

Assessments of Health and Environmental Risks of Management Options for Contaminated Land

A report prepared within the SAFEGROUNDS Learning Network

Revision 1: July 2005

Participation by HSE/NII in the SAFEGROUNDS Learning Network must not be taken as an indication of support for all the content of the guidance developed

Preface

The SAFEGROUNDS website has had on it for 2 years a document entitled 'Assessments of Health and Environmental Risks of Management Options for Contaminated Land', written by Graham Smith. As part of its on-going programme, SAFEGROUNDS has decided to provide resources for the updating of this document, taking account of recommendations and discussions within and among the Project Steering Group (PSG) members and of the more recent developments.

The updated version of the 'Assessments of Health and Environmental Risks of Management Options for Contaminated Land' document is being prepared taking account of SAFEGROUNDS own process for development of documents for publication on the website. A draft description of this process was distributed to PSG members on 27 August 2004. It should be noted that this process is still not finalised, and indeed is a living object which may be continuously improved.

Draft 1 of the updated document was prepared by Enviro staff, with input as noted above. It was discussed at meetings of a subset of the PSG in meetings on 2 July and 14 July 2004. Draft 2 has been produced by Enviro staff, taking account of the output from those meetings. Notes of those meetings are retained by CIRIA.

Draft 2 was distributed 3 September 2004 to PSG members. Initial discussion took place at the PSG meeting on 7 September 2004. PSG members were invited to obtain wider comments from within their organisations and provide these by 8 October 2004.

Draft 2.1 was prepared by Enviro, taking account of further input from PSG members, primarily. The Draft was circulated to PSG members for comment within each of their own organisations. The PSG members were invited to collate their organisation's comments and to return these by 19 November 2004.

Draft 3 was prepared by Enviro based on the feedback on version 2.1. Draft 4, which was prepared by Enviro in the light of comments on Draft 3 and also as a result of further consultation material produced by ICRP on the risks associated with low doses of radiation.

This is draft 5 prepared, by Enviro, in light of the discussions held during the PSG meeting of the 19 April 2005.

Acknowledgements

This document was developed by CIRIA with members of the SAFEGROUNDS Learning Network steering group. CIRIA's project manager was Jeff Kersey. Graham Smith of Enviros Consulting Ltd acted as technical consultant and report writer.

The following steering group members were particularly involved in producing this guidance document. Their support is gratefully acknowledged. Caveats apply to the degree to which some organisations were able to endorse all aspects of the content. These are noted below.

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Caveat

* These organisations do not agree to the inclusion of ECRR risk figures in Table A1 and A2.

Executive Summary

This document sets out guidance on Assessments of Health and Environmental Risks of Management Options for Contaminated Land.

It complements guidance on related issues, notably, principles and good practice for the management of contaminated land on nuclear and defence sites, available at <http://www.safegrounds.com/>

The guidance has been produced in consultation with a range of stakeholders which make up the SAFEGROUNDS Project Steering Group.

The guidance starts with a discussion of the scope of such assessments, largely defined by Principle 1 of the guidance referred to above, which requires that there be a high level of protection of people and the environment. A series of steps is then suggested for the assessment process. This begins with establishment of a preliminary view of the significance of the contaminating source term. Relatively simple assessments may be appropriate for minor source terms, and vice versa. It is important to have a clear process for determining whether something is significant or not.

The subsequent steps include:

- development of a description of the system under investigation,
- construction of scenarios for how radiation exposure may arise from contamination within the described system, giving rise to environmental and human health risks,
- development and/or application of assessment models, using relevant data, by which the radiation risks can be evaluated,
- sensitivity analysis.

The guidance also references advice on assessment of non-radioactive contaminants and mixed hazardous contamination. The use of the results in the context of options analysis is also discussed.

An appendix is included providing a greater description of the nature of the uncertainties associated with dose response relationship.

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1 Introduction

The purpose of this SAFEGROUNDS paper is to encourage a consistent approach to the assessment of the health and environmental risks associated with contaminated land management options. It compliments the SAFEGROUNDS Good Practice Guidance for the Management of Contaminated Land on Nuclear and Defence Sites, available at www.SAFEGROUNDS.org.

The paper deals with assessments for radioactively contaminated land, land contaminated with non-radioactive contaminants and land with mixed contamination. More detail is provided for radioactively contaminated land because there is little other existing guidance. The paper does not deal with assessments for the purpose of finding out whether land is contaminated in the sense of the definitions in Part IIA of EPA90, because the approach for these is largely described in regulatory guidance.

Within the framework of the SAFEGROUNDS guidance on the management of contaminated land on nuclear and defence sites, the main type of risk assessment required is as part of the detailed characterisation of those management options that are to be compared when identifying the preferred option(s) [SAFEGROUNDS, 2002]. This paper focuses on this type of assessment. The same assessment approach may also be useful for carrying out other types of assessments. Examples are scoping/screening assessments to distinguish options for further consideration from other envisageable options, and assessments made during site characterisation [SAFEGROUNDS, 2002; Baker et al, 2000]. However useful, the approach is not intended to be used for the safety cases produced to gain regulatory and other approvals for implementation of the option preferred by the site owner/operator. It has a wider context than that.

When results will feed into major decisions, it is recommended that stakeholders should either be involved in performing assessments (particularly in setting out the scope, methodology and basic assumptions) or be invited to review assessments before options are compared. The wider involvement of stakeholders in the contaminated land management process is discussed in a separate document (SAFEGROUNDS, 2005).

2 Scope of Assessments

The scope of assessments is defined largely by Principle 1 of the SAFEGROUNDS guidance, which requires that there be a high level of protection of people and the environment (see Section 2 of SAFEGROUNDS [2002]). The assessments considering risk are a consideration in any optioneering study (including BPEO) that may form part of the SAFEGROUNDS process. Scoping considerations are as follows.

In general, assessments should produce estimates of health risks to the public and workers, estimates of risks to organisms other than humans, and estimates of contamination levels in the relevant parts of the environment (air, soil, groundwater, foods, houses etc). The ICRP Recommendations in respect of estimates of risks relating to organisms are expected to be published in 2006. The assessments should address routine and incident/accident situations, both those current and those which might arise as time elapses.

Part II A of the EPA 90 introduced a regulatory regime for the identification and remediation of contaminated land, including the definition of land required to be designated as a special site. This includes, but is not limited to, land within a nuclear site, land comprising premises which are or were designated under the Atomic Weapons Establishment Act 1991. Although only applicable to non-radioactively contaminated land it does provide principles for risk assessment and management to ensure the effective management of contaminated land.

The level of detail required depends on the nature of the contaminated land situation (see Section 3) and on how the results are to be used in characterising options on their attributes (see Section 6). The assumptions for the long term land use of the site are also very pertinent. Separate assessments may be needed for different land use assumptions and for alternative options for remediation.

Estimates of risks during and after implementation of the management option are required, including risks in the long term. If a management option is intended to make the land fit for more than one end use, the assessment should cover all relevant uses.

If implementation of an option would produce effluent or solid wastes, the assessment should include estimates of risks associated with each step of the management of those wastes, e.g. treatment, storage, transport, and disposal. However, the guidance given here does not address impacts on facilities which are away from the site of current concern, such as specialist solid waste disposal facilities, see Section 3.1. Ideally, however, all such assessments should make similar assumptions on issues common to both.

It is generally appropriate to include information on uncertainties in estimated risks and contamination levels. Treatment of uncertainties in environmental and/or radiological risk assessment is not simple. A comprehensive review of the issues and methods for handling them is provided, for example, in Robinson and Copper (Eds.) [1995]. For current purposes, it is noted that consideration needs to be given to the conceptual understanding of potentially relevant processes by which radiation or other exposure can occur, and to the values of parameters used in any quantitative evaluation of the health or other impacts. The preferred approach is to use best estimate¹ assumptions about processes and parameter values in the first instance, and then go on to produce a range of results corresponding to different assumptions within a sensitivity analysis (see Section 3.6).

¹ 'Best estimate' is taken here to mean that which is most likely, in the opinion of the person making the assessment.

Results of assessments are to be used mainly in comparisons of options, so relative values of risks and contamination levels are generally more important than absolute values. This may influence both the methodologies and models used in assessments, and the extent of any sensitivity analyses.

3 Assessments of Options for Radioactively Contaminated land

3.1 General Approach

The guidance on assessment methods given in this section focuses on assessments of options for the remediation of contaminated land at the site concerned and its environs. Assessments for disposal of the types of wastes produced in implementing options for site remediation, for example, for solid waste to be disposed of at a specialist facility elsewhere, is expected to have been prepared separately. These other assessments are relevant to decisions on the management of the site concerned.

The set of potentially relevant assessment endpoints includes: radionuclide contamination levels, risks to the health of biota, people's radionuclide intakes and the individual risks, collective doses and number of health effects associated with those intakes, all as a function of time and space during and after the implementation of the management option. It may be sufficient to assess a subset of these assessment endpoints, depending on the nature of the contamination, the land concerned and the options under consideration (see Section 3.2) and on how the results of the assessment are to be used in characterising options on their attributes (see Section 6).

The time frame for the assessment will depend on the management option and on the radionuclides involved. It is unlikely to be shorter than a hundred years, because of the radioactive half-lives of most of the radionuclides of concern on nuclear and defence sites. It is also unlikely to be as long as thousands of years, because in most cases none of the management options being compared will leave land in a contaminated state for thousands of years or more.

The main calculations are commonly carried out using currently recommended values of environmental transport parameters for radionuclides, doses per unit intake of radionuclides and risk per unit dose. The International Atomic Energy Agency provides information on radionuclide transfer parameters, notably for the terrestrial environment in Technical Report 364 [IAEA, 1994]. The data here are being reviewed and updated within the IAEA's EMRAS programme - <http://www-ns.iaea.org/projects/emras/>, with the support of the International Union of Radioecology. The main reference from the International Commission on Radiological Protection (ICRP) for dose coefficients (relating intake of radionuclides to radiation dose) is ICRP Publication 72 [ICRP, 1996]. The relationships between radionuclide concentrations in various media outside the body and radiation doses to humans from external irradiation are comprehensively set out in FGR13 [USEPA, 1998].

The ICRP also provides recommendations on the relationship between radiation dose and the corresponding health risks to humans, in Publication 60 [ICRP, 1991]. ICRP are currently consulting upon proposed revisions to this set of recommendations. This process is due to result in revised recommendations during 2006.

It should be recognised that there are uncertainties in the dose to risk relationship, and some of these have been reviewed recently in the report of the Committee Examining Radiation Risks of Internal Emitters [CERRIE, 2004]. The CERRIE Majority Report notes many technical issues and concludes that risks should be calculated on the basis of 'best current information, using central values, with no bias towards conservatism or pessimism'. Such material will be taken into account along with many other sources in the revision of ICRP recommendations, referred to above.

In assessing potential risks from implementing alternative options, it should be noted that differing views of the best current information may be taken into account when forming a preliminary view on the significance of the source term (see Section 3.2) and should be examined in sensitivity analyses (see Section 3.6). Alternative views may in some cases lead to results that differ by orders of magnitude but it should be borne in mind that UK regulation is based upon advice and values provided to Government by the Radiation Protection Division of the Health Protection Agency (previously called NRPB). It should be recalled, however, that complete assessment of options would include, for example, assessment of the impacts of disposing of soil removed from a site as an element to balance against the reduction of risk on-site. Since the same views on radiation risks would apply to the assessment of all risks on- and off-site, the range of final decisions might not be so large.

The following assessment steps are offered as a practical way forward, based on a source, pathway, receptor approach, as discussed in CLR 11, Model Procedures for the Management of Contaminated Land [DEFRA/Environment Agency, 2004]. This approach takes note that any harm arising from remaining contamination (the source), arises due to transfer (via various pathways) to those media including humans in which the harm may be expressed (receptors). It is consistent with the process of identification of hazards, the subsequent assessment of these hazards to estimate the risks and finally the evaluation of those risks. It also reflects a tiered approach to evaluation of the problem, as discussed in CLR 11, so that the level of resources applied can be proportionate to the scale of the problem. The risk assessment process, if it reveals an unacceptable risk, will feed into the options appraisal stage which then results in the implementation of a remediation strategy.

3.2

Establish Preliminary View Of Significance Of Source Term

This step begins with identification of the relevant contamination source term in terms of the activity levels of the main radionuclides, their physico-chemical forms, the size and activity of any particles present, and their spatial distribution over and under the land concerned, and an early view of the immediate near surface litho-stratigraphy of the area. This information will be available from site characterisation. These levels are then compared with those published for other purposes, in order to gain a preliminary view of the order of magnitude of potential committed effective doses to individual people. Levels that might be used for comparison are given in NRPB [2000], European Commission [2000], Hill et al [1999] and WHO [1993]. If doses seem likely to be of the order of micro sieverts then a simple assessment may be sufficient². If doses are of the order of hundreds of micro sieverts or more then much more detail will be needed³. However, it is also necessary in this step to bear in mind scientific uncertainties and stakeholder views. It would be unwise to conclude that levels of a particular radionuclide are of little significance, and to then pay little attention to them in assessments, if recent evidence has called into question the scientific basis for the judgement of significance. Such an approach would be inefficient, because the assessment is likely to have to be repeated at a later stage. Similarly, it is sensible to take into account stakeholder concerns about particular radionuclides, and particular physico-chemical forms of radionuclides, when judging source term significance and establishing assessment methodology, because this could save time later on.

In addition, it should be noted that remediation work may result in a requirement to transport waste and to dispose of it elsewhere. This results in a need to consider the significance of a potentially wide range of issues marginal to the site being considered.

² The HSE Safety Assessment Principles - SAPs (1992) defines the Basic Safety Objective (BSO) as the point beyond which the assessors need not seek further safety improvements from the licensee in his quest for ALARP. Principle 14 sets the BSO for a member of the public from all sources of radiation on a site at 0.02mSv y^{-1} . Government policy on radioactive waste management advises regulators that further reductions below 0.02 mSv y^{-1} are not necessary provided the regulators are satisfied the operator is using best practicable means to limit discharges (HMSO, 1995). (It is noted that the HSE is currently undertaking a major review of SAPs). This is consistent with the EA / SEPA methodology for authorising discharges of radioactive waste to the environment under the Radioactive Substances Act 1993 defined in their "Principles for the assessment of prospective public doses (Environment Agency et al, 2001). The guidance also refers to "widespread international agreement that doses to members of the public of the order of 0.01 mSv y^{-1} or less are sufficiently low to be of no regulatory concern", noting that they still remain subject to the ALARA requirement.

³ The Ionising Radiations Regulations (1999) determines a limit on effective dose for members of the public of 1 mSv in any calendar year. In the environmental regulator's methodology guidance site constraints and source constraints of 0.5 mSv y^{-1} and 0.3 mSv y^{-1} are also identified (Environment Agency et al, 2001).

3.3

System Description

This step is to determine the features of the site and its environment. Relevant features will include soil type and land cover, surface and subsurface groundwater bodies, and the current land use. The amount of detail required will be influenced by the significance of the source term. Details of potentially relevant system components and how they can be characterised for the purposes of radiological assessment are available in the output from the International Atomic Energy Agency's BIOMASS programme [BIOMASS, 2003]. Such full details as shown in Table 1 would not normally be required but the table indicates the types of information that could be relevant.

Table 1: Example System Components based on BIOMASS [2003]

Principal Component	Definition	Required information
Climate and atmosphere	Climate is the expression of meteorological parameters over an area.	For example, rainfall, temperature, windrose, now and in possible future climate states...
Water bodies	Water bodies (surface and subsurface water masses) and may include near-surface aquifers	Whether such features are present in the biosphere system.
Human activity	Human activity describes the nature of the communities, their habits, their ways of life.	Nature of communities, their habits, their ways of life.
Biota	Biota are the terrestrial and aquatic plant and animal life in the biosphere system.	A distinction should be made between domestic and wild flora and fauna and between those in the food chain and those which are not but are used by humans for purposes other than food.
Near surface litho-stratigraphy	Near surface litho-stratigraphy describes the general characteristics of soils and sediments including both their composition and structure.	Near surface litho-stratigraphy includes all weathered material above the bedrock and associated life forms (excluding those predefined under flora). It can include bedrocks if they contain aquifers which are to be considered within the biosphere.
Topography	Topography is the configuration of the earth's surface including its relief and relative positions of natural and man-made features.	Information should be provided concerning the features of the system under consideration and its relief.
Geographical extent	Geographical extent defines the boundaries and/or spatial domain of the biosphere.	At a minimum, the area over which direct contamination of the biosphere may occur should be considered. It should be recognised that extent may change as a function of time.
Location	Location is the position of the biosphere system on the earth's surface.	Information concerning latitude and longitude should be provided for site-specific contexts. For more generic situations, less specific

Principal Component	Definition	Required information
		information might be available e.g. coastal, inland, distance from sea, altitude.

The system description needs to be understood sufficiently broadly to address all the environmental and human health risk endpoints of potential interest. Model requirements in terms of system description for assessing doses to humans in this context are presented in Oatway et al [2003] and BIOMASS [2003].

Apart from radiation risks to exposed people, increased emphasis is now being given to protection of media, e.g. via the Groundwater Directive, and of biota. The ICRP has just created a new committee to address technical issues of biota exposure, taking account, for example, of development in impact assessment of ionising radiation on wildlife [Coppelstone et al, 2001]. The European Commission is also supporting research in this area under its FASSET and ERICA projects. These sources are further indicative of the type of system description information which may be relevant.

3.4 Scenario Construction

This step is to construct scenarios, i.e. simple descriptions, for the evolution of the source term within the described system according to the assumed future land use associated with each option under evaluation. These descriptions should include:

- controls over land use
- assumptions for land use
- processes likely to result in migration and accumulation of radionuclides
- processes likely to give rise to radiation exposure of people and non-human biota as a result of the presence, or migration and accumulation of radionuclides.

The Environment Agency (2002b) establishes that the concept of pollutant linkage from a source, via a pathway, to a receptor, applicable in the context of non radioactive contaminated land, has an equivalent approach in dealing with radioactively contaminated land. There can be a radiological impact from the contamination only if there is a source, pathway and receptor. The receptor will usually be a representative member of an exposed population receiving the highest dose, often termed the critical group. In reality pathways can be very complicated and may need to consider the impact of radioactive decay and ingrowth of daughter radionuclides (Environment Agency, 2002b).

Modes of radiation exposure considered could include:

- ingestion of radioactively contaminated materials, including dust, aerosols, soil, foodstuffs and drinking water;
- inhalation of radioactively contaminated materials, including dust, aerosols and soil;

- external irradiation from contaminated soils and other materials; and
- contact with contaminated materials.

Not least since local people may be aware of local conditions, such possibilities should take into account local advice. Further advice on the exposure pathways in radiological assessment has been published by the National Dose Assessments Working Group (Allott, 2004), including checklists for unusual pathways. The level of detail to which pathways need to be analysed is case dependent (Environment Agency, 2002b).

The key issue is to identify the more significant mechanisms by which people and other biota could come into contact with the more significant levels of radionuclides. Scenarios should include likely as well as unlikely events and processes.

3.5 Develop Or Acquire And Apply Assessment Models And Data

An assessment model is no more than a set of assumptions on which a calculation can be based, in this case concerning the risks to people and the environment. It is recommended that the simplest models be used that meet the purpose of the assessment. That purpose is to be able to distinguish effectively between the options under consideration, taking account of the factors discussed in Section 2. Based on the output from the steps in Sections 3.2-3.4 above, a set of assessment endpoints should be chosen from those mentioned in Section 3.1.

The models are normally developed in stages, including a conceptual description, a mathematical representation of that description and then the selection of data for the mathematical models. In general, new models will not be required; rather, based on the output of previous steps and the choice of endpoints, models can be chosen from the literature, although the caveats of paragraph 3.2 should be borne in mind. Furthermore, many of these models can be implemented on spreadsheets and do not require sophisticated techniques or software. Useful examples, including some generic example results, are described in Hill et al [1999], NRPB [2000], IAEA [2001], FSA [2002], BIOMASS [2003] and Oatway et al [2003]. These documents focus on impacts on people. The Environment Agency R & D Report 128 [Coppelstone et al 2001] provides methods and data, as well as a CD for implementation of models, to assess the impacts on non-human biota.

The assessment process typically involves some iteration. For example, suitable data may not be available for the initial choice of model, or some variant exposure pathway which is locally relevant may have been identified, and so a variation in the model may be appropriate. Any such developments should be transparently documented and justified. Preliminary results may be used to identify the more significant impacts and hence guide assessment iterations.

In the case of more significant contamination it may be appropriate to apply more sophisticated models, e.g. for the long-term migration of contamination through the ground. Such methods and their application are being considered in the IAEA's ASAM programme [IAEA, 2002]. Site specific information on the near-surface hydrology may be required, or other detailed site investigation necessary, in order to provide suitable site specific input.

3.6

Sensitivity Analysis and Risk Management

In most cases a sensitivity analysis should be carried out to address variations in assumptions and parameter values, and perhaps models. The analysis could be quantitative or semi-quantitative, and need not involve complex calculations. The aim is to produce a range of results so that it can be seen whether the comparison of options has a different outcome if very different assumptions and parameter values are used in estimating risks.

4

Assessments of Options for Non-Radioactively Contaminated Land

Guidance on risk assessments for non-radioactively contaminated land is available in a number of publications (see, for example, Environment Agency [1999], SNIFFER [1999], CIRIA [1995], Welsh Development Agency [1993], Scottish Enterprise [1994]. The most recent guidance on human health risk assessments was published in 2002 [Environment Agency 2002a].

The approaches recommended in these publications are not dissimilar to that for radioactively contaminated land outlined in Section 4 but tend to be described in different terms. The endpoints of the assessments will also be different. For the reasons given in Sections 2 and 3, it is recommended that assessments for non-radioactively contaminated land include sensitivity analyses.

5

Assessments of Options for land with Mixed Contamination

The recommended approach is to do two separate assessments: one for radioactive and one for non-radioactive contamination. The radioactive assessment should take account of any likely effects of non-radioactive contamination on radionuclide movement through the environment and uptake by organisms. The opposite influence is unlikely since the radionuclide contamination is only likely to be present at very low levels in terms of chemical concentration and so is unlikely to affect the behaviour of other chemicals. As yet, it is not possible to deal with potential synergistic health effects, although research continues. Among the corresponding factors is the additivity of carcinogenic risks from radioactive and chemical contamination.

Depending on the nature of the contaminants and the land management options that are to be compared, it can be important that the methodologies used for the radiological and non-radiological assessments are consistent in key respects. One particular issue is the time frame considered. Non-radiological assessments in the past have tended to consider shorter time frames than radiological assessments. If the non-radioactive contaminants are ones that are persistent in the environment, and the radioactive contaminants have long half-lives, then it may be necessary to extend the non-radiological assessment to longer times. This can be done by bringing elements of the radiological assessment methodology into the non-radiological assessment, for example by including the same long-term scenarios for both types of assessment.

6 Use of Results in Characterisation of Options on Attributes

The results of the health and environmental risk assessments covered in this paper are to be used in characterising options on attributes related to impacts on human health and to impacts on the environment (see SAFEGROUNDS [2002]). They may also be used for attributes of a social nature. For example, it is clear that contamination levels in various environmental media may affect matters such as property prices, inability to sell land that has residual contamination, and reluctance to use groundwater that has residual contamination and foods and natural materials that are contaminated. Even if health risks are thought to be low, the existence of contamination levels that appear to be high (e.g. large Bq/g values) can have a real adverse impact that should be considered in comparing options.

In the case of radioactively contaminated land, sub-attributes for impacts on human health could be defined to be maximum individual risk and collective dose, and for impacts on the environment the sub-attributes could be doses to various species. Non-health impacts could be dealt with by attributes that are simply contamination levels in particular media.

Alternatively, sub-attributes could be defined in terms of fractions/multiples of reference levels e.g. for humans an individual risk of one in a million per year, a collective dose of 1 man sievert. However, the caveats in paragraph 3.2 should be borne in mind. For non-human organisms -they could be the levels at which damage to populations of that species is believed to occur. This latter approach is easier to use for non-radioactive contamination, where the endpoints of assessments are more likely to be in the form of fractions/multiples of reference levels (see Section 4). For mixed contamination it is usual to have separate sub-attributes for radiological and non-radiological impacts, since this provides the opportunity to weight these impacts differently, if required; it is worth noting that “double-counting” is seldom an issue.

It will often be the case that some assessment work is carried out before attributes and sub-attributes have been fully defined. This does not necessarily mean that assessments have to be repeated when the definitions are available. It will frequently be possible to convert existing results to the required form. If repetition is necessary this will be easier if simple assessment methodologies and models have been used.

7

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⁴ *Other publications in this series are:

CLR 8 Potential contaminants for the assessment of land

CLR 9 Contaminants in soil: collation of toxicological data and intake values for humans
CLR 10 The contaminated land exposure and assessment model (CLEA). Technical basis and algorithms.

SGV 1,3,4,5, 7, 9, 10. Soil guideline values for arsenic, cadmium, chromium, inorganic mercury, nickel, selenium, lead

TOX 1,2,3,4,5,6, 7 8, 10. Contaminants in soil, collation of toxicological data and intake values for humans for arsenic, benzo(a)pyrene, cadmium, chromium, inorganic cyanide, lead, mercury, nickel, selenium.

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Appendix A: Consideration of the different approaches to the dose response relationship and the associated uncertainty in risk calculations

The basis for ICRP's recommendations, which forms the basis of current UK regulatory standards, is the linear–no threshold hypothesis: that any radiation dose increases the exposed person's chance of subsequently developing cancer, by an amount directly proportional to the dose. The assumption that this hypothesis is true is inherent in the ICRP's definition of 'effective dose' and in the assumption that effective doses from different exposure situations (e.g. external and internal exposure) and radionuclides can be compared on an equal basis as indicators of risk. It is also inherent in ICRP's estimates of the risks associated with exposure to unit effective dose, e.g. ICRP estimates⁵ that the probability of fatal cancer resulting from an effective dose of 1 mSv is 5×10^{-5} .

ICRP considers that radiation exposure may cause detrimental health effects other than cancer and hereditary effects (e.g. heart disease, stroke, respiratory disease) at high doses (hundreds of mSv) but that there is not convincing evidence of such effects on general health at low doses. For illustration purposes, the ICRP position is represented here by a risk factor of zero for health effects other than cancer and hereditary effects for doses of less than about 50 mSv.

The ICRP position is used in most countries as the basis for national radiation protection legislation and regulations. It is not, however, universally accepted, and a wide range of criticisms have been made of the ICRP approach. To catalogue these criticisms and their implications is far beyond the scope of this report but, in order to provide an indication of the uncertainty in this element of assessing radiation risks, the spectrum of opinion has been simplified to three points:

- one representing the view that the risks from some internal radiation exposure regimes at low doses are substantially underestimated by ICRP models;
- one representing the view that the risks from radiation exposure are substantially overestimated by ICRP models; and
- the ICRP models.

It is noted that these positions are not necessarily mutually exclusive. The differing views – and particularly the arguments that the risks from internal radiation exposure are substantially underestimated by ICRP models – have been explored in detail by the Committee Examining Radiation Risks of Internal Emitters, which reported in October 2004 [CERRIE, 2004]. The main CERRIE report notes uncertainties of different degrees for different radionuclides, and in the subsequent COMARE (Committee on Medical Aspects of Radiation in the Environment) 9th report, COMARE has expressed the opinion that attention should be drawn to the uncertainties associated with determining the risk from internal emitters and that further work is required to help quantify these uncertainties.

The ICRP has since (10 December 2004) issued a consultation document on Low-dose Extrapolation of Radiation-Related Cancer Risk. The consultation period has since expired but the document can still be viewed, whilst final editing of the report takes place, at: http://www.icrp.org/draft_cancer.asp. Notably in the conclusions of the draft ICRP document it does recognise that “radiation related risk tend to be highly uncertain both because of weak signal-to-noise ratio and because it is difficult to recognise or to control for subtle confounding factors”. Furthermore, it states that there is “no direct evidence from epidemiological or experimental carcinogenesis studies, that radiation exposure at doses in the order of 1 mGy or less is carcinogenic”. However, there is epidemiological evidence linking “increased cancer risk at doses on the order of 10mGy”. Notwithstanding this

⁵ This is the estimate from the 1990 Recommendations: the draft 2005 Recommendations give a slightly lower estimate of 4.4×10^{-5} per mSv.

there is data from experimental carcinogenesis studies that support a linear no threshold dose response relationship at low doses.

At the time of writing a number of draft documents have been published on the ICRP web site for consultation. Those that are relevant to the discussion here include:

- Assessing dose of the representative individual for the purpose of radiation protection of the public;
- Basis for dosimetric quantities used in radiological protection;
- Biological and epidemiological information on health risks attributable to Ionising radiation: A summary of judgements for the purposes of radiological protection of humans;
- The optimisation of radiological protection; and
- The concept and use of reference animals and plants for the purposes of environmental protection.

These consultation documents recognise the role of uncertainty in assessment. In the draft “Basis for dosimetric quantities used in radiological protection” it refers to the main CERRIE report (2004) in that “uncertainties for assessments of radiation doses from internal exposures including the bio-kinetics of radionuclides are larger than those from external exposures”. The report goes on to say:

“ICRP is aware of these uncertainties and efforts are undertaken to critically evaluate and to reduce them wherever possible. However, for prospective dose assessments in regulatory processes the ICRP takes the position that the dosimetric models, as well as the parameter values, that the Commission recommends for determining doses from quantitative information about radiation fields at working places and in the environment or from intakes of radionuclides, should be taken as reference models and values which are not subject to uncertainty. Equally the Commission considers that the dosimetric models and parameter values which are needed for the purpose of recommending dose limits or constraints are defined as reference data and, therefore, are not uncertain. Nevertheless, these models and values are re-evaluated periodically and may be changed by ICRP in due time on the basis of such evaluations when new scientific data and information are available.”

Supra-linear / Bimodal hypotheses

An alternative view from that of the ICRP’s linear no threshold hypothesis is the supra-linear and bimodal hypotheses advocated in the 2003 Recommendations of the European Committee on Radiation Risk (ECRR)⁶. These have been taken as broadly representing a position characteristic of those who consider that the risks from internal radiation exposure are substantially underestimated by ICRP models.

For external exposure⁷, the ECRR report does not recommend an alternative to ICRP dosimetric models, but does recommend the use of risk coefficients derived for high dose–high dose rate situations without modification by the DDREF, i.e. for low doses and dose rates, twice the risk coefficients recommended by ICRP. Hence the risk of fatal cancer from 1 mSv is assumed to be 10^{-4} . For internal exposure, the ECRR recommends (in Annex A of its Recommendations) its own dose coefficients (Sv committed per Bq taken into the body), which are based on a model incorporating biophysical hazard factors (W_j) dependent on the exposure mechanism⁸ and biochemical enhancement factors (W_k) dependent on the chemical characteristics of the radionuclide. The ECRR also

⁶ ECRR, 2003 Recommendations of the European Committee on Radiation Risk: Regulators’ Edition, Brussels (2003). See <http://www.euradcom.org/2003/ecrr2003.htm>.

⁷ Except in circumstances in which external exposure would be likely to result in the same cell undergoing two ‘hits’ within 24 hours, in which case a W_j factor of 10–50 is recommended. However, ECRR cite the probability of this occurring as “vanishingly small”.

⁸ The situations in which a W_j greater than 1 is recommended are: ‘second event’ decays (such as the $^{90}\text{Sr} - ^{90}\text{Y}$ sequence); Auger or Coster-Kronig radiations; and radionuclides in the form of insoluble particulates (e.g. micron or sub-micron ‘hot particles’).

recommends that the unmodified ICRP risk coefficients for high dose-high dose rate situations (e.g. the value of 10^{-4} mSv⁻¹ for fatal cancer) be applied to internal doses calculated in this way.

The ECRR further recommends a risk factor for loss of quality of life pertaining to a reduction in general health excluding cancer. The figure given in their 2003 Recommendations is 0.1% (10^{-3}) per mSv, but there is no indication of how, or indeed whether, numerical values of this risk can be compared to cancer risks. They are therefore treated separately.

Threshold / Hormesis hypotheses

An alternative view to that represented by ECRR, cites radiobiological and epidemiological studies (sometimes the same ones as those cited by ECRR and/or ICRP) that they interpret as evidence for exposure at low doses and dose rates (usually meaning below around 50–100 mSv/y) having a reduced [no] detrimental health effect⁹ (i.e. harm occurs only above a threshold) or even having a beneficial effect (hormesis). See for example, recent discussion in Higson [2004].

The threshold position can be represented easily by using a risk coefficient of zero (for all detrimental effects) for all doses less than 50 mSv/y¹⁰, for doses above this threshold the risks given by ICRP models can be applied. There are three ‘levels’ of hormesis hypothesis¹¹:

- That a low dose protects against carcinogenic effects of subsequent radiation exposure;
- That low doses protect against cancer generally; and
- That low doses protect against other health effects as well.

The first two of these would be represented by a negative risk coefficient for fatal cancer; the third by a negative risk coefficient for other health effects. However, the hormetic response – if it exists – is a much more complex function of dose (and dose rate, and possibly timing) than those discussed above, and there does not appear to be any representative quantification of hormetic effects that could be applied generically. For simplicity, therefore, the end of the uncertainty range represented in the quantitative analysis has been taken to be the threshold response.

Range of uncertainties

The range of uncertainty has been described qualitatively in main CERRIE report (2004). For equivalent doses to organs and tissues this may be within a factor of 2 or 3 from the central estimate where the data is good. This may extend to over an order of magnitude where conditions are not favourable, this may include where data is scarce.

⁹ There is a separate argument – sometimes confused with this one – that the health effects of very low doses cannot be distinguished against the background rate of cancer in the general population, and that they should not therefore be taken into account in decision-making, i.e. that resources should not be expended to prevent effects that could never be detected. This is not the same as the argument there is no effect, and has been assumed here to be within the range of hypotheses already considered.

¹⁰ The 50 mSv/y cut-off is taken from the 2001 Position Statement of the (US) Health Physics Society on *Radiation risk in perspective* (<http://hps.org/documents/radiationrisk.pdf>), which states that below this dose “zero health effects is the most likely outcome”.

¹¹ The mechanistic basis for these hypotheses is that damage to DNA due to a radiation ‘hit’ stimulates cellular defence mechanisms that repair the damage perfectly (or at least as perfectly as DNA damage due to causes other than radiation) and may even protect against further damage by subsequent irradiation or another agent. The dose – or, more commonly, dose rate – is important because low dose rates allow sufficient time for the repair mechanisms to operate.

Furthermore, the use of effective doses includes an additional source of uncertainty from the use of tissue weighting factors.

Importantly the main CERRIE report (2004) recognises the concerns surrounding the uncertainty of risk estimates used in radiation protection, “particularly in the regulation of practices that result in exposures to radiation”.

The main CERRIE report (2004) identifies that uncertainties in dose estimates will vary substantially between radionuclides depending on their:

- types;
- energies of radiation emission;
- chemical form;
- complexity and knowledge of their behaviour in the body; and
- data availability on which to base the model parameters.

Moreover, it establishes that uncertainty will arise at every stage of the dose calculation from epidemiological and bio-kinetic models, the use of relative biological effectiveness, tissue weighting factors and deriving total risk.

One other aspect of uncertainty in radiation risk estimates is individual variations in genetic susceptibility. It is now generally accepted that some individuals have specific genetic characteristics that make them much more (or much less) susceptible to radiation-induced cancer than the majority of the population. This consideration is noted, but the complexities and uncertainties are too great to allow quantitative consideration in this example. There are, however, implications which some classes of stakeholder could consider significant.

For comparison, the risks of fatal cancer from intake of 1 Bq by inhalation and by ingestion are shown in Tables A1 and A2 respectively, for the ICRP, ECRR and threshold hypotheses. These numbers are calculated by taking the dose per unit intake value in Sv Bq⁻¹ and multiplying it by the risk factor (Sv⁻¹). ICRP data is taken from tables A1 and A2 in Publication 72¹² for ingestion and inhalation respectively. The ECRR data is taken from table A1 in their 2003 Recommendations¹³; these data for ingestion and inhalation dose coefficients and has not been disaggregated. The threshold hypothesis data is based on the 2001 Position Statement of the (US) Health Physics Society¹⁴. The values for the risk factors that have been applied are for the risk of developing fatal cancer; the ICRP risk factor of 0.05 per Sievert has been applied to the ICRP dose coefficients and the ECRR risk factor of 0.1 per Sievert has been applied to the ECRR dose coefficients.

Practitioners need to recognise the difference in opinion that exist over the dose response relationship, consequently they may need to engage with experts and stakeholders to determine the most appropriate data to estimate doses and quantify in a meaningful way the relative uncertainties specific to their particular situation. Doses from different pathways can be calculated using BNFL lookup tables Radcontab version 0.3, based on ICRP dose coefficients, available on the SAFEGROUNDS web site (www.SAFEGROUNDS.com).

¹² ICRP Publication 72, Age dependent doses to Members of the Public from Intake of Radionuclides: Part 5 Complication of Ingestion and Inhalation Dose Coefficients. Pergamon, Oxford. Annals of the ICRP, Volume 26, Number 1, 1996

¹³ 2003 Recommendations of the European Commission on Radiation Risk. Health Effects of Ionising radiation Exposure at Low Doses for Radiation Protection Purposes. Regulators' Edition: Brussels, 2003.

¹⁴ US Health Physics Society Radiation risk in perspective, 2001

Table A1. Fatal cancer risk from inhalation of 1 Bq

		ECRR	ICRP	Threshold*
H-3	Infant	1E-10 – 5E-10	1.3E-12 – 6E-11	0
	Child	4E-11 – 2E-10	4.1E-13 – 1.9E-11	0
	Adult	2E-11 – 1E-10	3.1E-13 – 1.3E-11	0
C-14	Infant	1.5E-9	3.1E-11 – 9.5E-10	0
	Child	5.8E-10	1.5E-11 – 3.7E-10	0
	Adult	2.9E-10	1E-11 – 2.9E-10	0
Sr+90	Infant	4.5E-6	7.2E-9 – 2.2E-8	0
	Child	1.8E-6	2.2E-9 – 9.2E-9	0
	Adult	9E-7	1.3E-9 – 8.1E-9	0
Tc-99	Infant	1.6E-9	2E-10 – 2.1E-9	0
	Child	6.4E-10	3E-11 – 8.5E-10	0
	Adult	3.2E-10	1.5E-11 – 6.5E-10	0
Cs+137	Infant	3.2E-8	4.4E-10 – 5.5E-9	0
	Child	1.3E-8	1.9E-10 – 2.4E-9	0
	Adult	6.5E-9	2.3E-10 – 2E-9	0
Pb+210	Infant	3.5E-7	2.4E-7 – 9.2E-7	0
	Child	1.4E-7	7E-8 – 3.7E-7	0
	Adult	7E-8	4.5E-8 – 2.9E-7	0
Ra+226	Infant	1.4E-7	1.3E-7 – 1.7E-6	0
	Child	5.6E-8	3.7E-8 – 6E-7	0
	Adult	2.8E-8	1.9E-8 – 4.8E-7	0
U+238	Infant	1.8E-8 – 1.8E-5	9.7E-8 – 1.5E-6	0
	Child	9E-9 – 9E-6	3.7E-8 – 5E-7	0
	Adult	4.5E-9 – 4.5E-6	2.5E-8 – 4E-7	0
Pu-239	Infant	1E-6 – 3E-5	2.2E-6 – 1.1E-5	0
	Child	5E-7 – 1.5E-5	9.5E-7 – 6E-6	0
	Adult	2.5E-7 – 7.5E-6	8E-7 – 6E-6	0
Am-241	Infant	1E-7	2.3E-6 – 9E-6	0
	Child	4E-8	9.5E-7 – 5E-6	0
	Adult	2E-8	8E-7 – 4.8E-6	0

* - Assuming doses are below a 50 mSv/y threshold; above the threshold the appropriate ICRP dose coefficient can be applied.

Ranges represent different chemical forms and/or particle sizes.

Table A2. Fatal cancer risk from ingestion of 1 Bq

		ECRR	ICRP	Threshold*
H-3	Infant	1E-10 – 5E-10	3.2E-12 – 6E-12	0
	Child	4E-11 – 2E-10	1.2E-12 – 2.9E-12	0
	Adult	2E-11 – 1E-10	9E-13 – 2.1E-12	0
C-14	Infant	1.5E-9	7E-11	0
	Child	5.8E-10	4E-11	0
	Adult	2.9E-10	2.9E-11	0
Sr+90	Infant	4.5E-6	1.3E-8	0
	Child	1.8E-6	3.3E-9	0
	Adult	9E-7	1.5E-9	0
Tc-99	Infant	1.6E-9	5E-10	0
	Child	6.4E-10	6.5E-11	0
	Adult	3.2E-10	3.2E-11	0
Cs+137	Infant	3.2E-8	1.1E-9	0
	Child	1.3E-8	5E-10	0
	Adult	6.5E-9	6.5E-10	0
Pb+210	Infant	3.5E-7	4.2E-7	0
	Child	1.4E-7	9.5E-8	0
	Adult	7E-8	3.5E-8	0
Ra+226	Infant	1.4E-7	2.4E-7	0
	Child	5.6E-8	4E-8	0
	Adult	2.8E-8	1.4E-8	0
U+238	Infant	1.8E-8 – 1.8E-5	1.9E-8	0
	Child	9E-9 – 9E-6	3.8E-9	0
	Adult	4.5E-9 – 4.5E-6	2.4E-9	0
Pu-239	Infant	1E-6 – 3E-5	2.1E-7	0
	Child	5E-7 – 1.5E-5	1.4E-8	0
	Adult	2.5E-7 – 7.5E-6	1.3E-8	0
Am-241	Infant	1E-7	1.9E-7	0
	Child	4E-8	1.1E-8	0
	Adult	2E-8	1E-8	0

* - Assuming doses are below a 50 mSv/y threshold; above the threshold the appropriate ICRP dose coefficient can be applied.

Ranges represent different chemical forms and/or particle sizes.