Committee on Medical Aspects of Radiation in the Environment (COMARE)

TENTH REPORT

The incidence of childhood cancer around nuclear installations in Great Britain.

Chairman: Professor B A Bridges OBE

CONTENTS

FOREWORD

i   There has been much discussion as to whether there is a raised risk of childhood cancer in the vicinity of certain nuclear installations which could be associated with radioactivity released from these nuclear sites. This has been an issue since 1983 when a possible connection was implicated in a Yorkshire Television documentary entitled *Windscale: The Nuclear Laundry*. As a result of concerns raised by this programme, the then Minister of Health set up the Black Advisory Group, in 1983, to investigate reports of a high incidence of leukaemia in young people living in the village of Seascale, adjacent to the Sellafield nuclear site, and the suggestion that there might be an association between the leukaemia incidence and the radioactive discharges from Sellafield. The report of this Group (Black, 1984) concluded that there was a higher incidence of leukaemia in young people resident in the area, but also concluded that the estimated radiation dose from Sellafield discharges and other sources, received by the local population, could not account for the observed leukaemia incidence on the basis of knowledge available at that time.

ii   The Committee on Medical Aspects of Radiation in the Environment (COMARE) was established in 1985 in response to the final recommendation of the Black Report (Black, 1984). The First Report of COMARE (1986) examined the implications of some further information concerning discharges of uranium oxide particles from Sellafield in the 1950s, which had not been available to the Black Advisory Group. The Committee concluded that this additional information did not change the essential conclusions of the Black Report.

iii   The findings raised concerns in other areas and in response COMARE published its Second Report (COMARE, 1988). This investigated an apparently similar childhood leukaemia cluster in the town of Thurso near the Dounreay nuclear establishment in the north of Scotland, which again found statistically significant increased levels of childhood leukaemia (Heasman et al, 1986, 1987).

iv   An increased leukaemia incidence was also reported among young people living in the vicinity of the Aldermaston Atomic Weapons Research Establishment (AWRE) in Berkshire and the Royal Ordnance Factory (ROF) at Burghfield in North Hampshire (Barton et al, 1985; Roman et al, 1987). The Third Report of COMARE (1989) considered these claims and concluded that there was a small but statistically significant increase in incidence rates of childhood leukaemia and other childhood cancers in children in the vicinity of the two sites. It was also noted that around another nearby site, the Atomic Energy Research Establishment (AERE) Harwell, Berkshire, there was no increase in registration rates of childhood leukaemia.

v   However, in its Third Report[*], the Committee concluded that the distribution of cases of childhood leukaemia, or other childhood cancer, around individual nuclear installations cannot be seen in a proper context in the absence of comparable information about the general pattern throughout the rest of the UK. Of the five recommendations made in the COMARE Third Report, two related to this conclusion. Recommendation 4 stated that 'studies of the geographical distribution of childhood cancer incidence on a nation-wide basis be carried out … thus enabling the patterns found around nuclear sites to be seen in the context of patterns in the rest of the UK'. Recommendation 5 of the Third Report went on to say that 'once the results of the studies outlined in Recommendation 4 are available, this Committee should be asked to participate in a review of the evidence relating to the incidence of childhood cancer around nuclear installations'.

vi   The work initiated in response to these two recommendations has now been completed. Approximately 32,000 cases of childhood cancer have been investigated in the time period 1969–1993 at county, county district and ward level throughout Great Britain and analysed in relation to population data and socio-demographic variables. We understand that this is the largest database on childhood cancer (in the sense that it contains details of the largest number of cases currently available for the types of analyses done here) anywhere in the world. This large database and the associated analyses are to be the topic of a separate report already in preparation by this committee. However, the information gathered so far does allow the review of the incidence of childhood cancer around nuclear installations in Great Britain and this topic is the subject of this, our Tenth Report.

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* COMARE has published several other reports which are not of direct relevance to the studies discussed in this report. However, details of earlier reports and the full Seventh, Eighth and Ninth Reports are available on our website, www.comare.org.uk.

CHAPTER 1

INTRODUCTION

1.1   The aim of this, our Tenth Report, is to review the earlier evidence and to present new data relating to childhood cancers around nuclear installations in Great Britain. By doing this we have attempted to see if the claims of an excess of childhood cancer around some specific nuclear installations are a regular feature of the majority of the largest nuclear sites in Great Britain.

Previous studies

1.2   The Black Report recommended a series of studies on individuals who had lived near Sellafield. These included a recommendation for a case–control study. A study led by Professor Martin Gardner (Gardner et al, 1990) was set up to examine the leukaemia clusters and to compare the demographic, social and behavioural factors and medical histories for leukaemia and lymphoma patients aged 0–24 years in this population. These cases were compared with those from a control group matched for date of birth and other relevant factors. An attempt was made to determine whether the excess risk of leukaemia in children born in the village of Seascale could be attributed to any other established risk factors for leukaemia including from exposure to radiation. The study found no association with factors such as eating locally produced vegetables and seafood and playing on the local beach. A significant finding of this study was that the risk decreased rapidly with distance of address of the child from Sellafield, indicating a geographical distribution of risk. The study also found a statistically significant raised risk for children whose fathers worked at the Sellafield plant. (Those with fathers in the iron and steel and farming occupations also showed comparably increased relative risks.) Most remarkably, the authors found an increased leukaemia risk associated with the recorded dose of external ionising radiation received by the father before conception of the child.

1.3   The Health and Safety Executive (HSE), in a subsequent case–control study (HSE, 1993, 1994), also found a statistical association between the incidence of childhood leukaemia and non-Hodgkin lymphoma (NHL) and the fathers' total external preconceptional radiation dose. This study was largely based on the same cases as were used in the study by Gardner et al. However, it used better dosimetric data than was available to Professor Gardner's team. The controls in this study were children born in West Cumbria between 1950 and 1990 who had not been diagnosed with cancer before the age of 25 years and whose fathers had worked at Sellafield. The association, however, was confined to the population of Sellafield workers who started work at the plant before 1965 and who were resident in Seascale at the time of their child's birth. The HSE studies showed that, for fathers resident outside Seascale when their child was born, there was no association between preconceptional radiation dose and the incidence of childhood leukaemia and NHL. Also, while an association was reported (for children born in Seascale) between the incidence of these diseases and the father's external radiation dose in the 12-week period

before conception, this was not statistically significant. No association was found for cancers other than leukaemia and NHL taken together, nor for any other factors studied such as internal radiation dose, chemical exposures or involvement in contamination incidents.

Co-ordinating Committee on Health Aspects of Radiation Research

1.4   The somewhat conflicting results of these studies led to the setting up of the Co-ordinating Committee on Health Aspects of Radiation Research, jointly funded by the Department of Health and the Health and Safety Executive. This committee commissioned four laboratory studies and two epidemiological studies. These and other related studies, were the subject of our Seventh and Eighth Reports (COMARE, 2002, 2004), which in turn reviewed the evidence concerning the incidence of cancer in the children of parents occupationally exposed to radiation and pregnancy outcomes following preconceptional exposure to radiation. With regard to cancer in the offspring of radiation workers we concluded that we could find no convincing evidence for a general parental preconceptional radiation effect in the populations studied.

Geographical studies

1.5   Various geographical studies have been carried out which have attempted to answer the question of whether there is an increased incidence of childhood leukaemia near nuclear facilities in the UK (Bithell et al, 1994; Sharp et al, 1996). Studies have also been conducted around particular sites, for example near the Sellafield plant (Draper et al, 1993), the Dounreay facility in Scotland (Black et al, 1994) and the Atomic Weapons Establishment at Aldermaston (Roman et al, 1993). We have also examined some specific publications from Green Audit, for example, covering areas close to the nuclear power stations such as Oldbury in Gloucestershire (Busby, 2001). We note that, with one exception, these latter studies have not been peer reviewed. Evidence from a number of other studies has cast doubt on the role played by radiation from such installations in cancer risk (Baron, 1984; Darby and Doll, 1987). These studies conclude that the increases in radiation exposure due to the nuclear installations considered here are far too small (sometimes by a factor of about 1000, although the size of this factor is a question of some dispute) to account for the increased incidence of certain malignancies. This has given rise to a number of alternative hypotheses (Ewings et al, 1989; Gardner et al, 1990; Kinlen, 1988). The role of other factors in causing leukaemias in Seascale and possibly Thurso, near Dounreay, has been more closely examined by other, more recent studies discussed in depth in our Seventh Report. Population mixing (large-scale mixing of rural and urban populations), possibly leading to exposure of susceptible individuals to infection and local epidemics, has been suggested as a possible cause of the observed clusters of leukaemia (assumed to be a rare response to a particular infection or infections) around nuclear installations, particularly as in these areas such mixing tends to involve a large influx of population into a sparsely populated area (Kinlen and Doll, 2004). The excess of leukaemia in Thurso has been shown to coincide with unusual population mixing in this area due to expansion of the North Sea oil industry (Kinlen et al, 1993).

1.6   There have also been many studies of the possible existence of clusters of these diseases and, more generally, of geographical variations in incidence. Although early studies (such as those by Gardner et al, 1990) indicated a possible link between nuclear facilities and childhood leukaemia, further investigations have found that clusters of leukaemia appear to be a feature of the general geographical distribution of this disease (Cartwright et al, 1990; OPCS, 1991).

Investigation of population groups with a possible increased incidence of disease

1.7   Evidence concerning causes of disease will often include the observation that the disease is more common in certain groups. These may, for instance, be people in particular occupational groups or in a particular area. Here we are concerned only with the latter, ie with geographical variations in the occurrence of disease.

1.8   The standard method of analysis, relevant to the detection of such geographical variations, is to calculate the *incidence* of the disease in various pre-defined areas and time periods and to determine whether there is evidence for an increase in particular areas of interest, eg those where some suspected causative factor is common.

1.9   It is also possible, though more difficult, to carry out analyses of *clustering,* designed to determine whether there is a general tendency for groups of cases to occur in clusters, ie more closely to each other geographically, or at shorter time intervals, than would be expected. With this approach it is again in principle possible to determine whether the individual clusters that contribute to such generalised clustering are associated with some possible causative factor.

Reports of individual clusters

1.10   The clusters that become a cause of public or media concern tend, however, to come to attention either through a chance observation or through a non-systematic collection of information that results in an apparently striking aggregation of cases. Such observations are impossible to evaluate in a precise statistical way and the process of assessing them is rather complex. A suspected cluster could be an indication of a causative factor in the local environment. However, it could also be the result of chance, or due to a misclassification of cancer cases, or a miscalculation of the number of cases (for instance, because some cases have been counted twice, are in the wrong age group, or were outside the area of interest at the time of their diagnosis).

1.11   Usually a local public health organisation provides the first response to a suspected cluster. It gathers information such as the precise diagnosis, the numbers of cases, addresses and so on, in order first to determine whether cases have been correctly identified and allocated to the correct location. It is then possible to compare the number of cases found in the cluster with what would be expected in the area concerned if the usual disease rates applied. However, the fact that the data have not been collected in a systematic way and that there is no *a priori* hypothesis or definition of the area being studied makes it impossible to apply standard statistical tests. In some cases the apparent cluster will be so striking that even without formal analysis it will be regarded as being most unlikely to be due to chance. However, in most cases, even where a cluster has been validated, clustering analysis methodologies based only on the geographical location or times of occurrence of cases cannot distinguish specific clusters that have a localised cause from those that are due to chance. Other types of epidemiological study may be able to do this but they require very detailed knowledge of individual cases and of 'controls', ie unaffected individuals.

Cancer

1.12   Cancer is a term that describes many individual diseases, each of which is likely to have a separate cause. Currently it is unclear what factors are involved that bring about the majority of childhood cancers. Possible risk factors may come from the environment, such as chemicals, radiation and infectious organisms, and these may affect individuals who are susceptible, either because of their genetic makeup or the presence of other conditions, such as diseases of the immune system. The time between exposure to a cancer causing agent and the subsequent development of a malignancy may be years

and for children it may even be exposures *in-utero* that are involved. This 'latent period' makes it difficult to identify what specific exposures may be related to the development of any cancer.

Cancer clusters and clustering

1.13   All types of cancer can occur in clusters by chance for purely statistical reasons. In a forthcoming report already in preparation, COMARE has used statistical approaches that enable the recognition of clustering over and above that which would be expected. In agreement with previous work, these analyses have shown that the main types of childhood leukaemia can indeed occur in clusters more frequently than would be expected by chance. It appears that other types of childhood cancer can also occur in validated clusters.

1.14   A cluster of cancer cases is more likely to reflect a causal mechanism if it involves one type of cancer (particularly a rare type of cancer), or a type of cancer in a group not usually affected by that cancer (for example, a cancer in children normally only seen in adults).

1.15   As can be seen, the study of cancer clusters and clustering is extremely complex and we will be addressing these problems in depth in the report that is in preparation. However, if a cluster is truly associated with an environmental agent present at a specific geographical site and the agent is causal, then clusters should be present around other sites where the environmental agent is also present. This is the test that we have utilised in this report.

Multiple and selective testing and data availability

We wish to make a general point concerning the interpretation of the analyses. First, in carrying out multiple statistical tests it is inevitable that a number of 'false positives' will occur. Consequently, if a large number of such tests are carried out the probabilities need to be adjusted to allow for this number. However, it must be borne in mind that a 'statistically significant' cluster could also be caused by chance. This is because results that are 'formally' significant may simply reflect the fact that if a large number of analyses are undertaken, then some extreme results can be expected to occur by chance. In interpreting the present results we have attempted to take into account not only the results of formal significance tests but also the patterns of results and their relation to previously published studies. In fact, the results reported here appear to be largely consistent with those from other studies.

Some commentators have highlighted apparent excesses around certain nuclear sites based on selected local areas, and selected types of cancer. It would be as easy to demonstrate apparent deficits by selecting other time periods, other local areas, and other types of cancer, so leading to a conclusion that nuclear sites protect against cancer. In both cases one is faced with very small numbers of cases and/or biased data collection. Such approaches are of little value as statistical analysis is completely unreliable when biased databases are used and may be misleading when databases are small.

We endorse the view that epidemiological studies should conform to the usual standards of peer and ethical review. When studies are to be published privately it is essential that they should still be reviewed by other experts prior to publication.
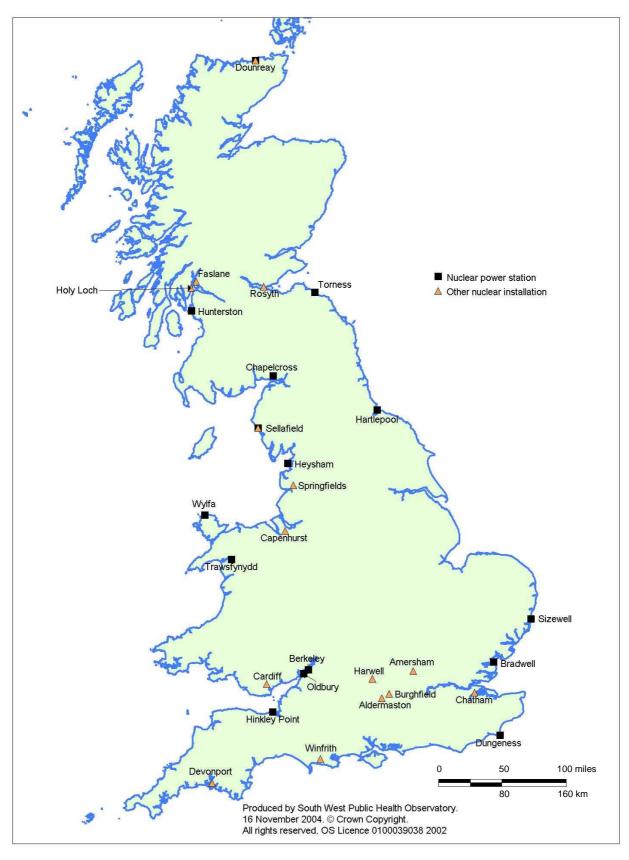
We wish, however, also to note that the increasing legislative and administrative requirements imposed to protect confidentiality have begun to interfere with the availability of data for proper research.

CHAPTER 2

INCIDENCE OF CHILDHOOD CANCER
AROUND NUCLEAR INSTALLATIONS
IN GREAT BRITAIN

Introduction

2.1   A paper by Bithell et al (1994) described a systematic analysis of the distribution of cases of childhood leukaemia and non-Hodgkin lymphoma (NHL) registered in the years 1966–1987 around 23 nuclear installations in England and Wales. With the exception of the previously known excess of cases in Seascale, near the nuclear reprocessing plant at Sellafield, the general conclusions were that there was no evidence of an increase of childhood leukaemia and NHL around nuclear installations and the evidence for a distance-related risk was very weak. Sharp et al (1996) carried out a similar study of the seven nuclear sites in Scotland for the period 1968–1993; the only statistically significant result from this study was the previously reported excess around the Dounreay reprocessing plant. Sharp et al (1999) also carried out a study in Scotland for malignancies other than leukaemia and NHL for the period 1975–1994; the only statistically significant finding from this study was an increase in the incidence of central nervous system (CNS) tumours in the vicinity of the Rosyth naval dockyard. These studies have now been extended by Bithell et al (In Preparation), to cover the period from 1969 to 1993. While this overlaps with the previous studies, it seems appropriate to update them, now that more extensive data are available.

2.2   The start date of the present analysis is a consequence of the difficulty of extrapolating some of the demographic data back before the 1971 census. The completion date, 1993, in part reflects the long lead-time in collecting and analysing adequately validated data. It also seems more appropriate to choose a period for analysis that can be centred on a census year (in this case 1981). A further five years of validated data have now become available but would require a disproportionate effort to include in the present study and would add relatively little statistical precision. These further data can be used in future studies. This new analysis is concerned with childhood cancer in the vicinity of 21 nuclear installations in England and Wales together with 7 Scottish sites. The locations of the sites are shown in the figure. In the tables that follow, the sites are grouped according to whether or not they were primarily power generating stations (except that Calder Hall is included with Sellafield). The census wards within a 25 km radius of the centre of each installation were identified, and the study is based on cases occurring within these wards. The choice of radius is somewhat arbitrary, but has the advantage of being the same as that used in a number of previous studies. In an annex to this chapter (Annex 2A), we discuss the hypothesis that there is a specific risk of childhood myeloid leukaemia in the vicinity of some sites. As explained in paragraph 2A.1, the suggestion that there might be such a risk arose from a report (Busby, 2001) concerning a single site; it is not clear from that report whether there was a reason for selecting this particular diagnosis and age group or whether the apparently increased risk was simply a chance observation.

Map of Great Britain showing the position of the nuclear installations included in the present study

Methods

2.3   The annual numbers of children in each census ward at ages 0–4, 5–9 and 10–14 years were estimated from population statistics provided by the Office for National Statistics and the General Register Office (Scotland). An indicator of socioeconomic status (SES) for each ward was calculated using data from the 1981 census. *Poisson regression modelling* (McCullagh and Nelder, 1989) was used to estimate the effects of geographical region and SES on ward incidence rates. The analyses reported here consist in comparing, for each nuclear site, the observed numbers of cases in wards in the vicinity of the site with the corresponding expected numbers, starting in 1969 or the start-up date for the installation if this is later. The expected numbers were calculated using Poisson regression modelling to adjust for region and SES, using the methodology described, for example, by Bithell et al (1995). The rationale for such adjustment is that the analysis of possible increases in rates around each nuclear installation should attempt to allow for any factors that might lead to high (or low) rates in the area in which that installation is situated.

2.4   The study was based on an analysis of the geographical distribution of the occurrence of cases, first, of childhood leukaemia and NHL as one group and, second, of malignant tumours other than leukaemia and NHL, which we refer to as solid tumours; this latter is a heterogeneous group of tumours which we analyse together because no subgroup would contain enough cases to provide a meaningful analysis. For each of these groups, we use statistical tests designed to detect variations in incidence rates related to distance from the sites being investigated. The tests, and their application in the present study, are discussed in Annex 2B to this chapter. Incidence rates were calculated for all census wards within a specified radius of the centre of a given site, and variations in these incidence rates were analysed using one of the five possible statistical tests described in Annex 2B. These tests are designed to determine whether there is a trend in incidence related to distance from the site being analysed. The 'unconditional' versions of the tests will also detect a generally increased or decreased incidence in the area being analysed; the 'conditional' versions are designed to detect trends after allowing for such a general increase or decrease. In cases where the unconditional test gave a statistically significant result, a conditional test was also carried out.

**Results 1
Childhood leukaemia
and NHL**

2.5   The data set analysed consists of 12,415 cases of leukaemia and NHL registered under the age of 15 years in England, Wales or Scotland from 1969 to 1993 inclusive.

2.6   Tables 2.1 and 2.2 show the results for nuclear power generating stations and other nuclear installations, respectively. They give the numbers of wards, the observed and expected numbers of cases of leukaemia and NHL within a radius of 25 km of each installation, observed to expected ratios (Obs/Exp, or Standardised Incidence Ratios, SIR), the statistical tests used and the significance levels (P-values) attained. The results show no evidence of a *general* excess for either category of installation, although some individual ratios are raised. Nor is there any evidence for a *general* effect of spatial proximity to the installations, as judged by the unconditional tests shown to be most powerful at each site.

2.7   The results for the areas around the nuclear power generating stations are given in Table 2.1. Using the most powerful statistical test in each case, none of the generating stations shows a significant result. The results for the other sites, which cover a wide range of different activities and levels of discharge, are given in Table 2.2: the only results significant at the 5% level were for Sellafield, Burghfield, Dounreay and Rosyth.

Sellafield	2.8 Table 2.2 shows that the most statistically significant results are those for Dounreay and Sellafield. The degree of significance for Sellafield is reduced as compared with the earlier analysis (Bithell et al, 1994), at least partly because the relative disparity between the observed and expected numbers of cases has decreased since the earlier analyses reported in 1994.
Aldermaston and Burghfield	2.9 Table 2.2 shows that the excess of cases around Burghfield is significant (P = 0.023). This result is clearly in part due to the elevated SIR in the circle, although the conditional test reported in Table 2.3 suggests that there is also a distance-related effect. The circle around Aldermaston overlaps with that around Burghfield and is relatively densely populated; it again shows a raised SIR, although this is not statistically significant.
Dounreay	2.10 The higher than expected incidence of leukaemia and NHL in children living near Dounreay has, like that at Sellafield, been the subject of a number of previous reports. The overall excess of cases undoubtedly contributes to the excess registered by the LRS (distance) test (Table 2.2). Sharp et al (1996) reported a non-significant result using the LRS (rank) test, but their version was conditional, and was therefore insensitive to the overall excess; using the unconditional MLR test, their result (P = 0.025) was similar to that reported in Table 2.2.

Table 2.1   Results for leukaemia and non-Hodgkin lymphoma in 1969–1993 in 25 km regions around British Energy and Magnox Generation stations in Great Britain

Site (start-up year)	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Berkeley (1961)	135	139	137.72	1.009	2	0.666
Bradwell (1961)	105	95	99.21	0.958	1	0.499
Chapelcross (1958)	33	24	29.83	0.805	2	0.732
Dungeness (1965)	37	21	22.80	0.921	2	0.536
Hartlepool (1983)	137	77	77.96	0.988	1	0.193
Heysham (1983)	97	26	32.08	0.810	2	0.907
Hinkley Point (1964)	80	67	65.32	1.026	1	0.275
Hunterston (1963)	58	43	50.92	0.844	2	0.741
Oldbury (1967)	150	177	170.19	1.040	1	0.432
Sizewell (1965)	32	11	14.23	0.773	2	0.616
Torness (1988)	11	0	2.33	0.000	2	0.901
Trawsfynydd (1964)	27	5	7.43	0.673	2	0.888
Wylfa (1969)	33	7	11.12	0.629	2	0.908

Notes

(a) Excluding wards with zero population under 15 years.

(b) The tests selected were as follows:

   (1)   LRS test using 1/(ward distance) as a score,

   (2)   LRS test using the square root of 1/(ward rank) as a score.

(c) P-value using chosen (unconditional) test, based on 10,000 simulations.

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Table 2.2   Results for leukaemia and non-Hodgkin lymphoma in 1969–1993 in 25 km regions around nuclear installations in Great Britain other than those in Table 2.1

Site (start-up year)	Operator	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Aldermaston (1952)	Atomic Weapons Establishment (AWE)	135	176	157.29	1.119	2	0.182
Amersham (1940)	Amersham plc	316	477	470.24	1.014	2	0.283
Burghfield (1950)	AWE	179	251	229.67	1.093	1	0.023
Capenhurst (1953)	British Nuclear Fuels (BNFL)	228	391	384.23	1.018	1	0.055
Cardiff (1979)	Amersham plc	151	132	129.58	1.019	2	0.247
Chatham (1967)	Ministry of Defence (MOD)	222	325	318.36	1.021	1	0.535
Devonport (1973)	Private (formerly MOD) dockyard	64	66	74.14	0.890	2	0.228
Dounreay (1959)	United Kingdom Atomic Energy Authority (UKAEA)	5	9	3.87	2.324	1	0.014
Faslane (1963)	MOD	42	41	47.72	0.859	2	0.645
Harwell (1946)	UKAEA	111	95	103.19	0.921	2	0.968
Holy Loch (1961)	US Naval Base	40	44	50.95	0.864	2	0.721
Rosyth (1963)	Private (formerly MOD) dockyard	168	218	210.77	1.034	2	0.021
Sellafield (1950)	BNFL and UKAEA	32	25	21.95	1.139	2	0.018
Springfields (1948)	BNFL and UKAEA	184	182	192.12	0.947	1	0.413
Winfrith (1967)	UKAEA	69	62	72.82	0.851	2	0.503

Notes

(a)   Excluding wards with zero population under 15 years.

(b)   The tests selected were as follows:

    (1)   LRS test using 1/(ward distance) as a score,

    (2)   LRS test using the square root of 1/(ward rank) as a score.

(c)   P-value using chosen (unconditional) test, based on 10,000 simulations.

Table 2.3   Conditional LRS-tests for leukaemia and non-Hodgkin lymphoma in 1969–1993 (the tests all used 10,000 simulated values of the test statistic, which was the same as that used in the unconditional test)

Site	No. wards	Obs	Exp	Obs/Exp (SIR)	P-value
Burghfield	179	251	229.7	1.093	0.063
Dounreay	5	9	3.9	2.324	0.480
Rosyth	168	218	210.8	1.034	0.009
Sellafield	32	25	21.9	1.139	0.002

Rosyth

2.11   The result of the significance test for Rosyth in Table 2.2 (P = 0.021 using the unconditional LRS test based on the square root of the rank) differs from that in the Scottish study by Sharp et al (1996). In that study, the Stone's unconditional MLR test shows a non-significant result (P = 0.244), as does the LRS rank test, although the SIR in the Scottish study (1.02) is very similar to the SIR in the present study (1.034). An increased risk of childhood leukaemia in part of Fife, the area in which Rosyth is situated, has been reported previously by Gerrard et al (1986) who analysed childhood leukaemia rates for South-east Scotland for the period 1970–1984. However, it is clear from the result of the conditional test reported in Table 2.3 (and explained at the end of paragraph 2.4) that the significant result here is at least partly explained by a relation between disease incidence and distance from the site. This discrepancy between the results of the present study and those of Sharp et al is presumably due either to differences in the groups of cases included or to the different statistical tests employed.

2.12   Using the most powerful statistical test in each case, no significant results were found for the other sites.

Results 2
Childhood tumours other
than leukaemia and NHL

2.13   A parallel analysis was undertaken of data for malignant tumours other than leukaemia and NHL (solid tumours), again for England, Wales and Scotland and the years 1969–1993. The same methods were applied here as were used in the analysis of leukaemia and NHL.

Table 2.4   Results for solid tumours in 1969–1993 in 25 km regions around British Energy and Magnox Generation stations in Great Britain

Site (start-up year)	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Berkeley (1961)	135	197	212.12	0.929	1	0.966
Bradwell (1961)	105	148	150.71	0.982	1	0.321
Chapelcross (1958)	33	51	48.51	1.050	2	0.527
Dungeness (1965)	37	35	34.83	1.005	2	0.375
Hartlepool (1983)	137	140	130.84	1.070	1	0.110
Heysham (1983)	97	55	60.00	0.917	2	0.640
Hinkley Point (1964)	80	99	101.33	0.977	1	0.671
Hunterston (1963)	58	90	83.22	1.082	2	0.553
Oldbury (1967)	150	252	263.54	0.956	1	0.897
Sizewell (1965)	32	22	24.81	0.887	2	0.689
Torness (1988)	11	2	3.62	0.553	2	0.831
Trawsfynydd (1964)	27	10	12.56	0.796	2	0.761
Wylfa (1969)	33	22	19.01	1.157	2	0.756

Notes

(a) Excluding wards with zero population under 15 years.

(b) The tests selected were as follows:

 (1)   LRS test using 1/(ward distance) as a score,

 (2)   LRS test using the square root of 1/(ward rank) as a score.

(c) P-value using chosen test, based on 10,000 simulations.

Table 2.5   Results for solid tumours in 1969–1993 in 25 km regions around nuclear installations in Great Britain other than those in Table 2.4

Site (start-up year)	Operator	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Aldermaston (1952)	Atomic Weapons Establishment (AWE)	135	278	239.27	1.162	2	0.003
Amersham (1940)	Amersham plc	316	717	718.73	0.998	2	0.559
Burghfield (1950)	AWE	179	398	347.92	1.144	1	0.011
Capenhurst (1953)	British Nuclear Fuels (BNFL)	228	654	665.17	0.983	1	0.941
Cardiff (1979)	Amersham plc	151	222	227.43	0.976	2	0.756
Chatham (1967)	Ministry of Defence (MOD)	222	466	486.67	0.958	1	0.833
Devonport (1973)	Private (formerly MOD) dockyard	64	121	112.34	1.077	2	0.572
Dounreay (1959)	United Kingdom Atomic Energy Authority (UKAEA)	5	3	6.29	0.477	3	0.868
Faslane (1963)	MOD	42	71	77.88	0.912	2	0.929
Harwell (1946)	UKAEA	111	188	156.19	1.204	2	0.003
Holy Loch (1961)	US Naval Base	40	75	83.06	0.903	2	0.834
Rosyth (1963)	Private (formerly MOD) dockyard	168	392	343.31	1.142	2	0.016
Sellafield (1950)	BNFL and UKAEA	32	40	35.96	1.112	2	0.177
Springfields (1948)	BNFL and UKAEA	184	348	327.82	1.062	1	0.245
Winfrith (1967)	UKAEA	69	113	111.55	1.013	2	0.782

Notes

(a) Excluding wards with zero population under 15 years.

(b) The tests selected were as follows:

    (1) LRS test using 1/(ward distance) as a score,

    (2) LRS test using the square root of 1/(ward rank) as a score,

    (3) Poisson maximum test.

(c) P-value using chosen (unconditional) test, based on 10,000 simulations.

Table 2.6   Conditional LRS-tests for solid tumours in 1969–1993 (the tests all used 10,000 simulated values of the test statistic, which was the same as that used in the unconditional test)

Site	No. wards	Obs	Exp	Obs/Exp (SIR)	P-value
Aldermaston	135	278	239.3	1.162	0.111
Burghfield	179	398	347.9	1.144	0.347
Harwell	111	188	156.2	1.204	0.097
Rosyth	168	392	343.3	1.142	0.362

2.14   The data set analysed consisted of 19,908 cases of children with solid tumours registered under the age of 15 years. The cases were allocated to one of 10,428 electoral wards or equivalent areal units and the resulting counts were compared with expectations computed by reference to population statistics for the numbers of children at risk in five-year age groups. As for leukaemia and NHL, a Poisson regression model was used to adjust the expectations taking account of certain demographic characteristics.

2.15   Tables 2.4 and 2.5 show the number of wards, the observed and expected numbers of cases of solid tumours within a radius of 25 km of each installation, the observed to expected ratio (Obs/Exp), the statistical test used and the significance level (P-value) for each site.

2.16   It will be seen that there are only four sites for which there is evidence from unconditional tests of a raised risk in the vicinity, namely Aldermaston, Burghfield, Harwell and Rosyth (P = 0.003, 0.011, 0.003 and 0.017, respectively). No significant results were found for any of the power generating stations. As explained in paragraph 2.4, the significance of the unconditional LRS test statistic derives in general partly from the overall elevation of the risk in an area and partly from the tendency of the cases to be nearer the centre of the circle than expected. It is clear that there is a contribution from the first component in each case as the observed to expected ratio in each area (column 6 in Table 2.5) is greater than unity. The question of which, if any, of the sites might exhibit a relation between disease registration rate and distance from the installation is best answered by an analysis using the conditional LRS (distance) test; this was carried out for each of these four sites and it will be seen (Table 2.6) that none reaches statistical significance, although the results for Aldermaston and Harwell are suggestive of a weak effect.

2.17   The fact that significant results are found for Aldermaston, Burghfield and Harwell, which are all in the same region of Oxfordshire/Berkshire, is at first sight remarkable, but the circles for Aldermaston and Burghfield overlap to a considerable extent, so that the analyses for these two sites are not independent. In fact it would appear that the unconditional tests yield positive results mainly because of an overall excess in the area that has yet to be explained. The reasons for this raised incidence are unknown, and may be difficult to elucidate in view of the heterogeneous nature of this group of tumours.

2.18   For solid tumours in the population living near the Rosyth site, the conditional test reported in Table 2.6 is not significant (P = 0.362), ie there is no evidence of a risk related to distance from the site. Sharp et al (1999) reported a similar finding using data for the period 1975–1994; they attributed their finding to 'the unexplained high incidence of tumours of the CNS in that area of Scotland'. (In Britain, CNS tumours account for about 35–40% of solid tumours in children, as defined in this report.)

> (i)   There has always been a major difficulty with a systematic approach to the analysis of incidence rates in particular areas and that has been the selection of an appropriate statistical test. On the one hand, choosing the 'best' test requires knowledge of at least some aspects of the pattern of risk in the vicinity. On the other hand, choosing an arbitrary test increases the chance of failing to detect a genuine effect. However, recent theoretical developments have made possible the identification of a reasonable test to use at each location. These developments have been used in the analyses employed in this report.

(ii) The tests have been applied to 28 sites for two diagnostic groups (leukaemia/NHL and solid tumours) of cases of childhood cancer registered at ages 0–14 years in England, Scotland and Wales between 1969 and 1993.

(iii) There was no evidence for a *general* increase in risk at these sites for these two major diagnostic groups, which cover all cancers in this age range.

(iv) There were no significant results relating to any of the power generating stations.

(v) For leukaemia and NHL there was some evidence of a raised risk near to the installations at Sellafield, Burghfield, Dounreay and Rosyth. The first three of these have been studied in some detail and are discussed in previous COMARE reports.

(vi) For solid tumours, ie tumours other than leukaemia and NHL, there were significant results at Aldermaston, Burghfield, Harwell and Rosyth. These results may be simply a reflection of the generally increased incidence in the areas containing these installations.

(vii) To summarise, several of the significant findings for the sites considered here are consistent with increased risks in the areas in which these particular sites are located. The causes of such increased risks are unknown.

ANNEX 2A

ANALYSIS OF INCIDENCE
OF MYELOID LEUKAEMIA
AT AGES 0–4 YEARS

2A.1   A report (Busby, 2001), using cancer registration data from the Welsh Cancer Registry, published on the website of the Low Level Radiation Campaign, claims that there was an excess of myeloid leukaemia (ML) among children aged 0–4 years in Chepstow in the period 1974–1990. This report has not been subjected to the peer review that would be expected for publication in a scientific or medical journal. It suggests that the reported excess was attributable to radioactive discharges from Oldbury nuclear power station about 10 km away. The excess was based on only three cases and it is not clear why this age and diagnostic group was studied. It appears possible that it was a result of examining various aspects of the data on childhood leukaemia in that area. Such observations, if selected for attention *post hoc,* are very difficult to evaluate.

2A.2   Busby (2001) suggested that two of the cases were within 10 km of Oldbury nuclear power station, and that the third was within 25 km. A subsequent analysis by the Welsh Cancer Intelligence and Surveillance Unit found that one case was within 10 km and the remaining two were between 10 and 25 km from the power station (Steward et al, 2002). COMARE was asked by the Welsh Assembly Government to comment on the significance of the findings, and issued a statement which agreed that the incidence rate was higher than would be expected by chance but pointed out that, because of the small number of cases (3 in 25 years and none in the latest 8 years 1991–1998), this could be due to chance. This report is available on the COMARE website: www.comare.org.uk. COMARE agreed to arrange for further analyses to be carried out in order to examine the incidence of myeloid leukaemia at ages 0–4 years around nuclear installations generally.

2A.3   These analyses use the same data as in the rest of the report, but include only cases with ML at ages 0–4 years. We consider first, in paragraphs 2A.4 and 2A.5, the results for 25 km circles as used in the analyses above. In paragraphs 2A.6 and 2A.7 we give the results for 10 km circles for comparison with the results of Busby (2001).

2A.4   The results for 25 km circles around each site are presented in Tables 2A.1 and 2A.2 in the same format as for the earlier analyses. Results are available for 23 of the 28 sites, there being no cases within the 25 km radius for the remaining 5 sites. Of the total of 23 sites with at least one case, there were 12 in which the observed number of cases was greater than expected, and 11 in which it was less, although the expectation in each was very small. In total, there were 212 cases within the 25 km circles as compared with 211.08 expected. Only one result was significant, that for Burghfield (P = 0.0499). In the absence of any biological reason for expecting a particular risk at this site, it would appear that the result should be regarded as due to chance.

Table 2A.1 Results for myeloid leukaemia diagnosed at ages 0–4 years in 1969–1993 in 25 km regions around British Energy and Magnox Generation stations in Great Britain

Site (start-up year)	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Berkeley (1961)	135	9	9.48	0.95	2	0.588
Bradwell (1961)	105	5	6.81	0.734	1	0.819
Chapelcross (1958)	33	2	1.57	1.270	2	0.480
Dungeness (1965)	37	1	1.51	0.660	2	0.671
Hartlepool (1983)	137	5	2.67	1.874	1	0.074
Heysham (1983)	97	2	1.98	1.012	2	0.401
Hinkley Point (1964)	80	7	4.43	1.579	1	0.188
Hunterston (1963)	58	5	3.28	1.526	2	0.151
Oldbury (1967)	150	14	11.99	1.167	1	0.149

Notes

(a) Excluding wards with zero population under 15 years.

(b) The tests selected were as follows:

    (1) LRS test using 1/(ward distance) as a score,

    (2) LRS test using the square root of 1/(ward rank) as a score.

(c) P-value using chosen test, based on 10,000 simulations.

Table 2A.2 Results for myeloid leukaemia diagnosed at ages 0–4 years in 1969–1993 in 25 km regions around nuclear installations in Great Britain other than those in Table 2A.1

Site (start-up year)	Operator	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Aldermaston (1952)	Atomic Weapons Establishment (AWE)	135	14	10.61	1.32	2	0.143
Amersham (1940)	Amersham plc	316	36	32.28	1.115	2	0.480
Burghfield (1950)	AWE	179	14	15.57	0.899	1	0.050
Capenhurst (1953)	British Nuclear Fuels (BNFL)	228	28	24.52	1.142	1	0.085
Cardiff (1979)	Amersham plc	151	6	8.42	0.712	2	0.909
Chatham (1967)	Ministry of Defence (MOD)	222	18	22.34	0.806	1	0.902
Devonport (1973)	Private (formerly MOD) dockyard	64	3	5.72	0.524	2	0.918
Faslane (1963)	MOD	42	5	3.16	1.585	2	0.106
Harwell (1946)	United Kingdom Atomic Energy Authority (UKAEA)	111	4	6.94	0.576	2	0.939
Holy Loch (1961)	US Naval Base	40	5	3.35	1.494	2	0.083
Rosyth (1963)	Private (formerly MOD) dockyard	167[d]	11	14.01	0.785	2	0.835
Sellafield (1950)	BNFL and UKAEA	32	2	1.00	2.007	2	0.162
Springfields (1948)	BNFL and UKAEA	184	11	12.04	0.913	1	0.644
Winfrith (1967)	UKAEA	69	5	5.04	0.992	2	0.388

Notes

(a) Excluding wards with zero population under 15 years.

(b) The tests selected were as follows:

    (1) LRS test using 1/(ward distance) as a score,

    (2) LRS test using the square root of 1/(ward rank) as a score.

(c) P-value using chosen test, based on 10,000 simulations.

(d) One ward near Rosyth had zero population at ages 0–4 years. Consequently the number of wards here is one fewer than in Tables 2.2 and 2.5.

2A.5   The result for Oldbury is not significant. The present analysis includes 14 cases in the 25-year period 1969–1993 as compared with the 3 found by Busby (2001) in the 17-year period 1974–1990. The present analysis includes cases on the English side of the power station (where there is a much greater population) in addition to those on the Welsh side studied by Busby. These data do not confirm the hypothesis of Busby.

2A.6   The above analyses relate to circles of 25 km radius, as used in the other analyses in this report. In order to replicate the analysis by Busby (2001) as closely as possible, a parallel set of analyses for ML at ages 0–4 years within 10 km of any of the nuclear installations studied here was also carried out. Results are presented in Tables 2A.3 and 2A.4 for the 15 installations where there was at least one case within this radius. For Oldbury, the site that generated the hypothesis, and where one might therefore expect to find an increase, there was a slight but not statistically significant increase in the SIR while the unconditional LRS distance test was not significant (P = 0.1296). The area defined by the 10 km radius here again differs from that used by Busby, in that it includes areas on both the Welsh and English sides of the River Severn. The LRS distance test was statistically significant for Burghfield (P = 0.0144) and Hartlepool (P = 0.0395), although the numbers involved were small. The SIR in each case was greater than one, but not significantly so. Overall, there were 38 cases observed against 36.38 expected at the 28 sites (including those not shown in the table – for which the expected numbers were non-zero even though no cases were actually observed).

2A.7   Although there is a slight tendency for cases to concentrate near the installations at Hartlepool and Burghfield, the numbers of cases are very small and there is no evidence of a consistent pattern nor of a general increase near installations of either type.

Table 2A.3 **Results for myeloid leukaemia diagnosed at ages 0–4 years in 1969–1993 in 10 km regions around British Energy and Magnox Generation stations in Great Britain**

Site (start-up year)	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Berkeley (1961)	16	1	0.96	1.042	2	0.537
Hartlepool (1983)	53	4	1.11	3.618	1	0.039
Heysham (1983)	20	1	0.58	1.716	2	0.364
Oldbury (1967)	15	2	0.80	2.492	1	0.130

Notes

(a) Excluding wards with zero population under 15 years.
(b) The tests selected were as follows:
   (1) LRS test using 1/(ward distance) as a score,
   (2) LRS test using the square root of 1/(ward rank) as a score.
(c) P-value using chosen test, based on 10,000 simulations.

Table 2A.4 **Results for myeloid leukaemia diagnosed at ages 0–4 years in 1969–1993 in 10 km regions around nuclear installations in Great Britain other than those in Table 2A.3**

Site (start-up year)	Operator	No. wards[a]	Obs	Exp	Obs/Exp (SIR)	Test choice[b]	P-value[c]
Aldermaston (1952)	Atomic Weapons Establishment (AWE)	22	2	1.19	1.676	2	0.182
Amersham (1940)	Amersham plc	49	3	2.62	1.145	2	0.566
Burghfield (1950)	AWE	41	8	4.33	1.850	1	0.014
Capenhurst (1953)	British Nuclear Fuels (BNFL)	48	5	3.24	1.545	1	0.085
Chatham (1967)	Ministry of Defence (MOD)	39	2	4.74	0.422	1	0.876
Devonport (1973)	Private (formerly MOD) dockyard	27	3	4.23	0.709	2	0.854
Faslane (1963)	MOD	4	1	0.40	2.494	2	0.174
Holy Loch (1961)	US Naval Base	8	2	0.97	2.064	2	0.090
Rosyth (1963)	Private (formerly MOD) dockyard	19	1	1.98	0.504	2	0.673
Springfields (1948)	BNFL and United Kingdom Atomic Energy Authority (UKAEA)	41	2	2.78	0.719	1	0.550
Winfrith (1967)	UKAEA	7	1	0.35	2.839	2	0.271

Notes

(a) Excluding wards with zero population under 15 years.
(b) The tests selected were as follows:
   (1) LRS test using 1/(ward distance) as a score,
   (2) LRS test using the square root of 1/(ward rank) as a score.
(c) P-value using chosen test, based on 10,000 simulations.

ANNEX 2B

STATISTICAL METHODS

2B.1   The analyses in this chapter are concerned with the geographical distribution in relation to sites of nuclear installations of, first, childhood leukaemia and NHL and, second, malignant tumours other than leukaemia and NHL (referred to here as 'solid tumours'). The relevant statistical tests are ones that examine the difference between the observed and expected numbers of cases in geographical areas in the vicinity (here, census wards), taking into account the distance of each such area from the site being considered. Such tests are described in the methods section of the paper by Bithell et al (1994) and in Bithell (1995).

Choice of test statistic   2B.2   In the present study, as in statistical analyses generally, there is a choice of possible tests to use. In order to choose between them, consideration should be given to the relative power of each to detect an effect – in this case a relationship between risk and the distance from a potential carcinogenic source, as described by the relative risk function. For any given shape of relative risk function and degree of risk in the population being studied, the statistically most powerful test will depend substantially on the geographical distribution of the population, in particular on the magnitude of the expected numbers of cases (Sharp et al, 1996). For this reason comparisons were made of the power of a number of contending test statistics *separately at each of the 28 sites* for each of a range of relative risk functions. The tests compared are: Stone's maximum likelihood ratio (MLR) and Poisson maximum (P-max) statistics; and the three linear risk score (LRS) statistics that score the cases in each ward by the inverse distance rank, the inverse distance and the inverse of the square root of the rank of the ward centres (Bithell et al, In Preparation; Sharp et al, 1996). The test that appeared to be the most powerful at each particular site was then used to carry out an *unconditional* test of the distribution of cases around that site: these tests are sensitive both to a spatial aggregation of cases towards the centre and to an overall excess in the area studied and are appropriate when the expectations are thought to be reliable predictors of the incidence under the hypothesis that there is no spatial aggregation. (A *conditional* test, by contrast, uses information only on the spatial distribution of the cases, and is not affected by an overall excess or deficit of cases in the area; this would be appropriate if it were thought that there may be a systematic over- or under-estimation of the incidence rate in the region in which the installation was situated or if the surrounding area had a generally increased or decreased incidence.) All the tests carried out for the initial analysis were unconditional. Where statistically significant results were obtained, a conditional test was also carried out to attempt to determine the degree to which the significance could be attributed to the proximity to the source.

2B.3   The power comparisons were made by averaging over 75 different risk functions chosen as follows. First, the risk functions were chosen to have each of five different functional forms, including exponential and reciprocal decay, for example. Second, for each different functional form, a decay rate was chosen such that the relative risk had a 'half life' of 5, 10 or 15 km. (These distances were scaled appropriately for the analyses of 10 km areas.) Finally, the overall

relative risk was scaled so that the power of the best test for that particular risk function would be successively 50, 60, 70, 80 and 90%. This choice was in line with the consideration that the tests would *all* be highly likely to reject the null hypothesis if the power is high, while very unlikely to do so in the low power range; at these extremes there would be little to choose between the tests. The best test for a given risk function is known and its power can be calculated to a good approximation; this provides a benchmark against which the different test statistics can be compared. The power was then estimated using simulation methods and averaged over the 75 risk functions. It is emphasised that the actual test on each real data set was carried out using the test statistic identified in this way as having the largest average power; details of these calculations will be described further in a forthcoming paper (Bithell et al, In Preparation). The LRS test using the square root of the rank (Lumley, 1995) turned out to be the most powerful at the majority of the sites. It is noteworthy that, with a uniform population distribution, it produces a scoring nearly equivalent to that of inverse distance, which was the next best performer at most of the 28 sites.

Estimation of statistical significance: P-values

2B.4   The null distributions of the statistics in each case were simulated, so that the P-values in the tables may be regarded as estimates of the true P-values based on the (unknown) true distribution of each test-statistic. In order to provide reasonably good estimates, 10,000 simulations were used at each site.

CHAPTER 3

DISCUSSION

3.1   Much of the public and media concern about the possibility of increased cancer rates around nuclear installations, and many of the scientific publications, relate to childhood leukaemia. This is perhaps not surprising as leukaemia is the most common of childhood cancers. In this report we have considered the results of a series of updated analyses concerning the incidence of childhood leukaemia and other childhood cancers in the vicinity of nuclear sites in England, Wales and Scotland. These analyses are new, both in the sense that they use new data and because, for each site, a series of computations was carried out to determine the most appropriate statistical test. Some statistically significant results are found in these new analyses: these are largely in line with previous findings.

Nuclear power stations

3.2   The results for nuclear power stations are unambiguous and, as might be expected from their very low discharges, there is no indication of any effect on the incidence of childhood cancer. For leukaemia and non-Hodgkin lymphoma (NHL) there were only three sites with marginally higher than expected numbers and ten where the numbers were less than expected. None of these was remotely significant from a statistical point of view. For solid tumours, there were five sites with very slightly raised values and eight sites with lower values. Again, none of these had any statistical significance. Moreover, within the 25 km circles around the sites there was no evidence of any trend for rates to be higher nearer to the sites. We can, therefore, say quite categorically that there is no evidence from this very large study that living within 25 km of a nuclear generating site in Britain is associated with an increased risk of childhood cancer.

Other nuclear sites

3.3   The situation with the other nuclear sites is more complicated. For leukaemia and NHL there are four sites where there is some evidence of a raised incidence close to the installation, namely Sellafield, Burghfield, Dounreay and Rosyth. Each of these sites has been identified previously as having a possibly increased risk in the vicinity. The most important finding in this new analysis is that none of the other sites in this group has a significantly increased rate of leukaemia and NHL. Five of these other sites have registration rates slightly higher than the expected value, whereas six sites have slightly lower rates than this value.

3.4   For solid tumours four sites in this study stand out as having rates that are significantly raised, namely Aldermaston, Burghfield, Harwell and Rosyth. Excluding these, there are four with slightly raised rates (but well below statistical significance), and seven with slightly lower rates. None of these rates differs statistically from the expected rates. We consider that there is no evidence to suggest that any of these sites, with the exception of Aldermaston, Burghfield, Harwell and Rosyth, are associated with raised rates of childhood solid tumours. It is interesting that Dounreay, with a documented increase in incidence of childhood leukaemia, has a markedly lower than expected rate for solid tumours (SIR 0.48). This rate is, however, based on only three cases

(Exp = 6.29) and is almost certainly a chance finding. It is noteworthy that two of the four sites with significantly raised rates for solid tumours also have significantly raised rates for leukaemia and NHL, namely Burghfield and Rosyth.

3.5   For Rosyth the pattern of incidence is significantly different from what would be expected, both for leukaemia and NHL and for solid tumours (Tables 2.2 and 2.5). However, these patterns are quite distinct for the two groups of cases.

> (i) For solid tumours, there is an overall excess incidence in the 25 km circle (SIR 1.14) which appears to reflect a previously reported high incidence of CNS tumours (which make up a large component of the 'solid tumours' category) in the surrounding Fife and Lothian areas (McKinney et al, 1994; Sharp et al, 1999).

> (ii) For leukaemia and NHL, however, there is no evidence of a substantially increased overall excess incidence in the 25 km circle (SIR 1.03), but there is a statistically significant tendency towards a higher incidence near the site than would have been expected.

In previous studies, Heasman et al (1987) reported a higher than expected incidence of leukaemia within 6.25 km of the site in 1974–1978, but not in the earlier and subsequent time periods 1968–1973 and 1979–1983. Sharp et al (1996) found no evidence of a significant overall excess of leukaemia or NHL or of a trend in risk related to Rosyth.

3.6   The true significance of the result for leukaemia and NHL in the population living near Rosyth is difficult to assess. It should be borne in mind that it is a product of multiple significance testing: this is in contrast to Sellafield, Dounreay, Aldermaston, Burghfield and Harwell which were all individually selected for investigation in earlier studies. It is also important to note that the magnitude of the possible increase in risk of leukaemia and NHL in the vicinity of Rosyth is very much smaller than those found in the studies of the sites listed above.

Sites previously considered in earlier COMARE reports

Sellafield

3.7   As we noted previously, Sellafield was the first site where it had been suggested that radioactive discharges were associated with local levels of childhood cancer. This hypothesis was examined by the Black Advisory Group in 1984 and by COMARE in 1985 with no conclusive evidence of an association being found between discharge levels and childhood cancer incidence. Historically, Sellafield is the UK nuclear site with the largest of all radioactive discharge levels, which peaked in the 1970s and have since declined to the much lower levels seen at present. We re-examined the original hypothesis, in considerable depth, in our Fourth Report (COMARE, 1996). We examined all the known pathways of exposure to man from both external and internal radiation sources, including sea to land transfer. We examined the risks to different stages of human development from the fetus and embryo to the adult and also the risk to different tissues and we incorporated as many of the variables that could introduce uncertainty in the dose calculations for which data were available. In our Fourth Report we also looked at other possible hypotheses concerning the site and the observed level of childhood cancer: these ranged from an investigation of the non-radioactive chemicals used and discharged from the site to hypotheses concerning infectious aetiologies for childhood leukaemia. We concluded that the excess of childhood leukaemia and NHL in the area, which is mainly located in the local village of Seascale, when examined in the context of the national distribution of these diseases, is highly unusual in that it has persisted for some tens of years and that it is unlikely to be due to chance. However, we found that no one factor could

account for the observed increase in the level of disease, although infection, at least in part, could not be ruled out as having some causal association. Some interaction between different factors could also not be ruled out.

Dounreay

3.8   During its enquiry concerning the area around Sellafield, the Black Advisory Group had requested information about the incidence of childhood leukaemia around Dounreay, the only other nuclear installation in the UK where nuclear fuel reprocessing was carried out. At that time the data did not suggest any evidence of an increase in leukaemia around this site. However, a further analysis (Heasman et al, 1986), prompted by the public enquiry into a new reprocessing site, suggested an elevated incidence of leukaemia in young people in the local town of Thurso. COMARE was asked to investigate and report, which we did in our Second Report (COMARE, 1988). We identified six cases of leukaemia among people aged up to 25 years living within 25 km of Dounreay during the period 1968–1984. We examined the radioactive discharges from the site and commented on the considerably lower levels of discharges from Dounreay than from Sellafield. We also noted that there was no excess of other types of childhood cancer in the area. We had to re-examine some of our conclusions on the possible health effects from radioactivity released from the Dounreay site when radioactive particles were found on the Dounreay foreshore (COMARE/RWMAC, 1995) and on a local beach, Sandside Bay (COMARE, 1999). Although highly critical of parts of the nuclear industry and its regulators concerning how this information came to light, we could still find no causal link between levels of radioactivity in the general environment and that of childhood cancer in the local area. A further study (R J Black, personal communication) showed that, although there was an increased level of childhood leukaemia in this area in the years 1968–1996, this increase did not achieve statistical significance, as no cases had occurred since 1992: hence the excess seen in the 1980s has not persisted over decades as it has in the case of Sellafield.

Aldermaston, Burghfield and Harwell

3.9   The leukaemia incidence in young people living in the areas around these sites was studied because clinicians at the Royal Berkshire Hospital, Reading, suspected that more cases of childhood leukaemia were being referred to the hospital than would normally have been expected. Although the incidence was relatively low compared to that at Seascale or the area around Dounreay, the area is much more densely populated and therefore larger numbers of cases were registered. The topic was the subject of a Yorkshire Television programme entitled *Inside Britain's Bomb*, broadcast in December 1985. A study by Roman et al (1987) found that there was a statistically significantly increased incidence of childhood leukaemia in an area within 10 km of either Aldermaston or Burghfield in the years 1972–1985. This increase was found only in the age group 0–4 years. These studies were referred to COMARE for advice. We also had access to registration data from the Childhood Cancer Research Group (CCRG) in Oxford. These data showed that for the years 1971–1982, there was also an excess of all childhood cancers, other than leukaemia, in the same area and in the same age group (0–4 years) as that found by Roman et al.

3.10   Our Third Report (COMARE, 1989) identified a significant excess of childhood leukaemia cases confined to those aged 0–4 years, among whom 29 cases were observed resident less than 10 km from Aldermaston or Burghfield against 14.4 expected. There were also 30 cases of other cancers in this age group and area compared to 19.4 expected. We concluded that although there is a small but significant excess of childhood leukaemia and other cancers in the vicinity of these establishments, the radioactive discharges from these and the Harwell site were far too low to account for the epidemiological findings.

3.11   The situation concerning these three sites is complicated because of their close proximity to each other. In fact, 25 km circles drawn around each site all overlap. The discharges from Aldermaston have historically been much greater than those from Burghfield; thus if the excess around Burghfield were due to radioactive discharges one would presumably expect a greater excess around Aldermaston than that observed. However, it has been argued that the liquid discharge point from Aldermaston is closer to Burghfield. To put the levels of discharge in further perspective, it should be pointed out that at peak levels the Sellafield discharges were over 200,000 times greater than the Aldermaston and Burghfield discharges combined. Furthermore, we noted that the radioactive discharges from Aldermaston and Burghfield were only half the level of the radioactive discharges from the nearby coal-fired power station at Didcot (COMARE, 1989). The Didcot discharges also contain a significant proportion of alpha emitters such as radium and polonium-210. We discussed all of these complexities in detail in our Third Report. Nevertheless, we noted that the rate around Aldermaston, in an analysis based on rates within 10 km circles around the sites, was raised, albeit without statistical significance. The new statistical analyses do not indicate any tendency for an increased rate closer to these sites within the 25 km circles, although the fact that these circles all overlap makes interpretation complex. However, it is possible that the significant effects are a reflection of the raised rates in Berkshire and south Oxfordshire. This is discussed in greater detail in a forthcoming report already in preparation by COMARE.

Overall distribution of childhood cancer in Great Britain

3.12   In considering all of these results, we need to do so in the light of the distribution of childhood cancer in Britain. This distribution will be considered in detail in the forthcoming report that is in preparation, but a few generally relevant points can be made. First, rates of childhood cancer do differ from one part of the country to another and these differences are unlikely to be due to differing extents of cancer registration. They reflect environmental, genetic or social and behavioural differences that are not yet understood. It is possible that the increased rates around some nuclear sites in Berkshire and south Oxfordshire may reflect a general increase in the incidence in these counties.

3.13   A second general point about cancer distribution concerns clustering. Both leukaemia/NHL and some solid tumours appear to occur in clusters over and above those that would occur by chance. Population mixing seems to be associated with some of these, but the underlying biological mechanism of population mixing remains obscure. Some authors have speculated that variations in exposure to infections may be involved. While plausible in principle, more definite evidence as to the role of infection is needed before this can be properly evaluated. Statistical analysis of the times and places of occurrence of cases cannot by itself tell us whether any particular cluster is a chance event or not. It means, though, for sites where observed rates are higher than expected this might be attributable to causative factors that result in clustering. In our opinion the excesses around Sellafield and Dounreay are unlikely to be due to chance, although there is not at present a convincing explanation for them (COMARE, 1988, 1996).

CHAPTER 4

SUMMARY AND CONCLUSIONS

4.1   Public and media concern about childhood cancer around nuclear installations has usually focused on reports of 'clusters' rather than on analyses reporting high incidence rates. Such reports are typically not based on systematic analyses but reflect a perception that an unusual pattern of occurrence has been identified. Such perceptions may well be correct but the way in which most clusters come to notice does not permit any formal analysis of their importance to be made.

4. 2   To avoid these problems we have, therefore, in this report considered the results of a series of updated analyses concerning the incidence of childhood leukaemia and other childhood cancers in the vicinity of nuclear sites in England, Wales and Scotland. These analyses use new data and, for each site, a series of computations was carried out to determine the most appropriate statistical test. Some statistically significant results are found in these new analyses but these are largely in line with previous findings.

4.3   Our analyses demonstrated similar findings to those in previous studies, such as the excess of childhood cancer in the village of Seascale near Sellafield and the excess of childhood leukaemia in Thurso near Dounreay. However, we have pointed out the anomalies between some of these studies such as the longevity of the excess in Seascale and the apparently transient nature of the excess in Thurso. The known excess around Aldermaston, Burghfield and Harwell has also been discussed in terms of both the lower doses the general public received by radioactive discharges from those sites than from the discharges from the local coal-fired power station at Didcot and the general incidence of childhood cancer in Berkshire and south Oxfordshire (COMARE, 1989).

4.4   We examined the incidence of childhood cancer in the vicinity of all nuclear power stations in Great Britain. We found no evidence of excess numbers of cases in any local 25 km area, which would include either primary exposure to radioactive discharges or secondary exposure from resuspended material.

4.5   Among nuclear installations other than power generating stations, only one finding differs from previously published results. Although the observed number of cases of leukaemia and non-Hodgkin lymphoma in children living within 25 km of Rosyth was close to that expected (ratio = 1.03), there was evidence of a trend in risk with distance from the plant. This latter aspect of our findings differs from previously published work using similar but not identical methods. Because of this, it is not possible to conclude that living near the site at Rosyth confers a genuinely higher risk of leukaemia and NHL. It is clearly of importance to establish the reasons for the differences between the two sets of results: therefore COMARE is encouraging the research workers concerned to undertake a detailed comparison of the data and methodologies used – see Recommendation 2, Chapter 5.

CHAPTER 5

RECOMMENDATIONS

Recommendation 1   We have previously recommended that the geographical studies around nuclear installations should be complemented by more general studies of variations in incidence and clustering in Britain as a whole. This work is now nearly completed and the results will be presented in a forthcoming report already in preparation by COMARE.

Recommendation 2   We recommend that the apparent trend in the incidence of leukaemia and non-Hodgkin lymphoma in the vicinity of the Rosyth site should be investigated. The finding differs from that previously published by Sharp et al (1996) and it is important to understand the reasons for this. The differences could, for instance, be attributable to differences in the cases of leukaemia and NHL included in the two studies, or to differences in statistical methodology. More importantly, we need to determine whether the results reported here indicate genuine variations in risk of leukaemia and NHL based on proximity of residence to Rosyth and, if they do, to investigate the reasons for this. We recommend that the necessary work should be undertaken as soon as possible and COMARE will review the results when this is complete and, if necessary, issue a statement.

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THE APPENDICES

APPENDIX A

GLOSSARY

AETIOLOGY
The study of causes of disease.

CENSUS
The enumeration of an entire population, usually with details being recorded on residence, age, sex, occupation, ethnic group, marital status, birth history, and relationship to head of household.

HODGKIN'S DISEASE
A form of malignant lymphoma that is characterised by painless enlargment of lymphatic tissue and the spleen and often involves symptoms such as fever, wasting weight loss, anaemia, and night sweats.

INCIDENCE
The number of instances of illness commencing, or of persons falling ill, during a given period in a specified population. More generally, the number of new events, eg new cases of disease in a defined population, within a specified period of time. The term incidence is sometimes used to denote 'incidence rate'.

INFECTIOUS AETIOLOGY
The process by which disease is brought about by a transmissible agent, eg a virus.

LEUKAEMIA
A group of malignant diseases of the blood-forming tissues in which normal control of cell production breaks down and the cells that are produced are abnormal. Leukaemia (L) can be classified as either lymphoid (L) or myeloid (M) and as either acute (A) or chronic (C) (eg ALL, AML, CLL and CML). Lymphoid and myeloid refer to the type of white cell affected. If this is a lymphocytic cell the condition is called lymphocytic or lymphoblastic leukaemia. Myeloid leukaemias affect any of the other types of white blood cells. Acute leukaemias develop quickly and progress rapidly, chronic leukaemias are slower to develop and slower to progress.

LNHL
Abbreviation for leukaemia and non-Hodgkin lymphoma.

LYMPHOMA (L)
A malignant *tumour* of the lymphatic system (lymph nodes, reticulo-endothelial system and lymphocytes).

MALIGNANCY
Cancerous growth, a mass of cells showing uncontrolled growth, a tendency to invade and damage surrounding tissues and an ability to seed daughter growths to sites remote from the primary growth.

NON-HODGKIN LYMPHOMA (NHL)
A group of lymphomas that differ in important ways from Hodgkin's disease and are classified according to the microscopic appearance of the cancer cells. In epidemiological studies, childhood NHL and leukaemias are often combined due to historical difficulties in making diagnostic distinctions.

NULL HYPOTHESIS
The statistical hypothesis that one variable has no association with another variable or set of variables, or that two or more population distributions do not differ from one another.

POPULATION MIXING

The population mixing hypothesis proposes that childhood leukaemia can be a rare response to a common but unidentified infection (hence the absence of marked space–time clustering). Epidemics of this (mainly sub-clinical) infection are promoted by influxes of people into rural areas, where susceptible individuals are more prevalent that the average. Such influxes would increase population density and hence the level of contacts between susceptible and infected individuals, thereby increasing the risk of childhood leukaemia.

POISSON REGRESSION MODELLING

The process of fitting to a data set consisting of Poisson distributed counts a model in which the logarithm of each mean count is estimated by a linear combination of terms representing the effects of different explanatory factors.

P-VALUE

A P-value provides an idea of the strength of the evidence against the null hypothesis. A low P-value points to rejection of the null hypothesis. The commonly used significance level is 0.05. On this basis, any result giving a P-value less than 0.05 would be termed statistically significant and lead to rejection of the null hypothesis in favour of an alternative hypothesis.

RELATIVE RISK (RR)

The ratio of the risk of disease or death for those exposed to a risk factor to that for those not exposed to the factor.

RISK

The probability that an event will occur, eg that an individual will become ill or die before a stated period of time or age. Also, a non-technical term encompassing a variety of measure of the probability of a (generally) unfavourable outcome. *(See RELATIVE RISK.)*

SIGNIFICANCE TEST

A result that lies outside the range of values expected to occur, if some specified (null) hypothesis is true, is said to be statistically significant. A probability (P-value) of 0.05 for such an occurrence if the null hypothesis is in fact correct is commonly used to separate 'significant' from 'non-significant' results. This boundary is arbitrary.

STANDARDISED INCIDENCE RATIO (SIR)

The ratio of the actual number of cases in the study group or population to the expected number. The expected number is calculated assuming that the age and sex specific incidence rates applying to the population under study are those taken as the `reference rates'. These will often be those of the national population but may also be taken from a smaller area.

TREND

Movement in one direction (increase or decrease) of the values of a variable, either over a period of time, or in relation to distance from the site being analysed.

APPENDIX B

COMMITTEE ON MEDICAL ASPECTS OF RADIATION IN THE ENVIRONMENT

CHAIRMAN

Professor B A Bridges OBE BSc PhD CBiol FIBiol
Genome Damage and Stability Centre
University of Sussex
Brighton
(retired as Chairman December 2004)

PRESENT MEMBERS

Professor Freda Alexander BA MSc PhD
Department of Community Health Services
University of Edinburgh

Dr T Atkinson BSc PhD
Department of Geological Sciences
University College London

Dr H R Baillie-Johnson MB BS FRCR FRCP
Department of Oncology
Norfolk and Norwich University Hospital

Professor A T Elliott BA PhD DSc CPhys FInstP FIPEM
Western Infirmary
Glasgow
(Chairman from January 2005)

Dr C J Gibson BA MSc PhD FIPEM
Medical Physics and Clinical Engineering
Oxford

Professor Neva Haites BSc PhD MBChB MRCPath
Department of Medical Genetics
Aberdeen Royal Hospital NHS Trust

Dr Patricia McKinney BSc PhD MFPHM(Hon)
Paediatric Epidemiology Group
University of Leeds

Professor T J McMillan BSc PhD
Institute of Environmental and Natural Sciences
Lancaster University

Professor J Little BA MA PhD
Department of Medicine and Therapeutics
University of Aberdeen *(until May 2004)*

Dr Margaret Spittle OBE MSc MB BS MRCS FRCP FRCR DMRT AKC
Meyerstein Institute of Radiotherapy and Oncology
Middlesex Hospital *(until September 2004)*

OTHER CONTRIBUTORS

Dr John Bithell of the University of Oxford also contributed significantly to the production of this report.

SECRETARIAT

Dr R Hamlet BSc PhD CBiol MIBiol (Scientific)

Dr Jill Meara MA MSc BMBCh FFPH (Medical)

Dr J R Cooper BSc DPhil (Scientific)

Dr G Kendall BSc MSc PhD (Scientific)

Miss Jane Bradley MRSC CChem

Miss Julie Kedward (Administrative)

ASSESSORS IN ATTENDANCE REPRESENTING THE FOLLOWING ORGANISATIONS

Department for the Environment, Food and Rural Affairs

Department of Health

Department of Health, Social Services and Public Safety (Northern Ireland)

Department of Trade and Industry

Environment Agency

Food Standards Agency

Health and Safety Executive

Information and Statistics Division, Common Services Agency, NHS Scotland

Medical Research Council

Ministry of Defence

National Radiological Protection Board
(now the Radiation Protection Division of the Health Protection Agency)

Office for National Statistics

Scottish Environment Protection Agency

Scottish Executive

Welsh Assembly Government

NUCLEAR INSTALLATIONS SUBCOMMITTEE

Chairman

Dr M Murphy

Members

Professor B A Bridges

Dr G Draper

Dr Julia Verne

Dr C J Gibson

Dr J Bithell

Secretariat

Dr R Hamlet

Dr W Zhang

APPENDIX C

DECLARATION OF MEMBERS' INTERESTS CODE OF PRACTICE

Introduction

1   This code of practice guides members of COMARE as to the circumstances in which they should declare an interest in the course of the Committee's work.

2   To avoid any public concern that commercial interests of members might affect their advice to Government, Ministers have decided that information on significant and relevant interests of members of its advisory committees should be on the public record. The advice of the Committee frequently relates to matters which are connected with the nuclear industry generally and, less frequently, to commercial interests involving radioactivity and it is therefore desirable that members should comply with the Code of Practice which is set out below.

Scope and definitions

3   This code applies to members of COMARE and sub-groups or working groups of COMARE which may be formed.

4   For the purposes of this Code of Practice, the 'radiation industry' means:

(a)   companies, partnerships or individuals who are involved with the manufacture, sale or supply of products processes or services which are the subject of the Committee's business. This will include nuclear power generation, the nuclear fuel reprocessing industry and associated isotope producing industries, both military and civil;

(b)   trade associations representing companies involved with such products;

(c)   companies, partnerships or individuals who are directly concerned with research or development in related areas;

(d)   interest groups or environmental organisations with a known interest in radiation matters.

It is recognised that an interest in a particular company or group may, because of the course of the Committee's work, become relevant when the member had no prior expectation this would be the case. In such cases, the member should declare that interest to the Chairman of the meeting and thereafter to the Secretariat.

5   In this code, 'the Department' means the Department of Health, and 'the Secretariat' means the secretariat of COMARE.

Different types of interest – definitions

6   The following is intended as a guide to the kinds of interests which should be declared. Where a member is uncertain as to whether an interest should be declared he or she should seek guidance from the Secretariat or, where it may concern a particular subject which is to be considered at a meeting, from the Chairman at that meeting. Neither members nor the Department are under an obligation to search out links between one company

and another, for example where a company with which a member is connected has a relevant interest of which the member is not aware and could not reasonably be expected to be aware.

If members have interests not specified in these notes but which they believe could be regarded as influencing their advice they should declare them to the Secretariat in writing and to the Chairman at the time the issue arises at a meeting.

Personal interests   6.1   A personal interest involves payment to the member personally. The main examples are:

> (a)   <u>Consultancies or employment</u>: any consultancy, directorship, position in or work for the radiation industries which attracts regular or occasional payments in cash or kind.
>
> (b)   <u>Fee-paid work</u>: any work commissioned by those industries for which the member is paid in cash or kind.
>
> (c)   <u>Shareholdings</u>: any shareholding in or other beneficial interest in shares of those industries. This does not include shareholdings through unit trusts or similar arrangements where the member has no influence on financial management.

Non-personal interests   6.2   A non-personal interest involves payment which benefits a department for which a member is responsible, but is not received by the member personally. The main examples are:

> (a)   <u>Fellowships</u>: the holding of a fellowship endowed by the radiation industry.
>
> (b)   <u>Support by industry</u>: any payment, other support or sponsorship by the radiation industry which does not convey any pecuniary or material benefit to a member personally but which does benefit their position or department, eg:
>
> > (i)   a grant from a company for the running of a unit or department for which a member is responsible;
> >
> > (ii)   a grant or fellowship or other payment to sponsor a post or a member of staff in the unit for which a member is responsible. This does not include financial assistance for students, but does include work carried out by postgraduate students and non-scientific staff, including administrative and general support staff;
> >
> > (iii)   the commissioning of research or work by, or advice from, staff who work in a unit for which the member is responsible.
>
> (c)   <u>Support by charities and charitable consortia</u>: any payment, other support or sponsorship from these sources towards which the radiation industry has made a **specific and readily identifiable** contribution. This does not include unqualified support from the radiation industry towards the generality of the charitable resource.

Trusteeships: where a member is trustee of a fund with investments in the radiation industry, the member may wish to consult the Secretariat about the form of declaration which would be appropriate.

Members are under no obligation to seek out knowledge of work done for or on behalf of the radiation industry within departments for which they are responsible if they would not reasonably expect to be informed.

Declaration of interests

Declaration of interests to the department

7   Members should inform the Department in writing when they are appointed of their <u>current personal</u> and <u>non-personal</u> interests and annually in response to a Secretariat request. Only the name of the company (or other body) and the nature of the interest is required; the amount of any salary, fees, share-holding, grant, etc, need not be disclosed to the Department. An interest is current if the member has a continuing financial involvement with the industry, eg if he or she holds shares in a radiation company, has a consultancy contract, or if the member or the department for which he or she is responsible is in the process of carrying out work for the radiation industry. Members are asked to inform the Department at the time of any change in their <u>personal</u> interests, and will be invited to complete a form of declaration once a year. It would be sufficient if changes in <u>non-personal</u> interests are reported at the next annual declaration following the change. (Non-personal interests involving less than £1000 from a particular company in the previous year need not be declared to the Department.)

Declaration of interests at meetings and participation by members

8   Members are required to declare relevant interests at Committee meetings and to state whether they are personal or non personal interests. The declaration should include an indication of the nature of the interest.

(a)   If a member has a current (personal or non-personal) interest in the business under discussion, he or she will not automatically be debarred from contributing to the discussion subject to the Chairman's discretion. The Chairman will consider the nature of the business under discussion and of the interest declared (including whether it is personal or non-personal) in deciding whether it would be appropriate for the relevant member to participate in the item.

(b)   If a member has an interest which is not current in the business under discussion, this need not be declared unless not to do so might be seen as concealing a relevant interest. The intention should always be that the Chairman and other members of the Committee are fully aware of relevant circumstances.

9   A member who is in any doubt as to whether he or she has an interest which should be declared, or whether to take part in the proceedings, should ask the Chairman for guidance. The Chairman has the power to determine whether or not a member with an interest shall take part in the proceedings.

10   If a member is aware that a matter under consideration is or may become a competitor of a product process or service in which the member has a <u>current personal</u> interest, he or she should declare the interest in the company marketing the rival product. The member should seek the Chairman's guidance on whether to take part in the proceedings.

11   If the Chairman should declare a current interest of any kind, he or she should stand down from the chair for that item and the meeting should be conducted by the Deputy Chairman or other nominee if he or she is not there.

12   Some members of the Committee may, at the time of adoption of this note, or (in the case of new members) of their joining the Committee, be bound by the terms of a contract which requires them to keep the fact of the contractual arrangement confidential. As a transitional measure, any member so affected should seek to agree an entry for the public record (see paragraph 14) with the other party. If such agreement does not prove possible, the members shall seek a waiver permitting them to disclose their interest, in confidence, to the Chairman and the Secretariat. The Secretariat will maintain a confidential register of such disclosures which will not form part of the public record.

13   On adoption of this note members shall not enter into new contractual obligations which would inhibit their ability to declare a relevant interest.

Record of interests

14   A record will be kept in the Department of the names of members who have declared interests to the Department on appointment, as the interest first arises or through an annual declaration, and the nature of the interest.

15   Information from the record will be made available by the Secretariat to bona-fide enquirers and published by any other means as and where the Department deems appropriate.

Members' declarations of interests – 2005

Member	Company	Personal interest	Company	Non-personal interest
Prof F Alexander		None		None
Dr T Atkinson		None	UKAEA	Consultancy
Dr H R Baillie-Johnson		None		None
Prof B Bridges		None		None
Prof A Elliott		None		None
Dr C J Gibson		None		None
Prof N Haites		None		None
Prof J Little		None		None
Dr P McKinney		None		None
Prof T McMillan		None	Westlakes Research Inst	PhD students and consumables
Prof M D Mason		None		None
Dr C D Mitchell		None		None
Dr M Murphy	International Power	Shares		None
Prof L Parker		None		None
Dr R A Shields		None		None
Dr M Spittle		None		None
Prof A M R Taylor		None		None
Prof J Thacker		None		None
Dr J Verne		None		None
Prof R Waters		None		None
Prof E Wright		None		None