The RR for posterior subcapsular lens opacities was 3.2-fold higher in the interventional cardiologists (95% confidence interval (95% CI) 1.7 – 6.1) than in unexposed controls, and non-significantly elevated in the nurses and technicians (RR 1.7).
40. The groups were chosen to be broadly similar in age, but in practice the interventional cardiologists were older (mean 46 vs. 41 years, range 30-69 vs. 20-66 years) and this crude matching may not have allowed adequately for the effects of age. (However, since posterior subcapsular cataract is less

strongly related to age than other forms of cataract, the ICRP concluded that this had only a minor influence on findings.) The study was also limited by its reliance on volunteers and the absence of a defined sampling frame.

Possibly, interventional cardiologists with nascent eye problems participated preferentially, which could lead to an overestimation of risks. A further question is whether findings in such a highly exposed group would be relevant to the experience of workers in the UK.

41. A second assessment of conference delegates was performed at an annual conference of the National Heart Association of Malaysia in Kuala Lumpur (Ciraj-Bjelac *et al.*, 2012). In all, 52 staff members of interventional cardiology facilities (30 interventional cardiologists and 22 radiographers) were compared with 34 unexposed controls of similar age and sex. As in the study by Vano *et al.*, all were volunteers with similar uncertainty over sampling, response rates and recruitment methods. Cardiologists were somewhat older than controls, while the support staff were younger.

42. Posterior lens opacities were graded by two ophthalmologists, although whether such assessments were performed without knowledge of the subject's exposure status ('blinded') is not clear.

43. The cumulative dose to the lens was estimated at 1.1 Sv for the interventional cardiologists (up to a maximum of 7.4 Sv), but higher in the support staff (1.8 Sv, maximum 21.0 Sv).

44. Posterior lens changes (of a minor degree unlikely much, if at all, to affect vision) were found in 53% of the interventional cardiologists, 45% of the support staff and 20% of controls, with RRs of 2.6 (95% CI 1.2-5.4) and 2.2 (95% CI 1.0-4.9) respectively for the exposed groups vs. the controls. No relation was found to dose of radiation (when categorised as less than or more than 1 Sv). Again, lens changes were mostly minor. Fewer than half of interventional cardiologists took precautions to protect their eyes at work.

45. A third study of interventional cardiologists, from Taiwan, reported a more

modest elevation in risks of cataract (Yuan *et al.*, 2010). Subjects were sampled from a database of outpatient and admission reimbursements employed by the Bureau of National Health Insurance care plan. Some 2,292 doctors were enrolled – apparently those making reimbursement applications for cardiac disease. These were subdivided into physicians who had performed cardiac catheterisation and those who had not; the split of almost 40:60 implies a degree of over-sampling of cardiologists, although no comment was made on this.

46. Among those aged 35-50 years, 9 of 733 (1.2%) interventional cardiologists were recorded as having a reimbursed diagnosis of cataract vs. 8 of 988 (0.8%) other doctors – a crude RR of 1.5 (95% CI 0.6 to 3.8, $P > 0.05$). However, because the age band was so wide, findings could have been confounded by ageing effects, if the cardiologists happened to be older.
47. As well as uncertainty over recruitment methods, inclusion criteria, potential confounding by age and lack of information on subjects' exposures, the study suffered the limitation that cataracts were identified only through a reimbursement code used in routine clinical care, rather than a standardised eye assessment. Different types of cataract were not distinguishable. Moreover, doctors who depended on good vision for their work (e.g. interventional cardiologists) may more readily have sought treatment for eye pathology than other doctors, a potential bias that such a study design cannot rule out.
48. In a pilot study from Finland (Mrena *et al.*, 2011), subjects with >15 years of dose monitoring records and cumulative effective whole-body doses of >10 mSv were identified from a nationwide registry of 1,312 physicians (mostly radiologists) with occupational exposure to ionising radiation. The study was restricted to registry members resident in southern Finland. In all, 59 of 120 subjects met these criteria, but two had had previous surgery for cataract and these were excluded (since the type of cataract was not known). Among the remaining 57 doctors (median age 60 years, range 46-70 years), 42% had some degree of lens opacity, 14% nuclear, 7% cortical and 5% a posterior

subcapsular lesion (three subjects aged 67-70 years, with cumulative doses of 11-24 m Sv). No comparative data were available on unexposed subjects.

49. After allowing for age, sex and smoking, it was estimated that, for any lens opacity, the excess odds ratio (OR) per 10 mSv of cumulative radiation dose was 0.13 (95% CI -0.02 to 0.28). An excess OR of 1.0 equates approximately to a doubling of RR, implying a doubling dose of about 77 mSv. Work in interventional radiology carried a 3.87-fold higher risk of lens opacity of any kind, but the RR for cortical and posterior opacities – the patterns most closely linked with radiation injury – was only marginally elevated (OR 1.28, 95% CI 0.08 to 19.38; excess OR per 10 mSv of cumulative radiation dose 0.04, 95% CI -0.02 to 0.28). None of the findings on radiation effects were statistically significant ($P > 0.05$).
50. All lesions were described as minor (unlikely to affect vision) and the findings as 'preliminary'. In practice, the sample was comparatively small, responses were incomplete and uncertainty existed over the relation between whole-body doses and those received at the lens of the eye.
51. Only one in 10 of the Finnish radiologists routinely used some form of eye protection.
52. In the Occupational Cataracts and Lens Opacities in Interventional Cardiology (OCLOC) study (Jacob *et al.*, 2013), interventional cardiologists aged ≥ 40 years from 140 French cardiology centres were invited to participate, as were unexposed non-medical workers from the Institute of Radiation Protection and Nuclear Safety (IRSN). In all, 106 of 526 interventional cardiologists and 99 of 1,082 controls completed an eye assessment. The groups were similar in age and sex (mean age about 50 years).
53. A somewhat higher proportion of the referent group had lens opacification of any degree (75% vs. 67%) and also cortical opacification (29% vs. 23%); but subcapsular opacities were significantly more frequent in the cardiologists (17% vs. 5%, OR 3.8, 95% CI 1.3-11.4 after adjustment for various risk

factors). ORs were higher for those with the lower cumulative numbers of procedures, but increased with duration of employment individually adjusted for age, from 1.9 for ≤ 17 years of work to 5.9 ($P < 0.05$) with > 25 years. Wearing lead eyeglasses for 75% or more of the time reduced risks by about 50% (from OR 3.9 to 2.2).

54. This study had a low response rate and it is conceivable that a study entitled "occupational cataracts and lens opacities in interventional cardiology" may have encouraged a stronger response from interventional cardiologists with visual problems. Since posterior subcapsular opacities tend to be more sight-limiting because of the location on the visual axis, this potential bias might in turn lead to their over-representation among the cardiologists in the survey. However, the specificity of effect (to radiation-associated lesions) and the relation to duration of employment (with more careful allowance for age) and worker protection are pointers in favour of a causal relationship.

Discussion and conclusions

55. Most, but not all of the studies identified by this review point to a more than doubling of lens opacification in healthcare workers involved in interventional cardiology and radiology.

56. All, however, had important methodological limitations, which may have led to overestimation of risks. Arguably, that by Jacob *et al.* provides the most compelling evidence of a doubling of the risk, since an attempt was made to collect representative information and the described effects could be related to duration of work and use of eye protection. However, the possibility that risk estimates were inflated by study limitations in most or all of these reports cannot readily be discounted.

57. Considering the specificity of detected effects across reports, two studies of the delegate-at-conference design (by Vano *et al.* and Ciraj-Bjelac *et al.*) found elevated risks of posterior subcapsular lens opacification – the pattern expected from radiation injury – but did not report the frequency of opacities elsewhere in the lens; while findings in two studies with more complete

reporting (those by Jacob *et al.* and Mrena *et al.*) were conflicting, the former finding higher risks only for posterior subcapsular disease but the latter finding the opposite.

58. A consideration relevant to prescription is that the opacities detected in healthcare workers tended to fall well short of affecting people's vision. The study by Yuan *et al.*, which focused on surgically treated cataract, found a much lower elevation in risk.
59. A follow-on consideration is whether early lens opacities inevitably progress to sight-limiting disease with sufficient passage of time. Currently, there is debate about risks of progression and no studies have presently been conducted in retired interventional cardiologists from which to assess the long-term risks. (In all likelihood the exposure-conferring procedures have not been used for long enough to collect such data at present.)
60. A further point against prescription is that the studies that point to an elevated risk all come from other countries, and the exposures described in them appear to be far above those believed to apply in the UK.
61. The Council is open to receiving further evidence on risks and exposures in the context of the UK. On balance, however, given the relatively few studies of limited quality on cataract in healthcare staff engaged in interventional cardiology and radiology, the non-disabling nature of their measured endpoints, and doubt over whether exposures in these studies are relevant to the UK experience, the Council considers that the case is not presently made to recommend prescription.
62. However, it seems likely that appreciation of the potential risks posed to the eye in a growing area of healthcare will spawn further and better studies in future; the Council will monitor evidence on the topic as it emerges and if necessary reconsider its position.
63. Evidence on risks in other potentially exposed occupations (such as industrial

radiographers (Lian *et al.*, 2015)), although tending in the same direction, is much sparser than for healthcare workers at present, and so is not reviewed here. This too will be monitored. The Council welcomes further evidence and evidence-gathering from stakeholders, including the research community.

Prevention

64. Work with ionising radiation should be controlled to minimise the risk of cataract or opacity formation from exposure. Health and safety legislation applies to routine work and accidents where radioactive substances and electrical radiation generators are used which could increase the occurrence of such damage. 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).

65. 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 a maximum exposure limit to the lens of the eye for 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). Dose limits for deterministic effects are set below the accepted threshold value determined by the International Commission on Radiological Protection (ICRP) and implemented in UK legislation as a result of EURATOM directives. The dose limit for the eye will be reduced from 150mSv per annum to 20mSv per annum in new UK regulations expected in early 2018.

66. 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. Workers likely to be exposed to the highest eye doses from routine

work or reasonably foreseeable accidents are subject to personal radiation monitoring, dose record keeping and annual health reviews. The annual eye doses to these workers and any suspected over-exposures must be reported to the Health and Safety Executive (HSE) and emergency dose levels for major radiation emergencies must be authorised by HSE.

Equality and diversity

67. IIAC seeks to promote equality and diversity as part of its values. 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. During the course of the review of the terms of prescription for cataracts due to ionising radiation no matters related to diversity and equality were apparent.

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Experts consulted

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Glossary

General

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.

Sievert (and mSv)

The Sievert (SV) is 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.

Cumulative Effective Dose: The radiation dose quantity **effective dose** is the tissue-weighted sum of the equivalent doses in all specified tissues and organs of the body: the total dose resulting from repeated exposures to radiation of the same part of the body or of the whole body.

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.

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.

Pathognomonic: Characteristic or indicative of a disease; denoting especially one or more typical symptoms, findings, or pattern of abnormalities specific for a given disease and not found in any other condition.

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 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**.)

Odds Ratio (OR): A measure of the strength of association between exposure and disease. It is the odds of exposure in those with disease relative to the odds of exposure in those without disease, expressed as a ratio. For rare exposures, odds and risks are numerically very similar, so the OR can be thought of as a **Relative Risk**. 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**.)

Confidence Interval (CI): The **Relative Risk** reported in a study is only an estimate of the true value of relative risk in the underlying population; a different sample may give a somewhat different estimate. The CI defines a plausible range in which the true population value lies, given the extent of statistical uncertainty in the data. The commonly chosen 95% CIs give a range in which there is a 95% chance that the true value will be found (in the absence of **bias** and **confounding**). Small studies generate much uncertainty and a wide range, whereas very large studies provide a narrower band of compatible values.

Other epidemiological terms

Confounding: Arises when the association between exposure and disease is explained in whole or part by a third factor (confounder), itself a cause of the disease, that occurs to a different extent in the groups being compared.

Bias: A systematic tendency to over- or under-estimate the size of an effect in a study because of errors in the way its sample was assembled, the evidence collected, or its data analysed.

P-value: A p-value is the probability of finding the observed or more extreme results when the so-called 'null' hypothesis is true. This means how likely are the data observed, given that there is **no** excess risk associated with the exposure of interest. Small p-values, conventionally less than 0.05, argue against the null hypothesis (no effect) and are described as 'statistically significant'.