

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

NINTH REPORT

Advice to Government on the review of the radiation risks from radioactive internal emitters carried out and published by the Committee Examining Radiation Risks of Internal Emitters (CERRIE).

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ISBN 0-85951-547-8

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FOREWORD

i The Committee on Medical Aspects of Radiation in the Environment (COMARE) was established in November 1985 in response to the final recommendation of the report of the Independent Advisory Group chaired by Sir Douglas Black*. Our terms of reference are

“to assess and advise Government and the Devolved Administrations on the health effects of natural and man-made radiation in the environment and to assess the adequacy of the available data and the need for further research”

ii In 2001, the Government requested COMARE to provide up-to-date advice on the risk estimates applied to radiation arising from radioactivity within the body. Consequently, on 31 July 2001, the then Environment Minister, Rt Hon Michael Meacher MP, after consulting COMARE, announced that a working group would be set up with the following remit,

“to consider present risk models for radiation and health that apply to exposure to radiation from internal radionuclides in the light of recent studies and to identify any further research that may be needed”

iii The group, later known as CERRIE (the Committee Examining Radiation Risks of Internal Emitters), was therefore set up with the composition as directed by the Minister. CERRIE held its first meeting in December 2001. Although established under the auspices of COMARE, CERRIE functioned independently of COMARE and of the Department for Environment, Food and Rural Affairs (DEFRA) and the Department of Health (DH). It was agreed that, following the publication of its report to COMARE, the Government would seek the views of COMARE on the CERRIE report. This report contains that advice.

* Black D (1984). Investigation of the possible increased incidence of cancer in West Cumbria. Report of the Independent Advisory Group. London, HMSO.

CHAPTER 1

INTRODUCTION

1.1 Government guidelines require the chairmen of formal scientific advisory committees such as COMARE to ensure that account is taken of views, sometimes of a more extreme nature, that may not be represented among the members of the committee. CERRIE was set up as a consultative exercise to elicit the widest spectrum of views, with members including those with extremely polarised positions. Indeed its first title was ‘Consultative Exercise on Radiation Risk Factors for Internal Emitters’; it was only later that it changed its title to ‘Committee Examining Radiation Risks of Internal Emitters’.

1.2 The wide range of views represented on CERRIE made it difficult to achieve a consensus in many areas, although there was usually a clear majority view. COMARE is grateful for the effort and time given by all of the members of CERRIE and for the many points raised for consideration. As a mechanism for exposing a wide variety of controversial issues it worked very well (although other less expensive and less time-consuming mechanisms might have been equally effective); as a mechanism for achieving consensus it did not succeed. Ultimately it has fallen to COMARE, a group of informed scientists and medical doctors who are completely independent of pressure groups or business, to wrestle with the issues and agree on advice to go forward to Government. In the deliberations of COMARE the emphasis is always on evidence (including its limitations and uncertainties) rather than on opinion or assertion.

Purposes of this report

1.3 In this short report we will summarise the conclusions and recommendations of the CERRIE report and then give our response, describing the underlying reasoning behind that response. We have always been aware that there are uncertainties in this area of scientific endeavour, and wherever possible we will use current information to put boundaries on those uncertainties.

1.4 Our response was made on the basis of a version sent to COMARE at the end of June. The final CERRIE report differs in minor editorial points with some reordering of material and also includes in its conclusions some additional comments and specific recommendations for further research that had previously appeared only in the body of the report. We do not believe that there are other significant changes in substance. Constraints of time prevented any further adjustment of the text as shown in the following pages given that the COMARE response was to be published at the same time as the CERRIE report. COMARE will respond to some of the additional comments and detailed recommendations for further research in due course.

1.5 Amongst most radiation scientists, there is broad agreement with the principles of the International Commission on Radiological Protection (ICRP)*,

* The International Commission on Radiological Protection, ICRP, is an independent registered charity, established to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionising radiation (website www.icrp.org).

as they relate to controlling the exposure of the population to ionising radiation. However, whilst these principles may adequately reflect regulatory needs they are often based on physical and mathematical approaches which cannot completely describe the biological parameters that they model.

1.6 In the field of radiation research there exists a lack of complete consensus amongst scientists about the quantification of risks from a variety of radiation exposure routes and radiation types. This lack of consensus can often be attributed to the gaps in knowledge about various biological pathways that ultimately result in uncertainties in risk calculations. The work of CERRIE and this COMARE response is limited to the risk to health from exposure to radioactive internal emitters, ie radionuclides that have been internalised (taken into the body) by a variety of routes but mainly by inhalation or ingestion. Where there is a lack of scientific consensus it helps if the size of any discrepancies can be quantified. When this can be achieved it is usually possible to consider what further research needs to be undertaken to help clarify the situation.

1.7 In this report we have indeed been able to make recommendations for further research. We hope serious consideration is given to these recommendations and to providing the increase in Government funding required to carry them out. We wish to emphasise the need for such an increase in funding as very little is spent by the Department of Health in this area and the absolute amount spent has been reduced by over 50% in the past 18 years. We are also aware that such research funds have sometimes been directed to obtaining advice on radiation matters and where this contributes to the research base it is totally acceptable; however, we note that CERRIE itself was 50% funded by the Department of Health Radiological Protection Research Programme (DH RPRP) budget and 50% from DEFRA funds. Thought should be given to whether the process was cost effective in terms of results and whether the money would have been better spent on other research projects.

CHAPTER 2

CERRIE CONCLUSIONS AND THE COMARE RESPONSE

COMARE welcomes the CERRIE report. In our opinion it is in general a very worthy report which contains much to be recommended. However, it is clear that the report contains a broad range of scientific opinion. In considering the effects of internal emitters, COMARE considers that its remit is to advise Government as to the scientific opinion best supported by the currently available evidence. More importantly, COMARE has to advise on what further research needs to be undertaken to address the current uncertainties.

For ease of reference the CERRIE conclusions are given in the panels below. Wherever possible, COMARE responses follow on directly.

CERRIE conclusions

Risks of internal emitters

1 To the extent that ionising radiations from both internal emitters and external sources generate similar physical and chemical interactions in living matter, there are no fundamental differences between the two sources of radiation that suggest that their effects cannot be combined for radiological protection purposes. However, short-range charged particle emissions, both electrons (eg low energy beta particles) and alpha particles, are important contributors to internal but not external radiation exposures. The potential heterogeneity of energy deposition in tissues resulting from these internal emitters contrasts with the relatively uniform irradiation of tissues from most external sources and defines the central difference between these two sources of radiation exposure. The Committee agreed that a methodology for combining radiation effects from both types of source should, in principle, be achievable. However, the Committee was more divided on the adequacy of methods used to take account of such heterogeneity, and these matters have been a central issue addressed by the Committee.

2 The chemical properties of an element determine its distribution and retention in body tissues and cells and hence determine the extent to which it may be located in a way that short-range emissions may have an accentuated effect in terms of damage caused to cellular targets for the induction of cancer and genetic effects. Biokinetic and dosimetric models are used to determine this relationship between the distribution of radionuclides and target cells. In some cases, simple models suffice because the element and its radioisotopes are known to be uniformly distributed in body tissues and the pattern of energy deposition is similar to that resulting from external irradiation. In other cases, complex models are required to account for heterogeneous energy distribution within tissues, requiring knowledge of the location of the radionuclide at different times after intake and the location of target cells. Data available for model development are of variable quality – in some cases, particularly for some of the more important radionuclides, good information is available, including human data, but in other cases reliance is placed on sparse animal data. In all cases, there is little information on variability between individuals and within human populations. The Committee concluded that in general the combination of biokinetic and dosimetric models gave rise to reasonable

estimates of central values, but with a widely variable uncertainty range. The Committee was more divided on the likely span of uncertainties for specific radionuclides and situations of exposure, but there was agreement that in some cases uncertainties could extend over at least an order of magnitude.

3 The location of radionuclides within tissues is particularly important for alpha particles that typically have a range of a few tens of μm (traversing a few cells), and for low energy electrons (eg beta particle emissions from tritium, range $<10 \mu\text{m}$, and from Auger electrons). For these radionuclides, sub-cellular location can be important, as location within the cell nucleus can increase carcinogenic potential while within cytoplasm it can decrease risk. On the basis of substantial experimental data, it is recognised that these radiation types can cause greater damage per unit energy deposition, because of the density of their ionisations in small tissue volumes, than sparsely ionising radiations such as gamma and X-rays, and higher energy electrons. The understanding of these differences, termed relative biological effectiveness (RBE), in terms of three-dimensional track structure, and consequent interactions with DNA and other molecules, is a key goal of microdosimetry. The Committee was generally in agreement that this field of research is not yet far enough advanced for microdosimetric techniques to present viable alternatives to current risk-related radiation dosimetry. However, there was agreement that advances in microdosimetry were likely to provide insights into the reliability of dose estimates and may ultimately provide complementary approaches. The desirability of further research was emphasised.

4 The ICRP provides comprehensive information on radiation doses estimated to result from radionuclide intake by ingestion or inhalation. The ICRP publishes biokinetic and dosimetric models, and values of weighting factors, used to calculate quantities called equivalent and effective dose. While the models are used to give estimates of absorbed dose (Gy) to target organs, tissues, or regions within tissues, equivalent and effective dose (Sv) introduce effects-related weightings to take account of RBE (w_R) and individual tissue contributions to total risk or detriment from cancer and hereditary effects (w_T). The calculation of equivalent dose to individual tissues appears to be a simple and convenient way of combining doses from different radiation types to assess overall risk of specific cancers (or genetic effects). The further step of combining and weighting equivalent doses to give an overall whole-body or effective dose is convenient in allowing summation of all radiation exposures, internal and external, for comparison with limits for whole-body exposure. However, exclusive use of effective dose can conceal very different patterns of dose delivery from different radionuclides, both in the irradiation of specific tissues and the time-course of dose delivery. Effective doses provide no information on the likely incidence of cancer of specific types, only on the overall probability of cancer induction (ie with no distinction of type). The Committee noted, and felt that it should be more strongly emphasised, that the ICRP recommends reserving the use of effective dose for radiological protection purposes at doses below dose limits. For specific assessments, the ICRP recommends that it will sometimes be better to use absorbed dose and specific data relating to RBEs for the radiations concerned and risk factors. The Committee considered that the use of such specific information should apply when doses are or may be a significant proportion of dose limits, for retrospective dose assessments and for the interpretation of epidemiological data. The Committee further concluded that it was important that the scientific basis of the ICRP methodology should continue to be challenged, and that developments in microdosimetry and radiobiology should inform judgements on their reliability.

5 Dose limits, constraints, and indeed tissue weighting factors are based largely on risk estimates for radiation-induced cancer resulting from external gamma ray exposure of the Japanese populations of Hiroshima and Nagasaki. The applicability of these risk estimates to internal exposure from short-range charged

particle emissions can reasonably be questioned, given the potential complexity of the steps involved in assessing internal dose and risk. Available human data that allow quantitative estimation of risks from internal radiations, for alpha particle emitters, provide a measure of support for the use of these risk estimates. Most Committee members agreed that there does not appear to be any indication, within the limitations of the data available and the overall uncertainties in the risk estimates, of fundamental differences between internal and external radiation that cannot in principle be accommodated through the use of appropriate parameters (eg RBE and kinetic factors) in physiological models. Some members did not accept this view, and considered that there are biophysical and biochemical mechanisms that result in an enhanced effectiveness of internal emitters over external radiation in specific instances that is not taken into account in current methodology. There was agreement that enhanced effectiveness may occur as a result of radionuclide binding to DNA, but most members considered that this was an issue specific to low energy beta emitters and Auger emitters.

6 Two members argued that such instances as those quoted above occurred largely with artificial as opposed to naturally occurring radionuclides. Furthermore, they suggested that because living organisms have evolved in the presence of natural radionuclides the organisms would have adapted to their presence, which will clearly not be the case for the range of artificial radionuclides. For these reasons, these members felt that artificial radionuclides, as a class, were likely to present an enhanced risk. However, most members of the Committee did not concur with this view.

Dosimetry

7 Committee members agreed that insufficient attention has been paid in the past to uncertainties in dose and risk estimates for internal emitters. Reliable quantitative estimates of uncertainties in dose coefficients for a range of radionuclides are not yet available. Uncertainties in estimating equivalent dose, which combine the uncertainties in estimating both absorbed dose and RBE, are always likely to be significant, and probably vary in magnitude from around a factor of two or three above and below the central estimate in the most favourable cases (ie where good data were available) to well over a factor of ten in unfavourable ones (ie where they were not). For effective doses, there are additional uncertainties in the use of tissue weighting factors. Further work is required to quantify uncertainties in dose estimates for important radionuclides, with transparent identification of all the underlying contributions to overall uncertainties and how to compound them. The Committee concluded that it was important that doses and risks from internal emitters should be calculated on the basis of best current information, using central values, and with no bias towards 'conservatism' or 'pessimism' (as is sometimes implied). Introduction of such subjective considerations had no place in an objective assessment. The Committee agreed that, where appropriate, dose and risk estimates should be combined with an appreciation and explicit statement of the uncertainties involved. This approach would help identify those situations in which a precautionary approach might be appropriate, and was greatly to be preferred over one in which conservative/pessimistic estimates were arbitrarily introduced at various stages in the calculation.

COMARE response to paragraphs 1–7

In general, COMARE endorses the CERRIE conclusions on risks and dosimetry.

Tritium

8 It was concluded by most members of the Committee that ICRP dose coefficients for ingestion of tritiated water (HTO) and organically bound tritium (OBT) by adults are not substantial underestimates. However, it was also concluded that the ICRP dose coefficient for HTO is not conservative and the value

for OBT must be used with caution since it may well not apply to specific materials. A minority of members did not agree with these conclusions, pointing to ECRR (2003) estimates of w_R values for tritium of 10–30. Several Committee members concluded that risks from tritiated DNA precursors were reasonably well understood on the basis of reliable experimental data, but others disagreed. Some members expressed concern about the possibility of environmental concentration of tritium contained in specific stable organic compounds and the potential for high RBE of tritium incorporated into DNA. Committee members were agreed that the possibility of increased risk from Auger emitters on the basis of cellular location and non-uniform distribution between cells within tissues should be examined for individual radionuclides and chemical forms of concern. This would involve experimental studies of distribution, together with studies of biological effects for those radionuclides/chemical forms showing significant presence in cell nuclei.

COMARE response to paragraph 8

The uncertainties in tritium dosimetry are appreciated by COMARE but it is not persuaded by the arguments of those members of CERRIE who maintain that the uncertainties are higher than a factor of ten. COMARE needs to come to a position on this topic and it recommends that the National Radiological Protection Board (NRPB) be asked to organise a review of this matter with the widest possible consultation. It may be practicable to ask the Advisory Group on Ionising Radiation (AGIR) to carry out this review.

Alpha emitters

9 Committee members agreed that the available data on the behaviour of radioactive particulates in the body do not support the proposal that they transfer readily to the fetus and pose a high risk of *in utero* leukemogenesis. However, the extent of possible risk was not agreed and individual members pointed to research in progress that might provide additional data.

COMARE response to paragraph 9

COMARE endorses the points made regarding alpha emitters.

Biological evidence

10 The views of the Committee were divided on many interpretational aspects of the biological data considered in Chapter 3. On induced genomic instability, bystander effects, minisatellite mutation induction and specific issues of micro-dosimetry, there was general agreement that many of the phenomena were real and some may well be an integral part of cellular and tissue response. There was, however, substantial disagreement as to whether the available data were sufficient to draw firm conclusions on the implications for radiation-induced health effects. A minority of the Committee held the view that the data clearly provided a major challenge to current estimates of low dose health effects and these members emphasised the implications for internal emitters. Other members were less persuaded on the scientific strength of the case. Many of these members believed that considerably more knowledge was needed and some considered that current epidemiological measures of risk were likely to incorporate contributions from these novel cellular responses, albeit with some low dose/low dose rate uncertainties.

COMARE response to paragraph 10

One of the arguments put forward for an underestimation of radiation risk by current models was derived from recent work in the area of genomic instability, minisatellite (Expanded Simple Tandem Repeats, ESTR) radiosensitivity, and the bystander effect. These areas are currently at the cutting edge of radiobiological research and past and present members of COMARE and its

sub-groups have been at the forefront both of this research and in drawing attention to its possible implications for radiological protection (Kahdim et al, 1992, 1994; Bridges, 2001; Dubrova et al, 2002; Dubrova, 2003). Those who know most about this work agree that the implications are complex and it would be premature to come to any conclusions, a view that is shared by COMARE and the majority of members of CERRIE. COMARE currently has a sub-group addressing much of this area, as have UNSCEAR and ICRP. A considerable amount of further research is needed before it can be established whether changes need to be made to risk factors and to ensure that appropriate data are available to aid these decisions. COMARE recommends that work in these areas should continue and that Government gives serious thought to increasing the small level of funding it currently provides for such research.

Second event theory

11 On the second event theory (SET), two members held the view that, according to their calculations, the theory could account for very high risks at low doses of certain dual-decay radionuclides. They also claimed that SET implied very high risks from specified particulate sources of alpha emitters. Other members disagreed and identified a series of computational and biological problems/inconsistencies with SET. These members also pointed out that to achieve optimum SET conditions for particulate alpha emitters required that cells receive supra-lethal radiation doses, ie second event cells will not remain viable and therefore not contribute to cancer risk.

COMARE response to paragraph 11

COMARE agrees with the CERRIE report that available data do not support this speculative hypothesis.

12 In the light of the above considerations and a data review from a consultant, the majority of the Committee concluded that SET had little or no biological support and that the evidence available substantially contradicted it. Although a minority of the Committee considered that differences in physical and biological properties clearly distinguish man-made radionuclides from those arising naturally, the majority did not share this view – some argued strongly against the proposition. This same minority of members believed that bimodal or polymodal dose–response relationships at low doses predicted health risks substantially above those currently estimated by radiological protection bodies. Other members were of the view that the data suggesting these complex dose–responses were inconclusive and, as presented by the proponents, many such dose–responses took little account of statistical uncertainty.

COMARE response to paragraph 12

COMARE agrees with the majority CERRIE opinion in paragraph 12 above.

Thresholds

13 Although there was not lengthy discussion of the issue, the majority of the Committee did not hold the view that a dose-threshold was a general feature of radiation cancer risk, ie no risk at low doses. Some members agreed, however, that dose–response for cancer in some tissues was highly curvilinear and in specific circumstances an apparent dose-threshold for risk might apply.

COMARE response to paragraph 13

One member of CERRIE put forward the view that very low doses of radiation are at least harmless, and may possibly be beneficial (Raabe, 2001; Calabrese and Baldwin, 2003; Johansson, 2003). This is a view shared by many in the USA (including members of the Health Physics Association). One of the arguments, but by no means the only one, that has been put forward has been that at sufficiently high dilution of radiation damage events there is no effect, ie a threshold. One may make the analogy of a phial of toxic material such as cyanide which if consumed by half a dozen individuals would kill them, but if diluted and shared among 100,000 people would have no detectable effect. However, radiation differs from a solution of toxic chemical in that it delivers its toxic effect in discrete packets of energy. An analogy for this would be six cyanide pills, each of which was poisonous, but mixed in with another 99,994 harmless tablets. If 100,000 people were each given one tablet, six people would still be killed. There are characteristics of radiation that make it sensible to assume that it acts in this way, even if this assumption is difficult if not impossible to prove. The precautionary approach encompasses this potential mechanism. ICRP recently put forward for consultation a proposal to abolish the concept of collective dose, which depends on this assumption. COMARE argued strongly against this proposal (www.comare.org.uk). Arguments that low doses of radiation are beneficial generally depend on an assumption that such exposures stimulate repair mechanisms which apply outside the original damage. COMARE does not regard such processes as impossible, but regards the present evidence as insufficient and thinks it unwise to place reliance on them.

14 There was general agreement that new findings on radiation-induced bystander effects and radiation-induced genomic instability should continue to be included in consideration of health risks at low doses and their quantitative uncertainty. In this respect, the Committee recognised that the current ICRP recommendations, formulated in 1990, pre-date much of the biological information discussed in Chapter 3. The Committee endorsed ongoing national and international radiobiology research programmes particularly in respect of microdosimetry, induced genomic instability, bystander effects, cancer mechanisms and germline minisatellite mutagenesis.

COMARE response to paragraph 14

See response to paragraph 10.

Precautionary approach

15 The Committee was not agreed on whether the biological evidence discussed in Chapter 3 had immediate implications for radiological protection standards. A minority of the Committee considered that this was so and that Government should give consideration to the Precautionary Principle. Other members, whilst generally supportive of a precautionary approach to the interpretation of the science, did not share this view, principally because of their perception of a current lack of coherence in the experimental data and absence of clear links with health effects.

COMARE response to paragraph 15

COMARE concurs with the majority view on CERRIE, that the biological evidence presently available does not imply a need for immediate changes in radiological protection standards. We believe that in the field of radiological protection in general, the precautionary approach has been standard practice and models have been refined as new information has become available.

Epidemiological evidence

16 All members of the Committee believe that the epidemiological evidence is compelling for moderate and high levels of exposure to internally incorporated radionuclides producing a raised risk of adverse health effects in those exposed. All but one member of the Committee believe that the low level intake of radionuclides leads to some increased risk of adverse health effects as a result of the internal irradiation of organs and tissues. Some members think that the epidemiological evidence as a whole does not suggest that the predictions of current risk models are materially in error. Other members consider that these models may underestimate risks from intakes of certain radionuclides by relatively modest factors. Two members think that current models underestimate risks from intakes of radionuclides by very large factors. Conversely, one member thinks that any observed increases in risks at low doses are most likely to have causes other than radiation, ie current models overestimate risks at low doses. As a consequence, there is little consensus amongst members on the epidemiological evidence as a whole.

17 The disagreements stem from differences of view about the appropriateness of the data and methodologies used in epidemiological studies and about interpretations of their findings. It is not anticipated that these can be resolved by further discussion. A core methodological concern is that the inherent limitations of epidemiological studies at low levels of exposure make it difficult to reliably quantify health risks. Most of the Committee consider that the nature of the epidemiological evidence, taken as a whole, inevitably leads to uncertainties in current internal radiation risk models, although there are different views on the magnitude of these uncertainties. There is a consensus within the Committee that epidemiological evidence is strengthened when supplemented by laboratory and theoretical information on underlying mechanisms to guide estimates of risk at low doses.

18 The Committee has general and specific recommendations on future epidemiological studies (Chapter 6). It is hoped that adherence to these recommendations may resolve disagreements in some areas. However, as indicated in paragraph 16, it seems likely that disagreements in other areas will remain for some years to come.

COMARE response to paragraphs 16–18

Epidemiology can provide direct evidence on the risks of radiation exposure. However, at low levels of exposure it will be difficult to distinguish risks from variations in background levels of disease. Advisory groups need to look at all available studies, weighting them according to study quality and judge the risks involved. Individual studies of small risks are not powerful enough in statistical terms to define risks sufficiently for radiological protection purposes. The most relevant exposures should be considered and sensitivity analyses of such data should be performed.

COMARE general comments on the CERRIE conclusions

The disparity of findings in relationship to human radiation risk calculations is reflected in the Techa River analyses initiated by COMARE and described in Chapter 4 of this report. The reported confidence limits indicate the need for further research to clarify these figures. However, we appreciate the limits under which low level radiation exposures can be addressed by epidemiological methodology. Where this is the case uncertainties can often be addressed by the use of detailed laboratory research.

COMARE has noted (Annex 4A of the CERRIE report) the considerable effort devoted to the discussion of post-Chernobyl epidemiology. In this area the European Childhood Leukaemia/Lymphoma Incidence Study (ECLIS) has international standing and has been underway for over ten years. The aim of this study is to investigate trends in incidence rates of childhood leukaemia and

lymphoma in 20 European countries, in relation to the exposure to radiation that resulted from the accident at the Chernobyl nuclear power plant in April 1986. Such large studies are much more likely to produce firm results than those proposed in the CERRIE report.

Again we note that CERRIE undertook a considerable reconsideration of the effect of weapons fallout in the UK and other northern European countries (Annex 4B of the CERRIE report). No effect (in terms of increased levels of childhood leukaemia) was seen. This parallels the findings of the original studies.

Cancer rates in areas near nuclear sites and in coastal and estuarine areas are discussed in Section 4.5 and Annex 4C of the CERRIE report. CERRIE appears to have given consideration to the idea that resuspended radionuclides from mudflats near discharge outlets from nuclear installations could produce sufficient exposure to increase the cancer risks in local populations. CERRIE recommends work on local monitoring and bioassay measurement. We are aware that in the past the United Kingdom Atomic Energy Authority (UKAEA) and the former Department for the Environment (DoE) commissioned many such studies. However, we believe these may have remained as internal reports. It may be that sufficient information already exists to test the suggested association between mudflats and cancer incidence. We recommend that the viability of retrieval and a review of such studies is examined before any new research is instigated. We appreciate that historical measurement data may not be computerised, a factor which may hamper such a review.

COMARE has already published a number of reports relating to childhood cancer around nuclear installations and in our Third Report we stated that individual studies around individual sites rarely had the statistical power to arrive at firm conclusions. Only a national study could address such issues. We wish to note that COMARE is examining the incidence of childhood cancer in the vicinity of all major nuclear installations in Great Britain since the 1960s to the 1990s. This forthcoming report will address a database of over 33,000 cases of childhood cancer. Such a large database may well be able to address some of the questions posed in this section of the CERRIE report.

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CHAPTER 3

CERRIE RECOMMENDATIONS AND THE COMARE RESPONSE

For ease of reference the CERRIE recommendations are given in the panels below. Once again COMARE responses follow.

CERRIE recommendations

Risks of internal emitters

1 With regard to the ICRP methodology, members concluded that more explanation should be given by the ICRP to make clear the intended use of effective and equivalent doses and their limitations. It was also agreed by most members that more attention should be given by the ICRP to uncertainties in risk factors and dose coefficients.

2 The Committee recommended that more work should be undertaken to quantify uncertainties in dose coefficients for a range of internal emitters. Members encouraged COMARE to foster such analyses. Information on uncertainties in dose coefficients would inform judgements on the reliability of dose estimates and would also help identify research priorities which should then receive attention.

3 A particular concern identified by members was the adequacy of current models for the estimation of risks from short-range alpha, beta and Auger emitters. The Committee concluded that research should be encouraged which was relevant to low level exposures to internal emitters and which addressed biological mechanisms and microdosimetric aspects.

4 The ICRP recommends the use of effective dose as a tool for prospective radiological protection at doses well below dose limits. For doses that are or may be a significant proportion of dose limits, for retrospective dose assessments and for the interpretation of epidemiological data, it is recommended that best current scientific information and approaches should be used. In such circumstances, it is likely that equivalent dose will provide a more useful investigative tool than effective whole-body dose, and that consideration of specific information on exposures and individual characteristics will be appropriate.

COMARE response to paragraphs 1–4

The CERRIE report clearly sets out the reservations that some members have about the procedures and models of ICRP. It is COMARE's understanding that these models were never intended, and should not be used, for any other purpose than the system of radiological protection developed by ICRP and operated by NRPB within the UK. This system of radiological protection is used, for example, for prospective risk assessment and for regulatory control of exposures. Because it would be difficult to operate a system that did not ascribe values to risk factors etc, this system may give the impression of a precision and certainty that does not really exist. COMARE has in the past pointed out that considerable uncertainties relate to these values, and this is generally accepted among those at ICRP and NRPB. COMARE, for example, prefers where possible to use the gray (a genuine scientific unit of energy absorption)

and not to use the sievert (a unit derived by multiplying by a weighting factor for various types of radiation). This weighting factor is determined by an ICRP committee consensus and is clearly a compromise value to make radiological protection assessments a practical proposition. Similarly, the use of organ weighting factors is subject to uncertainty since these are derived largely from acute exposures at Hiroshima and Nagasaki and may differ when exposures are chronic such as is the case with internal emitters. Such approximations can be justified when prospective assessments are being considered, but retrospective assessments of specific exposures, such as COMARE has had occasion to carry out, demand a minimum of subjective use of weighting factors etc.

Nevertheless, since ICRP risk factors are widely used it is right that they should be subject to test, and that their uncertainties be clearly appreciated. CERRIE has made an excellent analysis of the uncertainties involved in making risk assessments, and pointed out that these uncertainties are considerably greater when considering internal emitters than when considering external radiation exposure. COMARE agrees with this analysis. However, it should not be forgotten that uncertainties usually apply in two directions; they can result in both underestimation and overestimation of risk. Moreover, where statistical uncertainties are concerned, while confidence limits (a measure of uncertainty) may be wide, in practice the real value is much more likely to be close to the central value than to the extremes.

Members of CERRIE vary in the degree to which they consider the ICRP model to underestimate the risk of internal emitters. One member considers that there is more likely to be an overestimation of risk. The two members who consider that the ICRP risk factors underestimate the risk from man-made fission products by very large factors (100–500-fold) have not, in our view, justified their position. They have ignored a great deal of sound work over half a century of radiation research and they have failed to see the extent of the uncertainties and errors in the work that they cite to support their case. COMARE's position is that uncertainties exist but are not of such magnitude and this is also the position of the majority of the members of CERRIE. We have addressed the possible errors in risk factors in a few situations where recent data are available (see Chapter 4 of this report).

COMARE agrees that attention should be drawn to the uncertainties associated with determining the risk from internal emitters. It believes further work is required and that this may in the future take advantage of the fact that internal emitters have been used for many years in various medical procedures.

Biological evidence

5 There was general agreement that new findings on the biological effects of radiation should continue to be included in consideration of health risks at low doses and their quantitative uncertainty. In this respect the Committee recognised that current recommendations from the ICRP, formulated in 1990, pre-dated much of the biological information discussed in Chapter 3. The Committee endorsed ongoing national and international radiobiology research programmes particularly in respect of microdosimetry, induced genomic instability, bystander effects, cancer mechanisms and germline minisatellite mutagenesis.

COMARE response to paragraph 5

COMARE endorses the statements on research in paragraph 5 above.

6 The Committee agreed to recommend the investigation of whether a large fraction of a given strontium-90 intake bound preferentially to chromosomes rather than being distributed homogeneously or being bound to non-cellular matrices. The Committee therefore recommends that, in order to investigate this, the following research be carried out:

- (a) *in situ* determination of strontium-90 binding to chromosomes;
- (b) determination of strontium-90 in isolated chromatin;
- (c) cytogenetic analysis of strontium-90 induced chromosomal aberrations, in the same human cell culture system as (a) and (b); and
- (d) follow-up of an *in vivo* study carried out in the late 1960s on the effects of low doses from strontium-90 on numbers of cells in rat bone marrow (Stokke et al, 1968), so as to measure chromosomal aberrations.

COMARE response to paragraph 6

We wish to note that research into whether strontium is bound preferentially to DNA is already underway, as commissioned by COMARE. We also wish to note that future work on internal emitters should not necessarily confine itself to the most common nuclides. Medical exposure to internal emitters is an expanding clinical area and may provide useful opportunities for further research. COMARE also notes that CERRIE recommended that more emphasis should be given to research in whole organs rather than in isolated cells; COMARE supports this.

Epidemiological studies

7 The Committee has become aware of a few instances where errors have been made in epidemiological analyses carried out by governmental and non-governmental organisations, and where these errors have not been discovered until after the findings have been made public. The Committee has also become aware of one instance in which the data provided to epidemiologists by a government-funded organisation were subsequently found to be incorrect, or at least presented in a confusing way. The Committee supports the COMARE recommendation that organisations and research groups should establish scientific protocols and internal managerial controls to prevent such errors before distributing data or conducting epidemiological analyses and making public their results.

COMARE response to paragraph 7

We welcome the CERRIE endorsement of our recommendation.

8 A difficulty for those outside the epidemiological field who seek to judge the quality of epidemiological results is that some of the organisations involved do not trust each other. This has led to unproductive and emotive arguments in print, often in newspapers rather than scientific journals. The Committee recommends that there should be better communication between the various organisations that conduct epidemiological analyses. It stresses the importance of using rigorous scientific methods, including the establishment of prior hypotheses, proper statistical analysis, objective interpretation and peer review of proposed articles. The Committee considers that there is scope for more joint analyses by governmental organisations and other groups. However, it also notes that recent administrative provisions on ethical and data protection are making it difficult in practice to carry out epidemiological research: this matter merits careful consideration by the Government. These difficulties were emphasised by a number of participants at the CERRIE Workshop.

COMARE response to paragraph 8

We also wish to endorse the view that epidemiological studies should conform to the usual standards of peer and ethical review. However, we would like to note that control of national statistics, under the auspices of data protection, should not be so limiting so as to actively interfere with proper scientific research. We also wish to reinforce the need for researchers to look at the published literature as a whole, ideally by systematic review of the literature with critical review of individual studies in order to determine the weight to attach to them. This is the only way to get enough information to reach conclusions on the risks from low level radiation exposures.

9 The Committee recommends that groups of individuals exposed to radiation from internally deposited radionuclides should continue to be the subject of epidemiological studies. A number of such groups have already been investigated in some depth, including patients and workers exposed to radioisotopes of radium, patients exposed to thorium in the contrast medium Thorotrast, and workers and members of the public exposed to radon and its decay products. The Committee encourages the continued study of these groups where profitable, and is aware that substantial effort is being expended in the study of groups exposed to radon. Since exposure to radon is the most extensive exposure to radiation, this continued programme of epidemiological work is welcomed. In addition, the Committee recommends that consideration be given to epidemiological studies of potential heritable effects following exposure to internal emitters – for example, among the offspring of Mayak workers and of Techa River residents in Russia.

COMARE response to paragraph 9

The largest environmental exposures of the general public are from radon and its decay products in the home. Radon is a natural gas and also an alpha emitter and its main pathway of exposure is inhalation, although there is some contribution from ingestion. Large studies are already either complete or still underway. They are expected to report in the near future and will be considered by the Advisory Group on Ionising Radiation (AGIR). We have already commissioned some further analyses relating to radon and to the Techa River residents (see Chapter 4 of this report).

10 Nuclear industry workers are exposed to a range of radionuclides and the Committee recommends that studies of workers exposed to internal emitters continue. There is scope for further evidence to be obtained from internally exposed workers in the UK, the rest of Europe (especially France) and North America, and such epidemiological studies should be supported appropriately. In recent years, important data from workers exposed in the former USSR have become available. These include the Chernobyl clean-up workers and, in particular, the workers at the Mayak nuclear facility in the Southern Urals. The latter group experienced particularly high levels of exposure to plutonium, and careful assessments of the organ-specific doses received by these workers and of their health status (including non-cancer effects) could lead to reliable risk coefficients for plutonium. The Committee recommends that the Mayak workforce continues to be carefully studied. It may be the case that other groups of workers become available for study in future (for example, nuclear workers in China) and the scientific community should remain alert to these possibilities.

COMARE response to paragraph 10

COMARE agrees with CERRIE regarding the importance of improving the exposure estimates in such studies and the continued follow-up of workers

exposed to internal emitters. COMARE has commissioned new analyses of the data on the Sellafield plutonium workers and on workers at the Mayak plant (see Chapter 4 of this report).

11 The Committee was unable to complete its proposed study of cancer incidence and mortality near the Bradwell facility due to lack of time. In view of this, it recommends that further epidemiological studies be considered in an attempt to resolve the question of whether cancer rates are generally higher in coastal and estuarine areas and in the vicinities of nuclear sites. Members are aware that a study by COMARE of the geographical distribution of childhood cancer cases in Britain, particularly near nuclear sites, is currently nearing completion. When this study is completed the results should be reviewed to determine whether they justify a broader study of adult cancers around nuclear sites and contaminated estuaries.

COMARE response to paragraph 11

We have already commented on studies around Bradwell. The following is a summary of our investigations and conclusions.

Two groups – Green Audit (Busby et al, 2001a,b, 2002) and the Small Area Health Statistics Unit (SAHSU, 2001, 2002) – produced reports drawing conflicting conclusions about deaths from cancer, particularly breast and prostate cancer, around Bradwell nuclear power station in Essex. Both groups used mortality data from the same source – the Office for National Statistics (ONS). There were large differences in the figures presented in the first two reports from the two groups. COMARE asked the ONS to investigate these differences and report back to the Committee. COMARE has subsequently made a detailed study of three reports from Green Audit and two from SAHSU. All three Green Audit reports contained errors in the actual numbers of deaths and erroneous or inappropriate figures for the expected numbers of deaths which, together with inappropriate comparisons of various areas, resulted in overestimation of the risks. Errors in the first SAHSU report, which underestimated the cancer risks, were corrected in the second. Analyses using correct mortality figures and the most appropriate expected values do not indicate any significant excess of cancer mortality around Bradwell, nor do they indicate any substantial or statistically significant risk of breast cancer mortality in groups of wards bordering the Blackwater estuary, or in Maldon compared with Burnham-on-Crouch.

Furthermore, we have noted the imminent publication of our Tenth Report on the distribution of childhood cancer around nuclear sites in Britain. We have already stated that when our Tenth Report is completed we will consider whether the data it contains justify further studies of adult cancer.

12 The Committee recommends that further epidemiological studies, using more realistic methodological approaches, be carried out to resolve the question of whether cancer rates are higher in coastal and estuarine areas. It would be important to use realistic dispersion models of environmental radioactivity, for example. Members are aware that a study by COMARE of the geographical distribution of childhood cancer cases in Britain, particularly near nuclear sites, is currently nearing completion. It also recommends further measurements of

radioactive particulate levels in air, soil and other materials in coastal, estuarine and inland areas, so as to establish whether there are significant differences between the types of areas.

COMARE response to paragraph 12

We have noted our comments in the section ‘COMARE general comments on the CERRIE conclusions’ (Chapter 2).

13 It should be noted that patients and medical workers are increasingly exposed to internal emitters as a result of diagnostic investigations and therapeutic treatments. Epidemiological study of these groups would be of value, and the Committee recommends that these be undertaken.

14 A number of groups of members of the public have been exposed to radionuclides of man-made origin. In particular, groups exposed in the former USSR are of special interest because large numbers of people experienced a range of exposures. Those exposed to Chernobyl fallout should continue to be the subject of study, particularly those heavily exposed as children. Other specific examples are the residents of the area that received fallout from the Semipalatinsk nuclear weapons test site in Kazakhstan and the inhabitants of communities neighbouring the Techa River. The Techa River received large quantities of highly radioactive waste from the Mayak facility in the late 1940s and early 1950s, which resulted in high exposures to local residents. The Committee supports the continuing effort to study these groups.

COMARE response to paragraphs 13 and 14

We endorse these CERRIE recommendations. COMARE has commissioned a new analysis of data on the Techa River residents (see Chapter 4 of this Report).

15 The Committee considers that a valuable complement to epidemiological studies of those exposed to internal emitters is the measurement of the presence (and levels) of radionuclides in study subjects through appropriate bioassay techniques. This is becoming increasingly common in studies of workers, a trend that is to be encouraged, but has not often been carried out in studies of those environmentally exposed. Such bioassay measurements would provide an important aid to the interpretation of epidemiological studies, and many of these methods (such as the measurement of radionuclides in urine or in teeth removed for orthodontic purposes) are not invasive and could be carried out relatively easily. The possibility of such bioassay measurements being made on appropriate samples from members of the public resident in various parts of the country, to determine general levels of radionuclides around, and distant from, nuclear sites should also be considered. The Committee recommends that greater use is made of presently available bioassay techniques.

COMARE response to paragraph 15

COMARE concurs with the statement that the best epidemiology should be married to the best dosimetric data available for individual studies. Furthermore, COMARE appreciates the difficulties associated with certain alpha emitters that have localised distribution in tissues and welcomes work to improve internal dosimetry. However, we must point out the severe practical and ethical difficulties in undertaking such studies in human populations. Laboratory studies can, however, frequently clarify basic underlying principles, and we recommend the funding of projects addressing these principles.

16 A related and complementary issue is biodosimetry measurements of study subjects. Certain measures of biological damage (such as chromosomal aberration rates in peripheral blood lymphocytes) have been developed which can be related to the dose received by the relevant cells. However, this is not straightforward for internal emitters such as plutonium since the dose may not be delivered to the cells that are the basis of the assay. Further, such techniques usually involve the sampling of blood, which could present ethical difficulties under certain circumstances. Nonetheless, biodosimetry has proved to be of value in specific instances, and the Committee recommends monitoring the suitability of these techniques for measuring biological damage to assess the appropriateness of their application to epidemiological studies of internal emitters.

COMARE response to paragraph 16

COMARE has a sub-group looking at new molecular approaches to biological dosimetry and endorses the general thrust of CERRIE remarks on these and other techniques applied to internal emitters.

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CHAPTER 4

ADDITIONAL REVIEWS AND ANALYSES REQUESTED BY COMARE

4.1 Many of the available epidemiological studies considered by CERRIE involved either small populations or were impossible to interpret because the levels of exposure were undocumented. COMARE sought to identify groups of people exposed at higher than average levels to internal emitters where recent information, particularly about exposure levels, was available that was not considered by CERRIE. We identified four such groups. It was felt that an analysis of these might bring valuable insight into the comparison of the risks of external radiation doses and exposures to internal emitters. COMARE asked Dr Mark Little of the Department of Epidemiology and Public Health, Imperial College Faculty of Medicine, and Dr Monty Charles of the School of Physics and Astronomy, University of Birmingham, to undertake studies on three of the four populations. These were the Sellafield plutonium workers, workers at the Mayak plant in the former USSR and the residents of the Techa River region exposed to the discharges from the Mayak plant.

4.2 The dosimetric details of the internal exposures of these three groups are complex, but in general terms it can be said that the Sellafield plutonium workers were exposed to low levels of plutonium, whereas for the Mayak workers internal doses were dominated by exposure to plutonium at relatively high levels. For the Sellafield workers the available analyses considered the sum of estimated doses from plutonium and from external radiation. For the Mayak workers, estimates of internal dose were available only for the lung. The Techa residents were mainly exposed to nuclear fission products discharged from the Mayak site. In many cases internal doses were dominant but only aggregated internal and external doses were available. Individual exposures could vary considerably (for example, those exposed to the fallout from the Kyshtym explosion received much higher doses from rare earth radionuclides than other Techa residents). Dr Little and Dr Charles were asked to compare the risks seen in these populations with those seen in the survivors of the atomic bombings in Japan, since this is the single most informative group on the risks of exposure to external radiation. In their analysis they were particularly concerned with upper limits on risk estimates for those populations which were exposed to internal emitters. In view of the incomplete nature of the assessment of internal doses and the overlap with external doses, the interpretation of the central estimates of risk is difficult; however, they are given here to allow a more concrete discussion.

4.3 An abstract of this paper is given in Annex 4A and the calculated central estimate of risks, relative to the atomic bomb survivors, is shown in the table, together with the upper 97.5% confidence limits on the risk ratio. In strict statistical practice, the lower (2.5%) confidence limit would also be given. However, in the cases shown in the table, only for solid tumours in the Mayak workers would the lower limit lie above one (ie in all other cases there is no evidence for a statistically significantly higher risk from the combined internal and external doses than can be explained on the basis of risk figures from the atomic bomb survivors). The confidence interval would indicate the range of values in which the correct value would be found in 95% of cases. In layman's

Ratio of risks associated with three populations exposed to internal emitters compared to that found in the atomic bomb survivors in Japan, together with their upper Bayesian 97.5% confidence limits

		Central estimate	Upper limit
Leukaemia (exposure all ages)	Techa River residents	1.1 to 1.6	5.1
	Sellafield plutonium workers	4.8	14.3
	Mayak workers	0.3 to 0.8	4.8
Leukaemia (childhood exposure)	Techa River residents	1.7	5.7
Solid cancers	Techa River residents	-0.4 to -0.3	0.3
	Sellafield plutonium workers	-0.7	0.3
	Mayak workers	1.8 to 2.6	3.5
Lung cancer	Sellafield plutonium workers	0.4	3.4
	Mayak workers	0.1 to 0.4	0.9

terms it may be said that the real value of the relative risk could *possibly* be as high as the 97.5% limit, or as low as the 2.5% limit, but is *probably* nearer to the central estimate.

4.4 It can be seen that the broad estimates of risks for leukaemia in these three populations are close to those estimated from the atomic bomb survivors with upper confidence limits around 5–14 times higher. The risks for solid cancers are in two cases well below those estimated from the atomic bomb survivors and in one case somewhat higher; the upper confidence limits range from 0.3 to 3.5. The lung cancer risks for Sellafield plutonium workers and Mayak workers were below those found for the atomic bomb survivors. The upper confidence limits were less than 4 for the plutonium workers and about 1 for the Mayak workers.

4.5 It can be concluded that the risks of radiation-associated cancers among groups exposed to substantial quantities of internal emitters are compatible with those observed in the atomic bomb survivors, although there are substantial uncertainties in these. The lack of separate internal dose estimates (rather than aggregated, external plus internal, dose estimates) precludes other than qualitative statements regarding the risks of internal emitters alone for the Sellafield workforce. However, the availability of separate lung doses from plutonium for the Mayak workers and the dominance of internal doses for the Techa River cohort suggest that for these two cohorts one can rule out risk factors of several hundred times those in the atomic bomb survivors, as asserted by some members of CERRIE.

4.6 The fourth group of exposed people consists of those exposed to high levels of radon, a radioactive gas that is found in dwellings in certain parts of the UK. Radon is inhaled and, although the greatest exposure is to the lung, a significant amount reaches the bone marrow and results in exposure to alpha particles. A very large study (the UK Childhood Cancer Study, UKCCS) recently examined the incidence of childhood leukaemia as a function of domestic exposure to radon. It found no evidence that childhood leukaemia was associated with domestic exposure to radon. We asked Dr Gerry Kendall of the National Radiological Protection Board to use dosimetric arguments to examine whether the uncertainties would have allowed a significant effect from radon exposures to go undetected and, if so, what would be the maximum likely size of such an effect. Dr Kendall's note is reproduced in Annex 4B. Its conclusion is very clear. The maximum likely effect that could have gone undetected is about six times greater than that estimated using the ICRP model.

ANNEX 4A

SUMMARY OF LITTLE AND CHARLES PAPER

<i>Three populations exposed to internal emitters</i>	Radiation-induced cancer risks associated with internal emitters traditionally requires extrapolation of risk from high dose groups and use of dosimetric models. Concerns have been expressed that extrapolated risk estimates from internal emitters are greatly underestimated, by factors of 100 or more, by current risk factors and dosimetric models.
Background	
Methods	Data on cancer mortality in three groups exposed to substantial quantities of internal emitters, namely the residents of the Techa River villages, and the Mayak and Sellafield workers, are analysed together with the Japanese atomic bomb survivors, using linear relative risk models taking account of errors in dose estimates.
Findings	The central estimates of the ratio of leukaemia risks in the Techa River, Mayak and Sellafield cohorts to that in the atomic bomb survivors are between 0.3 and 4.8, with an upper 97.5% confidence limit of 14.3, depending on the assumed dosimetric error in these cohorts. The central estimates of the ratio of solid cancer risks in the Techa River, Mayak and Sellafield cohorts to that in the atomic bomb survivors are between -0.7 and 2.6, with an upper 97.5% confidence limit of 3.5, depending on the assumed dosimetric error in these cohorts; for lung cancer similar or slightly lower central estimates of this risk ratio are indicated.
Interpretation	These comparisons demonstrate no elevated radiation-associated risks among groups exposed to substantial quantities of internal emitters compared with those observed in the atomic bomb survivors, although there are substantial uncertainties in these calculations. The lack of separate internal dose estimates (rather than aggregated, external plus internal, dose estimates) precludes other than qualitative statements regarding the risks of internal emitters alone for the Sellafield workforce. However, the availability of separate lung doses from plutonium for the Mayak workers and the dominance of internal doses for the Techa River cohort suggest that for these two cohorts one can rule out very large risk factors, which have been proposed by some, of several hundred times those in the atomic bomb survivors.

ANNEX 4B

SUMMARY OF KENDALL PAPER

Radon and childhood leukaemia

Although the main hazard of exposure to radon is of lung cancer and arises through radon's short-lived decay products, radon gas will also deliver a dose to various organs and tissues of the body. Radon is more soluble in fat than in water and therefore gives somewhat higher doses to tissues with a higher proportion of fat, such as red bone marrow. Calculations have been performed which suggest that radon might be responsible for a significant proportion of childhood leukaemia and related diseases. This annex describes these calculations and explores the implications for assessments of the maximum credible risk from radon and, by extension, from other alpha emitters.

Richardson et al (1991) calculated an annual dose to red bone marrow of about 0.89 mSv y^{-1} from inhaling radon at 200 Bq m^{-3} . Similar, if slightly lower, dose coefficients were calculated by Khursheed (2000) and used by Kendall and Smith (2003) to estimate an annual dose to red bone marrow of 0.65 mSv y^{-1} . The uncertainties in the calculations are large compared to the difference between these dose estimates.

Simmonds et al (1995) used the calculations of Richardson et al in an estimation of the risks of leukaemia and non-Hodgkin's lymphoma (LNHL) from all sources of ionising radiation in a cohort of births in Seascale. They calculated that the total number of fatal LNHL expected on the basis of national rates was 0.78. The number of fatal LNHL calculated to result from radiation exposure from all sources was 0.36, of which 0.14 were due to high LET radiation. Of the high LET dose 89% was from natural sources and 37% of the total high LET dose was from radon-222 and radon-220. These figures imply that radon causes 0.046 deaths from LNHL or 6% of the expected total of 0.78. The proportion of fatal childhood LNHL caused by high LET natural radiation is about 16%.

If the broad outline of the analysis above is correct, there is no scope to increase the proportion of childhood cancer attributed to high LET radiation by more than a factor of 100/16 or about six.

It might be argued that, in fact, effectively all childhood LNHL is induced by high LET radiation. In this case, under a linear risk model, any increase in the high LET bone marrow dose would increase the rate of childhood LNHL pro-rata. However, the suggestion that childhood LNHL is overwhelmingly a result of high LET radiation seems implausible, and if it were the case it would be expected that a link would readily be detected by epidemiology.

Some geographical correlation studies have reported a link between radon levels and leukaemia, but more reliable case-control studies have not (Lubin et al, 1998; Laurier et al, 2001). Further evidence that radon does not contribute a large fraction of childhood cancers comes from the United Kingdom Childhood Cancer Study which investigated the possibility of a link between domestic radon exposures and a variety of childhood cancers. The study found no evidence to support an association between higher radon concentrations and risk of any of the childhood cancers studied (UKCCS, 2002).

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CHAPTER 5

COMARE OVERALL CONCLUSIONS AND RECOMMENDATIONS

Conclusions

5.1 COMARE welcomes the CERRIE report and the COMARE responses to particular CERRIE conclusions and recommendations are given throughout this report. In this chapter we would like to bring together our overall conclusions under some general headings, and then give our most pressing recommendations in more specific terms.

ICRP methodology

5.2 We wish to reiterate that ICRP models were never intended and should not be used for any purposes other than the system of radiological protection of which they are a part. However, we recognise the uncertainties involved in the use of such methodologies and that these uncertainties must be tested. CERRIE has made an excellent analysis of the uncertainties involved in making risk assessments and in pointing out that these uncertainties are greater for internal emitters than for external radiation. However, it should not be forgotten that uncertainties apply in two directions and that they can equally result in both an underestimation and an overestimation of risk. We accept that current uncertainties for internal emitters may be of the order of a factor of ten. Current ICRP recommendations are some years old and indeed are under review and consultation as this report is being produced. We hope that ICRP takes this opportunity to reassess uncertainties and also address them in an accessible manner in its new recommendations, when they are complete.

Biological variability

5.3 CERRIE spent considerable time examining possible uncertainties concerning the dosimetric aspect of certain radionuclides (such as tritium and strontium) or those uncertainties that could be introduced by the new paradigms such as the bystander effect and genomic instability. We accept the conclusions drawn in the CERRIE report on these matters and also accept that considerable further work is needed to understand and adequately to quantify the risk of these uncertainties. However, we wish to note that although these paradigms are new to the scientific community they have always been in biological operation and thus to some extent are considered in the currently available epidemiological data. Thus, the levels of these uncertainties in current risk estimates are to some extent incorporated in current models. We also wish to note that the biological variability of response between individuals to internal emitters is likely unknown, but could be comparable to the uncertainties in dosimetric calculations themselves.

Epidemiology

5.4 We have pointed out that considering individual or small epidemiological studies is not the best way to examine uncertainties. Wherever possible, large studies are required, particularly when examining effects at low levels of exposure. Although large and well-designed studies take a long time to carry out, they present the best way of estimating future risks. Also we endorse the ideal that all epidemiological studies should be accompanied by the best dosimetric estimates. However, we appreciate the difficulties of obtaining such data. For example, estimating the uptake and subsequent biokinetic behaviour of a radionuclide in volunteer studies often involves analysing the

total urinary and faecal output over a considerable time scale. Other body fluids often have to be sampled. In practice, these procedures would be impossible in population studies. In fact, in those likely to be at greatest risk (eg children and pregnant women), such procedures would be deemed unethical, even in volunteer studies. We endorse the view of CERRIE that epidemiological studies should conform to the usual standards of peer and ethical review but also wish to note that the control of national statistics, under the auspices of data protection, should not be so limiting as to interfere with proper scientific research.

Further work required

5.5 Apart from the specific scientific research already included in the report we wish to reiterate in this chapter what we have said previously regarding exposure of the general population to the natural radioactive gas radon and its decay products. This is the largest source of exposure to internal radiation emitters for the general population. Efforts need to be devoted both to studying the risk of such exposure and also to reducing that risk by remediation of already affected buildings and changes to new building regulations. Other large populations of workers have been exposed to internal emitters and, where possible, investigations of these populations should continue.

Recommendations

5.6 We recommend that the NRPB carry out a review of internal tritium dosimetry paying particular attention to tritiated water and organic compounds containing tritium.

5.7 We recommend that Government review its spending on radiobiological research, which we believe has become seriously under funded over a period of years due to Government 'savings cuts'. For example, when the Department of Health set up its Radiological Protection Research Programme in the late 1980s it had a budget of approximately £2 million per annum. We understand that the budget currently stands at less than £1 million per annum. Specifically we recommend increased funding to examine the biokinetics of and tissue responses to internal emitters and the possible health effects of genomic instability, the bystander effect and ESTR radiosensitivity.

5.8 The largest environmental radiation exposures to members of the general public are from radon and its decay products in the home. We recommend that Government review its spending on radon research, on the remediation of homes with significant radon levels and on radon preventative measures in new homes. This would be a method by which overall population radiation doses might be significantly reduced. We believe the amount spent by Government in promoting awareness of this radiation risk is small, for example, in comparison to the sums of money spent on reducing doses from radioactive discharges from nuclear installations in the UK which are already very much smaller than doses from radon.

5.9 We recommend a review of the available and possibly unpublished data relating to radiation monitoring around nuclear installations and bioassay measurements carried out on a variety of biological systems. This will allow a decision to be made on whether further research needs to be undertaken.

5.10 We recommend that Government ensures that when seeking to obtain scientific and medical advice it does not use a process or a method of funding which reduces spending clearly originally designed for research purposes.

5.11 We note that CERRIE was not set up under the guidance of the Office of the Commissioner of Public Appointments (OCPA); it was set up as an ad hoc group with the composition directed by ministers rather than by open

advertisement. We hope that the OPCA guidance will be adhered to more strictly in the future.

5.12 Notwithstanding point 5.11 above, we also wish to note that whilst admirable for most executive non-departmental government bodies, OPCA guidance for open advertisement may not always be so relevant to advisory committees such as CERRIE and COMARE where specific, scarce expertise is often required and therefore an open advertisement may not always be the most appropriate form of recruitment. COMARE suggests that the guidance should be revisited to consider first that recruitment to advisory bodies should be made easier and second to ensure that the most appropriate membership is realised.

CHAPTER 6

EPILOGUE: THE CONSULTATIVE PROCESS

6.1 COMARE is a group of independent experts mandated to advise Government on matters related to the health effects of radiation in the environment. Its members comprise medical doctors, research scientists, epidemiologists, hospital physicists etc, who work in medical schools, cancer research institutes, hospitals, and similar places. While having a considerable background in radiation and its effects, they are not employed by, or linked to, the nuclear industry or any group of activists. Although thought of by some as a watchdog, COMARE does not set its own agenda but is asked for advice on specific issues by Government Departments and the Devolved Authorities. In the past it has been critical of parts of the nuclear industry, Government, and special interest groups. Its deliberations have always been guided by the quality of the scientific information that is available and an acknowledgement of the uncertainties associated with it.

6.2 Because it does not have members representing stakeholder interest, it is charged under current draft guidelines to seek the views of those interests who are not represented on the Committee. In the past this has been achieved by asking such individuals to make presentations to the Committee. In the present case of internal emitters, it was decided, given the wide range of disparate views, to initiate a consultative exercise. One previous consultative exercise on dose assessment undertaken by the Chairman of COMARE for the Food Standards Agency had been very successful (CEDA^{*}). Its participants included a good representation both from the nuclear industry and from various environmental groups. The areas of disagreement were made very clear together with the further work that would be needed to resolve them. In the case of CERRIE, the participants were asked to go further and try to come to a consensus position. To achieve this they were given independence from COMARE in their deliberations and allowed to meet over an extended period of time. Their remit both from the then Minister for the Environment, Mr Michael Meacher, and from the Chairman of COMARE was to set out the various views, to try to come to a consensus, and to make very clear the reasons for failure to agree on specific issues.

6.3 The Chairman of COMARE was present as an observer at all the meetings of CERRIE but did not participate in the discussions. In his opinion CERRIE succeeded in setting out the widely differing views of its members, and most members tried hard to achieve consensus. However, the CERRIE report does not always clearly set out the reasons for lack of consensus. It was noted that members at the extreme ends of the spectrum of views did not change those views and some showed a reluctance to consider any data other than those that they presented to support their own case.

^{*} Food Standards Agency (FSA) (2001). Report of the Consultative Exercise on Dose Assessments. FSA, London.

6.4 To be of use to Government it is necessary to state clearly what conclusions can be derived from the available good quality research. Where the available research does not allow a generally agreed conclusion it is necessary to set out clearly point by point what further research would be needed to resolve the remaining questions. Most members of CERRIE, including those from both industrial and environmental backgrounds, worked hard to that end. However, two members felt that the CERRIE report, which they themselves had agreed, did not adequately reflect the reasons for their position and wrote their own lengthy dissenting report rather than add their reasons for disagreement point by point in the consensus report. This failure to work to the rules given at the outset has seriously compromised the workings of the group. The dissenting report was not accepted by the other members of CERRIE and the two members withdrew their agreement to the CERRIE report.

6.5 These possible failings had been pointed out to Ministers before CERRIE was set up. COMARE feels that without disparaging the members who contributed so much to the final CERRIE report, it has to conclude that the setting up CERRIE was not the ideal way for Government either to obtain a wide range of independent views or to reach a consensus position that could form the basis of advice to Government. It was neither time nor cost efficient when compared to the CEDA exercise referred to earlier in this chapter.

APPENDIX A

COMMITTEE ON MEDICAL ASPECTS OF RADIATION IN THE ENVIRONMENT

CHAIRMAN

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Genome Damage and Stability Centre
University of Sussex, Brighton

PRESENT MEMBERS

Professor Freda Alexander BA MSc PhD
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University of Edinburgh

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

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

Professor A T Elliott BA PhD DSc CPhys FInstP FIPeM
Western Infirmary, Glasgow

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

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

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
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SECRETARIAT

Dr R Hamlet BSc PhD CBiol MIBiol (Scientific)

Dr Jill Meara MA MSc BMBCh FFPH (Medical)

Dr J R Cooper BSc DPhil (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

Office for National Statistics

Scottish Environment Protection Agency

Scottish Executive

Welsh Assembly Government

CERRIE SHADOW SUBCOMMITTEE

Chairman

Professor B A Bridges

Members

Professor Freda Alexander

Professor A T Elliott

Dr Patricia McKinney

Professor T J McMillan

Professor E Wright

Secretariat

Dr R Hamlet

Dr Jill Meara

APPENDIX B

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) Consultancies or employment: any consultancy, directorship, position in or work for the radiation industries which attracts regular or occasional payments in cash or kind.
- (b) Fee-paid work: any work commissioned by those industries for which the member is paid in cash or kind.
- (c) Shareholdings: 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) Fellowships: the holding of a fellowship endowed by the radiation industry.
- (b) Support by industry: 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) Support by charities and charitable consortia: 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 current personal and non-personal 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 personal interests, and will be invited to complete a form of declaration once a year. It would be sufficient if changes in non-personal 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 current personal 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 – 2004

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 A Bridges		None		None
Prof A T Elliott		None	1 Nycomed Amersham 2 CIL Ltd	1 PhD students 2 Equipment loan for collaborative project
Dr C J Gibson		None		None
Prof N Haites		None		None
Prof J Little		None		None
Dr P McKinney		None		None
Prof T J McMillan		None	Westlakes Research Inst	PhD students and consumables
Prof M D Mason		None		None
Dr C D Mitchell		None declared		None declared
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 declared		None declared
Prof R Waters		None		None
Prof E Wright		None		None