

Appendix B

A restatement of the natural science evidence base concerning the health effects of low-level ionizing radiation

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INTRODUCTION AND AIMS

1. The UK National Physical Laboratory has an educational poster on the subject of ionizing radiation <http://www.npl.co.uk/educate-explore/factsheets/ionising-radiation/>. Three major publications summarise the natural science evidence base: that from the United Nations UNSCEAR (2006a), that from the US National Academies BEIR VII (2006) and the latest recommendations of the International Commission on Radiological Protection ICRP 103 (2007).
2. See UNSCEAR (2006a) (Annex A, Section I), and the epidemiology guidelines published by Bradford-Hill in 1965 and reproduced in 2015 Hill (2015) with the accompanying editorial Wakeford (2015). Doll (2002) gives a further review.
3. UNSCEAR (2008) gives global figures on natural and artificial background radiation. Abbot (2015) gives comparative figures for different countries and different years. In this paper we define, for sparsely ionizing radiation, a low dose as being <100 mGy and a low dose-rate as being <0.1 mGy/min averaged over one hour, following UNSCEAR (2012b).
4. The use of the descriptors [Cons], [Emco], [Noco] and [Projn] follows practice in previous restatements Godfray *et al.* (2013), Godfray *et al.* (2014), Godfray *et al.* (2015), Dadson *et al.* (2017).
5. Since its inception UNSCEAR has published 25 major reports available here: <http://www.unscear.org/unscear/en/publications.html>. The National Academies series of BEIR reports are available here: <http://www.nap.edu/search/?term=BEIR>. ICRP publications are here: <http://www.icrp.org/publications.asp>.

THE SYSTEM OF RADIOLOGICAL PROTECTION

6. Chapter 5 of ICRP 103 (2007) describes the system of radiological protection of humans. Wrixon (2008) provides a summary and contextualises the changes in recommendations.
7. ICRP website at: <http://www.icrp.org/index.asp>
8. See Cooper (2012) for a summary of current radiation protection principles. Chapter 8 of ICRP 103 describes protection of the environment.
 - a. ICRP 103 (2007), IAEA (2014). Countries within the European Union are currently working to enact the Basic Safety Standards in BSS 2013/59/Euratom Euratom (2013), work which they are obliged to complete by February 2018. The most recent and only change to the 2007 ICRP recommendations is the Statement on Tissue Reactions, specifically the reduced dose limits to the eye lens Stewart *et al.* (2012).
 - b. UNSCEAR (2008), BEIR VII (2006). Figure 3.1 in Clarke and Valentin (2009) represents the basis for and use of ICRP

recommendations in a flow chart. Some of the proponents of alternative theories about the dangers (or otherwise) of radiation do not view reports by these international bodies as authoritative and instead view them as representing an establishment position that attempts to argue 'from authority'. However, these reports are widely recognised as representing the views of the majority working in the field.

9.
 - a. UNSCEAR (2008). Table 8, pages 116-117 of ICRP 103 (2007) summarises the current recommendations for radiological protection in planned, emergency and existing situations.
 - b. See Oatway *et al.* (2016) for UK radiation exposures.
 - c. ICRP 103 (2007) Paragraph 2.2, page 42 and Paragraph 5.6, page 88.
 - d. ICRP 103 (2007) Paragraph 5.7, page 89.
 - e. ICRP 103 (2007) Paragraph 5.8, page 91, Mobbs *et al.* (2011). For an example of an optimization procedure in the context of management of occupational exposure, see Figure 1 in IAEA (2002).
 - f. For example, the average annual dose to occupationally exposed workers in the UK is 0.0004 mSv Oatway *et al.* (2016). For sources that arise from the disposal of radioactive waste the recommended effective dose constraint for public exposure is 0.3 mSv/yr and for prolonged exposure from long-lived radionuclides, if dose assessment is problematic, the recommended dose constraint is <0.1 mSv/yr. A radionuclide is a particular version of an atomic nucleus characterised by its number of protons and neutrons and their arrangement within the nucleus. For example iodine-131 (¹³¹I) is the radionuclide of iodine with 53 protons and 78 neutrons, whereas the nucleus of technetium-99m has 43 protons and 56 neutrons in a metastable state.
 - g. Lecomte *et al.* (2014) refers to an upper reference level of 300 Bq/m³ for radon-222 corresponding to about 4.5 mSv/y in workplaces and 15.8 mSv/y in homes. Radon-related risk in the home is determined by a person's smoking status as well as indoor radon concentration Gray *et al.* (2009). The phrase "according to the situation" is a quote from Table 8 ICRP 103 which refers to the judgement required when levels of radiation are abnormally high.
 - h. Chapter 7 of ICRP 103 (2007) describes the system of recommendations for medical exposures. See also Wrixon (2008).
10. Brenner (2010), Muller (2015), Auvinen *et al.* (2015).
11. Morgan and Bair (2013), Niles (2014), Pearce (2015). Annex IV of UNSCEAR (2008) and the WHO (2006) Chernobyl Forum report both document the large health impact of the Chernobyl accident because of fears about radiation.
12. Authors' summary.

DEFINITIONS AND UNITS

Table 6. List of abbreviations.

Organizations	
BEIR	Biological Effects of Ionizing Radiation
CERRIE	Committee Examining Radiation Risks of Internal Emitters
COMARE	Committee on Medical Aspects of Radiation in the Environment
IAEA	International Atomic Energy Agency
ICRP	International Commission on Radiological Protection
ICRU	International Commission on Radiation Units and Measurements
RERF	Radiation Effects Research Foundation
UN	United Nations
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
WHO	World Health Organization
Units	
Bq	becquerel
Gy	gray
PM	Particulate Matter
Sv	sievert
WLM	Working Level Month
Cohorts/Studies	
ECLIS	European Childhood Leukaemia-Lymphoma Study
KiKK	Kinderkrebs in der Umgebung von Kernkraftwerken
LSS	Life Span Study
OSCC	Oxford Survey of Childhood Cancers
Other Acronyms	
ALL	Acute lymphocytic leukaemia
CI	Confidence interval
CLL	Chronic lymphocytic leukaemia
CT	Computed tomography
DDREF	Dose and dose-rate effectiveness factor
DNA	Deoxyribonucleic acid
DSB	Double strand break
EAR	Excess absolute risk
ERR	Excess relative risk
HR	Hazard ratio
LD	Lethal dose
LET	Linear energy transfer
LNT	Linear no threshold
NIC	Not in city
NPP	Nuclear power plant
OR	Odds ratio
RBE	Relative biological effectiveness
RR	Relative risk
SI	System Internationale d’Unites or international system of units
SIR	Standardized incidence ratio
SMR	Standardized mortality ratio
SRR	Standardized rate ratio (or standardized registration ratio)
UV	Ultra violet

13. Chapter 4 in ICRP 103 (2007) is devoted to explanations and definitions of doses, exposures and the associated uncertainties. The International Commission on Radiation Units and Measurements (ICRU) issues periodic reports, in particular see ICRU (2011).
14. Chapter 1 in Mettler and Upton (2008) covers basic radiation physics, chemistry and biology and Chapter 2 covers sources of exposure. CERRIE (2004) reviewed data on radiation risks of internal emitters as does COMARE (2004). Tables 2 and 3 in ICRP 103 (2007) document radiation weighting factors and tissue weighting factors. There are no universally agreed definitions of low dose or low dose-rate. Tables 6 and 7 in UNSCEAR (2006a) summarize definitions that have been used for low dose and low dose-rate respectively. Ruhm *et al.* (2016) summarise recent evidence and debate on the impact of dose-rate upon the health effects of radiation.
15. BIPM (Bureau International des Poids et Mesures) pages defining SI units for ionizing radiation are at: <http://www.bipm.org/en/measurement-units/history-si/radioactivity/>. Tables 2 and 3 in ICRP 103 (2007) document radiation weighting factors and tissue weighting factors.
16. Streffer *et al.* (2003). The recommended ICRP limits to prevent deterministic effects are set in equivalent dose, although strictly these should be set in absorbed dose.
17. The relationship between activity (Bq) and the resulting dose (Sv) depends on multiple factors including the nature and energy of the decay, and the location of the radioactive material with regards to the receptor. See Marsh *et al.* (2010), Tirmarche *et al.* (2010), Harrison and Marsh (2012), Muller *et al.* (2016).
18.
 - a. Tissue reactions are discussed more fully under the section “Acute high dose exposures”, paragraphs 26-31.
 - b. Stochastic effects are discussed more fully under the section “Lower dose exposures”, paragraphs 32-40.
 - c. Brenner *et al.* (2003), Doss (2013).
 - d. The matched pair of review articles by Little *et al.* (2009) and Tubiana *et al.* (2009) presents the arguments for and against LNT. Also see paragraph 24.
 - e. Stewart *et al.* (2012) is the ICRP document reviewing both circulatory disease and diseases of the eye after radiation exposure. Little *et al.* (2008b), Little *et al.* (2012), Little (2013) review the literature on the risks of non-cancer disease and radiation. Kitahara *et al.* (2015) summarise data on low dose radiation and circulatory disease or cataracts published after 2006. Darby *et al.* (2013) found a linear dose-response relationship between radiation-related risks and major coronary events, suggesting that the LNT concept may be relevant to some forms of circulatory disease, although this was a study of high doses received during radiotherapy.

Table 7. Major types of ionizing radiation and their properties.

Radiation type	Wave or particle type	Radiation weighting factor, w_R	Effective Shielding	High/Low Linear Energy Transfer	Common source
X rays	Electromagnetic wave	1	Lead plate	Low	Diagnostic x rays
Gamma rays	Electromagnetic wave	1	Lead plate	Low	Terrestrial radionuclides and building materials
Beta particles	Emitted electron or positron	1	Aluminium plate	Low	Strontium-90 in radiotherapy
Neutrons	Emitted neutron	5-20	Metres of water or concrete	High	Neutron component of cosmic radiation
Alpha particles	2 protons + 2 neutrons	20	Sheet of paper	High	Radon

19. See UNSCEAR (2006a) pages 32-33 on human genetic susceptibility. Susceptibility and the development of biomarkers to identify radio-sensitive cancer patients is discussed in Manning and Rothkamm (2013).
 - a. Whilst the excess relative risk of cancer is higher for exposures in childhood than for those in adulthood, the difference in excess absolute risk is not as marked (see paragraph 37b). Ozasa *et al.* (2012) document the impact of age at exposure on solid cancer mortality risk in Japanese atomic bomb survivors; Hsu *et al.* (2013) do the same for leukaemia.
 - b. BEIR VII (2006) reviews data on genetic susceptibility to radiation-induced cancer noting unambiguous evidence of radio-sensitivity for two human genetic disorders: ataxia-telangiectasia Easton (1994) and Nijmegen breakage syndrome Zhao *et al.* (2000).
 - c. See Sigurdson and Stram (2012) on potential implications for risk assessment.
 - d. Darby *et al.* (2005), Pierce *et al.* (2003), Furukawa *et al.* (2010).
20. Authors' summary.

BACKGROUND EXPOSURE AND UNCERTAINTIES AT LOW DOSE

21. Oatway *et al.* (2016) review radiation exposure of the UK population based on data for 2010. Their Table 1 breaks exposure down for UK doses by source. UNSCEAR (2008) gives global averages. See NCRP (2009) for US exposures. Reference levels for exposures in emergencies would be much greater than background levels. The limits for planned situations are predicated on what might be acceptable or tolerable levels of risk for on-going continuous exposures from operations involving the use of radiation – for instance in the nuclear power industry or in hospitals.
22. For radon measurements at fine scales see Chen and Ford (2016). Hughes *et al.* (2005) report that some homes in the UK give rise to individual annual effective doses exceeding 100 mSv from radon, and a house with a very high radon level giving an annual effective dose to the occupants of 1.2 Sv has been reported from Ireland Organo *et al.* (2004). Construction differences such as sealed double glazing and closed cycle heating have an impact on radon levels via pressure differences UNSCEAR (2006b). Bossew *et al.* (2015) report on the European atlas of natural radiation. The map of indoor radon concentration, which covers 25 countries, is the most advanced component of that project Tollefsen *et al.* (2014), Hoffmann *et al.* (2016). Maps of geogenic radon potential, secondary cosmic radiation, terrestrial gamma radiation and concentration of the elements U, Th and K are also under construction.
23. Figure 2 refers to data from large studies of excess relative risk at different radiation doses. In this figure, relative risk (RR), odds ratios (OR) and standardised rate ratios (SRR) have been approximated to excess relative risk (ERR), under the assumption that the populations are homogenous and that the probabilities of the underlying diseases are small. Figure 2a describes excess relative risks of solid cancers. The **Japanese Life Span Study (LSS)** cohort are Japanese atomic bomb survivors Ozasa *et al.* (2012). The **international workers** cohort is a very large pooled study of radiation workers (INWORKS), most of whom are employed in the nuclear industry, from the UK, US, and France Richardson *et al.* (2015). Kashcheev *et al.* (2015) describe risks in **Chernobyl workers** who cleaned up after the accident. **Mayak workers** at the eponymous nuclear plant were subject to prolonged low

dose-rate external gamma radiation and plutonium exposure Sokolnikov *et al.* (2015), as were nearby **Techa River residents** due to discharges of radioactive waste Davis *et al.* (2015).

Yangjiang is an area of high natural background radiation in China Tao *et al.* (2012) and **Kerala** is an area of high natural background radiation in India Nair *et al.* (2009). **Ankylosing spondylitis** patients in the UK were historically treated with X-rays in the mid-20th century Weiss *et al.* (1994).

Figure 2b describes excess relative risks of leukaemia for the **Japanese Life Span Study (LSS)** Hsu *et al.* (2013), **international workers** in the INWORKS nuclear worker cohort Leuraud *et al.* (2015), **Chernobyl clean-up workers** Zablotska *et al.* (2013) as well as a different cohort of **Chernobyl liquidators** Kesminiene *et al.* (2008), **Mayak workers** Kuznetsova *et al.* (2016), **Techa River residents** Krestinina *et al.* (2013b), residents receiving exposure from **Kerala** background radiation in India Nair *et al.* (2009) and patients with **ankylosing spondylitis** in the UK Weiss *et al.* (1995). For the purposes of representation and as the studies pertain almost entirely to low-LET radiation, Sv and Gy are assumed to be equivalent in Figures 2a and 2b. For the purposes of representation, ERRs for cancer incidence and mortality are also plotted on the same axis. In reality, the relationship between cancer incidence and mortality will depend on the ability and availability of diagnostics and therapies to improve survivorship. See Coleman *et al.* (1993).

Figure 2c describes excess relative risks of lung cancer for underground miners Lubin *et al.* (1995), Villeneuve *et al.* (2007), Schubauer-Berigan *et al.* (2009), Lane *et al.* (2010), Tomasek (2012), Kreuzer *et al.* (2015a) or after exposure to residential radon in Europe Darby *et al.* (2005), China Lubin *et al.* (2004) and North America Krewski *et al.* (2006).

For underground miners, risks are expressed relative to cumulative radon exposures given in WLM, and for domestic exposures to radon, risks are expressed relative to concentrations in Bq/m³.

These diverse studies include individuals who have been exposed at greatly varying dose-rates – some briefly, others very slowly. Ruhm *et al.* (2016) summarise recent evidence and debate on the impact of dose-rate upon the health effects of radiation, although a distinction needs to be made between low-LET and high-LET radiation.

Table 8 contains further detail about the data in this figure.

Table 8. Components of Figure 2.

	Cohort	Reference	Reference	Endpoint	Confidence Intervals	Y-Axis	X-Axis
Figure 2a	Japanese life span study (LSS)	Ozasa <i>et al.</i> (2012)	Figure 4	solid cancer mortality	95%	ERR	weighted colon dose, Gy
	International workers (INWORKS)	Richardson <i>et al.</i> (2015)	Figure 1	all cancer mortality other than leukaemia	90%	RR*	cumulative colon dose, Gy
	Chernobyl workers	Kashcheev <i>et al.</i> (2015)	Figure 6	solid cancer mortality	95%	RR*	dose, Gy
	Mayak workers	Sokolnikov <i>et al.</i> (2015)	Figure 2	solid cancer mortality ex bone, lung and liver	95%	ERR	colon dose, Gy
	Techa River residents	Davis <i>et al.</i> (2015)	Figure 1	solid cancer incidence	none	ERR	cumulative dose, Gy
	Kerala background radiation	Nair <i>et al.</i> (2009)	Table 4	all cancer incidence other than leukaemia	95%	RR*	cumulative radiation dose, Gy
	Yangjiang background radiation	Tao <i>et al.</i> (2012)	Table 2	all cancer mortality excluding leukaemia	95%	RR*	cumulative individual dose (range midpoint), mGy
	Ankylosing spondylitis patients	Weiss <i>et al.</i> (1994)	Figure 2	all neoplasms mortality except leukaemia	95%	RR*	total body dose, Gy
Figure 2b	Japanese life span study (LSS)	Hsu <i>et al.</i> (2013)	Figure 1b	leukaemia incidence ex CLL & ALL	none	ERR	weighted red bone marrow dose, Gy
	International workers (INWORKS)	Leuraud <i>et al.</i> (2015)	Table A2	leukaemia mortality excluding CLL	90%	RR*	dose, Gy
	Chernobyl workers (Ukraine)	Zablotska <i>et al.</i> (2013)	Figure 1	leukaemia incidence excluding CLL	95%	RR*	bone marrow dose, Gy
	Chernobyl liquidators (Belarus, Russia & Baltic countries)	Kesminiene <i>et al.</i> (2008)	Figure 1	leukaemia incidence excluding CLL	95%	OR	total red bone marrow dose, Gy
	Mayak workers	Kuznetsova <i>et al.</i> (2016)	Table 3	leukaemia incidence excluding CLL	None	RR	external dose to bone marrow, Gy (range midpoint)
	Techa River residents	Krestinina <i>et al.</i> (2013b)	Figure 1	leukaemia incidence excluding CLL	none	ERR	red bone marrow dose, Gy
	Kerala background radiation	Nair <i>et al.</i> (2009)	Table 6	leukaemia incidence	95%	RR*	cumulative radiation dose, Gy
	Ankylosing spondylitis patients	Weiss <i>et al.</i> (1995)	Table IV Figure 1	leukaemia mortality excluding CLL	95%	RR*	total marrow dose, Gy
Figure 2c	Canadian uranium workers	Lane <i>et al.</i> (2010)	Figure 1	lung cancer mortality	95%	RR*	WLM
	Uranium & tin miners	Lubin <i>et al.</i> (1995)	Figure 1a	lung cancer mortality	95%	RR*	cumulative WLM
	German uranium miners	Kreuzer <i>et al.</i> (2015a)	Figure 1a	lung cancer mortality	95%	RR*	cumulative WLM
	Colorado uranium miners	Schubauer-Berigan <i>et al.</i> (2009)	Table 4	lung cancer mortality	95%	SRR*	cumulative WLM (range midpoint)
	Czech uranium miners	Tomasek (2012)	Figure 1	lung cancer mortality	90%	O/E*	cumulative WLM
	Newfoundland fluorspar miners	Villeneuve <i>et al.</i> (2007)	Table 4	lung cancer mortality	95%	RR*	cumulative WLM
Figure 2c	China residential	Lubin <i>et al.</i> (2004)	Table 3	lung cancer incidence	95%	OR*	Radon concentration (range midpoint) Bq/m3
	North America residential	Krewski <i>et al.</i> (2006)	Figure 1A	lung cancer incidence	95%	OR*	Radon concentration Bq/m3
	Europe residential	Darby <i>et al.</i> (2006)	Figure 7	lung cancer incidence	95%	RR*	radon concentration Bq/m3 (corrected for random variation)

*converted to ERR by the approximations RR=SRR=OR=ERR+1

24. Figure 3 is adapted from Brenner *et al.* (2003) who review the biophysical processes that could generate the different curves. Valentin (2005) is a comprehensive review of radiation-related cancer risk extrapolation at low dose. The matched pair of review articles by Little *et al.* (2009) and Tubiana *et al.* (2009) present the arguments for and against LNT. There are many different experimental systems and different endpoints for modelling radiation carcinogenesis. Within one system, experiments are often replicable but they do not give a common answer to describe the shape of the dose response curve at very low dose.
- Little *et al.* (2009) argue that LNT is "... (almost) the best we can do". Shah *et al.* (2012) argue that LNT is "prudent" as the basis for radiation protection policy. Calabrese and O'Connor (2014) give a critical history of the development and adoption of the LNT model.
 - The BEIR VII (2006) report used a Bayesian analysis that combined epidemiological and experimental data and settled on an estimate of DDREF = 1.5. Page 53 of ICRP 103 (2007) uses DDREF = 2. DDREF combines considerations of total dose and rate of delivery. Sometimes those are given separate consideration as: LDEF (low-dose effectiveness factor); and DREF (dose-rate effectiveness factor) Ruhm *et al.* (2016). Ruhm *et al.* (2015) summarises the development of the DDREF concept and the current findings of the active ICRP Task Group 91 in assessing its applicability. See our paragraph 122.
 - Figure 5 in Brenner *et al.* (2003) illustrates how a very small, highly radiosensitive population could generate a downwardly curving dose-effect relationship. To date, most studies do not support a dose response curve of this shape. Other hypothetical mechanisms could also lead to such an expectation, for example bystander effects or low-level radiation-induced instability discussed at paragraph 107.
 - Cornforth *et al.* (2002a) and Sachs *et al.* (1997) model the formation of chromosome aberrations. In their models it is interaction between points of damage from separate radiation tracks that brings in the upward curvature of the dose response. In Cucinotta *et al.* (2000) it is competition between repair pathways that brings in the curvature. Other biophysical mechanism/models are reviewed in Bodgi *et al.* (2016).
 - Tubiana (2005) summarises the conclusions of a joint report by the French Academie des Sciences and the Academie Nationale de Medecine which argues for the existence of threshold doses below which risk is negligible or zero. See Fritz (2002) for a study on dogs examining chronic whole-of-life effects which has similar conclusions.
 - Vaiserman (2010) gives a historical review of arguments in favour of radiation hormesis. Feinendegen (2005) presents a mechanistic argument for radiation hormesis, in particular his Figure 3 presents the argument that whilst the induction of DNA damage is expected to be linear in dose, protective responses against such damage are so strongly stimulated at low dose that there is a net hormetic effect. Luckey (2011) hypothesises that the optimal dose is 100 mGy/yr with a threshold at 10 Gy/yr separating beneficial from harmful effects. Sacks *et al.* (2016) argue that epidemiological studies based on linear assumptions are invalid because of hormesis, although it is usual in such studies to test for the appropriateness of a linear fit to the data.
25. Authors' summary.

ACUTE HIGH DOSE EXPOSURES

- The Office of Science of the US Department of Energy has produced a chart summarizing the health effects of radiation at doses at different orders of magnitude.
<https://www.nrc.gov/docs/ML1209/ML120970113.pdf>
- ICRP 103 (2007) (Table A.3.3 page 167) lists cause of mortality at different dose thresholds. See also Edwards and Lloyd (1998) Table 1 which gives threshold doses for different tissue syndromes leading to mortality. Mettler and Upton (2008) Chapter 6 reviews tissue reactions across a range of tissues and doses. See Donnelly *et al.* (2010) on medical aspects of acute radiation syndrome.
- ICRP 103 (2007) (Tables A.3.4. and A.3.3 pages 167-8) and Stewart *et al.* (2012) (Table 2.4, page 298) list thresholds for 1% incidence of morbidity and mortality involving various tissues. Edwards and Lloyd (1998) and Mettler and Upton (2008) as above. Several of the morbidity early effects in Table 1 are primarily of concern in partial body irradiation, for instance erythema (skin) and permanent sterility (gonads). Radiation effects upon cataracts and circulatory disease do not fall neatly into either tissue reaction or stochastic effects.
- Streffer *et al.* (2003). Chapter 8 in Mettler and Upton (2008) gives a detailed review of tissue reactions of *in utero* exposure to radiation. Otake and Schull (1998) review radiation-related brain damage and growth retardation amongst prenatally exposed survivors.
- Otake *et al.* (1990) describe studies of untoward pregnancy outcome (defined as stillbirth, major malformation or death within 14 days) amongst >65,000 offspring of atomic bomb survivors finding a positive association with joint parental dose, but the regression slope was not statistically significant. Fujiwara *et al.* (2008) found no evidence of an increased prevalence of adult-onset multi-factorial disease amongst 11,951 adult offspring (median age 50 years) of atomic bomb survivors. Odds ratios at a paternal or maternal dose of 1 Gy were 0.91 (0.81 – 1.01) and 0.98 (0.86 – 1.10) respectively. Neel and Schull (1991) is a book-length collection of essays on the children of atomic bomb survivors. Nakamura (2006) reviews more recent studies of the same children. Neel *et al.* (1990) summarise 40 years' effort to quantify the genetic effects of the atomic bombs with the words "no statistically significant findings have emerged". The most recent report of mortality amongst 75,000 offspring, after 62 years of follow-up, showed no excess of either cancer or noncancer mortality in relation to either paternal or maternal radiation dose Grant *et al.* (2015). See Searle (1974) and Nakamura *et al.* (2013) for animal studies.
- Authors' summary.

LOWER DOSE EXPOSURES

- Preston *et al.* (2003), Ozasa *et al.* (2012) Grant *et al.* (2017).
- Preston *et al.* (2003), Shimizu *et al.* (2010), Little *et al.* (2012), Ozasa *et al.* (2012), Ozasa *et al.* (2016), Baselet *et al.* (2016), Little (2016), Ozasa *et al.* (2017), Shore (2016a).
- Brenner *et al.* (2003), National Research Council (1995). New approaches in genomics and epigenetics offer promising advances in the ability to distinguish radiation induced cancers Behjati *et al.* (2016).
- Shore (2009).
- Land (1980). UNSCEAR 2006 Annex A Paragraph 16 discusses the problems of inadequately powered studies generating results which can overstate true risk despite being statistically significant. Pooled analyses and meta-analyses can sometimes

combine data from several smaller studies to create one well-powered study. Studies of radon in the home Lubin *et al.* (2004), Darby *et al.* (2006), Krewski *et al.* (2006) and of nuclear fuel cycle workers Leuraud *et al.* (2015), Richardson *et al.* (2015) have exploited this strategy.

37. The glossary in ICRP 103 (2007) defines ERR and EAR. Siström and Garvan (2004) explains relative risk (RR) and odds ratios (OR). Hernán (2010) discusses hazard ratios (HR). The standardized incidence ratio (SIR) is explained in Breslow (1987) and the standardized mortality ratio (SMR) in Everitt and Skrondal (2010). Schubauer-Berigan *et al.* (2009) describes the calculation of the standardized rate ratio (SRR).
38. Public Health England – guidance publication <https://www.gov.uk/government/publications/ionising-radiation-dose-comparisons/ionising-radiation-dose-comparisons>
39. Brenner *et al.* (2003), Little (2003), Wakeford (2004), Mullenders *et al.* (2009), Mobbs *et al.* (2011), Preston *et al.* (2013), Shore (2014), Kitahara *et al.* (2015), Mattsson and Nilsson (2015).
40. Authors’ summary.

THE JAPANESE LIFESPAN STUDY (LSS)

Table 9. RERF reports on cancer mortality in LSS subjects

RERF report	12	13	14
Author	Pierce <i>et al.</i> (1996)	Preston <i>et al.</i> (2003)	Ozasa <i>et al.</i> (2012)
Time period	1950-1990	1950-1997	1950-2003
Solid cancer deaths	7,578	9,335	10,929
ERR/Gy solid cancer			
95% confidence intervals	0.29	0.37	0.47
	0.23 to 0.35	0.26 to 0.49	0.38 to 0.56

41. The Radiation Effects Research Foundation website www.rerf.jp describes the LSS and lists publications based upon the cohort. Key papers describing solid cancer mortality in the LSS are in Table 9. After the bombs were detonated 60-80,000 people were killed instantly in Hiroshima and another 90-166,000 died in the ensuing 4 months. In Nagasaki there were 22-75,000 instant fatalities and another 60-80,000 deaths in the ensuing months. The LD₅₀ dose (at which 50% of the exposed population died) occurred at a radius of 1-1.3km of each blast and later dose reconstruction yielded a bone marrow dose estimate for the LD₅₀ of 2.9-3.3 Gy Pierce *et al.* (1996), Preston *et al.* (2003), Wakeford (2004). The key message from the LSS papers is that risk of cancer mortality for people exposed on the day remains elevated 60 years on. The ERR is approximately linear with dose, persistently higher for those who were younger at exposure and approximately doubled for women Ozasa *et al.* (2012). The Ozasa report indicated that by 2003 about 525 radiation-associated excess solid cancer deaths had occurred in the LSS cohort. A detailed presentation of cancer incidence by tumour site is provided in Preston *et al.* (2007), and an up to date report of solid cancer incidence including sex-specific analyses and the joint effects of smoking is Grant *et al.* (2017).
42. Stewart and Kneale (2000), Little and Charles (1990), Little (2002b), Tubiana *et al.* (2009). If there were a healthy survivor effect, LSS ERRs would be underestimates of the true values.
43. www.rerf.jp gives further details on cohort structure. The 55,000 individuals situated within 2.5 km of the blast were exposed to levels of radiation of 5 mGy or higher with a mean dose of 200 mGy. The 38,500 people 2.5-10 km from the blast received doses below 5 mGy. The 26,500 people not in the city were unexposed residents of Hiroshima or Nagasaki who were not in either city

(‘NIC’) at the time of the bombings. 85% of the cohort experienced irradiation below the mean level of 200 mGy. Dose distribution of the cohort is given in Table 1 of Ozasa *et al.* (2012).

Table 10. Dose distribution amongst the LSS.

Weighted Colon Dose (Gy)	# Subjects	%
Not in City	26,500	22%
<0.005	38,500	32%
0.005-0.1	30,000	25%
0.1-0.2	6,000	5%
0.2-0.5	6,400	5%
0.5-1	3,400	3%
1-2	1,700	1.5%
>2	600	0.5%
Unknown dose	7,000	6%
TOTAL	120,000	

Concerns have been raised that internal or short-range external exposure from contaminated rainfall over the cities and surrounding areas following the atomic bombings distorts the dose distribution measurements in the LSS Takada *et al.* (1983), Sawada (2007). While data are limited, systematic analyses have failed to find deleterious health effects from rain exposure Sakata *et al.* (2014).

44. Up to date cause of death data is in Ozasa *et al.* (2012). The breakdown of excess deaths attributable to radiation is: ~500 from solid cancer, ~ 100 from leukaemia, and ~400 from non-cancer disease. See Ozasa’s Table 9. Detailed analysis of leukaemia mortality is in Richardson *et al.* (2009) and incidence in Hsu *et al.* (2013). The not in city group has been included in some analyses, for instance Sugiyama *et al.* (2014).
45. For a list of Adult Health Study report titles, see http://www.rerf.jp/library/archives_e/ahstitle.html. On cardiovascular disease see Ozasa *et al.* (2017). Also see Shimizu *et al.* (2010) on circulatory disease and Yamada *et al.* (2004) on non-cancer disease.
46. Figure 1 in Ozasa *et al.* (2012) contains ERR per gray estimates for all specific causes of death in the latest LSS analysis. Also see Tables 2a and 2b in Furukawa *et al.* (2010). Hsu *et al.* (2013) report recent data on leukaemia incidence.
47. Ozasa *et al.* (2012).
48. Minamoto *et al.* (2004), Neriishi *et al.* (2007), Shore *et al.* (2010), Little (2013), Nakashima *et al.* (2006) .
49. The ERR/Sv for solid cancer incidence is 1.0 (95% CI: 0.2 to 2.3) for *in utero* exposure. The EAR did not increase with time/age as it did for an equivalent cohort exposed in early childhood, suggesting that lifetime risks following *in utero* exposure may be lower than for early childhood exposure Ohtaki *et al.* (2004), Preston *et al.* (2008). During the first 15 years of life for the *in utero* cohort 1 death and 2 cases of solid cancers were recorded, but no leukaemias Delongchamp *et al.* (1997) Jablon and Kato (1970). A surprising absence of stable chromosome aberrations among intrauterine exposed survivors who had received moderate and high doses (>100 mGy) contrasted with findings for mothers, and suggests high sensitivity of the haematopoietic system *in utero* to cell killing. This may be a reason for the absence of childhood leukaemia in this group. See Ohtaki *et al.* (2004).
50. Schull and Otake (1999), Otake and Schull (1998).

51. Jablon and Kato (1970), Delongchamp *et al.* (1997). The study of children of survivors is known as the F1 cohort. Little *et al.* (1994), Neel and Schull (1991), Nakamura (2006), Otake *et al.* (1990), Tatsukawa *et al.* (2013), Fujiwara *et al.* (2008), Neel *et al.* (1990), Kodaira *et al.* (2004), Kodaira *et al.* (2010), Izumi *et al.* (2003), Satoh *et al.* (1996), Grant *et al.* (2015). For a recent review see Little *et al.* (2013). For further discussion of genetic effects, see UNSCEAR (2010) Section B, ICRP 103 (2007) Annex A and BEIR VII (2006).
52. Authors' summary. The excess relative risk quoted here is different from the nominal cancer risk coefficient of 5.5% per Sv derived by the ICRP and used in optimization calculations. The ERR of 0.47 per gray for solid cancer is an estimate of the amount by which the underlying risk of solid cancer is increased proportionally for each gray of exposure. The ICRP's "nominal risk coefficient" of 5.5% per Sv is an estimate of the health detriment due to cancer experienced in a population exposed to low level radiation; it includes attributable fatal and non-fatal cancer, years of life lost and pain and suffering.
- THE CHERNOBYL NUCLEAR POWER PLANT ACCIDENT**
53. UNSCEAR (2008)'s Table 1 page 49 describes the accident and documents the principal radionuclides released. The radioactive release from Chernobyl lasted around 10 days, and two radionuclides, the short-lived iodine-131 and the long-lived caesium-137, were particularly significant. The radioactive plume spread over much of the western USSR and Europe. Maps are in Figures I and II in UNSCEAR (2008) and at <http://www.unscear.org/unscear/en/chernobylmaps.html>.
54. Data from Table 11 is from UNSCEAR (2008) Table 2, page 54. Extensive further details of radiation doses are presented in their Appendix B.
55. Local populations continued to drink milk that had been contaminated with radioactive iodine when cows grazed on contaminated pastures WHO (2006).
56. As of 2016 the most recently published summary figures are in UNSCEAR (2008). A recent update is at http://www.who.int/ionizing_radiation/chernobyl/Chernobyl-update.pdf?ua=1. Table D7 page 189 in UNSCEAR (2008) lists the causes of death of the 19 Chernobyl ARS survivors who died between 1993 and 2004. Of these 19 deaths only the 5 from malignancy are likely to be related to radiation. Literature on childhood thyroid cancer post-Chernobyl is discussed below.
57. The figure of 6,000 cases is given in Volume II, Annex D of UNSCEAR (2008) where Paragraphs 66-73 summarise childhood thyroid cancer as a confirmed effect of Chernobyl radiation exposure. Cardis and Hatch (2011) is a more recent review of published work. See also Cardis *et al.* (2006a), Boice (2005), Zablotska *et al.* (2011), Tronko *et al.* (2006) and Brenner *et al.* (2011). Ivanov *et al.* (2012) report that ERR/Gy is decreasing with time since exposure in a Russian cohort exposed as children.
- Suzuki and Yamashita (2012) summarises the debate about low dose risk of thyroid cancer, concluding that a statistically significant increase has hardly been described with radiation doses below 100 mSv. A recent pooled analysis of 12 studies of thyroid cancer after childhood exposure to external radiation found a significant increase in RR for doses <0.10 Gy with no significant departure from linearity Veiga *et al.* (2016).
58. Zablotska *et al.* (2013) give the ERR of 1.26. See also Kesminiene *et al.* (2008) and Romanenko *et al.* (2008). Paragraphs D173-D179 in UNSCEAR (2008) summarise a large number of studies of leukaemia in emergency and recovery workers at Chernobyl. Reports of chronic lymphocytic leukaemia in Chernobyl liquidators Zablotska *et al.* (2013) and Kesminiene *et al.* (2008) showed positive non-significant increases in risk. A significant dose response was seen in the LSS cohort based on a simple trend test on 12 eligible cases of CLL, 4 of which occurred among survivors with doses in excess of 0.2 Gy Hsu *et al.* (2013). A significantly increased risk of the incidence of CLL was observed in uranium miners Rericha *et al.* (2006). However, no evidence for an increase in CLL risk has been seen in several other major studies Krestinina *et al.* (2013b), Leuraud *et al.* (2015), Kuznetsova *et al.* (2016). For a review of the open questions surrounding the radiogenicity of chronic lymphocytic leukaemia see Hamblin (2008) and Richardson *et al.* (2005).
59. Parkin *et al.* (1996) describe the largest and most comprehensive study to date, the European Childhood Leukaemia-Lymphoma Study (ECLIS), in particular their Figure 3, page 92, shows the lack of a dose-response relationship between leukaemia incidence and radiation dose. Davis *et al.* (2006) and Noshchenko *et al.* (2002) describe studies showing mixed results regarding leukaemia incidence amongst exposed children in the Ukraine which are criticised regarding selection bias in WHO (2006). Noshchenko *et al.* (2010) found an increase in leukaemia among Ukrainian children exposed at ages 0-5 to more than 10 mSv, but less than that reported by Noshchenko *et al.* (2002), and there are questions about possible biases in control selection UNSCEAR (2013b). Paragraphs D169-D172 in UNSCEAR (2008) review other peer-reviewed publications. Petridou *et al.* (1996) describe a low-powered study that suggested *in utero* radiation exposure from Chernobyl increased risk of infant leukaemia in Greece. Similar studies in Germany were unable to replicate the Greek results Steiner *et al.* (1998). The UK Committees COMARE and CERRIE concluded that there is insufficient evidence to support hypotheses of increased childhood leukaemia in European countries linked to Chernobyl CERRIE (2004) pages 67-68, COMARE (2004). Two members of the CERRIE committee criticized this conclusion of the majority and recorded in the report their belief that the current risk estimates are appreciably in error. Peer-reviewed scientific analyses of this argument have not lent support to this critique. For a review of the debate around risks of internal emitters subsequent to the publication of the ICRP 2007 recommendations, see Harrison and Day (2008).

Table 11. Dose distribution from the Chernobyl accident.

Population	Number	Average effective dose (mSv) from external and internal radiation* 1986 - 2005	Average thyroid dose (mGy) 1986
Recovery operation workers	530,000	117.0	- [‡]
Evacuees	115,000	31.0	490.0
Residents of contaminated areas (>37kBq m ⁻²)	6,400,000	9.0	102.0
Residents of Belarus, Russian Fed and Ukraine	98,000,000	1.3	16.0
Other European Residents	500,000,000	0.3	1.3

*Excluding thyroid dose

[‡]Data unavailable

60. Reviewed in Cardis and Hatch (2011) and UNSCEAR (2000a) Paragraphs D182 – D199. Ivanov *et al.* (2004), Rahu *et al.* (2006b), Ivanov *et al.* (2008), Rahu *et al.* (2013a), Rahu *et al.* (2013b) all study recovery workers and find non-significant dose-responses. Kashcheev *et al.* (2015) report the ERR/Gy of 0.47 for incidence, but find the studied cohort has lower solid cancer mortality than controls – attributed either to monitoring or a healthy worker effect. It is notable that Kashcheev *et al.* have a longer follow-up than the other studies of solid cancers in highly exposed workers. Ivanov *et al.* (2004), Prysazhnyuk *et al.* (2007) and Table D19 in UNSCEAR (2008) describe solid cancer risks for exposed (non-worker) population groups.
61. Pukkala *et al.* (2006), Bogdanova *et al.* (2010), Dardynskaia *et al.* (2006).
62. Cotterill *et al.* (2001) and Tondel *et al.* (2004) are studies of cancer trends in Western and Northern Europe finding increases of cancer that are attributed to Chernobyl. Cardis *et al.* (2006b) refute these (in particular their Figure 5, page 1232) with temporal trends in cancer incidence grouped by average dose and age at diagnosis across Europe that found no measurable association between solid cancer trends and the Chernobyl accident. Alinaghizadeh *et al.* (2014) (with authorship including Tondel) similarly found no measurable effect from Swedish data. Yablokov and Nesterenko (2009) is a book of papers published in Russian and then republished (but not peer-reviewed) in the Annals of the New York Academy of Sciences which contains a number of low-quality analyses and uncorroborated statements that have been misleading for those attempting to gauge the evidence surrounding Chernobyl and radiation impacts. <http://www.nvas.org/Publications/Annals/Detail.aspx?cid=f3f3bd16-51ba-4d7b-a086-753f44b3bfc1> gives access to the explicit statement from the journal that the publication is not peer reviewed and links to negative reviews (Charles (2010), Balonov (2012) and Jargin (2010)).
63. Hatch *et al.* (2015), Ostroumova *et al.* (2016).
64. Zablotska *et al.* (2008), Ostroumova *et al.* (2009), Ostroumova *et al.* (2013), Zablotska *et al.* (2015).
65. Worgul *et al.* (2007) is the key cataract risk study which calculated an ERR/Gy of 0.4 (95% CI 0.01 to 2.00). Ivanov *et al.* (2006) and Kashcheev *et al.* (2016) report on cerebrovascular disease in Chernobyl emergency workers. Kashcheev *et al.* (2016) report an increased incidence risk for cerebrovascular diseases (ERR/Gy = 0.45, 95% CI: 0.28 to 0.62). While the Kashcheev study was large, observing over 61,000 workers between 1986 to 2012, it was not able to adjust for known risk factors like weight, smoking and alcohol consumption, and the proportion of workers reported to have been diagnosed with a cerebrovascular disease is surprisingly high (43%).
66. For an assessment concluding that there is no convincing evidence of increased risk of birth defects from exposure to radiation in contaminated areas see UNSCEAR (2001) part VI-A, section 3-4, page 57. See WHO (2006) for data showing that increases in birth defects between 1986 and 1999 in Belarus were not different between contaminated and uncontaminated areas. This WHO study was criticised by some groups for underestimating the impact of low-level radiation on health in general. Holt (2010) gives some perspective. Wertenlecker (2010) describes a study showing above average rates of birth defects in the Ukraine including neural tube defects (odds ratio 1.46 (95% CI: 1.13-1.93)) and microcephaly (odds ratio 2.8 (95% CI: 1.15-6.79)). This study lacked data about confounding risk factors such as maternal alcohol intake and diet. Weinberg *et al.* (2001) and Aghajanyan and Suskov (2009) describe genomic abnormalities in children born to exposed individuals. Bridges *et al.* (2013) discuss potential design flaws in these studies. A series of studies describe germline excess minisatellite mutations in a Belarusian population exposed to Chernobyl radiation Dubrova *et al.* (1996), Dubrova *et al.* (1997), Dubrova *et al.* (2002). This phenomenon has not been observed in offspring of Japanese bomb survivors Satoh *et al.* (1996), Asakawa *et al.* (2004), Kodaira *et al.* (2004), Kodaira *et al.* (2010), nor in other Chernobyl-exposed groups Livshits *et al.* (2001), Kiuru *et al.* (2003), Slebos *et al.* (2004), Furitsu *et al.* (2005), nor in Sellafield workers Tawn *et al.* (2015). Little (2015) discusses possible reasons for differences. Mughal *et al.* (2012) suggests that genomic instability in offspring may be triggered only by a dose in excess of a threshold, higher for chronic exposure than acute. The implication for expressed phenotype of increased frequencies of minisatellite mutations is not known Bouffler *et al.* (2006).
67. Cardis *et al.* (1996) give a calculation suggesting that the predicted lifetime excess of cancer and leukaemia deaths due to Chernobyl radiation is 4000 for liquidators, evacuees and residents of the strict control zones, and a further 5000 deaths for the most exposed persons in Belarus, Russia and Ukraine (about 1% of the total numbers of cancers expected in these populations). Cardis *et al.* (2006b) give further extrapolation to European countries and conclude that Chernobyl radiation may eventually be responsible for 16,000 cases of thyroid cancer (95% CI: 3,400 to 72,000) and 25,000 cases of other cancer (95% CI: 11,000 to 59,000). This accounts for around 0.01% of total cancers expected over the time period to 2025. Concerns have been expressed about the calculation of numbers of potential deaths from theoretical risk models (for instance Gonzalez *et al.* (2013)).
68. For reviews finding elevated levels of depression and post-traumatic stress disorder in first responders and clean-up workers, as well as poor quality of life measures amongst the general population, see Kinley (2006), WHO (2006), Bromet *et al.* (2011), Bromet (2012). Rahu *et al.* (2006a) finds an increased risk of suicide amongst 5000 Estonian clean-up workers. Havenaar *et al.* (1996), Havenaar *et al.* (1997) describe a study showing that exposed Belarusian residents had poorer mental health scores than controls. Adams *et al.* (2002), Adams *et al.* (2011) demonstrate the lasting nature of psychological impacts on evacuees in Kiev. There is no evidence of a dose response effect for psychological effects amongst evacuees or the general population. In one major study the key risk factors were the belief that one's health was affected by Chernobyl, and being diagnosed with a Chernobyl-related health problem Bromet and Havenaar (2007). A study on mental health of Ukrainian clean up workers found that high exposure level (roof workers) was associated with current somatic and post-traumatic stress disorder symptom severity Loganovsky *et al.* (2008).
69. Men *et al.* (2003).
70. Authors' summary.

THE FUKUSHIMA DAI-ICHI NUCLEAR ACCIDENT

71. A brief description of the accident is given in Hasegawa *et al.* (2015) and a longer one in part II (page 28) of UNSCEAR (2013a).
72. Table 2 of Hasegawa *et al.* (2015), summarised in Table 12 below.

Table 12. The distribution of effective radiation doses to workers in the emergency and recovery operations at the Fukushima Dai-ichi nuclear power plant.

Dose (mSv)	Number of Workers
<10	19,198
10-50	8,614
50-100	1,347
100-150	138
>150	35

73. Tanigawa and Chhem (2013).
74. Table 5 page 53 in UNSCEAR (2013a) and Table 3 in Nagataki and Takamura (2016) show estimated effective doses for the first year following the accident for members of the public. Tables 4.4-1 to 4.4-3 in IAEA (2015) present calculated additional lifetime risks for emergency workers. Section 4.4 to 5.3 in the same document describes modelled lifetime risks for members of the public.
75. Measured doses are summarised in Nagataki and Takamura (2016) and Tokonami *et al.* (2012). Table 6 page 57 in UNSCEAR (2013a) shows estimated effective doses to evacuees.
76. UNSCEAR (2013a).
77. Between October 2011 and March 2014 300,476 residents of Fukushima Prefecture aged 18 or under at the time of the accident were screened Suzuki (2016a). The sensitive ultrasound technique revealed 113 cancers or suspected cancers. This number was around 30-fold higher than would have been expected from cancer registry data. Tsuda *et al.* (2016b) attributed the findings to radiation exposure, but this conclusion was vigorously contested Jorgensen (2016), Korblein (2016), Sallmen *et al.* (2016), Shibata (2016), Suzuki (2016b), Takahashi *et al.* (2016), Takamura (2016), Tsuda *et al.* (2016a), Wakeford *et al.* (2016) on multiple grounds. Wakeford (2016) and Suzuki (2016a) enumerate the reasons why this is an incorrect interpretation. There is a well-documented precedent for this pattern in South Korea where the introduction of sensitive ultrasound thyroid screening caused over-diagnosis of thyroid cancer Ahn *et al.* (2014), Ahn and Welch (2015), Williams (2015). A smaller but more directly applicable study of three unexposed Japanese prefectures, which found similar results to those observed iCardis *et al.* (2007) in Fukushima prefecture, is Hayashida *et al.* (2013). See Normile (2016) for an overview.
78. Tanigawa *et al.* (2012). See also an editorial Thomas and Symonds (2016) and reviews of Hasegawa *et al.* (2015) and Hasegawa *et al.* (2016). During evacuation there were over 50 deaths amongst vulnerable populations and in the 3 months after the accident mortality among elderly people at nursing facilities increased three-fold.
79. Authors' summary.

STUDIES OF WORKERS EXPOSED TO RADIATION.

80. Wakeford (2009) gives an overview focussing on occupational exposure.
81.
 - a. See Wernli (2016) for a history of individual monitoring and Ainsbury *et al.* (2011) for a review of retrospective dosimetry techniques. The studies' results are presented as ERR/Gy, although some studies include neutron doses in sieverts.

The large pooled study, INWORKS, includes studies of worker cohorts in the UK, France and the US. The results for the nuclear worker studies and the LSS are in broad agreement even though the workers usually accumulated their doses over many years, whilst the LSS subjects received theirs in a few seconds – supporting the assumption of additivity and dose-rate independence of radiation doses. There are other key differences between the LSS and worker studies, including exposure to different types of radiation (e.g. gamma rays of different energies), and differences in the demographics, genetics and lifestyle features of the subject population Stewart and Kneale (2000), Little (2002a). The LSS figures for working-age males in Table 4 are as calculated by Cardis *et al.* (2005) and Muirhead *et al.* (2009). INWORKS is described by Richardson *et al.* (2015) for solid cancer risk and Leuraud *et al.* (2015) for leukaemia risk. See Nagataki and Kasagi (2015) and also Doss (2015) for comments and concerns regarding the INWORKS study design. The INWORKS study is a refinement of previously published pooled cohort studies known as the 14- and 15-country studies (the former being the 15-country study minus Canada); results from the 15-country study were found to be affected by historic dose estimate issues in one contributing cohort (i.e. Canada) Cardis *et al.* (2005), Cardis *et al.* (2007), Thierry-Chef *et al.* (2007), Ashmore *et al.* (2010), Wakeford (2014b), Zablotzka *et al.* (2014). Japanese nuclear worker data originates from Akiba and Mizuno (2012), where they also discuss the risk of alcohol consumption confounding this result. The ERR/Sv estimate of all cancers excluding leukaemia and alcohol-related cancers in the Japanese study was 0.2 (95% CI -1.42 to 2.09). The Chernobyl Russian clean up worker cohort was analysed by Kashcheev *et al.* (2015). Mayak nuclear worker risks for solid cancers other than lung, liver and bone are from Sokolnikov *et al.* (2015) and for leukaemia from Kuznetsova *et al.* (2016). Rocketdyne data is from Boice *et al.* (2011) and US nuclear power plant workers from Howe *et al.* (2004).

- b. See Stabin and Xu (2014) for an explanation of basic principles in internal radiation dosimetry, focussing on the concept of phantoms. See Gilbert *et al.* (2013) for a Mayak study on lung cancer and Sokolnikov *et al.* (2015) for solid cancer other than lung, liver and bone. Vasilenko *et al.* (2007) details internal dosimetry methods at Mayak. A question of other factors influencing risks in groups of nuclear workers is raised by Gillies and Haylock (2014) and commented on in Boice (2014). A further (environmental) study examining the effects of intake of I-131 from emissions at the Hanford Nuclear Site in the USA is Davis *et al.* (2004).
- c. UNSCEAR (2006a) lists 18 studies of non-cancer disease risks in nuclear workers. Kitahara *et al.* (2015) update this list with a further 3 studies. Little *et al.* (2012) is a systematic review and meta-analysis of circulatory disease risk in 9 studies including 7 nuclear worker studies. Little (2013) is a further review. A series of studies of the Mayak cohort have appeared since the Kitahara update: Moseeva *et al.* (2014), Azizova *et al.* (2015). Azizova *et al.* (2016) report on cataract incidence in the Mayak cohort.
82. See paragraph 81a for references in Table 4.
83. Radiologists.
 - a. Wakeford (2004), Mutscheller (1925). A review of the history of dose limits is given by Inkret (1995). Yoshinaga *et al.* (2004) review 8 studies of medical radiation workers. Those studies are of: 6,500 US radiologists (Matanoski *et al.*

- (1987); 2,700 UK radiologists Berrington *et al.* (2001); 146,000 US radiological technologists Mohan *et al.* (2003); 6,600 US Army radiological technologists Jablon and Miller (1978); 27,000 Chinese X-ray workers Wang *et al.* (2002); 4,200 Danish radiation therapy workers Andersson *et al.* (1991); 12,200 Japanese radiation technologists Yoshinaga *et al.* (1999) and 73,100 Canadian radiation workers Ashmore *et al.* (1998).
- b. Hauptmann *et al.* (2003) describe the circulatory risk for US radiological technicians. Shore (2014) summarises studies from this and three other studies of circulatory disease in medical radiation workers.
 - c. See Table 3 in Shore (2016b) for a summary that suggests that there is occupational radiation cataract risk amongst medical specialists who receive large cumulative doses (with estimated mean doses from various studies ranging from 0.028 Gy to 6 Gy).
84. 10 Gy is the average alpha dose to the skeleton as a whole: to endosteal surfaces, the putative originating cells for osteosarcoma, the average alpha dose would be about half this. In a US cohort of 820 people there were 46 deaths from bone cancer where less than 1 would have been expected, and a clear excess of cancers of the paranasal sinuses and mastoid air cells was also apparent due to radon formed on the decay of ²²⁶Ra in the bones of the head. The equivalent UK workers ingested less radium and experienced 1 bone cancer death against 0.17 expected in a cohort of 1110 individuals. For studies on the US radium dial workers, see Rowland *et al.* (1978), Thomas (1994), Fry (1998) (US overviews), Spiers *et al.* (1983) (US leukaemia), Adams and Brues (1980) (US breast cancer). For studies on the UK radium dial workers, see Baverstock and Papworth (1989) (UK leukaemia) and Baverstock and Vennart (1983) (UK breast cancer). A careful analysis of the data on breast cancer in US radium dial painters suggested that the reported association may have been due to other factors and may not have been causal Stebbings *et al.* (1984).
 85. Sigurdson and Ron (2004), Yong *et al.* (2014), dos Santos Silva *et al.* (2013), Hammer *et al.* (2014), Sanlorenzo *et al.* (2015), Shantha *et al.* (2015).
 86. A working level (WL) is defined as any combination of the short lived progeny of radon in one litre of air that will result in the emission of 1.3×10^5 MeV of potential alpha energy, and a working level month (WLM) is defined as the cumulative exposure from breathing in an atmosphere at a concentration of 1 WL for a working month of 170 hours Tirmarche *et al.* (2010).
 - a. The 2006 UNSCEAR report combined data from 9 studies comprising over 3,000 lung cancer cases in miners and found an ERR per 100 WLM of 0.59 (95% CI: 0.35 to 1.0), in close agreement with an estimate of 0.49 (95% CI: 0.2 to 1.0) per 100 WLM made 10 years earlier, and a recent assessment concluded that a reasonable summary ERR estimate is 0.5 per 100 WLM. Reviewed in Tirmarche *et al.* (2010) and UNSCEAR (2006b), Annex E. For results from individual studies see Table 21 in UNSCEAR (2006b). For comparisons of meta-analyses see Tirmarche *et al.* (2010) Annex A page 51, UNSCEAR (2006b) Paragraph 427, Lubin (1994), BEIR VI (1999) and Tirmarche *et al.* (2012). A single large study of German Wismut uranium miners (3,016 lung cancer deaths in just under 2 million person-years of follow-up), not included in the earlier pooled analyses, found a smaller risk of 0.19 per 100 WLM (95% CI: 0.16 to 0.22), but when the study was limited to miners with comparatively low cumulative exposures the ERR became 1.3 per 100 WLM (95% CI: 0.7 to 2.1) Walsh *et al.* (2015). Studies of hard rock miners show a *decrease* in ERR per unit of exposure as the rate of exposure *increases*, which may explain differences in results for different studies.
 - b. Reviewed in Darby *et al.* (1995), UNSCEAR (2006b) Annex E Paragraphs 485 – 491, Tirmarche *et al.* (2010) and (for the German uranium miners) Walsh *et al.* (2015). Also see Kreuzer *et al.* (2015b) and Mohnner *et al.* (2010). The ERR of 2.18 is from Kreuzer *et al.* (2016).
 - c. UNSCEAR (2006a) Annex B, Table 11 summarises results on circulatory disease for 5 studies of miners. Walsh *et al.* (2015) summarise current results for the German uranium miners.
 87. Authors' summary.
- ### ENVIRONMENTAL EXPOSURE
88. UNSCEAR (2008), Table 1 in Hughes *et al.* (2005). Bossew *et al.* (2015) map indoor radon across Europe. Because radon is localised in some areas only, exposure prevention is required in such areas known to be affected.
 - a. Becquerels per metre cubed is strictly an improper (summary) measure: it is practical to use it because it is the ambient concentration that corresponds to a certain dose-rate. Pooled analyses from Europe Darby *et al.* (2006), North America Krewski *et al.* (2006) and China Lubin *et al.* (2004) are summarised in Table 2.2, page 30 of Tirmarche *et al.* (2010). When uncertainties associated with variations in exposure were accounted for, the estimated relative risk in the European pooled analysis increases from 0.08 to 0.16 per 100 Bq/m³ Darby *et al.* (2006).
 - b. Figures 2 and 3 in Darby *et al.* (2005) compare risks for smokers and non-smokers. See also the large paper Darby *et al.* (2006). The small study of Torres-Duran *et al.* (2014) reviews studies of residential radon and lung cancer risk in never smokers.
 - c. See Raaschou-Nielsen *et al.* (2008) for the study of acute lymphoblastic leukaemia in Denmark and Kendall *et al.* (2013) for the study in the UK.
 89. Radiation risks in areas with high natural background radiation are reviewed by Hendry *et al.* (2009) Boice (2010) and Aliyu and Ramli (2015). For Kerala results see Nair *et al.* (2009) and for Yangjiang results see Tao *et al.* (2012), the confidence intervals for Tao *et al.* are calculated in Shore (2014). The results of these studies are not statistically significant, although they are of comparable size and dose to some of the worker studies that have identified positive, statistically significant estimates of ERR/Gy. Nevertheless, there is no statistical inconsistency between these estimates, although the Kerala risk estimate is close to statistical incompatibility with the LSS risk estimate.
 90. A case-control study in Great Britain based on >27,000 cases from the National Registry of Childhood Tumours compared risks of childhood leukaemia and other cancers with cumulative dose through exposure to indoor gamma radiation and radon based on the mother's address at the time of the child's birth Kendall *et al.* (2013). It found a statistically significant relationship between dose from naturally occurring gamma radiation and the risk of childhood leukaemia, with an ERR/Sv = 120 (95% CI: 30 to 220). Radon exposure did not predict childhood leukaemia, and other childhood cancers were not related to either radon or gamma radiation exposure. UNSCEAR (2013b) cautions that there are large

- uncertainties associated with this study with respect to its use of an ecological measure of dose. A census-based cohort study of childhood cancer in Switzerland (with 1,800 incident cases) reported positive relationships between cumulative dose of external radiation and both childhood leukaemia (ERR/Sv = 50 (95% CI: 0 to 100)) and central nervous system cancers (ERR/Sv = 50 (95% CI: 0 to 110)) Spycher *et al.* (2011). A Finnish case-control study (1093 cases) with full residential history found a non-significant odds ratio increase for childhood leukaemia with increasing dose-rate of background radiation, with a significantly elevated odds ratio in the age group 2-7 years Nikkila *et al.* (2016). These relationships between exposure to background gamma radiation and childhood leukaemia incidence are broadly comparable to those from the LSS, lending some support to the application of risk estimates derived from the LSS to the very low dose-rates received from naturally occurring background gamma radiation. However, a French census-based analysis with 9,056 incident cases over 20 years found no evidence of an association of childhood leukaemia risk with either radon (SIR by 100 Bq/m³ 1.01, 95% CI 0.91 to 1.12) or gamma radiation (SIR by 10 nSv/h 1.01, 95% CI 1.00 to 1.02) Demoury *et al.* (2016).
91. For Techa River residents see Schonfeld *et al.* (2013) and Davis *et al.* (2015) for solid cancer, Krestinina *et al.* (2013b) for leukaemia and Krestinina *et al.* (2013a) for cardiovascular disease.
 92. Cancer risks due to fallout are reviewed in, for example, Simon *et al.* (2006), Simon and Bouville (2015). The analysis of 11 cancer registries is reported in Wakeford *et al.* (2010) and the study focussing on the Nordic countries is reported in Darby *et al.* (1992). The relative risk of leukaemia for ages 0-14 in the high exposure period versus the medium exposure period was 1.07 (95% CI: 1.00 to 1.14). Other populations exposed during fallout include the Marshall Islanders Land *et al.* (2010), Simon *et al.* (2010), inhabitants of Utah near to the Nevada Test Site Stevens *et al.* (1990) and inhabitants of Semipalatinsk in Kazakhstan Abylkassimova *et al.* (2000), Akleyev (2007). See Wakeford (2014a) for a discussion of fallout in the context of discharges from nuclear installations.
 93. Residential areas around nuclear facilities.
 - a. The epidemiology of childhood leukaemia near nuclear installations has been reviewed in Laurier *et al.* (2008). See also Laurier *et al.* (2014), Kinlen (2011), Janiak (2014) and COMARE (2011). Wakeford (2014a) briefly summarises the history of investigations of childhood leukaemia near Sellafield and Dounreay. Bunch *et al.* (2014) report recent

follow-up data from the same populations which have not exhibited excess cases of leukaemia since the early 1990s. The cluster near Krummel was first reported by Schmitz-Feuerhake *et al.* (1993). COMARE (2011) comprehensively reviews studies of the risk of leukaemia in young people living in the vicinity of nuclear power plants in Great Britain and other countries in Chapter 3 and in Germany in Chapter 4. COMARE (2016) reviews the incidence of childhood cancer around the Sellafield and Dounreay nuclear installations with data up to 2006 concluding that in the time period 1991-2006 the incidence rates of leukaemia and non-Hodgkins lymphoma had reduced to unexceptional levels in both locations.

- b. The KiKK study was a German case control study of cancer diagnosed in children below the age of 5. Its main finding was a statistically significant positive association between the risk of leukaemia before 5 years of age and living less than 5km from a nuclear power plant Kaatsch *et al.* (2008a). A commentary by Little *et al.* (2008a) gives context. Chapter 4 of COMARE (2011) summarises further descriptions and analyses of the KiKK study. Additional analysis of the KiKK data compared observed and expected numbers of cases in the same group of children (leukaemia below 5 years of age and living within 5km of a nuclear power plant in Germany) and reported a standardised incidence ratio (SIR) not significantly different from 1 Kaatsch *et al.* (2008b). The KiKK case-control study design was repeated in France and Britain (set in context in Muirhead (2013)). The geographical approach was also repeated for the same risk group in France, Britain and Switzerland. Neither case-control study recapitulated the odds ratio (OR) significantly different from 1 and just one time interval from the French geographical study generated an SIR marginally significantly different from 1. When the French study broadened the age group under consideration to include children under 15, a marginally significant result was observed (see Table 2, Sermage-Faure *et al.* (2012)). Table 13 summarises numerical values of ORs and SIRs from these studies and gives references. Other recent studies in Finland (2 NPPs (nuclear power plants)), Canada (3 NPPs) and Belgium (5 NPPs) report non-significant SIRs for children below 15 years with various definitions of residing close to NPPs Heinavaara *et al.* (2010), Bollaerts (2012), Lane (2013). Table 5.1, page 59 in COMARE (2011) calculates an SIR from a meta-analysis of older (pre-2009) data for children under 5 years "in the vicinity" of 80 nuclear power plants in 5 countries. The resulting SIR is 1.07 (0.92 to 1.26).

Table 13. Childhood leukaemia in children < 5 years old living < 5 km from a nuclear power plant published as the KiKK study and since. N is the number of cases of leukaemia in children below 5 years of age resident < 5km from a nuclear power plant (NPP).

Country	OR from case control studies	SIR from ecological and cohort studies
Germany	2.19 lower 95% CL = 1.51 1980-2003 N=37 Kaatsch <i>et al.</i> (2008a)	1.41 (0.98 to 1.97) 1980 - 2003 N = 34 Kaatsch <i>et al.</i> (2008b)
France	1.6 (0.7 to 4.1) 2002 - 2007 N=6 Sermage-Faure <i>et al.</i> (2012)	2.2 (1.0 to 4.4) 2002 – 2007 N=8 1.4 (0.8 to 2.3) 1990 – 2007 N=14 Sermage-Faure <i>et al.</i> (2012)
Britain	0.86 (0.49 to 1.52) 1962 - 2007 N = 10 Bithell <i>et al.</i> (2013)	1.22 (0.75 to 1.89) 1969 - 2004 N=20 COMARE (2011)
Switzerland		Incidence Rate Ratio 1.2 (0.6 to 2.41) 1985 - 2009 N = 8 Spycher <i>et al.</i> (2011)

- c. See Black (1984) for Sellafeld, COMARE (1999) for Dounreay, SSK (2008) for Kikk.
- d. COMARE (2006) found that childhood leukaemia in Britain tends to cluster, but this is not a consistent result across all such studies. For example Alexander (1998) finds evidence of clustering in a dataset of 13,351 cases of childhood leukaemia from 17 countries, whilst Schmiedel *et al.* (2010) found no evidence of a tendency to clustering amongst 11,946 cases of childhood leukaemia in Germany. The town of Fallon in Nevada USA had an unusually high incidence of childhood leukaemia (14 cases) during the years 1997–2003 Francis *et al.* (2012). The town is not near a nuclear installation and the cause of the cluster remains unknown.
- e. Kinlen (1988) first proposed the population mixing hypothesis. Kinlen (2012) presents a review and meta-analysis of 20 years' data on childhood leukaemia and population mixing. Lupatsch *et al.* (2015) describe a Swiss cohort study in which population mixing did not predict the risk of childhood leukaemia, but see Kinlen's letter of response Kinlen (2015) and also Lupatsch *et al.* (2016) which found an association between Swiss population growth and childhood leukaemia.
- f. Gardner *et al.* (1990) proposed paternal pre-conceptional radiation as the cause of the cluster near Sellafeld. Doll *et al.* (1994), COMARE (2002) and COMARE (1999) summarise the evidence against the hypothesis. Recent reviews are Wakeford (2013), Wakeford (2014a).
- g. Fairlie (2014), CERRIE (2004), Wakeford (2014a).
- 94. Industrial processes such as the burning of coal, the production of phosphate fertilizers and the extraction of oil and gas have the potential to increase exposure to naturally occurring radioactive materials (NORMs) and hence to elevated exposure in workers and in the environment. Individuals in such industries have received less scrutiny than other exposed individuals described here. Doyi *et al.* (2016) IAEA (2003) and <http://www.world-nuclear.org/information-library/safety-and-security/radiation-and-health/naturally-occurring-radioactive-materials-norm.aspx>
- 95. Authors' summary.

MEDICAL EXPOSURE

- 96. Dose fractionation (in which the total dose is delivered as a number of doses separated in time) allows the optimization of the lethal effect on diseased cells while sparing healthy tissues. There are known risks from such therapy which have to be balanced against the benefits of treating the underlying disease. There is a large body of data on those risks which is growing as radiotherapy becomes more successful and people survive ever longer after their radiotherapy. These data have to be treated with caution as individuals treated with radiotherapy are already patients, so they are not a representative sample of the general population, and this could affect estimates of radiation risks. Further, radiotherapy is usually focused on localised diseased tissues, leading to a highly heterogeneous distribution of doses within the body. There is an overall pattern that the ERR/Gy from radiotherapy tends to be lower than the corresponding values in the LSS. This pattern is more marked at higher average radiotherapy dose and is therefore thought to be explained by spatially-focussed radiation used in therapy killing a large proportion of cells that might otherwise have become cancerous due to irradiation – the so called sterilization effect.

- However these two patterns are not ubiquitous: some individual radiotherapy studies have a higher ERR/Gy than the corresponding values in the LSS. Little (2001) reviews 116 radiotherapy studies and compares ERRs for incidence and mortality with comparable risks in the LSS. Travis *et al.* (2003a) found that radiation related risk remained high even at the highest doses in women < 30 years of age treated for Hodgkin disease with radiotherapy (i.e., there was no evidence of a sterilization effect). Wakeford (2004) reviews cancer epidemiology amongst medically irradiated groups. Two of the largest studies are of 14,000 ankylosing spondylitis patients Weiss *et al.* (1994), Weiss *et al.* (1995) and 80,000 women treated for cervical cancer Boice *et al.* (1985), Boice *et al.* (1987), Boice *et al.* (1988). Little (2016) reviews risks from therapeutic and diagnostic doses, and Tran *et al.* (2017) updates analyses for two diagnostically treated groups.
- 97. For studies on Ra-224 see Wick *et al.* (1999), Nekolla *et al.* (2000). For Thorotrast studies see Travis *et al.* (1992), Travis *et al.* (2001), Travis *et al.* (2003b).
 - 98. Linet *et al.* (2012) review risks from diagnostic imaging and their Table 4 gives estimates for dose from various different examinations.
 - a. Bithell and Stewart (1975) describe the OSCC, Wakeford (2008) reports pooled results from 32 smaller studies of X-rays *in utero*. See Doll and Wakeford (1997) for dose estimates and comparisons with risks from post-natal radiation, and also Preston *et al.* (2008) for a study on the LSS.
 - b. Linet *et al.* (2012) discuss the wide range of results of studies of X-rays in children and adults, and why they might be so variable. Table 2 in Shore (2014) summarises leukaemia risks from larger studies of medical exposures. Little and Boice (1999) compare breast cancer risks in fluoroscopy patients and the LSS. Ronckers *et al.* (2010) examines breast cancer and scoliosis. Howe (1995) reports strictly null dose-response results for lung cancer risk after multiple fluoroscopic examinations.
 - c. A UK study calculated absorbed dose from CT scans to the red bone marrow and the brain and found an ERR/Gy = 37 (95% CI: 6 to 121) for leukaemia and ERR/Gy = 24 (95% CI: 11 to 47) for brain tumours Pearce *et al.* (2012). The equivalent values from the LSS based on age at exposure and follow up time were an ERR/Sv of 45 (95% CI: 16 to 188) for leukaemia and an ERR/SV of 6.1 (95% CI: 0.1 to 64) for brain tumours. An Australian study reported: an ERR/Gy = 39 (95% CI: 14 to 70) for leukaemia, using bone marrow dose; an ERR/Gy = 21 (95% CI: 14 to 29) for brain cancer after brain CT using dose to the brain; and an ERR/Sv = 27 (95% CI: 17 to 37) for solid cancer (excluding brain cancer after brain CT) using effective dose Mathews *et al.* (2013). See, for example Brenner (2014), Walsh *et al.* (2014), Journy *et al.* (2015) for discussion of these results. A French study Journy *et al.* (2015) that attempted to take into account predisposing factors was shown to suffer from some methodological limitations Cardis and Bosch de Basea (2015), Muirhead (2015). A further overview is Boice (2015).
 - 99. Authors' summary.

EXPERIMENTAL STUDIES OF MECHANISMS OF DAMAGE

- 100. Valentin (2005), page 11 and pages 313-315 of BEIR VII (2006), Annex A2 of ICRP 103 (2007), UNSCEAR (2012a) and NCRP (2015) all offer reviews of radiobiology. Complex DSB are a

- combination of strand breaks and base damages all within a few nanometres along the DNA, containing at least one break on each strand of the DNA (hence “DSB”) and at least one more break and/or base damage (hence “complex”). These are illustrated in Figure 5 of Goodhead (2009). Goodhead (1994) and Lomax *et al.* (2013) give general introductory explanations of the generation and relevance of clustered damage. Choi *et al.* (2015) give an explanation of indirect damage.
101. Molecular mechanisms of DNA repair are reviewed in pages 32-39 of BEIR VII (2006) and in Shibata and Jeggo (2014). Molecular mechanisms of DNA repair including a consideration of damage complexity are reviewed in Moore *et al.* (2014). At high doses the linear quadratic dose response saturates for counts of chromosome aberrations (e.g. for human lymphocytes saturation occurs at 4-5 Gy).
 102. On checkpoints see ICRP 99. Lobrich and Jeggo (2007), Deckbar *et al.* (2007) and Fernet *et al.* (2010) discuss the threshold below which the G2/M checkpoint does not operate. Martin *et al.* (2013) review low dose hypersensitivity.
 103. Hlatky *et al.* (2002) and Goodhead (2009) describe diversity in chromosome aberrations. Annex A, Paragraph A45 of ICRP 103 (2007) on radiation-associated tumours states “evidence for the presence of specific mutational signatures of radiation is currently lacking”. The European research initiative DoReMi has this research area as one of its main priorities Salomaa *et al.* (2015). Pernet *et al.* (2012) provides a comprehensive review of attempts to identify biomarkers that would be of use in the epidemiology of radiation risk. There is current research into biomarkers for thyroid cancer Dom *et al.* (2012), Suzuki *et al.* (2015) and in experimental systems Sherborne *et al.* (2015).
 104. The multistep model of carcinogenesis was proposed by Armitage and Doll (1954) and is supported by molecular data from human colon cancers Vogelstein *et al.* (1988). For a comprehensive review of cancer biology see Chapter 18 (p273) in Hall and Giaccia (2011). For a recent review see Mullenders *et al.* (2009).
 105. Stem cell biology and its implications for radiological protection are discussed by Hendry *et al.* (2016). The important role of stem cells in carcinogenesis generally is supported by the recent observations of a strong correlation between cancer incidence and the number of lifetime stem cell divisions Tomasetti *et al.* (2017).
 106. Adaptive responses appear to involve transcriptional modulation of specific gene sets Tapio and Jacob (2007). See Mullenders *et al.* (2009) for in vivo studies showing evidence of adaptive response, and Wolff (1996) on adaptive responses to very low radiation doses.
 107. So-called “non-targeted effects” are reviewed by Morgan (2003a), Morgan (2003b). UNSCEAR (2012a) reviews more recent evidence. Little (2010) considers the shape of the dose response in light of non-targeted effects. Not all authors would categorise the adaptive response and genomic instability as non-targeted effects, but they are included in Little’s 2010 review. A contrasting review of non-targeted effects is Hei *et al.* (2011).
 108. Ding *et al.* (2005), Hauptmann *et al.* (2016) and Wahba *et al.* (2017) describe qualitative differences in cellular responses to low dose radiation. The proteomics of low dose radiation is reviewed in Leszczynski (2014). Brooks *et al.* (2016) reviews molecular and cellular events after exposure to ionizing radiation at low dose-rate.
 109. Preston (2017) and Ruhm *et al.* (2017) explain how the combination of biological and epidemiological data should, in time, allow development of a data-driven model of the dose-response curve at low dose and low dose-rate. The Euratom project DoReMi has produced a substantial body of literature towards a better understanding of the biological effects of ionizing radiation at low dose and low dose-rates. The project is described in Belli *et al.* (2011), Aerts *et al.* (2014), Belli *et al.* (2015) and the project’s publications with their abstracts are listed at www.melodi-online.eu/DoReMi/Publications.html.
 110. Animal studies of carcinogenesis directly illustrate the diversity of dose response curves for different cancers. See paragraph 118.
 111. Premature cellular senescence after low dose-rate radiation is described in Yentrapalli *et al.* (2013b), Yentrapalli *et al.* (2013a), Rombouts *et al.* (2014).
 112. A comprehensive review of radiation specific biomarkers from 2012 Pernet *et al.* (2012) has recently been updated Hall *et al.* (2017) emphasising the potential of a systems biology approach to integrate the rapidly growing “omics” into a mechanistic understanding.
 113. Bouffler (2016) reviews variation in individual radiosensitivity. Individual sensitivity was one of the foci of the Euratom DoReMi research programme Belli *et al.* (2011), Aerts *et al.* (2014), Belli *et al.* (2015), with resulting advances in understanding of susceptibility due to genetic and epigenetic mechanisms Sagne *et al.* (2013), Flockerzi *et al.* (2014), Gurtler *et al.* (2014), Pernet *et al.* (2014), Sagne *et al.* (2014), Schanz *et al.* (2014). An ATM mutation is emerging as a relative contraindication for radiotherapy. For example, ATM mutations in female breast cancer patients predict for an increase in radiation-induced late effects Iannuzzi *et al.* (2002). A-T heterozygotes may comprise 1% of the population, 4% of the cancer population and up to 14% of the breast cancer population Swift *et al.* (1991). The emerging field of radiogenomics aims to understand genetic risk factors for adverse reactions to radiotherapy (for a review see Roberson *et al.* (2016)).
 114. Biological mechanisms whereby ionizing radiation causes cardiovascular disease have been reviewed recently in Stewart (2012), Baselet *et al.* (2016) and Boerma *et al.* (2016). Atherosclerosis is described in Hansson and Hermansson (2011). Animal models have contributed to our understanding of the role of inflammation Monceau *et al.* (2013), Mathias *et al.* (2015) and also of the disruption of cellular organization Barjaktarovic *et al.* (2013) in low dose radiation damage to the heart.
 115. Ainsbury *et al.* (2016) offer a recent review on mechanisms of cataract induction by ionizing radiation. Genomic damage is specifically discussed in Worgul *et al.* (1989), oxidative stress in Hamada (2016) and downstream effects including cell division in Jacob *et al.* (2012).
 116. Authors’ summary.
- EXPERIMENTAL STUDIES THAT INFORM RISK ASSESSMENT**
117. See, for example, Peacock *et al.* (2000) and Brooks *et al.* (2009) with reviews in Dauer *et al.* (2010) and Morgan and Bair (2013). Figure 2.4 in BEIR VII (2006) (p59) illustrates abnormal chromosome count data as a function of dose from studies of thousands of cells exposed up to 50 mGy. The

original data sources are Pohl-Ruling *et al.* (1983) and Lloyd *et al.* (1992). For studies examining values of DDREF see Lloyd *et al.* (1992), Thacker (1992), UNSCEAR (2000b), Cornforth *et al.* (2002b).

118. Figure 3b in Haley *et al.* (2015) reviews dose response curves from 11 animal carcinogenesis experiments. These experiments and others are described on p73-4 of BEIR VII. The original data for leukaemia in mice is in Bouffler *et al.* (1996b), Bouffler *et al.* (1996a), Bouffler *et al.* (1997); for mammary cancer in mice in Ullrich *et al.* (1987); and for mammary cancer in rats in Shellabarger *et al.* (1980). Radiation induced skin cancer in mice and rats is reviewed in Coggle and Williams (1990).
119. Figures 5 in Haley *et al.* (2015) reviews life shortening data from 16 mouse studies. Life shortening studies in dogs are reviewed in Thompson *et al.* (1989) and Muggenburg *et al.* (2008).
120. Section A16, page 217 in ICRP 103 (2007) describes how the risk estimates for human heritable disease were calculated. Searle (1974) and Sankaranarayanan and Chakraborty (2000) review the large body of data on mutagenesis studies in mice whilst Nakamura *et al.* (2013) compare human and animal data.
121. ICRP (2003), ICRP 103 (2007).
122. Pages 246-250 of BEIR VII (2006) describe the methodology and results for calculating DDREF from animal experiments and human epidemiological data combined. Haley *et al.* (2015) performed an equivalent analysis with a larger database of animal experiments and a different methodology and challenged the BEIR estimate. Different radiation protection organisations use different measures of DDREF. ICRP used a different method and considered that a value of 2.0 was most appropriate for radiation protection purposes ICRP 99 (2005). There is a growing indication that the LDEF and DREF components of DDREF may differ Niwa (2010) with higher values suggested for DREF, e.g. Paunesku *et al.* (2017). Shore *et al.* (2017) conducted a meta-analysis of low dose-rate epidemiologic studies that provide dose-response estimates of total solid cancer risk in adulthood in comparison to corresponding acutely-exposed atomic bomb survivor risk, in order to estimate a dose rate effectiveness factor (DREF) of between 1 and 2. Ruhm *et al.* (2015) describe the historical development of the DDREF concept in light of emerging scientific evidence on dose and dose-rate effects, summarises the conclusions recently drawn by a number of international organisations, mentions current scientific efforts to obtain more data on low dose and low dose-rate effect effects at molecular, cellular, animal and human levels, and discusses future options to improve and optimize the DDREF concept for the purpose of radiological protection.
123. Authors' summary.

PERSPECTIVES

124.
 - a. Smith (2007), Cologne and Preston (2000).
 - b. Lim *et al.* (2013). For individuals in situations where radiation levels are high, radon dose represents a large risk and exposure prevention measures are well justified.
125. Smith (2007), Cologne and Preston (2000) Lim *et al.* (2013).
126. Authors' summary. Small health risks of radiation are due in part to the active prevention policies which have been implemented

and improved for decades in both industry and medicine. Clarke and Valentin (2009), Figure 1 in Inkret (1995).

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