Health Protection Agency

Comparison of Processes and Procedures for Deriving Exposure Criteria for the Protection of Human Health:

Chemicals, Ionising Radiation and Non-ionising Radiation

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Abstract

The Centre for Radiation, Chemical and Environmental Hazards is the Health Protection Agency's focal point for work on hazards associated with radiation and chemicals. An important component of the Centre's work is the provision of advice on the corresponding, scientifically based, criteria for the protection of human health. In order to promote a common understanding of heath based protection criteria setting, the Centre has undertaken a review of the bases for establishing such criteria that have been used in the relevant areas: chemicals, ionising radiation and non-ionising radiation. This paper presents the conclusions of that review. Appendices provide detailed descriptions of the processes and procedures adopted for setting scientifically based exposure criteria for the protection of human health in the various areas.

This paper from the Health Protection Agency reflects understanding and evaluation of the current scientific evidence as presented and referenced here.

1 Introduction

The Centre for Radiation, Chemical and Environmental Hazards is the Health Protection Agency's focal point for work on hazards associated with radiation and chemicals, which in the case of radiation includes occupational exposure. An important component of the Centre's work is the provision of advice on the corresponding, scientifically based, criteria for the protection of human health. In order to promote a common understanding of health based protection criteria setting in these areas, the Centre initiated a review of the bases for establishing these criteria*. This paper presents the conclusions of that review. It identifies similarities and differences in the criteria-setting process between the various areas. The appendices to this paper provide detailed descriptions of the processes and procedures adopted for setting scientifically based exposure criteria for the protection of human health for chemicals, ionising radiation and non-ionising radiation (electromagnetic fields and optical radiation†), together with a comprehensive list of references.

This paper addresses primary exposure criteria for the protection of human health, the process for deriving these criteria, their means for promulgation and their scientific bases. It is not the purpose of this paper to describe in any detail the process surrounding the translation of these criteria into legislation or to summarise the corresponding laws or statutory instruments. In some circumstances it is more useful to use measurable quantities that are derived from these primary criteria by defined models. These measurable quantities are referred to as secondary standards in the radiation area and as standards (rather than health based guidance values) in the chemicals area and are not referred to in detail here.

This document is intended to be used by, and be useful to, people responsible for developing guidance for occupational and public exposures to environmental pollutants such as chemicals and radiation. Methods used to develop new guidance can be compared with existing methods for developing guidance for radiological or toxicological hazards. This will help to ensure that new guidance is consistent with that for other similar hazards and the level of protection afforded to the public and workers is proportionate compared to other hazards.

2 Comparison of Criteria

There are a number of common features and differences in the processes and procedures used to set criteria for the protection of human health for chemicals and radiation. These attributes can be divided into the system for providing advice on the criteria and the approaches taken to establish the criteria themselves.

* Health based criteria relating to medical uses of chemicals, ionising radiation and non-ionising radiation are outside the scope of this review.

† Optical radiation includes ultraviolet radiation (UVR), visible radiation (light) and infrared radiation; sources can be broadband or laser.

2.1 Provision of advice

In all areas considerable use is made of independent expert advisory committees at a national and international level. The consensus of an expert committee, whose members are appointed on the basis of merit and with a balance of relevant skills and backgrounds, provides authoritative advice which is particularly valuable in areas where there is uncertainty and the need for expert judgement. It is important that appointments to these committees are fair and that the process is transparent.

In the chemicals area nationally there are a number of independent expert advisory committees covering various sectors (eg occupational exposure limits, approval of medicines and veterinary medicines, and approval of pesticides and biocides). Many of these have a statutory basis. The various committees are outlined in Appendix A. They all have a wider remit than providing scientific advice on the toxicity of chemicals, and although all have expert toxicologists as members, this is only one of several areas of expertise covered. For advice on complex toxicological issues they can refer to the specialised expert advisory committees on the toxicity, or specifically the carcinogenicity or mutagenicity, of chemicals. These specialised committees, namely the Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) and its sister committees on carcinogenicity (COC) and mutagenicity (COM) provide a central source of authoritative advice across government departments and agencies. Appointments to these three expert advisory committees are made by the Government's Chief Medical Officer and the Chair of the Food Standards Agency acting jointly. The secretariat is provided by the Health Protection Agency (HPA) [until January 2006 by the Department of Health (DH)] and the Food Standards Agency (FSA), again acting jointly. Appointments to all these UK committees are made in accordance with best practice outlined in the guidelines of the Office of the Commissioner for Public Appointments (OCPA, 2005).

The European Commission has a number of expert advisory committees in the chemicals area that advise the Commission and member states. In addition, there are a number of international expert advisory committees under the auspices of the World Health Organization (WHO) and related organisations [eg the International Programme on Chemical Safety (IPCS) and the Food and Agriculture Organization (FAO)]. In some cases the advice of these committees on standards (eg the WHO guidelines for drinking water quality) are generally incorporated into European Union (EU) directives (and hence UK regulations), whereas in other cases the information regarding the health effects of chemicals is advisory only (eg the IPCS documents).

The HPA, through its Chemical Hazards and Poisons Division (CHaPD), plays a central role at the national level on advising on the effects of chemicals on public health. In addition to providing the secretariat (jointly with the FSA) for the COC/COM/COT, toxicologists from CHaPD provide advice on the health effects of chemicals to a range of government departments and agencies. These include the Department of Health (DH), Department for Environment, Food and Rural Affairs (Defra), Department of Trade and Industry (DTI), Drinking Water Inspectorate (DWI), and the Environment Agency (EA). In addition, input is provided to the appropriate regulatory agencies concerned with the approval of pesticides, biocides and veterinary medicines (Pesticides Safety Directorate (PSD), Health and Safety Executive (HSE) and Veterinary Medicines Directorate (VMD), respectively); this is to ensure that due consideration is given to public health aspects regarding the effects of the chemicals under consideration.

The systems in the ionising and non-ionising radiation areas are to a large extent similar. There are international bodies that make recommendations for the protection of human health: the International Commission on Radiological Protection (ICRP) in the case of ionising radiation and the International Commission on Non-Ionizing Radiation Protection (ICNIRP) for non-ionising radiation. The ICRP reports to the International Society of Radiology. Each body consists of a main commission and a number of standing committees with new main commission members being elected by the existing commission. For ICNIRP, nominations are invited from all the national radiation protection bodies represented by the International Radiation Protection Association (IRPA) and from the main commission. For both bodies members of the standing committees are appointed by the main commission. The international advice is considered within the European Union (EU), often leading to the issuing of directives to member states. Directives are required to be implemented in the national legislation of EU member states. Of particular importance in the ionising radiation area is the directive laying down basic safety standards for the health protection of the general public and workers against the dangers of ionising radiation issued in 1996 (EC, 1996). Of importance in the non-ionising area are the physical agents directives on the minimum health and safety requirements regarding exposure of workers to the risks arising from electromagnetic fields issued in 2004 (EC, 2004) and artificial optical radiation issued in 2006 (EC, 2006). Advice has also been given on electromagnetic field (EMF) exposure guidelines for the public (EC, 1999).

At a national level in the two radiation areas advice is provided by the HPA, primarily by its Radiation Protection Division (RPD), informed by two advisory groups of independent experts: the Advisory Group on Ionising Radiation (AGIR) and the Advisory Group on Non-ionising Radiation (AGNIR). These two advisory groups are administered by the RPD and report to a sub-committee of the HPA Board. In addition, there is an independent UK committee, the Committee on Medical Aspects of Radiation in the Environment (COMARE), which provides advice on topics referred to it by UK Government. It operates under the auspices of the DH with a secretariat provided by the RPD and has been principally concerned with exposures to ionising radiation, although its remit also covers non-ionising radiation.

There are some differences in the relative emphasis attached to international guidance and recommendations between the chemicals area and the two radiation areas. In the radiation areas there is a tendency for international guidance from the ICRP and ICNIRP to be incorporated into EU directives which are subsequently enacted at a national level. For chemicals the situation is more complex, the focus is more towards the development of advice by national or EC committees using international guidance as one input.

The establishment of the HPA will enable the synthesis of approaches for setting criteria for the protection of human health in the chemicals and radiation areas. Notably CHaPD and RPD are working together in a number of areas including modelling of releases to the environment and approaches to managing accidents and emergencies.

2.2 Approaches to deriving health based protection criteria

Broadly the approaches to deriving health based protection criteria for exposures to people can be divided into two groups: one where the effect of the hazardous agent is believed to have a threshold

and the other where no threshold can be assumed. For electromagnetic fields only threshold effects are considered for the purposes of deriving such criteria. In the cases of ionising radiation and ultraviolet radiation (UVR) both threshold and non-threshold effects are assumed to occur; for these hazards the protection criteria for the two types of effects are discussed separately. Most chemically induced toxicity is regarded as being in the threshold category, with the exceptions being noted in the section on non-threshold effects (Section 2.2.2).

Protection criteria are set at exposure levels that are intended to prevent adverse human health effects (threshold) or limit their likelihood to acceptable levels (non-threshold). Biological effects (for example, at a cellular level) may occur at lower exposure levels, but these effects would not be expected to result in adverse effects on health. In some cases the only data available relate to biological effects. Expert judgement is then needed to assess whether adverse health effects would be expected to occur as a result of the biological effects identified. Judgement is sometimes also required when assessing whether an effect upon health could be considered to be 'adverse'.

There are two general differences in the approaches to setting health based protection criteria that deserve initial discussion. The first difference is the consideration given to background levels of exposure, in relation to both the derivation of criteria and their application. Typical levels of background radiation exposure have formed one input to the development of protection criteria for ionising radiation. Such criteria are, however, defined in terms of doses over and above those due to natural background levels. In contrast, for many chemical contaminants, criteria are set which relate to total exposure levels (ie exposures from a particular source plus any background exposures). The second difference is that there is considerably more direct evidence on the effects on humans of ionising radiation than there is in the chemicals area where, of necessity, more reliance is placed on animal studies. This difference is reflected in the way health based protection criteria are set in the two areas. For the other area, non-ionising radiation, the criteria are based on human studies, which often demonstrate no effects at the levels of interest, underpinned by animal and modelling studies.

The health based protection criteria discussed below apply generally to normal situations. Accidents and emergencies are considered separately under 'other exposure situations' (Section 2.3).

2.2.1 Hazardous agents believed to exhibit a threshold

The approach here is to select a level that would not be expected to produce adverse health effects. There are, nevertheless, problems even with such a straightforward approach. The main problem occurs primarily in the chemicals area and is caused by the uncertainty that arises from the fact that toxicological data are usually available only from studies in animals. This uncertainty largely reflects interspecies variability and individual variation in the human population. Traditionally in the chemicals area, for the purposes of setting health based protection criteria for public exposure, each of these uncertainties has been taken into account separately by a factor of 10. Thus, for a particular chemical, the protection criteria for public exposure would be the critical 'no observed adverse effect level' (NOAEL) from animal data divided by 100. Recently, consideration has been given to replacing the 'factor of 100' approach by a more scientifically based system, although such attempts are limited by the availability of relevant data. The setting of protection criteria for occupational exposure to chemicals has not used such

a formalised process with specific uncertainty values. Generally, smaller margins (often by a factor of up to 10) between the toxicological reference point and the acceptable level of exposure are deemed to be satisfactory for occupational exposure.

Currently for non-ionising radiation, with the exception of UVR exposure of the skin, there is no clear scientific evidence for the existence of serious health effects such as cancer that have no exposure threshold. It is noted that pooled epidemiological studies have shown an association between high levels of exposure to extremely low frequency (ELF) magnetic fields (>400 nT) associated with the power frequency of 50 Hz and childhood leukaemia (NRPB, 2004a,b). There is no clear evidence of a carcinogenic effect of ELF electromagnetic fields (EMFs) in adults and no plausible biological explanation of the association can be obtained from experiments in animals or from cellular and molecular studies. Therefore, in the non-ionising radiation area, the established effects on which protection criteria are based have thresholds. For electromagnetic fields, the observed effects range from induction of electric currents in body tissues in the case of static and low frequency fields, to heating of body tissues in the case of electromagnetic fields of frequencies above about 100 kHz. Health based criteria for protection against electromagnetic fields in the range 0–300 GHz are derived from a combination of theoretical modelling studies, animal studies, human volunteer studies and epidemiological studies. More restrictive criteria are set for public exposure than for occupational exposure because of the wider variability in health status and possible response to exposure in the general public. The ratio of the public and occupational protection criteria is about a factor of five. For UVR exposure, quantitative exposure limits are intended to prevent threshold effects such as erythema and photokeratitis of the eye. The limits apply to artificial sources, where the source of the exposure can at least in principle be controlled. The basic exposure limit is the same for both workers and members of the public because it is not clear whether there would be any differences in response to UVR exposure between these two groups. Other strategies are needed for public exposures to the sun as it is not practicable to apply exposure limits. Often the aim of exposure is to obtain a suntan and exposure limits will then be exceeded. Advice is provided on limiting exposure to solar radiation and preventing damage to the skin and eyes.

Broadband optical radiation, other than UVR, may present a risk of photoretinitis, retinal burn, corneal burn or cataractogenesis depending on wavelength from 380 to 3000 nm. Limits are set to prevent these effects. However, in the wavelength range from 380 to 780 nm, optical radiation may be seen as light, which may cause adverse functional effects if too 'bright'. At wavelengths close to the peak of the eye's response (550 nm) the optical radiation will be disablingly bright at levels well below exposure limits. Thus, the natural aversion responses, including the blink reflex, may be expected to limit exposures.

Quantitative exposure limits are recommended for protection against lasers where the eye and the skin are the organs of concern. The limits are the same for workers and members of the public. The HPA has recommended that the availability of lasers to members of the public should be restricted to the least powerful lasers, Classes 1 and 2. However, it is recognised that higher Class lasers may be available.

In the case of ionising radiation, there are limits set on the doses to some organs in order to prevent the occurrence of threshold effects. These limits are set for members of the public an order of magnitude lower than the corresponding limits for occupational exposure to allow for the possibility of greater

sensitivity in some groups such as children. The protection criteria themselves are determined by expert judgement following a review of the scientific evidence. Criteria based on non-threshold effects for ionising radiation are discussed in Section 2.2.2.

Conclusion on threshold effects

With the exception of optical radiation exposure, protection criteria for public exposure are set at lower exposure levels than those for occupational exposure. The difference is normally a factor of around five to ten but can be more in the case of some chemicals. For UVR exposure and lasers, the criteria are the same for exposure of workers and members of the public.

2.2.2 Hazardous agents with non-threshold effects

Hazardous agents which are assumed to exhibit no threshold for the effects of concern are some chemicals, ionising radiation and UVR. The primary health effects of concern are the induction of cancer and hereditary disease. In the case of chemical carcinogens, however, it is recognised that some induce cancer by a mechanism that does not involve their causing damage to DNA, and for such non-genotoxic carcinogens a threshold approach is appropriate.

With the genotoxic chemicals and ionising radiation, observable effects either from animal studies or human epidemiological studies have been seen only at levels in excess of those relevant to setting protection criteria. The question then becomes: what are the health risks to humans at lower levels of exposure?

A somewhat different approach is followed in the chemicals area to that in the ionising radiation area, although in both cases an overall risk management policy of reducing exposures to as low as reasonably practicable is adopted. This difference reflects the availability of data on human health effects in the two areas.

There is extensive knowledge on the effects of ionising radiation on humans at relatively high levels, ranging upwards from a few times the occupational dose limit. This knowledge provides confidence in the model used to extrapolate to the relevant lower levels of exposure. Further confidence is provided by animal and cellular studies on the mechanism of cancer induction by ionising radiation. In contrast, in the chemicals area there are rarely any relevant human data on health effects and instead reliance has to be placed upon animal studies. Considerable uncertainties surround extrapolation from animal studies at very high levels of exposure to the possible effects on humans at much lower levels of exposure, a factor which influences the criteria setting process.

In the ionising radiation area, for the purposes of setting protection criteria, the assumption is made that there is a linear relationship between a dose of radiation and the corresponding risk (up to levels where threshold effects could become important). Risks observed in humans at high doses are extrapolated to low doses using a dose and dose rate adjusted projection. This so-called ‘linear no-threshold’ (LNT) assumption underpins the principles of radiation protection. Because there is no level of exposure to ionising radiation that can be considered to have no associated risk to health, radiation protection requires that any deliberate change to an individual’s exposure should overall do more good than harm

(the principle of justification) and that the margin of good over harm should be maximised (the principle of optimisation). The optimisation principle is also known as ALARA – as low as reasonably achievable – and includes consideration of economic and social factors. It is synonymous with the principle of ALARP – as low as reasonably practicable – which is applied in the UK to the regulatory control of some occupational risks.

The LNT assumption has other important consequences: doses from different sources to the same individual may be summed for protection purposes and doses from the same source to many individuals may be summed to give an indication of the total overall number of health effects expected in the exposed population, albeit with significant associated uncertainties. The LNT assumption has also enabled the development of a common metric for ionising radiation, the quantity 'effective dose'. This quantity allows, for example, the summation of doses from intakes of radionuclides and external exposure.

Limits are set on the exposure to ionising radiation of members of the public and workers which apply to summed exposures from a set of human activities termed practices. Practices comprise, in the main, industrial processes involving radiation, such as nuclear power generation. The limits apply to the normal, controlled operation of practices but not directly to exposures arising from accidents. A multiattribute process is adopted for establishing values for these limits. The various attributes include annual risk from lifetime exposure, lifetime risk and comparison with natural background. The annual limit recommended by the ICRP for controlling non-threshold effects from practices for members of the public is set at a value 20 times lower than the corresponding limit for workers. Importantly, compliance with dose limits is not in itself sufficient: as noted earlier, efforts should also be made to ensure that doses are ALARA.

In contrast, in the chemicals area the relevant expert advisory committee, the COC, has consistently expressed concerns at the use of models to extrapolate from the extremely high dose levels used in animal bioassays of chemicals to the much lower levels relevant to exposure criteria. In the light of these concerns, the COC recommended that risk managers adopt measures so that exposure to compounds believed to be human genotoxic carcinogens should be controlled to be as low as reasonably practicable (ALARP). It was added, however, that in some cases such as contaminants or impurities, the ALARP approach may be supplemented by deriving a minimum risk level, ie a dose considered to represent a negligible carcinogenic risk, in order to aid risk management decisions.

Some effects of UVR exposure of the skin, specifically ageing and cancer induction, are assumed not to exhibit a threshold. There are no exposure criteria set specifically to limit the risks of cancer induction by ultraviolet irradiation but there is general guidance to limit exposure to UVR where it is practicable to do so. It should be noted, however, that countervailing arguments have been advanced based on suggestions that a certain amount of UVR exposure is beneficial due to production of vitamin D.

For electromagnetic fields concern has been raised about their potential to cause cancer or other long-term health effects. However, the evidence is limited and in relation to cancer no clear causal relationship has been demonstrated between EMF exposure and risk. It has been concluded that currently the results of epidemiological studies on EMFs and health are insufficient either to make a conclusive judgement on causality or to quantify appropriate exposure restrictions. However, such studies taken together with people's concerns provide a basis for considering the possible need for further precautionary measures in addition to the application of quantitative restrictions on exposure to

EMFs based on threshold effects. In particular, there remain concerns about possible effects of exposure of children to power frequency magnetic fields as some studies have suggested a doubling of the risk of childhood leukaemia at high levels of exposure (>400 nT). The view of the HPA is that it is important to consider the possible need for further precautionary measures in respect of exposure of children to power frequency magnetic fields. This has led to the setting up by the Department of Health of the Stakeholder Advisory Group on extremely low frequency electromagnetic fields (ELF EMFs), SAGE.

Conclusions on non-threshold effects

In all cases, the approach is to control the incidence of non-threshold effects to acceptable levels by reducing exposure when it is practicable to do so. In the chemicals and ionising radiation areas this approach is embodied in the ALARP (as low as reasonably practicable) and optimisation (ALARA, as low as reasonably achievable) principles, respectively. In the ionising radiation area, in a specific group of situations, the incidence of non-threshold effects is also limited by application of dose limits. These limits are derived, at least in part, from risk-based considerations by extrapolation of risks observed at much higher levels of dose. Such an approach has not been generally followed in the chemicals area because it is rarely possible to quantify risk of cancer at low exposure levels due to the lack of appropriate human data and the uncertainties involved in extrapolation from high dose animal bioassay data to low dose human exposures.

2.3 Other exposure situations

Thus far the discussion of health based protection criteria has focused on exposures under controlled situations. Here criteria for exposures under other conditions are considered. These other conditions include accidental exposures and exposures from natural sources.

In the ionising radiation area, the ICRP has recommended a system of protection which, at least in principle, addresses all conceivable exposure situations (ICRP, 1991). This system is predicated on the LNT dose–response relationship and is based on judging the benefits and disadvantages of exposures in particular situations. It follows that the appropriate level of protection will be different in different situations. The clearest example of such different levels of protection is that the dose limits that are applied in practices (where the source is under control) do not in themselves determine whether actions should be taken to reduce exposures in emergencies (where the source is not under control). Thus it would be acceptable within this system that, in emergencies, individuals could receive doses in excess of these dose limits. Such a system introduces its own complexities and problems as well as having the benefit of being comprehensive.

An essentially separate system for accidents and emergencies has therefore evolved in the ionising radiation area with its own specific criteria that are different from those that apply to controlled situations, although there are some common features, eg a requirement to optimise protection. The potential for serious accidents at nuclear installations is the main reason for developing this system for accidents. In contrast, in the other areas addressed in this document no such separate systems currently exist and, by default, the same protection principles and criteria would apply in both controlled and

accident/emergency situations. This situation may change in the future and in the USA the Environmental Protection Agency has a programme for developing acute exposure guideline levels (AEGLS) for exposure to chemicals by inhalation for use in emergency planning and response (accidents or intentional release).

For some of the types of potential environmental hazard considered in this document, there can be significant natural contributions. Examples are the often high and variable exposure to ionising radiation from natural sources, exposure to solar UVR and, in some cases, exposure to natural deposits of harmful chemicals. These natural exposures are addressed somewhat differently in the different areas.

In the system of protection for ionising radiation a distinction is normally made between exposures that are amenable to control and those that in general are not; emphasis is placed on the former. The primary example of a natural source of ionising radiation that is amenable to control is radon in buildings. Relatively straightforward actions such as sealing floors can produce worthwhile reductions in exposure. Criteria have been promulgated by the ICRP and by the National Radiological Protection Board (now the Radiation Protection Division of the HPA) for indicating when such actions should be taken. Other sources of natural radiation, eg cosmic radiation at the Earth's surface and radiation from natural gamma emitters in the ground, are less amenable to control and, as such, protection criteria specific to such sources have not been developed. The ICRP has, however, framed some protection criteria in terms of total dose (natural plus man-made) with the purpose of providing guidance on when actions should in general be taken to reduce exposures (ICRP, 1999). These criteria have not, however, been widely adopted.

Advice for protection against optical radiation exposure also varies according to whether the exposure is controllable at source, such as from artificial sources, or not, such as from natural sources, including the sun. The quantitative limits, termed exposure limit values, apply only to artificial sources where irradiances and exposure durations can be controlled. In the case of exposure of members of the public or workers to solar UVR, enforcement of an exposure limit value is not practicable. Instead, emphasis is placed on providing information about the risks and guidance on risk reduction.

In the chemicals area a distinction between the contributions to exposure from natural and man-made sources is, in general, not made. Thus, the tolerable daily intake (TDI) for a chemical applies to the total intake including any natural contribution.

There are no relevant exposures to natural electromagnetic fields or lasers, other than the Earth's static magnetic field.

3 General Conclusions

This review has addressed exposure criteria in the following areas: chemicals, ionising radiation and non-ionising radiation. Criteria based on both threshold and non-threshold effects have been considered.

An important general conclusion is that in all areas extensive use is made of independent expert committees to evaluate and advise on the health implications of the various hazards. These committees exist at both national and international levels. There are some differences, however, in the relative

emphasis attached to such advice. In the radiation areas there is a tendency for international guidance from the ICRP and ICNIRP to be incorporated into EU directives which are subsequently enacted at a national level. For chemicals, the focus is more towards the development of advice by national or EC committees using international guidance as one input.

In principle, systems of protection need to appropriately address exposures from man-made controlled sources, accidents and emergencies, and natural sources. In all of the areas covered by this document there are exposure criteria for protection against man-made controlled sources which address protection of workers and members of the public. With two exceptions, the criteria for public exposure are more restrictive than those for occupational exposure because of the wider variability in health status and possible response to exposure in members of the general public. The exceptions are the criteria for optical radiation exposure, from both broadband sources and lasers, which are the same for both classes of individuals. The reason is that in these cases it is not clear whether there are any differences in response between workers and members of the general public for the effects of concern, erythema and photokeratitis in the case of UVR exposure, photoretinitis, retinal burn, corneal burn and cataractogenesis for visible and infrared exposure, and damage to the eye and skin in the use of lasers.

In general, there are two types of adverse health effect that need to be considered in setting exposure criteria: effects with a response threshold and effects without such a threshold.

There are differences between the approaches taken to set criteria for protection against non-threshold effects, predominantly cancer induction, between the ionising radiation and the chemicals areas. These differences relate to the quantity and quality of data relevant to health effects at the exposure levels of concern that are available in the two areas. In the case of ionising radiation, where there are considerable human data at levels of exposure ranging upwards from a few times the occupational dose limit, the extrapolation to the lower levels relevant to environmental exposures is based on a linear relationship between radiation dose and risk of health effects. In the chemicals area there are rarely any adequate human data and risk assessment has to be based, at best, on a few data points at very high dose levels in animal bioassays. These data are generally considered insufficient to establish any basis for extrapolation to lower exposures.

A consequence of the differences in the approach to the extrapolation to low doses is that health based exposure criteria are set in the ionising radiation area. However, in both areas, chemicals and ionising radiation, emphasis is placed on the concept of reducing exposures where it is practicable and reasonable to do so. In the ionising radiation area this concept is embodied in the ICRP system of protection as the principle of optimisation of protection (ALARA). In the chemicals area it is reflected in a recommendation from the COC that exposure to chemical carcinogens believed to cause non-threshold effects should be controlled to be as low as reasonably practicable (ALARP).

The common approach for agents believed to exhibit a threshold is to select a level that would not be expected to produce adverse health effects in humans. There are, however, differences in practice between the chemicals and ionising and non-ionising radiation areas, reflecting differences in the quantity and quality of the data available for chemicals. In the chemicals area, reliance has usually to be based on the use of animal data, with extrapolation to humans with expert judgement. The limit for threshold effects is usually based on the lowest level where no adverse effect is observed in animal

studies divided by an uncertainty factor, to take account of interspecies variability and individual variability in the human population. Additional factors may be used to account for the severity of effects or limitations in the database. In the other areas where there are generally better data and/or a theoretical basis for limits, the levels set for preventing threshold effects are usually derived by a process of expert judgement based on human and experimental data supported by modelling studies.

Turning to other situations, a comprehensive protection system for addressing accidents and emergencies has evolved in the ionising radiation area which has been prompted, at least in part, by the possibility of incidents and accidents in the nuclear power industry. In the other areas such a requirement is not as pressing and protection criteria specific to accidents or emergencies have not been developed in the UK. By default, the same protection principles and criteria would apply in both controlled and accident/emergency situations.

Exposures from natural sources are dealt with somewhat differently in the different areas. In the ionising radiation area criteria exist for protection against exposures from natural sources that are amenable to control and there is also general guidance on when action should be taken to reduce doses. The situation with UVR, where the main natural source is the sun, is to some extent similar. Emphasis is placed on informing the public of the risks and providing guidance on risk reduction. In the chemicals area, a distinction between the contributions from natural and artificial sources is in general not made and exposure criteria refer to total intake including any natural contribution.

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Appendix A

General Principles for Assessing Risks and Deriving Health Based Guidance Values for Exposures to Chemicals in the UK

A1 Introduction

A range of government departments and agencies have responsibility for assessing risks to health from chemicals, depending on the different exposure scenarios – for example, at work (HSE), from food or drink (FSA), from drinking water (DWI), in the home from consumer products (DTI) or by environmental pathways (Defra/EA). In addition, in a few areas, products need to be approved by government agencies before they can be used – for example, human medicines (MHRA), veterinary medicines (VMD), pesticides (PSD) and biocides (HSE). The general principles involved are, however, similar and well established, the only area where there are significant differences in the approach being with human medicines, where the health benefits to humans are balanced against any risk to health, rather than trying to ensure that no adverse health effects occur. This document focuses on the general principles used in deriving exposure levels that would not be expected to have adverse effects (often referred to as health based guidance values or reference doses). It does not attempt to cover specific approaches that have been adopted in the few cases where there may be good quality data from epidemiological studies. However, for illustrative and comparative purposes, an example of such an approach used for the derivation of air quality standards is briefly discussed in Section A5.

These general principles are based on an assessment of the inherent ability of the chemical to cause adverse health effects (its toxic properties), together with an estimate of human exposure. The assessment of the hazard to humans from specific chemicals is nearly always based on toxicity data obtained from animal studies and from experimental systems and extrapolation of these data to humans, taking into account the uncertainties involved.

The aims of most toxicological risk assessments are to determine whether there are sufficient data to provide reassurance that there is little likelihood of adverse health effects occurring under given exposure conditions, rather than trying to arrive at an estimate of the magnitude of any likely risk. Toxicological studies are primarily directed at what may be regarded as 'safety evaluation' and setting intake or exposure levels that are believed to be the maximum that would not result in any significant adverse health effects.

This approach can be used for most types of toxic effect (acute and repeated dose toxicity, organ-specific effects, behavioural effects, effects on the reproductive system, etc) since it is considered that there is a dose or concentration below which adverse effects will not occur, ie there is a threshold. However, there are a few exceptions to this approach, specifically compounds that are mutagens in animals and those that induce cancer by a mechanism relating to direct effects on DNA (such compounds are commonly referred to as genotoxic carcinogens). It is assumed for these that there is

some probability of adverse effects occurring at any level of exposure, albeit this may be very small. This concern arises because one 'hit' on DNA can produce a mutation, leading to clonal transformation of somatic or germ cells which can eventually result in a malignant tumour. It is accepted that this is a conservative approach and that there are many pathways whereby the damage to DNA may be prevented (eg by metabolic detoxification before the compound reaches DNA), or repaired prior to fixation as a mutation, resulting in a threshold in practice. However, this is difficult to demonstrate and the prudent assumption is made that such compounds do not have a threshold.

Thus in considering risk assessment of the health effects of chemicals, it is first necessary to divide this topic into those effects that are assumed to have a threshold (most compounds fall into this category) and those for which it is assumed that the effects do not have a threshold (predominantly *in vivo* mutagens and genotoxic carcinogens).

A2 Interdepartmental and Interagency Advisory Groups

Before considering these two areas of chemical risk assessment in turn, it is appropriate to review the ways in which the various government departments and agencies work together to provide a common approach and consistent advice on specific chemicals. Toxicologists in the various agencies do not work in isolation. A central source of authoritative advice is provided across government departments and agencies by the Committee on Toxicology of Chemicals in Food, Consumer Products and the Environment (COT) and its sister committees concerned specifically with Mutagenicity (COM) and Carcinogenicity (COC). Members of these committees are appointed by the Government's Chief Medical Officer and also, since the establishment of the FSA, by the Chairman of the Board of that agency. These committees provide independent, authoritative advice on all aspects of the toxicology, and specifically mutagenicity and carcinogenicity, of chemicals. Their advice tends to be sought on the more controversial issues relating to specific chemicals. All relevant government departments and agencies provide assessors. The secretariat is provided by the HPA (prior to January 2006 this function was provided by the DH) and the FSA acting jointly. Of particular relevance to the general principles of risk assessment are the guidance documents provided on a strategy for investigating carcinogenicity and mutagenicity of chemicals; these are periodically updated (COM, 2000; COC, 2004).

In addition to these independent expert advisory committees, close working of those involved in chemical risk assessments is also facilitated by the Interdepartmental Group on Health Risks from Chemicals (IGHRC). The secretariat for this is provided by the Institute for Environment and Health (IEH) based at Cranfield University. One of the aims of the IGHRC is to promote coherence and consistency in the practice of toxicological risk assessment as used by the different sectors and regulatory frameworks across the various government departments and agencies. In this regard the IGHRC has provided a number of guidance documents that have been agreed across government. Of particular interest regarding the subject of this paper are documents on the assessment of chemical carcinogens (IGHRC, 2002) and uncertainty factors (IGHRC, 2003).

In the international area, there is widespread consensus on approaches to the risk assessment of the health effects of chemicals for which a threshold is assumed. The approaches outlined in this document

are, for example, consistent with those recommended by the WHO International Programme on Chemical Safety (IPCS) (WHO/IPCS, 1994, 1999). There is less agreement, however, regarding the risk assessment of effects for which no threshold is assumed, and specifically for genotoxic carcinogens. Here some countries, notably the USA, use mathematic models to extrapolate from high dose animal data to low dose risks to humans, an approach that is not recommended in the UK (see Section A5).

Regarding the methodology for investigating the various aspects of the toxicity of chemicals, this is internationally harmonised under the auspices of the Organisation for Economic Co-operation and Development (OECD), and its test guidelines programme and mutual acceptance of data agreement (OECD, 2006).

Details of the relevant national and international committees are provided in an annex (see pp 24–28).

A3 Role of the HPA CHaPD

The HPA, through its Chemical Hazards and Poisons Division (CHaPD), plays a central role at the national level on advising on the effects of chemicals on public health. In addition to providing the secretariat (jointly with the FSA) for the COC/COM/COT, toxicologists from CHaPD provide advice on the health effects of chemicals to a range of government departments and agencies. These include the DH, Defra, DTI, DWI, and the EA. In addition, input is provided to the appropriate regulatory agencies concerned with the approval of pesticides, biocides and veterinary medicines (the PSD, HSE and VMD, respectively); this is to ensure that due consideration is given to public health aspects regarding the effects of the chemicals under consideration.

A4 Risk Assessment for Threshold Effects

As noted earlier, this is the approach adopted for most types of toxic effect.

A4.1 Health based guidance values for exposure of the general public

The starting point in any risk assessment is consideration of the overall toxicological profile of a substance. This will usually comprise mainly data from experimental studies in animals and related data (eg *in vitro* studies on mutagenicity and data on metabolic pathways). Occasionally data on effects in humans from epidemiological studies will be available and these will provide important information in assessing the overall health effects.

In those areas where approval by a government department or agency is needed prior to marketing (eg pesticides), a comprehensive package of experimental data will be available covering acute toxicity, skin and eye irritancy, skin sensitisation, mutagenicity, repeated dose toxicity (sub-chronic and chronic/carcinogenicity bioassays) and studies to investigate effects on the reproductive system, both developmental toxicity (including teratogenicity) and fertility. Information from more than one species will usually be available together with data on absorption, distribution, metabolism and elimination.

For most chemicals, however, a much less complete data set will be available.

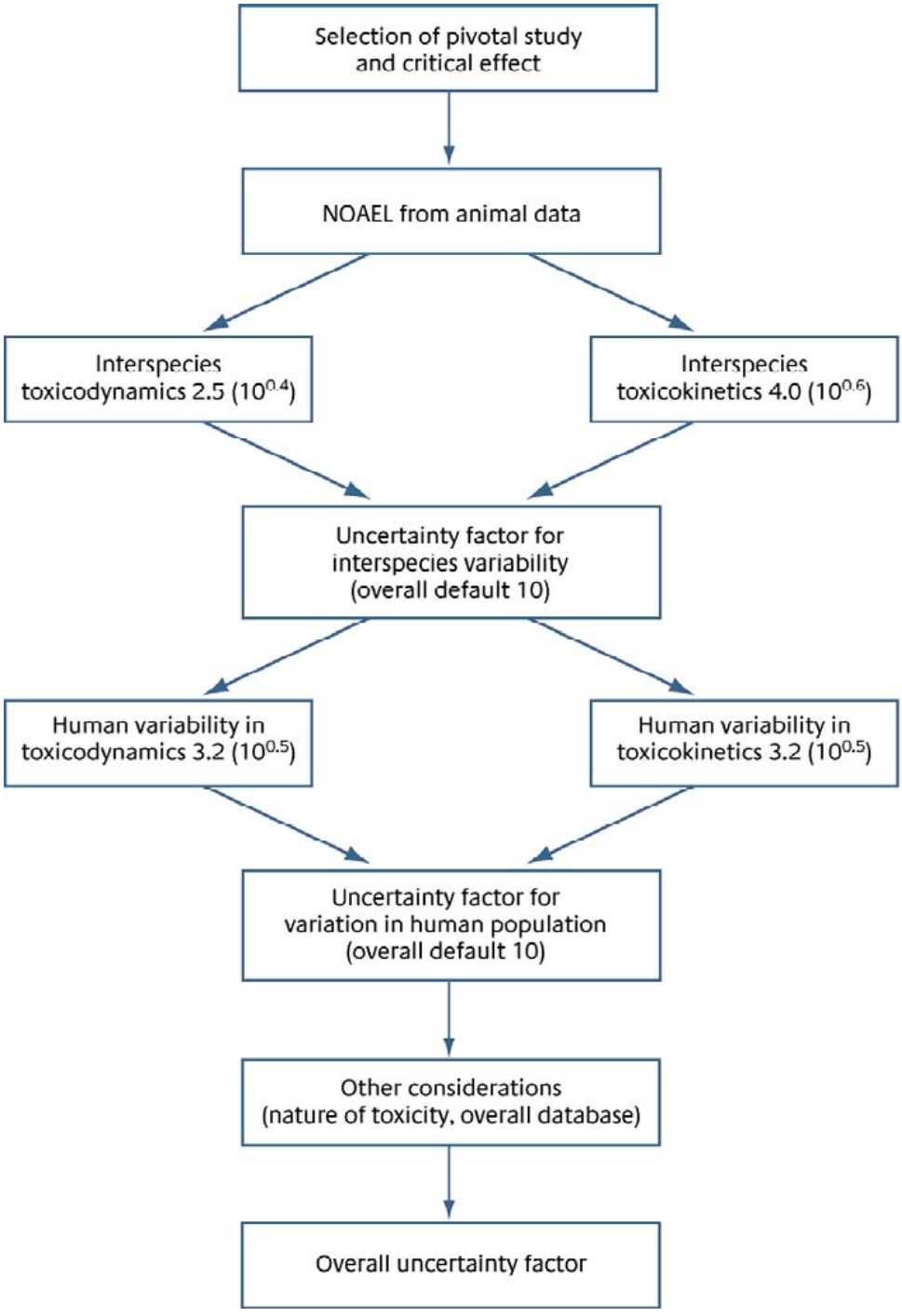
A key component in the risk assessment is the identification of what is known as the critical NOAEL (no observed adverse effect level) from the animal data. In general, this is based on the most sensitive species or study giving the lowest NOAEL, but this may not always be the case. Factors such as information suggesting a particular species is more relevant to humans or consideration of the severity of the toxic effects seen at higher dose levels in a particular study may also impact upon this decision. Expert judgement is needed both when assessing the NOAEL in a given study (and distinguishing, for example, adverse effects from an adaptive response) and in identifying the pivotal study and the critical NOAEL from a range of studies for a given compound.

The uncertainty in extrapolating from animal data to humans due to interspecies variability is recognised, as is the much greater diversity of the human population compared to the inbred strains of animals used in laboratory studies. Cognisance of these two important factors (interspecies variability and individual variation in the human population) is taken into account by the use of what are generally known as uncertainty factors (or, in the older literature, safety factors).

Traditionally, factors of 10 have been applied to each stage. The overall factor of 100 has, for example, been used for over 50 years in the derivation of acceptable daily intakes (ADI) for food additives by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO/IPCS, 1987). Additional uncertainty factors may also be applied to take into account, for a given compound, the inadequacy of the database (eg the need to extrapolate from a sub-chronic (90 day) study to chronic (lifetime) exposure), and from a LOAEL (lowest observed adverse effect level) to a NOAEL. In addition, a factor may be added because of particular concerns about the severity of a specific toxic effect. Expert judgement is needed with consideration of all the available data on a case-by-case basis.

Over recent years consideration has been given to replacing the 10 times 10 default by scientifically derived data. Knowledge of actual interspecies differences and inter-individual variability in the biokinetic behaviour of a given compound (toxicokinetics) and its target organ response (toxicodynamics) would enable chemical-specific factors to be used rather than the default. Such complete data sets, however, are very rarely (if ever) available.

Schemes have been developed to allow partial replacement of defaults. One of these, originally proposed by Renwick (1993), has been taken up by the WHO IPCS with minor modification (WHO/IPCS, 1994). This allows for the subdivision of the default values to allow for toxicokinetic and toxicodynamic factors separately. The values proposed were based on an analysis of the data from a limited number of compounds (mainly pharmaceuticals) for which data on interspecies and inter-individual variability were available. Values of $10^{0.6}$ (ie 4.0) for the interspecies difference in toxicokinetics and $10^{0.4}$ (ie 2.5) for toxicodynamics, were proposed. In the case of the subdivision of the factor for inter-individual variability in humans, an equal division between toxicokinetics and toxicodynamics was made in the WHO scheme as it was felt that the data were inadequate to allow any distinction to be made. The approach allows the default values for toxicokinetics and toxicodynamics to be replaced by data-derived values when available. Although such data are not commonly available, they are more frequently found regarding toxicokinetic aspects rather than toxicodynamics; data on the latter are only very rarely available. An outline of the generalised scheme for assigning an overall uncertainty factor is shown in the figure.



General scheme for derivation of uncertainty factors

Using this approach an intake value can be calculated that represents a level that can be ingested daily over a lifetime by humans without appreciable health risk. This may be referred to as an acceptable daily intake (ADI) or a tolerable daily intake (TDI). The latter term is used for contaminants and the former for approved food additives, approved pesticides and veterinary medicines. It is always expressed on a body weight basis (eg mg per kg body weight). The ADI or TDI is obtained by dividing the critical NOAEL by the overall uncertainty factor.

An alternative approach, often used in the general chemicals area, is to estimate exposure to the compound and then to compare this with the critical NOAEL from animal data. This is often referred to as the 'margin of safety' or 'margin of exposure' approach and is used, for example, in the risk assessments carried out under the EC Existing Substances Regulation (ESR) (EC, 1993). In general, if the margin of safety is 100 or more, a conclusion of 'no concern' is drawn. However, the value of 100 may be changed, taking into account the same considerations as used when deriving an overall uncertainty factor to estimate an ADI or TDI. The two approaches are based on the same fundamental principles.

The ESR (and also other EU-wide legislation on chemicals) has recently been revoked and replaced by an EC Regulation on the Registration, Evaluation and Authorisation of Chemicals (REACH) (EC, 2006). This entered into force in June 2007, but it will be many years before this complex regulation is fully implemented. The general principles involved in assessing health risks of chemicals will be similar to those described above.

A4.2 Occupational exposure standards

The above discussion relates to the derivation of acceptable or tolerable exposures of the general public to chemicals. In the field of occupational safety, the establishment of occupational exposure standards has not used such a formalised framework with the incorporation of specified default uncertainty factors. The procedure for setting occupational exposure standards in the UK reflects traditional practice by which such standards have been established around the world over many years, eg the American Conference of Governmental Industrial Hygienists (ACGIH) in the USA and the MAK Commission in Germany. This involves moving directly from the NOAEL (or LOAEL) to the derived standard usually involving judgement from an expert advisory committee. In the UK occupational standards are set by the Health and Safety Commission (HSC), and represent a consensus of this tripartite organisation, involving representation of trade unions, industry and local authorities as well as independent members. The HSC and its tripartite Advisory Committee on Toxic Substances (ACTS) and the scientific subcommittee of ACTS, namely the Working Group on Action to Control Chemicals (WATCH), are all involved in the setting of occupational exposure standards. The first stage is the consideration by WATCH of a package of information, including data on both hazard and exposure; recommendations are then made to ACTS which, after further consideration, makes formal recommendations to the HSC for an occupational exposure standard.

It should be noted that when making recommendations WATCH has to accommodate other considerations such as the reasonable practicality of controlling exposure to the standard and the ability to monitor exposure at the level of the standard. These considerations, and socio-political traditions surrounding the accommodation of risk in the workplace relative to risk in other aspects of life, have

meant that uncertainty has been dealt with rather differently in the occupational setting, with smaller margins between the toxicological reference point and the exposure deemed to be satisfactory. One study involving retrospective analysis of 24 occupational exposure standards established in the UK between 1990 and 1993 indicated that assessment factors in the range 1–10 emerged for most substances where the critical data were available from animals alone, with higher factors sometimes being evident where the critical effect was of particular concern, such as development effects. Uncertainty factors of 1–2 were evident when the database contained key human evidence, normally for effects such as sensory irritation (Fairhurst, 1995).

A5 Risk Assessment for Non-threshold Effects

As noted earlier, mutagenic and genotoxic carcinogenic chemicals are assumed not to have a threshold for such effects. The assumption is made for these chemicals that any exposure is associated with an increase in risk, albeit this may be very small. The theoretical basis for this is that one 'hit' on DNA can produce a mutation that may eventually lead to a tumour. An exception to this general rule may be made if it can be clearly demonstrated that the target for the chemical mutagen is not DNA but, for example, the spindle apparatus of the cell and it is damage to this that produces the mutation.

Guidance on a strategy for investigating the mutagenicity of a chemical has been provided by the COM (2000). This is based on a series of steps, namely investigating mutagenic potential by *in vitro* studies, assessing whether activity seen *in vitro* can be expressed in somatic cells *in vivo*, and finally (and if necessary) investigating whether activity can be expressed in germ cells *in vivo*. It is pertinent to note that at no stage is any information provided that can be used to quantify risks of heritable effects in future generations. This is because no practical methods are available. The only animal models that give such data (mouse heritable translocation test and the mouse-specific locus test) use very large numbers of animals and can only be used in very exceptional cases.

With regard to carcinogenicity, the COC has recently updated its guidance on a strategy for risk assessment of chemical carcinogens (COC, 2004). Procedures for identifying compounds that are carcinogenic based on pre-screening data (mutagenicity), animal carcinogenicity bioassays and, where available, epidemiological data, are well established. The difficulty is in the calculation of cancer risk from mathematical modelling of the animal bioassay data. The COC has consistently expressed concerns at the use of such models for extrapolating from the relatively high dose levels used in the bioassays to levels that are orders of magnitude lower, as expected to occur from environmental exposure. These concerns have been reiterated in the latest guidelines. The reasons are based on the limitations of the various mathematical models that have been used (which do not take into account the biological complexity of the carcinogenesis process), the fact that the extrapolations are based on a few data points over a very narrow and high dose range compared to the levels to which the extrapolations are being made (the results being very dependent on the high dose level selected), and the very wide variations in risk estimates depending on the model used. The use of these models gives an impression of precision that cannot be justified. As a result of considering all aspects of these models, the COC agreed that they do not simulate the carcinogenic process adequately, and accuracy at extrapolated low doses cannot be determined. Therefore, the COC did not recommend their use for routine risk assessment.

In light of this conclusion, the COC recommended that risk managers adopt measures so that exposure to compounds believed to be human genotoxic carcinogens should be controlled to be as low as reasonably practicable (ALARP).

In its recent guidelines the COC considers that under certain specific circumstances – for example, very low exposures to genotoxic carcinogens present as contaminants or impurities – a pragmatic minimal risk level for these compounds may be identified (ie an exposure level identified by expert judgement to be likely to be associated with a negligible risk of carcinogenic effect). Derivation of such a value would involve assessment of all the available data on dose–response regarding carcinogenic effects in animals, identifying a level without any discernible effects and the use of expert judgement to derive an appropriate margin of safety; a value of 10,000 was given in one reference quoted by the COC. There would always be a requirement, on top of this, to ensure that ALARP applied. This is the first time that the COC has recommended the estimation of minimal risk levels, albeit under certain defined conditions, for genotoxic carcinogens. With regard to non-genotoxic carcinogens, these are believed to induce tumours as a secondary event following an effect such as sustained cell proliferation or sustained hormonal stimulation, and emphasis is placed on understanding their mode of action. Risk assessment is based on identifying the no-effect level for the key precursor event. Uncertainty factors are then used to determine an ADI or TDI as in the general 'threshold' approach to risk assessment.

This document has concentrated on generic approaches to assessing the risks of chemicals rather than trying to cover specific aspects of each of the sectors noted in the introduction. However, it is pertinent to note that there is one specific area in the development of exposure criteria for the general public for genotoxic carcinogens where uncertainty factors are used. This is for three compounds where air quality standards (AQS) have been developed based on human data (EPAQS, 1994, 1999, 2002). In all cases there were good quality epidemiological data based on a number of studies of occupational exposure to the chemicals. In two cases (benzene and 1,3-butadiene) it was possible to identify from these studies a level at which no increase in tumours was detected (but recognising that larger studies may have detected an increase). This value was divided by a factor of ten to account for the difference between a full lifetime and that part of a lifetime spent at work and a further factor of ten to account for variability in the sensitivity of the general population. Furthermore in one case (1,3-butadiene) the value obtained was higher than the ambient air concentration, and hence because of the need for ALARP, the AQS was set at the lower value corresponding to ambient air levels. In the case of the third compound (polycyclic aromatic hydrocarbons) it was only possible from the epidemiological studies on occupationally exposed groups to identify the lowest level at which effects were observed, rather than a no-detectable effect level. Thus a further uncertainty factor was used in addition to the two noted above to give an overall value of 1000.

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Annex to Appendix A

National and International Committees relating to the Health Effects of Chemicals

UK Independent Expert Advisory Committees

Statutory Committees

Advisory Committee on Pesticides (ACP)

Secretariat provided by the Pesticides Safety Directorate (PSD, a Defra agency). The ACP advises Ministers involved in pesticide approvals, namely Defra, DWP (for HSE), DH and the devolved administrations, on all matters relating to the control of pesticides. Specifically this relates to protection of the health of human beings, creatures and plants and safeguarding the environment. The ACP advises on approval of pesticide products. It is supported in its work by two panels, namely the Medical and Toxicology Panel and the Environmental Panel.

Veterinary Products Committee (VPC)

Secretariat provided by the Veterinary Medicines Directorate (VMD, a Defra agency). The VPC advises Defra Ministers on any aspect of veterinary medicine products and specified food additives. It advises on the safety, quality and efficacy of veterinary medicine products and whether marketing authorisation should be granted, refused, varied, suspended or revoked. It also promotes the collection of information relating to suspected adverse reactions. It is supported in this work by two panels. These are the Medical and Scientific Panel and the Appraisal Panel for Human Suspected Adverse Reactions.

Commission on Human Medicines (CHM)

Secretariat provided by the Medicines and Healthcare Products Regulatory Agency (MHRA, a DH agency). The CHM advises Health Ministers on the quality, efficacy and safety of human medicines to ensure that appropriate public health standards are maintained. This involves providing advice to the licensing authority (Health Ministers) on whether new products submitted to the MHRA should be granted market authorisation. It also monitors the safety of human medicines by post-market surveillance. The CHM is supported in its work by three statutory Expert Advisory Groups, namely Chemistry, Pharmacy and Standards; Biologicals and Standards; and Pharmacovigilance.

Advisory Committee on Toxic Substances (ACTS)

Secretariat provided by the Health and Safety Executive (HSE). The ACTS advises the Health and Safety Commission (HSC) on matters relating to the prevention, control and management of hazards and risks to the health and safety of people arising from the supply or use of toxic substances at work, with due regard to any related risks to consumers, the public and the environment. There is a ACTS subcommittee that provides specific advice on issues relating to the assessment and control of health risks from chemicals. This is called the Working Group on Action to Control Chemicals (WATCH).

Non-statutory Committees

Cross-government Advisory Committees that provide Specialised Advice

Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT)

Secretariat provided by the Food Standards Agency (FSA) and HPA acting jointly (prior to January 2006 the HPA input was provided by the DH) – FSA lead. Its remit is to assess and advise on the toxic risks of chemicals, at the request of the DH, FSA, HPA, Defra, DTLR, DTI, HSE, PSD, VMD, MHRA, Home Office, Scottish Executive, National Assembly of Wales, Northern Ireland Executive, and other government departments and agencies. It also advises on important general principles or new scientific discoveries in connection with toxic risks, co-ordinates with other bodies concerned with the assessment of toxic risks, and presents recommendations for toxicity testing.

Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment (COC)

Secretariat provided by the HPA and FSA acting jointly (prior to January 2006 the HPA input was provided by the DH) – HPA lead. Its remit is similar to that of the COT, but specifically relating to the carcinogenicity of chemicals.

Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment (COM)

Secretariat as for the COC. Its remit is similar to that of the COT but specifically relating to the mutagenicity of chemicals.

Committees that Advise on Specific Sectors

Committee on Medical Effects of Air Pollutants (COMEAP)

Secretariat provided by the HPA (prior to January 2006 this was provided by the DH). Its remit is as follows: at the request of the DH, to advise the UK Health Departments on the effects on health of both outdoor and indoor air pollutants on the basis of data currently available, to assess the need for further research, and to liaise as necessary with other government bodies to assess the effects of exposure and associated risks to human health.

Expert Panel on Air Quality Standards (EPAQS)

Secretariat provided by Defra and HPA acting jointly (prior to January 2006 the HPA input was provided by the DH) – Defra lead. Its remit is to advise Defra Ministers, Scottish Ministers, the National Assembly of Wales, and the Department of Environment (Northern Ireland), as required, on non-occupational ambient air quality standards, with particular reference to the levels of airborne pollutants at which no or minimal effects on human health are likely to occur, taking into account the best available evidence and without reference to the practicality of abatement measures, the economic costs and economic benefits of pollution control measures, or other factors pertinent to the management rather than the assessment of risk. Where appropriate – for example, for pollutants where no threshold for adverse effects can be determined, the EPAQS may wish to recommend exposure–response relationships or other information Government might use to set policy objectives. In addition, it identifies gaps in the knowledge needed for standard setting and suggests priority areas for future research, and advises on

other aspects of air quality and air pollution referred to it. It also has the purpose of informing the development of policy on the improvement of air quality and increasing public knowledge and understanding of air quality issues.

In 2007 the EPAQS and COMEAP will merge; the enlarged body will retain the name of COMEAP.

Advisory Committee on Hazardous Substances (ACHS)

Secretariat provided by Defra. Its remit is to advise Defra Ministers and Environment Ministers in the devolved administrations, and other Ministers as appropriate, on the exercise of power to make regulations under Section 140 of the Environmental Protection Act 1990 to prohibit or restrict the importation, use, supply or storage of specified substances or articles. The ACHS advises Ministers on the exercise of power to make regulations under Section 142 to obtain information about potentially hazardous substances; it also advises the UK Chemical Stakeholder Forum (CSF) and other bodies as appropriate, on criteria, prioritisation and risk assessment of potentially harmful substances. It advises Ministers, the CSF and other bodies as appropriate, on research needs and the development of relevant indicators.

WHO Activities and Advisory Groups

General Chemicals

International Programme on Chemical Safety (IPCS, a WHO/ILO/UNEP venture; WHO lead)

The IPCS prepares (drafts subject to wide consultation followed by ad hoc expert group meetings) and publishes internationally agreed assessments of specific chemicals as follows:

a monographs on specific chemicals together with guidance on various aspects of the risk assessment methodology – about 200 have been published to date in the Environmental Health Criteria (EHC) Document series,

b Concise International Chemical Assessment Documents (CICADs) – about 60 published to date,

c monographs on general principles of assessing health effects of chemicals or on specific aspects such as immunotoxicity, neurotoxicity and allergic reactions – these are published in the EHC Document series.

Also, in co-operation with the FAO, it evaluates the safety of food components, specifically food additives and contaminants, and pesticides and veterinary residues. These are considered below.

Specific Sectors

Joint FAO/WHO Expert Committee on Food Additives (JECFA)

The JECFA has annual meetings (with ad hoc advisers) and publishes evaluations (over 1500 since it was established in 1964).

Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The JMPR has annual meetings (with ad hoc experts) and publishes evaluations (about 1000 since 1965).

WHO Guidelines for Drinking Water Quality

These are published/updated periodically; currently guidelines are available for around 150 chemicals. Guidelines are developed following ad hoc expert consultations (Geneva), and drafts are subject to open consultation. Work proceeds via a programme of rolling revisions of the WHO Guidelines. WHO recommendations are a key consideration regarding the EU directive on water quality standards and are generally adopted as EU-wide standards

WHO Air Quality Guidelines for Europe (WHO Euro)

Recommendations are available for 63 chemicals. These are developed and updated on the basis of work of ad hoc expert group meetings. They provide the scientific basis for the EU clean air strategy.

EC Expert Advisory Committees

DG Health and Consumer Protection (DG SANCO)

This Directorate General is responsible for a number of scientific committees that provide the independent expert advice to the European Commission that it needs when preparing policy and proposals relating to consumer safety, public health and the environment. The advice is published as opinions of the committees. The names of these committees are given below together with their mandates.

Scientific Committee on Consumer Products (SCCP)

The SCCP considers questions relating to the safety of consumer products (non-food products intended for the consumer) – in particular, the safety and allergenic properties of cosmetic products (including personal care products) and ingredients in toys, textiles, clothing, detergents and consumer services such as tattooing.

Scientific Committee on Health and Environmental Risks (SCHER)

The SCHER considers questions relating to the toxicity and ecotoxicity of chemicals, biochemicals and biological compounds whose use may have harmful consequences for human health and the environment – in particular, questions relating to new and existing chemicals and marketing and use restrictions; biocides; waste environmental contaminants; plastic and other materials used in water pipes; drinking water; indoor and ambient air quality.

Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR)

The SCENIHR considers questions concerning emerging or newly identified risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other EC risk-assessment bodies.

Inter-Committee Co-ordinating Group (ICCG)

The ICCG comprises the Chairs and Vice-Chairs of the above three committees. Its role is to assist the EC on matters relating to the co-ordination of the three committees including the harmonisation of risk assessment and dealing with questions common to more than one of the committees and diverging scientific opinions.

DG Employment, Social Affairs and Equal Opportunities

Scientific Committee on Occupational Exposure Limits (SCOEL)

The remit of the SCOEL is to provide scientific advice to the EC to underpin regulatory proposals on exposure limits for chemicals in the workplace within the framework of the Chemical Agents Directive (98/24/EC) and the Carcinogens at Work Directive (90/394/EEC).

European Food Safety Authority (EFSA)

The EC established the EFSA in 2003 to provide independent scientific advice on food safety issues throughout the food chain. In preparing its risk assessments on all matters relating to food safety, including animal health and plant protection (pesticides) the EFSA is advised by a scientific committee and a number of expert panels. There are nine scientific expert panels that report to the scientific committee. They cover the following specialised areas.

Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC)

Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)

Panel on Plant Protection Products and their Residues (PPR)

(It is pertinent to note that the remit of the PPR is to provide expert advice on the safety of plant protection products (pesticides) for the user/worker, the consumer of treated products and the environment.)

Panel on Plant Health (PLH)

Panel on Genetically Modified Organisms (GMOs)

Panel on Dietetic Products, Nutrition and Allergies (NDA)

Panel on Biological Hazards (BIOHAZ)

Panel on Contaminants in the Food Chain (CONTAM)

Panel on Animal Health and Welfare (AHAW)

European Medicines Agency (EMEA)

Committee for Medicinal Products for Human Use (CHMP)

Committee for Medicinal Products for Veterinary Use (CVMP)

These committees consider applications for marketing authorisation of medicinal products made under the centralised procedure. If they conclude that the quality, safety and efficacy are sufficiently proven they adopt a positive opinion. This is sent to the EC to be transformed into a single market authorisation valid for the whole of the EU.

Appendix B

Health Based Exposure Criteria for Protection against Ionising Radiation

B1 Introduction

The primary international advisory body in the area of setting standards* is the International Commission on Radiological Protection (ICRP). The Second International Congress of Radiology established this commission in 1928, under the name of the International X-ray and Radium Protection Committee. In 1950 it was restructured and acquired its present name. Since then the ICRP has published a series of recommendations, reflecting the increased understanding of the biological basis of radiation-induced tissue damage. Protection standards in almost all countries are based on ICRP recommendations.

In 1991 the ICRP issued recommendations for a 'system of radiological protection' as ICRP Publication 60 (ICRP, 1991). A number of policy documents were subsequently issued by the ICRP which amplified aspects of that system. In this document these recommendations and the policy documents are collectively referred to as ICRP recommendations and, unless otherwise stated, all reference to ICRP recommendations should be taken to refer to ICRP Publication 60. The ICRP has recently embarked on a process of updating its recommendations. Draft recommendations were issued for comment in 2005 and, in a revised form, in 2006. These new draft recommendations do not differ substantially on points of principle from those currently in use.

The ICRP is registered as a charity in the UK. It is composed of a main commission and five standing committees: on radiation effects, on doses from radiation exposure, on protection in medicine, on the application of the commission's recommendations, and on the protection of non-human species. The commission itself comprises twelve members and a chairman, assisted by a scientific secretary. Members are elected for four-year terms, with the proviso that no less than three and no more than five of the members must be replaced each time.

A number of international organisations issue guidance, recommendations or standards that are based on the ICRP recommendations. These organisations are discussed below.

The International Atomic Energy Agency (IAEA) came into existence in 1957. Its statute was agreed at an international conference held at the United Nations Headquarters, New York, and it has formal links with the United Nations (UN). The role of the IAEA is broadly to promote the peaceful use of atomic energy and it issues advice through several sets of publications. The IAEA is specifically authorised under the terms of its statute to establish basic safety 'standards for protection against ionising radiation and for the safety of radiation sources'. It published its first standard in 1962 and revised versions were published in 1967, 1982 and 1996. The latest IAEA standards (IAEA, 1996), published jointly with five other

* In the ionising radiation field health based exposure criteria for the protection of human health are generally referred to as standards.

organisations, are based primarily on the recommendations of the ICRP. They are not legally binding in the UK. However, the IAEA has developed a binding international convention on nuclear safety and a similar convention on radioactive waste management.

The Nuclear Energy Agency (NEA) of the Organisation for Economic Co-operation and Development (OECD) was established in 1958. The primary objective of the NEA is to promote co-operation among the governments of participating countries in furthering the development of nuclear power as a safe, environmentally acceptable energy source. One way it attempts to achieve this is by issuing collective opinions on various topics such as aspects of radioactive solid waste disposal. The NEA works closely with the IAEA.

Under the terms of the Euratom Treaty, one of the Treaties of Rome, the European Union establishes uniform safety standards to protect the health of workers and the general public from the hazards of ionising radiation. The latest standards, which took account of the ICRP recommendations, were issued in 1996 (EC, 1996). They are binding on member states.

The United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) was established in 1955 in response to concerns about the effects of ionising radiation on health and the environment by the testing of nuclear weapons in the atmosphere. UNSCEAR collects and evaluates information on the levels and effects of ionising radiation and periodically publishes its conclusions (eg UNSCEAR, 2000).

B2 Role of the HPA RPD

The Radiation Protection Division of the HPA has a responsibility, inherited from the National Radiological Protection Board (NRPB), to advise on the acceptability to and application in the UK of standards recommended by international and intergovernmental bodies. In discharging the responsibility, the NRPB issued guidance on the acceptability of the ICRP recommendations in the *Documents of the NRPB* series of publications (NRPB, 1993a,b). Broadly, the NRPB has endorsed ICRP recommendations. However, there have been exceptions, including the following.

a The NRPB saw no need for the five-year averaging in the dose limit for members of the public (see Table B2). This recommendation from the NRPB was subsequently accepted by Government (Department of the Environment et al, 1995).

b The NRPB recognises a third principle for interventions which is to avoid serious deterministic effects (see Section B5.2).

In the absence of guidance from the ICRP, the NRPB also recommended a value for the dose constraint for members of the public (NRPB, 1993b) which was accepted by Government (Department of the Environment et al, 1995). The same numerical value was subsequently adopted by the ICRP (ICRP, 1997).

In 1990, the NRPB advised on emergency reference levels for application in radiation emergencies (NRPB, 1990). These levels are consistent with ICRP recommendations (see Table B4) but are specifically for UK circumstances. The levels have been adopted by Government (HSE, 2001).

B3 Quantities and Units

Individuals can be exposed externally to radiation emitted by sources outside the body and internally to radiation emitted by radionuclides taken into the body by, for example, ingestion or inhalation. Of the common types of radiation, external irradiation is usually only important for beta particles and gamma rays as the range of alpha particles is generally insufficient to penetrate the dead outer layer of skin cells. All types of radiation can give rise to internal exposure.

The ICRP has developed specific dosimetric quantities for radiation protection that allow the extent of exposure to ionising radiation both from whole and partial body external irradiation and from intakes of radionuclides to be quantified. The calculated doses can then be compared with recommended dose-based standards for people who are occupationally exposed or who are members of the public. One issue is the variation in the response of biological matter to radiations of different types and the varying sensitivity to radiation damage of the organs and tissues of the body. The ICRP has introduced a single quantity, the effective dose, as an approach to overcome some of these problems.

An underlying premise is that the biological effects of ionising radiation result from radiation depositing energy in tissues; therefore the fundamental quantity of absorbed dose is joules per kilogram (one joule per kilogram of absorbed dose is called a gray, Gy). However, the effectiveness of damaging tissue is different for different types of radiation. Therefore, the absorbed dose averaged over a tissue or organ is multiplied by a specific radiation weighting factor for different types of ionising radiation; the resulting quantity is called equivalent dose (this is still in the units of joules per kilogram but is termed the sievert, Sv).

When radionuclides enter the body by inhalation or ingestion, they may irradiate particular organs preferentially depending on the chemical properties of the element. For example, isotopes of plutonium concentrate in the bone and liver, whereas isotopes of iodine concentrate in the thyroid. Different tissues have different sensitivities to the induction of stochastic effects, such as cancer, and so in order to present all doses on a common basis, doses to individual tissues are weighted. The equivalent dose to each organ and tissue is multiplied by a tissue weighting factor and the sum of the weighted doses is called the effective dose. The tissue weighting factor reflects the radiosensitivity of the tissue or organ. This is again in terms of sieverts.

Some radionuclides persist in the body irradiating tissue for many years. The total dose delivered over the lifetime, taken to be age 70 years for infants and children, and 50 years for adults following an assumed intake at age 20, is called the committed dose. The effective dose received in a given period is the sum of the committed effective doses from intakes of radionuclides in that period together with the effective dose from external irradiation in the same period.

When discussing only external exposure, particularly in circumstances when all tissues are reasonably uniformly irradiated, the term whole-body exposure (or dose) is often used. The units are usually given in gray.

B4 Biological Information on the Health Risks from Exposure to Ionising Radiation

There are two types of injuries that can result from exposure to ionising radiation: deterministic effects and stochastic effects.

B4.1 Deterministic effects

Deterministic effects occur at relatively high levels of dose and have a threshold below which they do not occur. Above the threshold the severity of the effect increases with dose. Essentially, deterministic injuries happen when the amount of energy deposited in a tissue is sufficient to cause gross damage. The thresholds for the various types of deterministic injuries are much higher than the doses normally experienced from exposure to natural sources. Information on deterministic injuries comes from a number of sources including accidental exposures and animal experiments. Current estimates for the thresholds for serious deterministic effects are given in Table B1. The thresholds in Table B1 refer to acute exposure to gamma radiation. If the dose is given over a longer period, the dose thresholds increase. For example, if the dose rate is about 0.2 Gy per hour, LD_{50} values may be increased by around 50%.

Less serious deterministic effects, which are nevertheless relevant to setting standards, can occur in the skin, where acute doses of 2 Gy can lead to reddening and doses of about 10 Gy can give rise to ulceration, and in the lens of the eye where acute doses of a few gray (currently under review by the ICRP) can cause cataracts. The NRPB reviewed the risks from deterministic effects in 1996 (NRPB, 1996).

TABLE B1 Illustrative deterministic effects

Acute whole-body exposure (Gy)		
LD_{50}	**Cause of death**	**Time of death**
4	Haemopoietic failure	Within 60 days
10	Gastrointestinal failure	Within 7–14 days
50	Nervous and cardiovascular system failure	Within a few days

B4.2 Stochastic effects

The characteristic feature of stochastic effects is that their probability of occurrence, but not their severity, is related to dose. The types of stochastic effects currently of concern are the induction of cancer in those exposed and induction of hereditary effects in their descendants. It is an underlying tenet of radiation protection that any exposure to radiation carries with it a risk to the health of the individual. For the purposes of setting standards for protection against stochastic effects, it is assumed that there is a linear relationship between dose and risk with no threshold below doses where deterministic effects

may become important (the so-called linear no-threshold hypothesis). An important implication of this assumption is that it is not possible to define a harmless level of exposure and that, in any given situation, it is necessary to balance the level of risk against the anticipated benefits. The evidence for the linear no-threshold assumption is briefly outlined below.

Cancer

An important body of evidence for assessing the risk of stochastic effects comes from the follow-up of the Life Span Study of the Japanese atomic-bomb survivors. This study provides evidence for an increased risk of cancer above acute whole-body doses of low LET radiation (beta and gamma radiation) of the order of 100 mSv in a mixed population of adults and children. Separate studies on individuals exposed *in utero* during diagnostic X-ray examinations show a significant and quantifiable excess risk of childhood cancer following an acute dose of around 10 mSv. There have also been studies on populations receiving excess protracted exposures, such as nuclear workers. Overall, these studies have been taken to suggest an increased risk of cancer above protracted doses in the range 50–100 mSv (Brenner et al, 2003).

In terms of quantifying the risk to the general population, for reasons related to statistical power, the most reliable data are provided by studies on individuals receiving acute doses greater than about 200 mSv. Experimental studies indicate that fractionation or protraction of dose and much lower doses are associated with a reduced dose-specific risk. To take account of this phenomenon, the ICRP applies a dose and dose rate effectiveness factor (DDREF) of two in assessing risks at low doses and dose rates. In other words, the risk per unit dose observed at high doses and dose rates is divided by two for the purposes of assessing risks at lower doses and dose rates. Having applied a DDREF of two, the ICRP assumes a linear relationship between dose and risk at low doses.

The studies discussed above were nearly all on external exposure to low LET radiation (beta and gamma radiation). Controversy exists in some areas over the health risk from internal exposure, particularly to high LET radiation (eg alpha particles). There are a number of human studies that provide data on risks from internal emitters which are summarised by Harrison and Muirhead (2003). These studies include:

a liver cancer in patients given Thorotrast, which is colloidal thorium dioxide (thorium-232 is an alpha emitter), as a contrast medium,

b bone cancer following occupational exposure of radium dial painters and in patients given radium-224 for medical reasons,

c lung cancer following occupational exposure of uranium miners to radon together with consistent data from residential exposure.

Overall, the estimates of risk from these studies show reasonable consistency with those based on studies of external irradiation (CERRIE, 2004).

The ICRP recommends a nominal risk factor of $5\ 10^{-2}\ Sv^{-1}$ for fatal cancer following exposure of the whole population. The corresponding value for exposure over a working lifetime is $4\ 10^{-2}\ Sv^{-1}$.

Hereditary effects

There is little or no direct evidence for radiation-induced hereditary effects in humans. The estimates for hereditary effects used by the ICRP are derived from theoretical studies and mouse data. The ICRP currently recommends a risk factor of 1.3 10^{-2} Sv^{-1} for exposure of the whole population (ICRP, 1991). This has been weighted for severity and years of life lost. It is expected that this risk factor will be somewhat reduced in the new ICRP recommendations following review by UNSCEAR (UNSCEAR, 2001).

Other effects

Since publication of the ICRP recommendations in 1991, evidence has emerged primarily from the atomic-bomb survivor data for an increased risk of non-cancer disease that could be associated with exposure to radiation. The non-cancer diseases of interest are heart disease, stroke, digestive disorders and respiratory disease. The strongest evidence for these effects is for doses of around 1 Sv. It is unclear whether these results can be extrapolated to lower doses and, if so, how. UNSCEAR is currently developing a view on these non-cancer effects.

B5 System of Protection

The ICRP system of protection is divided into two broad areas: practices and intervention. Practices are deliberate human activities which, as a byproduct, result in increased exposure of individuals or populations and, in principle, can be designed and operated to meet requirements for radiation protection that are specified in advance. An example of a practice is the generation of electricity by nuclear power. Interventions are human activities intended to decrease overall exposure to radiation and apply in situations in which the source of exposure is already present when decisions on protective actions are to be taken. These situations include, for example, exposure that results from an accidental release of radionuclides into the general environment. The basic principles of radiation protection are used to establish the levels of control of exposure in both practices and interventions but are applied in different ways.

B5.1 Practices

The system of radiation protection recommended by the ICRP for proposed and continuing practices has the following principles.

a No practice involving exposures to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society to offset the radiation detriment it causes. *Justification of a practice*

b In relation to any particular source within a practice, the magnitude of individual doses, the number of people exposed, and the likelihood of incurring exposures where these are not certain to be received should all be kept as low as reasonably achievable, economic and social factors being taken into account. This procedure should be constrained by restrictions on the doses to individuals (dose constraints), or the risks to individuals in the case of potential exposures (risk constraints), so as to limit the inequity likely to result from the inherent economic and social judgements. *Optimisation of protection*

c The exposure of individuals resulting from the combination of all the relevant practices should be subject to dose limits, or to some control of risk in the case of potential exposures. These are aimed at ensuring that no individual is exposed to radiation risks that are judged to be unacceptable from these practices in any normal circumstances. Not all sources are susceptible to control by action at the source and it is necessary to specify the sources to be included as relevant before selecting a dose limit. *Individual dose and risk limits*

In simpler terms, these principles may be phrased as follows:

> Radiation can cause harm and therefore any intended use should be worthwhile (*justification*) and, this being the case, all reasonable steps should be taken to reduce exposures (*optimisation*). Doses and risks from uses of radiation should be kept within predefined limits or constraints (*dose and risk limitation*) – obviously, this principle does not apply to sources that cannot be controlled.

B5.1.1 Standards for practices

The primary quantitative standards for practices are dose limits and dose constraints. Dose limits are applied to the summed dose from all sources subject to control. Doses incurred in circumstances where the only available course of action is intervention are not included in comparisons with the dose limit. Within the ICRP system of protection, dose limits are regarded as backstops; emphasis is instead placed on optimisation whereby an acceptable level of protection is established. Dose constraints are applied during the optimisation of protection of a single source.

The ICRP specifies different values for dose limits for members of the public and workers. Limits for members of the public are lower than those for workers because of the involuntary nature of public exposure.

The ICRP sets its dose limits at the boundary between exposures that are unacceptable and those that are tolerable. Exposures are deemed to be acceptable when protection has been optimised.

It is tempting to try to establish numerical values for dose limits by comparing risks from exposure to radiation with fatal risks incurred in occupations and in public activities. Indeed, this approach was investigated by the ICRP in recommendations issued in 1977 as Publication 26 (ICRP, 1977) where its nominal risk factors were used to facilitate comparison of risks from radiation exposure with acceptable risks in other walks of life. The ICRP now acknowledges that there are problems with this simple approach. These problems stem from the nature of radiation risks. Firstly, there is a latent period between exposure and the fatality from cancer, a period which can vary from cancer to cancer and is often many years in length. Secondly, the risk of many radiation-induced cancers is a multiplier on the background incidence which itself varies markedly with age, usually showing an increase with age. Thus in the case of continuous exposure, the annual incremental probability of death expressed at different ages will vary considerably. In contrast, according to the ICRP, the risks being used for comparative purposes, from say other industries, are usually for fatal accidents. Such risks are usually averaged over time and populations and may hide information on high risk groups – for example, within a particular occupation. Thus, the ICRP now adopts a judgemental multiattribute approach to setting dose limits.

Public exposure

Dose limits and constraints in this context apply to the mean dose in a critical group, which is defined as a group which is typical of those most highly exposed.

Dose limits The ICRP dose limits for members of the public are summarised in Table B2. The ICRP recommends an annual limit on effective dose for members of the public of 1 mSv with the additional flexibility of allowing a higher effective dose in some years provided the average over five years does not exceed 1 mSv per year. Limits are also recommended for the lens of the eye and localised areas of the skin as these tissues may not be protected against deterministic effects by the limit on effective dose. The limits on these tissues are an order of magnitude lower than the corresponding limits for occupational exposure (see Table B3) and more than an order of magnitude lower than the levels where deterministic effects may generally be expected. The rationale for these lower limits is usually given as the perceived need to protect unspecified sensitive individuals in the general population.

TABLE B2 ICRP recommended dose limits for members of the public

Effective dose	1 mSv y^{-1}, in special circumstances a higher value can be allowed in a single year provided the 5 year average does not exceed 1 mSv y^{-1}
Annual equivalent dose in	
the lens of the eye	15 mSv
the skin	50 mSv, averaged over any 1 cm^2 area of skin

The ICRP emphasises the multiattribute process for the selection of a numerical value for the limit on effective dose. Attributes considered include annual risk from lifetime exposure, lifetime risk and comparison with natural background.

The average annual risk from continuous lifetime exposure at 1 mSv y^{-1} is about 3 10^{-5}. Risk modelling studies show that the annual probability of dying of cancer does not exceed 10^{-5} until around age 50 years for a continuous lifetime exposure at this level. The lifetime fatal cancer risk at a rate of exposure of 1 mSv y^{-1} is estimated by the ICRP at 0.4%, which represents an increase of about 1.5% of the natural probability of dying of cancer (20 to 25%). It is important to note that consideration of risks was not the only factor in the ICRP decision on the level for the dose limit. The ICRP also took account of doses from natural background and their variation. The ICRP concluded 'This natural background may not be harmless, but it makes only a small contribution to the health detriment which society experiences. It may not be welcome, but variations from place to place (excluding the large variations in the dose from radon in dwellings) can hardly be called unacceptable' (ICRP, 1991). The selection of the value of 1 mSv y^{-1} was therefore a judgement.

History may also have played a role. In its previous recommendations (ICRP, 1977), the ICRP more clearly linked selection of the value of the dose limit to risk-based considerations. At that time, the ICRP was of the view that 'a [fatal] risk in the range of 10^{-6} to 10^{-5} per year would be likely to be acceptable to any member of the public'. Using the then current risk factor of 10^{-2} Sv^{-1}, this corresponded to a whole-body exposure of 1 mSv y^{-1}. The ICRP, however, wished to retain its current (pre-1977) public dose limit of

5 mSv y^{-1} noting that this limit 'as applied to critical groups, has been found to provide this degree of safety'. The ICRP gave some further thought to this issue and in a statement from the 1985 Paris meeting (ICRP, 1985) noted that 'The Commission's present view is that the principal limit [for members of the public] is 1 mSv in a year'. In the late 1980s evidence emerged from the follow-up of the atomic-bomb survivors that radiation risks were a few times larger than 10^{-2} Sv^{-1}. In the context of public protection, the ICRP responded to this evidence in its 1987 Como statement (ICRP, 1988) by noting 'the increase in risk indicated by the new data is also not considered to require change in recommended dose limits, following the reduction (in 1985) in the principal limit from 5 to 1 mSv in a year'.

Dose constraints These are applied during the optimisation of protection of a single source. Protection options implying doses greater than the value of the constraint should be rejected. The 1990 ICRP recommendations did not specify any values for dose constraints. Subsequently, the ICRP proposed a value of no more than 0.3 mSv y^{-1} for members of the public from the disposal of radioactive waste (ICRP, 1998). The rationale provided for this value is that it allows for the possibility of exposures to multiple sources from practices (the sum of which must comply with the dose limit).

Occupational exposure

The ICRP defines occupational exposure as 'exposures incurred at work as the result of situations that can reasonably be regarded as being the responsibility of the operating management'.

Dose limits The ICRP dose limits for occupational exposure are given in Table B3. The dose limits for the lens of the eye, the skin, and the hands and feet are set such as to avoid the possibility of deterministic effects. The limit on effective dose was selected by the ICRP using a multiattribute approach.

TABLE B3 ICRP recommended dose limits for occupational exposure

Effective dose	20 mSv y^{-1}, averaged over defined periods of 5 years
Annual equivalent dose in	
the lens of the eye	150 mSv
the skin	500 mSv, averaged over any 1 cm^2 area of skin
the hands and feet	500 mSv

The ICRP estimates the lifetime risk of induced fatal cancer from an exposure rate of 20 mSv y^{-1} over a working lifetime to be nearly 4%. The mean annually committed probability of attributable fatal cancer risk is about 8 10^{-3}. The annual cancer death probability caused by this continuous exposure varies with age, however, not exceeding 10^{-3} until around age 65 years. On the basis of this type of information, the ICRP decided that the risks from using a limit greater than 20 mSv y^{-1} would not be acceptable.

To assist in managing occupational exposure, the ICRP recommends that workplaces are classified into controlled areas and supervised areas. A controlled area is one in which normal working conditions, including the possible occurrence of minor mishaps, require the workers to follow well-established procedures aimed at controlling exposures. A supervised area is one in which the working conditions are kept under review but special procedures are not normally needed.

Dose constraints As is the case with public exposure, dose constraints apply during the optimisation of protection. The ICRP has not provided any numerical values noting, however, that it is implicit that the dose constraint for optimisation should not exceed 20 mSv y^{-1}. Some further guidance on the selection of constraints is provided: 'For many types of occupation, it is possible to reach conclusions about the level of individual doses likely to be incurred in well-managed operations. This information can then be used to establish a dose constraint for that type of occupation' (ICRP, 1991).

B5.2 Interventions

In some cases the sources, pathways and exposed individuals are already in place when a decision on control has to be taken. In such situations, protection can only be achieved by intervention; that is, by removing or modifying existing sources or pathways, or reducing the numbers of people exposed. The system of radiation protection recommended by the ICRP for intervention has the following principles.

a The proposed intervention should do more good than harm, ie the reduction in detriment resulting from the reduction in dose should be sufficient to justify the harm and the costs, including social costs, of the intervention. *Justification of intervention*

b The form, scale and duration of the intervention should be optimised so that the benefit of the reduction of dose, ie the benefit of the reduction in radiation detriment, less the detriment associated with the intervention, should be maximised. *Optimisation of intervention*

In most cases intervention cannot be applied to the source of the exposure and has to be applied in the environment and to an individual's freedom of action. Thus a programme of intervention will always have some disadvantages but should always be justified in the sense that it does more good than harm. It follows that the use of dose limits, or constraints, specified for practices as the basis for deciding on a level at which intervention is invoked, might involve measures that would be out of proportion to the benefit obtained and, therefore, would conflict with the principle of justification. Thus, the ICRP recommends that dose limits for practices (and, by inference, dose constraints) do not apply in intervention situations. There will, of course, be some level of dose approaching that which would cause serious deterministic effects, where some form of intervention will be almost always required.

Intervention situations span a wide range of types of action; examples include intervention against high levels of natural radiation, decontamination of public land and property contaminated by past industrial activities, and countermeasures taken to protect the public following a serious accident. Intervention may be applied to reduce the impact of short- or long-term exposures.

B5.2.1 Standards for intervention

Rather than dose limits or dose constraints, it is the level of avertable dose that is of primary importance in intervention situations. The avertable dose is the dose saved by the introduction of a particular countermeasure. The avertable dose should be compared with the costs, etc, of a countermeasure in order to decide whether the countermeasure is worthwhile, ie optimisation of radiation protection. There is one proviso which is that it is sometimes necessary to specify in advance a level of dose above which action should be taken. This leads to the following terminology.

a **Intervention level** – the level of avertable dose at which a particular countermeasure should be taken (it should be noted that the ICRP is not consistent in its use of this term).

b **Action level** – the level of dose, or directly measurable quantity, as appropriate (eg dose rate or activity concentration) above which action should be taken.

It should be emphasised that if the anticipated dose averted by introducing a particular countermeasure is bigger than the intervention level for that countermeasure then it strongly indicates that the countermeasure should be adopted. Conversely, if the anticipated dose averted is less than the intervention level then the countermeasure should almost always not be invoked. Furthermore, avertable dose and action levels are not necessarily expressed in terms of dose in a year – the quantity normally considered in practices. Lifetime doses and doses over much shorter periods, eg days and weeks, may all feature in decisions on intervention.

The ICRP basis for selecting values for intervention levels and action levels is in some cases not clear. Some general points can, however, be made. Firstly, the range of possible values is from a few mSv per year to a few hundred mSv per year. The lower boundary is set paradoxically by the dose limit for members of the public in that it would seem illogical to intervene to reduce doses at levels which the system of protection deemed acceptable in other circumstances for incidental exposure of members of the public. The upper boundary is set by the desire to prevent serious deterministic effects. Secondly, within this range, the ICRP usually selects values for particular situations from generic optimisation considerations taking account, *inter alia*, of the practicability of intervention and the dose that would be averted.

The main areas where the ICRP has provided guidance on intervention are radon, radiation emergencies and prolonged exposure situations.

Radon

The guiding principle for setting an action level for radon in dwellings is stated by the ICRP as follows: 'the best choice of an action level may well be that level which defines a significant, but not unmanageable, number of houses in need of remedial work. It is then not to be expected that the same action level will be appropriate in all countries' (ICRP, 1991). In Publication 65 (ICRP, 1994) the ICRP recommends that action levels for radon in dwellings are set in the range 3–10 mSv annual effective dose from radon exposure. The basis for the selection of the upper value is not clear. The lower value is selected from a general consideration of the doses from natural background (average 2–3 mSv per year, around 50% or more from radon).

Radiation emergencies

In Publication 63 (ICRP, 1993) the ICRP recommended intervention levels for protection of the public in a radiation emergency. The levels for sheltering, evacuation, administration of stable iodine and relocation are given in Table B4. They are all in terms of avertable dose and are stated by the ICRP to be derived on 'a generic basis' or from 'generic considerations'. Example calculations supporting selection of the values for the control of foodstuffs and for relocation are provided in appendices to Publication 63. The calculations apply a form of cost–benefit analysis.

The levels in the table are those where the intervention would almost certainly be justified, even under unfavourable conditions. Under favourable conditions, where risks from implementation are less, the intervention could be undertaken in order to avert a lower dose but in most cases not more than a factor of ten lower.

TABLE B4 Summary of intervention levels recommended by the ICRP

	Intervention level of averted dose (mSv)	
Type of intervention	**Almost always justified**	**Range of optimised values**
Sheltering	50	not more than a factor of 10 lower than justified value
Administration of stable iodine – equivalent dose to thyroid	500	
Evacuation (< week)		
whole-body dose	500	
equivalent dose to skin	5000	
Relocation	1000	5–15 mSv per month for prolonged exposure
Restriction to a single foodstuff	10 (in 1 year)	1000–10 000 Bq kg^{-1} (beta/gamma emitters) 10–100 Bq kg^{-1} (alpha emitters)

Prolonged exposure situations

Prolonged exposures, in ICRP terms, are adventitiously and persistently incurred by the public over long periods. They include exposures from natural background radiation and from long-lived residues from past accidents and past industrial processes that were not conducted within the system of protection. Guidance on application of the system of protection to these situations is provided in ICRP Publication 82 (ICRP, 2000). Two action levels, confusingly referred to as generic reference levels, are recommended. The higher action level, 100 mSv y^{-1}, is a level where intervention to reduce doses would almost certainly be justified. It is set at this level in order to prevent serious deterministic effects. The ICRP also notes that the risk of stochastic effects from continuous exposure at this dose rate would be too high to be generally acceptable. The lower action level, 10 mSv y^{-1}, represents a level below which intervention is not likely to be justifiable for some prolonged exposure situations. The basis for this numerical value is stated to be two-fold:

a review of current practice indicated that elevated natural background levels up to around 10 mSv y^{-1} do not necessarily trigger intervention by national authorities,

b existing ICRP publications on radon and emergencies (see above) indicated that doses of a few mSv up to around 10 mSv do not necessarily trigger intervention.

B6 Conclusions on ICRP Recommendations

Standards worldwide are based on the ICRP system of protection, which is divided into two subsystems: practices and interventions.

Practices are activities that add radiation exposures and risks, eg the nuclear power industry. The ICRP standards for practices are derived from consideration of several factors including lifetime attributable probability of death, the increase in the age-specific mortality rate, and the annual distribution of the attributable probability of death. Comparison with the levels of natural background radiation is also a factor in selecting standards for members of the public. The process of arriving at a value is judgemental.

Interventions are activities that reduce radiation exposures and risks, eg actions taken to reduce radon exposure or to reduce exposures during a radiation emergency. The ICRP standards for intervention are derived in most cases from a generic consideration of the practicability of intervention and of the benefits obtained.

B7 References

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Appendix C

Health Based Exposure Criteria for Protection against Non-ionising Radiation

C1 Introduction

Non-ionising radiation includes electromagnetic fields and radiations (EMFs) and optical radiations (broadband and laser). EMFs occupy the region of the electromagnetic spectrum that ends in static fields and is bordered by optical radiations. They have frequencies less than 300 GHz and include the electricity mains frequency, which is 50 Hz in the UK and with a wavelength of 6000 km, and radiofrequencies between about 100 kHz and 300 GHz with wavelengths down to about 1 mm. Optical radiation includes ultraviolet radiation (UVR), visible radiation (light) and radiant heat. It covers three adjacent regions of the electromagnetic spectrum, from the ultraviolet with wavelengths from 100 to 400 nm, through the visible from 400 to 770 nm, to infrared with wavelengths from 770 nm to 1 mm.

There are a number of international bodies that have significant roles in relation to the provision of advice on protection standards* and assessment of health effects related to exposures to non-ionising radiation. The main advisory body on protection standards for exposures to EMFs and optical radiation is the International Commission on Non-Ionizing Radiation Protection (ICNIRP). The organisation was formed in 1992 from the International Non-Ionizing Radiation Committee (INIRC) of the International Radiation Protection Association (IRPA) at the 7th International Congress in Montreal. A number of standing committees support the work of the commission. These cover epidemiology, biology, physics and engineering, and optical radiation. ICNIRP – and its predecessor organisation INIRC – has published a series of reports giving advice on protection standards. In addition, the World Health Organization, through its EMF and INTERSUN programmes, co-ordinates research internationally on health effects studies concerned with exposures to EMFs and UVR, organises meetings and symposia on related topics and publishes Environmental Health Criteria Documents. The International Agency for Research on Cancer (IARC) carries out comprehensive reviews of experimental studies and epidemiological investigations concerned with possible effects of EMFs on health (eg IARC, 2002).

The EC has also given advice on EMF exposure guidelines for the public (EC, 1999) and a directive on physical agents has been issued (EC, 2004a,b) covering occupational exposure to EMFs. This is scheduled to be implemented in the UK in 2008 following consultation by the Health and Safety Executive. A further physical agents directive on occupational exposure to artificial optical radiation has been published (EC, 2006), which has to be transposed into UK law by April 2010.

* In the non-ionising radiation field health based exposure criteria for the protection of human health are generally referred to as standards.

C2 Role of the HPA RPD

The Radiation Protection Division of the HPA has the statutory responsibility for giving advice on protection standards for non-ionising radiation, as did its predecessor the National Radiological Protection Board (NRPB). To support the development of its advice the Director of the NRPB, in 1990, established the Advisory Group on Non-ionising Radiation (AGNIR) with terms of reference: 'to review work on the biological effects of non-ionising radiation relevant to human health and to advise on research priorities'.

The AGNIR was reconstituted in 1999 as an independent body that then reported directly to Board of the NRPB and now reports to a sub-committee of the Board of the Health Protection Agency. The AGNIR has to date issued eleven major reports on possible effects on health of exposure to EMFs and UVR as well as a number of statements (see the HPA website). The reports by the AGNIR have made a major contribution to the development of NRPB, and now HPA, advice on exposure guidelines for non-ionising radiation.

C3 Guidance on Limiting Exposure to Electromagnetic Fields (0–300 GHz)

C3.1 Basis for guidelines

International and national guidelines for limiting exposure to EMFs have the objective of preventing adverse effects on health. The interaction of EMFs with the human body leads to *direct effects*, while *indirect effects* result from the interaction between EMFs and another object, such as a vehicle or other mechanical structure, with which the body comes into contact.

Guidelines for limiting exposure of people to EMFs are intended to provide a framework for a system of protection by recommending limits on exposure, generally termed *basic restrictions*, to avoid adverse health consequences. Generally the basic restrictions are not readily measurable.

Another set of levels, generally termed *reference levels* (or *investigation levels*), is also provided in exposure guidelines. These are expressed as measurable field and electric current quantities in order to assist the assessment of compliance with the basic restrictions for particular exposure situations.

Reviews of epidemiological and biological data, together with dosimetric information, underpin the basic framework for exposure restrictions on EMFs and the derivation of external field strength levels used in assessing compliance with the guidelines. Review of the scientific information embodies caution and judgement, both in assessing individual studies and their significance in identifying possible adverse effects on human health, and in addressing the uncertainties in the science.

Epidemiology has proved to be of great value in studying the effects of various agents on human health and, particularly for cancer, in quantifying risks. The observational nature of epidemiology makes it difficult, however, to infer causal relationships based on epidemiological studies alone, and such inferences are possible only when the evidence is strong. Nevertheless, in combination with information from other sources, including experimental studies, epidemiological studies can assist in testing for

causality – for example, using the guidelines suggested by Bradford Hill (1965). Epidemiological results can, therefore, provide an input to guidelines for limiting exposure, although the importance of information from other sources must also be recognised (NRPB, 2004a,b).

C3.2 Scientific evidence

In May 2004 the Board of the NRPB recommended the adoption in the UK of the guidelines for exposure to EMFs given by ICNIRP in 1998. This superseded earlier advice from the Board (NRPB, 1993). This recommendation to adopt ICNIRP guidelines (NRPB, 2004a) followed a comprehensive review of the scientific basis for the guidelines by NRPB staff (NRPB, 2004b). The Board also recognised the need to adopt a cautious approach to the interpretation of the data and recognised the benefits of international harmonisation of exposure guidelines. The review of the scientific evidence covered static, low frequency (<100 kHz) and high frequency (>100 kHz) fields, and is summarised below. A feature of the recommendations by ICNIRP in 1998 is that exposure guidelines for the public are lower than those for workers by about a factor of five. Generally occupational exposure concerns healthy adults working under controlled conditions. These conditions include the opportunity to apply engineering and administrative measures and, where necessary and practical, to provide personal protection. For members of the public, similar controls do not generally exist, and individuals of different ages can have wider variability in health status and responses to exposures to EMFs. For these reasons exposure restrictions for the public are lower than those recommended for the working population.

C3.2.1 Static electric and magnetic fields

Effects

Static electric fields interact directly with the body by inducing a surface electric charge. Movement of the body in the field can induce electric fields in the body. Indirect effects can also occur when a person is in contact with a charged conducting object, eg a vehicle exposed to a static field. At sufficiently high voltage the air will ionise and become capable of conducting an electric current between the charged object and a person in good electrical contact with the ground. A charged insulated person touching a grounded object would receive a micro-shock (spark discharge). Very few laboratory studies have, however, investigated the effects of exposure of people to static electric fields.

Cutaneous perception is the most robust biological consequence of exposure to static electric fields. A threshold for perception has been reported around 20 kV m^{-1} and annoying sensations are induced above about 25 kV m^{-1}.

Very low frequency electric fields are induced in the body whenever movement of electrically conductive biological materials, such as blood, occurs in a static magnetic field. Vertigo, nausea, a metallic taste and phosphenes (in the eye) can be induced during movement of the head in static magnetic fields larger than about 2 T. In addition, flow potentials induced by the flow of blood in a magnetic field of this value have been calculated to generate electric fields of about 200 mV m^{-1} near the sino-atrial (pacemaker) node of the heart during the relative refractory period of the cardiac cycle, when cardiac excitability is relatively low.

Studies of workers exposed to static magnetic fields up to several tens of millitesla (mT) have not demonstrated raised health risks. However, the number of studies, their size, and the information on exposure levels are generally limited.

The effects of static magnetic fields have been investigated using a wide variety of animal models and exposure conditions. Apart from possible field-dependent changes on localised blood flow in the skin, and on neuroendocrine effects associated with migratory behaviour in some animal species, no consistent effects have been reported using fields below 2 T, although the possibility of biological effects increases with exposure to fields of 5–8 T and above. There is little information regarding possible effects of chronic exposure. Overall, the available data remain insufficient to draw any firm conclusions regarding long-term health effects due to chronic exposure to static electric and magnetic fields.

Occupational exposure

On the basis of the evidence on acute effects, and the uncertainty concerning long-term effects, a cautious approach to restricting exposure to static magnetic fields is merited. It is concluded that restricting whole-body time-weighted average exposure to a magnetic flux density of 200 mT is appropriate for occupational exposure to static magnetic fields with an instantaneous ceiling of 2 T. For exposure of the limbs, a ceiling of 5 T is judged to be appropriate.

General public exposure

Restricting time-weighted average magnetic flux density of 40 mT for whole-body exposure, a fifth of the value for workers, is considered appropriate for the general public. Exposures in excess of 40 mT are appropriate for occasional access to special facilities under controlled conditions provided that the occupational exposure restrictions are not exceeded.

C3.2.2 Electromagnetic fields of frequencies below 100 kHz

Effects

The main physical effect of high levels of exposure to EMFs of frequencies less than about 100 kHz is the induction of electric fields and currents in body tissues. These can cause adverse health effects and provide the basis for exposure guidelines. However, there remains concern that power frequency (50/60 Hz) magnetic fields are implicated in the development of cancer, and in particular childhood leukaemia. The AGNIR and a number of other expert groups have addressed this issue. The NRPB concluded 'that the results of epidemiological studies, taken individually or as collectively reviewed by expert groups, cannot currently be used as a basis for restrictions on exposure to EMFs' (NRPB, 2004a, paragraph 60).

The primary means by which electric fields and currents induced in the body by exposure to external fields interact with biological tissue is through voltage-gated ion channels situated in cell membranes. The effect is to alter the flux of certain ions and the electric potential difference across the cell membrane leading to subsequent biological responses. The most sensitive tissues are those comprising interacting networks of electrically excitable tissue, such as the central, autonomic and enteric nervous systems. The heart, other muscle tissue, and 'non-excitable' tissues with voltage-sensitive ion channels are expected to show a lower sensitivity.

An ad hoc expert group on weak electric field effects in the body (NRPB, 2004b, pp 197–205) concluded that electrical stimulation of the retina can be used to assess the potential for effects on the nervous system in general. The group considered threshold internal electric field strengths of around 100 mV m^{-1} would be sufficient to protect normal adults against the potentially adverse effects on the function of the central, autonomic and enteric nervous systems. However, there is considerable uncertainty associated with these values, which cannot be resolved without further research. The group considered that restricting the induced electric field to about a factor of five lower would be adequate to protect people who are at increased risk from induced electric fields. These include people with epilepsy, a family history of seizure, or those using tricyclic antidepressants, neuroleptic agents and other drugs that lower seizure threshold. In addition, this value is considered adequate to protect the developing nervous system *in utero*, and in neonates and young children.

Precise comparison of basic restrictions expressed in terms of induced electric field strength with those expressed in terms of induced current density requires computational modelling employing tissue- and frequency-dependent values of electrical conductivity. At present, simple comparisons can be made with existing guidelines assuming a fixed chosen value of electrical conductivity.

Although the frequency response of these effects is not known, the group considered threshold values can be conservatively applied over a broad frequency range (approximately 10 Hz – 1 kHz) and to a minimum of 1000 interacting cells, which would occupy approximately 1 mm^3 in tissue of the central nervous system (CNS).

With regard to effects of surface charge induced by exposure to low frequency electric fields, exposure to fields less than 5 kV m^{-1} will have a low risk of painful discharge from a person to ground. Thresholds for the discharge from an object through a grounded person depend on the size of the object and therefore require specific assessment. In environments where appropriate control is possible, the risk of painful discharge can be minimised by engineering or administrative means (including training).

Occupational exposure

A restriction of the induced electric field in the central, autonomic and enteric nervous systems to less than 100 mV m^{-1} is considered adequate to protect most adult members of the population. The value of 100 mV m^{-1} was derived primarily from a consideration of weak electric field effects in the CNS and corresponds approximately to the existing ICNIRP (1998) basic restriction on current density of 10 mA m^{-2}, assuming an electrical conductivity of CNS tissue of 0.1 S m^{-1}. The NRPB concluded that 10 mA m^{-2} is an appropriate basic restriction on induced current density in the CNS for occupational exposure (NRPB, 2004a).

General public exposure

In respect of general public exposure, those exposed might include people potentially at increased risk from induced electric field effects, ie people with epilepsy, a family history of seizure, or using tricyclic antidepressants, neuroleptic agents and other drugs that lower seizure threshold. It should be noted that some workers may have these conditions. The ad hoc expert group (NRPB, 2004b, pp 197–205) considered that such sensitive people should be adequately protected at lower induced electric field strengths, possibly about a factor of five lower than for normal adults. In addition, the group considered

that this reduction factor would be adequate to protect the developing nervous system *in utero*, and in neonates and young children. It is concluded that a restriction of the induced electric field in the tissue of the CNS to less than 20 mV m^{-1} is adequate to protect these members of the population. The value of 20 mV m^{-1} was derived from a consideration of weak electric field effects in the CNS and corresponds approximately to the existing ICNIRP basic restriction on current density of 2 mA m^{-2}, assuming an electrical conductivity of CNS tissue of 0.1 S m^{-1}. The NRPB concluded that 2 mA m^{-2} is an appropriate basic restriction on induced current density in the CNS for general public exposure (NRPB, 2004a).

Reference levels

Calculations have been carried out by the NRPB, to judge the appropriateness of the ICNIRP (1998) reference levels for occupational and general public exposure to electric and magnetic fields of frequencies less than 100 kHz. These calculations indicate that the ICNIRP reference levels are appropriate for use at the initial stage of assessing compliance with the relevant basic restrictions on induced current density.

Further precautionary measures

There remain concerns about possible effects of exposure of children to power frequency magnetic fields (see, for example, Ahlbom et al, 2001). The view of the HPA is that it is important for Government to consider the possible need for further precautionary measures in respect of exposure of children to power frequency magnetic fields. In responding to this recommendation Government has set up a stakeholder group, SAGE (Stakeholder Advisory Group on ELF EMFs – see www.rkpartnership.co.uk/sage).

C3.2.3 Electromagnetic fields of frequencies above 100 kHz

Effects

The main physical effect of exposure to EMFs at frequencies above 100 kHz is heating of tissues (NRPB, 2004b). Adverse health effects may occur as a result of such heating. There have also been concerns that other adverse health effects may occur, including the induction of cancer and changes to cognitive function.

Epidemiological studies of groups exposed to radiofrequency (RF) fields have been variable in quality but reviews of the literature do not indicate that exposure to RF fields below guideline levels causes cancer.

Experimental studies indicate that heat-related disorders should not occur in the majority of healthy adults provided core body temperature does not rise above 38°C. Restricting exposures so as to ensure that any temperature increases are limited to less than a degree is judged to prevent adverse effects on the performance of all but the most demanding cognitive tasks. High rates of physical activity and/or warm, humid environments will reduce the additional RF heat loads that most adults can tolerate without exceeding 38°C. An RF heat load of 0.4 W kg^{-1} averaged over the whole body should be sufficiently low that these other factors can be ignored.

Individual susceptibility to heat-related disorders varies considerably in the general population. Infants, children and those in the later years of life may be considered particularly susceptible, although detailed information is lacking. In addition, adults taking certain drugs and other chemicals that have direct

effects on the control of body temperature, or on metabolism or heat production of the body, may also be considered at greater risk. An RF heat load of 0.1 W kg^{-1} averaged over the whole body should be physiologically trivial in this context. In addition, exposure of pregnant women to an average whole-body specific energy absorption rate (SAR) of 0.1 W kg^{-1} should not result in adverse effects on the development of the embryo and fetus *in utero*.

With regard to localised heating and the susceptibility of individual tissues to heat, the CNS, the testes and the lens of the eye seem particularly sensitive, the last more through a limited ability to dissipate heat than a greater sensitivity to heat *per se*. Temperature rises in the CNS (ie the brain, retina and spinal cord) to above 38°C, of the other tissues of the neck and trunk (with the exception of the testes) to above 39°C, and of the tissues of the limbs to above 40°C may result in localised heat-induced damage. The testes are particularly sensitive to the effects of heat; adverse effects should not occur in this tissue provided temperature increases are less than 1°C.

A number of studies suggest that low level RF fields may induce a variety of subtle biological responses. Of particular note are possible effects of pulsed fields on brain function and on changes in heat shock protein expression. Further work is needed to examine these and other possibilities, especially to consider if local heating effects may explain these results. Overall, none of these possible effects is considered sufficient to provide a coherent framework on which to base restrictions for human exposures.

Computational dosimetry enables the calculation of the link between external non-perturbed fields and the fields induced within the body. There are still relatively few dosimetric studies linking localised temperature increases and SAR in most parts of the body. However, with respect to exposure of the head from the use of mobile phones, there is a growing body of computational work available. These studies provide insight on the relationship between temperature rise and SAR in this case. The results indicate a range of localised temperature increases of 0.1 to 0.12°C in the brain from a localised SAR of 1 W kg^{-1}. The highest of this range of values indicates that, in order to limit the temperature in all parts of the brain to 38°C (corresponding to a temperature rise of 1°C above baseline) the SAR in the head, averaged over any 10 g cube, should not exceed about 8 W kg^{-1}.

Studies of heating in the eye suggest that an SAR of 1 W kg^{-1} averaged over the eye may lead to a temperature rise of up to 0.25°C in the region of the lens. Therefore, these studies indicate that in order to limit the temperature in the eye to 39°C, the SAR averaged over 10 g should be limited to about 8 W kg^{-1}.

A cautious approach has been used to derive thresholds for adverse health effects that are scientifically plausible. There is a need for key uncertainties in these data to be addressed through further research. The exposure metric for restricting exposure to fields of frequencies between 100 kHz and 10 GHz is the specific energy absorption rate (SAR), unit W kg^{-1}. For frequencies between 10 and 300 GHz, because of diminishing penetration into the body, the exposure metric is power density, unit W m^{-2}.

Occupational exposure

Whole body It is considered that limiting whole-body heat load induced by exposure to RF fields to less than 0.4 W kg^{-1} will prevent heat-related disorders (NRPB, 2004a). For most adults it is unnecessary to additionally account for high rates of physical work and/or hot, humid environments.

Partial body With regard to partial-body (localised) heating, limiting the rise in the temperature of the head and spinal cord to 38°C, of the other tissues of the neck and trunk (with the exception of the testes) to 39°C, and of the limbs to 40°C, should avoid any heat-induced damage in the tissues of these regions of the body. For the testes, the increase in temperature should be limited to 1°C, because of their greater sensitivity to heat. It is concluded that occupational basic restrictions on exposure should be aimed at limiting localised temperature rises to these values.

Calculations on possible temperature rises in the head and eye indicate the need to restrict localised SAR to about 8 W kg^{-1} averaged over a 10 g cube. These calculations also indicate that the highest average SAR over any contiguous 10 g mass is typically at least 50% greater than this. Adequate protection is therefore afforded by restricting localised SAR in the head and trunk to 10 W kg^{-1} averaged over any contiguous 10 g mass. However, given the range of published dosimetric data relating temperature rise with localised SAR, further dosimetric studies addressing this topic should be carried out.

General public exposure

Whole body General community protection, including of people potentially susceptible to heat-related disorders, will be assured if the whole-body RF heat load is kept below an SAR of about 0.1 W kg^{-1} (NRPB, 2004a). This will provide protection to older people, infants, children, pregnant women, other adults taking certain medications, and to people undertaking cognitively demanding tasks.

For frequencies between 100 kHz and 10 GHz this agrees reasonably well with the ICNIRP exposure guidelines basic restriction of 0.08 W kg^{-1} for the general public, a value that is a fifth of that for workers.

Partial body With regard to partial-body (localised) heating, limiting the rise in temperature of the head and spinal cord – and of the embryo and fetus – to 38°C, of the other tissues of the neck and trunk (with the exception of the testes) to 39°C, and of the limbs to 40°C, should avoid heat-induced damage in the tissues of these regions of the body. For the testes, the increase in temperature should be limited to 1°C, because of their greater sensitivity to heat. It is concluded that basic restrictions on exposure for the general public should be aimed at limiting localised temperature rises to these values.

Computational studies have been published on temperature rises that might arise from exposure of the head associated with the use of mobile phones. These studies provide insight on possible temperature increases that could result from a localised SAR of 2 W kg^{-1} averaged over 10 g mass of tissue. This value is one that has been adopted by ICNIRP as a basic restriction on localised SAR in the head and trunk for general public exposure and recommended by the Independent Expert Group on Mobile Phones (IEGMP, 2000), the Department of Health and the Board of the NRPB (NRPB, 2004c) as being appropriate for restricting exposure associated with mobile telephony. Computational results indicate localised temperature increases up to around 0.2–0.25°C could result in the brain from a localised SAR of 2 W kg^{-1}. Little work has been carried out on thermal dosimetry of the fetus or with computational models incorporating reduced organ perfusion rates as might be relevant to people with cardiovascular or other diseases.

It is considered that the appropriateness of the field reference levels for exposure of the general public needs to be reviewed for frequencies between about 50 and 100 MHz and above 1 GHz. Nevertheless, given the conservative assumptions used to derive the basic restrictions for the general public and the

assumption of optimal coupling to the field in deriving the reference levels, it is considered appropriate to use the ICNIRP reference levels at present.

The ICNIRP basic restrictions on whole-body and localised SAR should be used for restricting occupational and general public exposure to EMFs of frequencies greater than 100 kHz. Similarly, the ICNIRP (1998) reference levels for contact currents should be used for analysing the possibility of indirect effects of exposure (shock and/or burn).

Electrical effects on body tissues are also possible at frequencies above 100 kHz and up to about 10 MHz; hence basic restrictions to prevent these effects should also apply up to 10 MHz.

Reference levels

Calculations have been carried out by the NRPB to judge the appropriateness of the ICNIRP power density and limb current reference levels for occupational exposure to plane wave EMFs of frequencies greater than 100 kHz (NRPB, 2004b). These indicate that, with some minor reservations about the use of reference levels for small children above about 1 GHz, the reference levels for occupational and public exposure are appropriate for use at the initial stage of assessing compliance with basic restrictions on SAR. Further investigations of compliance, if indicated by exceeding these reference levels, should use the most up to date dosimetry methods.

C3.3 Future development of exposure guidelines

Recommendations for studies of the possible effects of EMF exposure, including epidemiological studies, especially in relation to cancer, reproductive and behavioural effects, have been given in a number of recent reviews (see NRPB, 2004b). Further work is being supported in the UK and in other countries, much co-ordinated through the WHO International EMF Project. In addition, the AGNIR is presently reviewing the effects of static magnetic fields and is expected to complete its report in about two years time. It will take into account work being conducted by the WHO and ICNIRP. The AGNIR has issued reports on possible health effects of exposure to extremely low frequency (ELF) and radiofrequency (RF) EMFs. It has a watching brief to keep this work under review.

ICNIRP is currently undertaking updates of its guidelines on limiting exposure to:

a static magnetic fields,

b time-varying electric and magnetic fields of frequencies <100 kHz.

Both of these will draw on health risk assessments of static magnetic fields (carried out in December 2004) and ELF electric and magnetic fields (carried out in October 2005). Both guidelines are expected to be completed by the end of 2007.

An update of the ICNIRP exposure guidelines on limiting exposure to RF radiation will follow:

a reviews of epidemiological, biological, and physics and engineering studies relating to exposure to RF radiation, being undertaken by the three ICNIRP standing committees for these areas of work,

b an IARC review of the carcinogenicity of RF radiation,

c a WHO health risk assessment of RF radiation.

C4 Guidance on Limiting Exposure to Ultraviolet Radiation

Ultraviolet radiation (UVR) is electromagnetic radiation covering the range of wavelengths 100–400 nm. It is divided into UVA 315–400 nm, UVB 280–315 nm and UVC 100–280 nm. The direct potential radiation hazards to health arise from UVR with wavelengths greater than 180 nm, since UVR of lower wavelength is strongly absorbed in air and common materials.

For most people the main source of UVR exposure is the sun, but for some individuals substantial exposures can also occur from artificial sources including tanning devices, industrial lamps, arc welding, and medical UVR therapies.

The health effects of UVR have been comprehensively reviewed by a number of scientific bodies (eg Gezondheidsraad, 1993; UNEP/WHO/ICNIRP, 1994; AGNIR, 1995, 2002; ICNIRP, 1999). Because of the limited penetration of UVR into the body, the main organs likely to be adversely affected as a result of excessive exposure are the skin and the eyes. Other possible adverse effects may occur as a result of systemic actions in the body, including those resulting from changes in the immune system.

The NRPB provided guidance on practical strategies for protection of workers and members of the general public against UVR (NRPB, 2002). It recognised that:

a the nature of the adverse health effects and how they relate to UVR exposure are diverse,

b exposures arise from a range of sources and in a variety of different circumstances,

c susceptibility to UVR varies among individuals.

C4.1 Summary of scientific evidence on health effects

The main tissues of the body affected by UVR are those of the skin and eye. Excessive short-term UVR exposure to the skin causes sunburn, and to the eye can cause acute damage to the cornea and conjunctiva; staring at the sun can damage the retina permanently. Certain individuals have abnormal skin responses to UVR exposure ('photosensitivity') because of genetic, metabolic or other abnormalities, or show photosensitive responses because of intake or contact with certain drugs or other chemicals. There is considerable experimental evidence in animal models and human subjects of suppressive effects of UVR on the immune system, but their significance for human health is generally unclear (AGNIR, 2002).

Chronic sun exposure leads to skin ageing and can raise the risk of both non-melanoma and melanoma skin cancers; the latter are the main cause of skin cancer death. Short, intense exposures of the type arising from sunbathing appear to be important in the causation of melanoma and possibly basal cell skin cancers. Childhood exposures may be particularly important. Although it has not been established directly whether sunbeds cause skin cancer, they are an appreciable source of intense, intermittent UVR exposure, and as such represent a potential health risk.

The main known benefit of UVR exposure is the generation of vitamin D, which is essential for healthy bone growth and maintenance. Vitamin D can be ingested from fatty foods, or synthesised in skin exposed to UVR. Dietary intakes of vitamin D may be insufficient to maintain adequate vitamin D levels. For most people, short periods outdoors in everyday life will produce sufficient vitamin D, and

additional or intensive exposures does not confer further benefit. Research is continuing into the possibility that dietary factors may limit risks of UVR-associated skin cancer, but this is not established.

C4.2 Advice on protection

Advice on limiting exposure to UVR aims to reduce the risk of adverse effects on human health. Because of the diversity of possible adverse health effects, their temporal, spatial and spectral dependence, the range of individual sensitivities to these effects and the variety of possible exposure conditions from many different types of sources, both artificial and the sun, such advice needs to include both quantitative advice on limits of exposure and qualitative guidance on protection methods.

An exposure limit is a quantitative value of exposure to UVR that is set below a level of exposure where a specific adverse health effect occurs. Exposure limits are based on scientific knowledge of the significance of temporal and spatial variations of exposure as well as the spectral efficacy of the radiation with respect to the adverse health effect. Advice on quantitative limits of exposure for the skin and eye has been derived directly from thresholds for erythema of the skin and photokeratitis of the eye, and additionally takes account of the risk of lenticular cataract.

Where a clear quantitative basis for exposure limits does not exist but where, nevertheless, there is acceptable scientific evidence of a quantitative or qualitative nature of a specific adverse effect, then advice is provided on measures that can be taken to reduce exposure. The measures recommended for reducing the risk of occurrence of adverse health effects depend on the practicality of their implementation. The advice from the NRPB (2002) sets out a balanced, cautionary approach to the provision of advice and its implementation based on these principles. Recommended measures include:

a limiting exposure of the eye to reduce the risk of lenticular cataract or other damage,

b preventing intense, repeated and cumulative exposure to UVR to reduce the risk of skin cancer.

The nature of the advice on reducing exposure varies according to the conditions – for example, whether the exposure is controllable at source, such as from artificial sources, or not, such as from the sun. There is a wide range of scenarios that might arise and these influence the nature of the measures that are appropriate to reduce exposure.

The risks of adverse health effects from the different exposure situations are considered to be additive. However, in practice, advice on assessments of corresponding risks and judgements as to appropriate protective measures can only be provided for each exposure situation.

The scope of the advice provided sets out to address all foreseeable circumstances of exposure, except those related to patients under qualified medical supervision. In the advice from the NRPB (2002) quantitative limits to avoid specific adverse health effects are given where the scientific evidence supports them and where the exposure circumstances provide the opportunity to implement them in practice. Practical advice is provided on engineering and administrative controls and on personal protection where appropriate. The situations that can give rise to exposure for workers and members of the public are summarised below.

C4.2.1 Occupational exposure

Exposure of a worker can arise from:

a the use of artificial sources of UVR in the workplace (a controlled environment) when exposure limits apply – engineering and administrative controls and personal protection are necessary to limit exposure,

b the sun – while the strict application of quantitative exposure limits is not practical because of considerations of exposure geometry and human behaviour, it is important to limit exposure by the use of engineering and administrative controls and personal protection.

C4.2.2 Public exposure

Exposure of a member of the public can arise from:

a the use of artificial sources of UVR in an environment where the exposure can be controlled when exposure limits apply – engineering and administrative controls are needed to avoid or limit exposure (this applies, for example, to a member of the public exposed to a lighting system, such as unfiltered tungsten halogen lamps, used for entertainment or display),

b the use of artificial sources of UVR where it is not always possible to control the exposure, and the strict application of quantitative exposure limits is not practical – however, it is important to limit exposure by the use of administrative controls and, where appropriate, personal protection (for example, a member of the public inadvertently exposed to a welding arc in a garage or similar accessible environment),

c elective exposure to artificial sources (such as tanning devices) – application of exposure limits is not practical because the intended outcome of the elective exposure (for example, a suntan) would not be achieved – advice is needed on adherence to published manufacturing and use standards and on protective measures,

d elective exposure from the sun (sunbathing) – strict application of the exposure limits is not practical because the exposure cannot normally be accurately measured, and the intention is to achieve a suntan in which case the exposure limits are likely to be exceeded,

e incidental exposure to the sun during outdoor activities.

C4.2.3 Exposure limits

A number of comprehensive reviews of biological effects associated with UVR exposure have been undertaken in recent years (UNEP/WHO/ICNIRP, 1994; AGNIR, 1995, 2002). The rationale for the exposure limits for UVR produced by ICNIRP was reviewed in 1999 (ICNIRP, 1999). A number of other national and international organisations have also produced guidelines on limiting exposure to UVR (Gezondheidsraad, 1993; ACGIH, 2001). These are based on the same basic biological criteria. The quantitative limits on exposure to UVR are derived from the threshold levels that produce short-term adverse health effects. A review of uncertainties in threshold measurement data and the reliability in deriving occupational exposure limits from such data has also been published (Sliney, 1998).

In view of the uncertainties in scientific data and the lack of quantitative information on exposure-response relationships for some effects, it is considered that a balanced, cautionary approach is required in relation to UVR exposure, which will ensure that exposures are kept below thresholds for short-term health effects where practical, and also reduce the risk of long-term damage. These effects include short-term damage, such as erythema of the skin and photokeratitis of the eyes, and long-term damage, such as the induction of cancers and lenticular cataract, and acceleration of skin ageing.

Advice on limiting exposure has to account for the diversity of the possible health effects, their temporal, spatial and spectral dependence; the range of individual sensitivities to these effects; and the diversity of possible exposure conditions from many different types of sources, both artificial and the sun.

The nature of the advice provided necessarily varies according to the circumstances of the exposure. Quantitative limits are particularly applicable for circumstances where the cumulative exposure can readily be measured or estimated and where the exposure limits can be practically implemented. For other circumstances – for example, where compliance with quantitative limits on exposure cannot readily be assessed – strict implementation of quantitative limits is not practicable and advice is therefore provided on cautionary measures that can be taken to limit exposure.

The limits defined are those for which current biological studies (AGNIR, 2002) indicate levels at which nearly all individuals may be repeatedly exposed without adverse health effects. The limits, termed exposure limit values (ELVs), apply to exposure to artificial sources where irradiances and exposure durations can be controlled. Hence, they apply directly to workers exposed to artificial UVR sources, and, wherever possible, to non-elective exposure of members of the public to UVR from artificial sources such as those used in industry and general and localised task lighting.

Exposure limit values are derived from threshold levels that produce short-term adverse effects on the skin and eyes. They apply to exposures equivalent to that directed perpendicular to those surfaces of the body facing the radiation source, measured with an instrument having an appropriate angular response (ICNIRP/CIE, 1998). The irradiance and the radiant exposure should be measured using an aperture, which is adequate to detect any areas of high irradiance in the incident radiation field.

In recommending ELVs for protection from UVR, the NRPB took into account the limits published by ICNIRP (1999). Other limits, published by national bodies, are in broad agreement with these values (Gezondheidsraad, 1993; ACGIH, 2001); however, the NRPB recognised that there are uncertainties related to the experimental data on which these limits are based, and scientific evidence of the existence of detrimental long-term health effects (AGNIR, 2002). Therefore, the NRPB recommended the adoption of ELVs proposed by ICNIRP (1999), and additionally a balanced, cautionary approach to reducing exposure wherever possible.

Exposure limit values relate to both the skin and the eye and may be used to evaluate potentially hazardous exposures from incoherent UVR sources, such as arcs, gas and vapour discharges, fluorescent lamps and incandescent sources. Most incoherent UVR sources are broadband, although single emission lines can be produced from low pressure gas discharges.

It was recommended that the ELVs be used as guides in the control of exposure to UVR sources and as limits for non-medically-supervised exposures of people and for non-elective exposures.

The spectral designations published by the International Commission on Illumination (CIE) (CIE, 1970; IEC, 1987) are used in defining ELVs. These are UVA (315–400 nm), UVB (280–315 nm) and UVC (100–280 nm). UVR exposure is quantified in terms of irradiance (W m^{-2}) for continuous exposure or in terms of radiant exposure (J m^{-2}) for time-integrated (or pulsed) exposures of the eye and skin.

The basic exposure limit value (ELV) for both general public and occupational exposure to UVR incident perpendicular to the skin or eye is an effective radiant exposure of 30 J m^{-2} within any 8-hour period (ICNIRP, 1999). This assumes that the exposure is delivered during any period of 8 successive hours, even where such a period overlaps work shifts or calendar days. Effective radiant exposure (J m^{-2}) is the product of exposure duration (s) and effective irradiance (W m^{-2}). Effective irradiance is the spectral irradiance at the eye or skin surface, mathematically weighted with the hazard relative spectral effectiveness factor and summed from 180 to 400 nm, as follows:

$$E_{\text{eff}} = \sum E_{\lambda}\, s(\lambda)\, \Delta\lambda$$

where E_{eff} is the effective irradiance in W m^{-2}, E_{λ} is the spectral irradiance from measurements in W m^{-2} nm^{-1}, $s(\lambda)$ is the relative spectral effectiveness factor, and $\Delta\lambda$ is the bandwidth of the calculation or measurement in nm. At 270 nm in the UVC, $s(\lambda)$ is 1.0, but at 360 nm in the UVA, its value falls to 0.00013, and continues to fall for longer wavelengths. In addition to limiting E_{eff} to 30 J m^{-2}, the total UVA radiant exposure incident on the unprotected eye should also not exceed 104 J m^{-2} within any continuous 8-hour period (ICNIRP, 1999).

The ELVs defined above might readily be exceeded for solar radiation exposure and by elective exposures such as the use of sunbeds. For example, in the UK the ELVs can be exceeded by solar radiation exposure around noon in summer in less than about 20 minutes. They can also be exceeded for UVR exposures of patients required as a part of medical diagnosis or treatment or for elective cosmetic purposes (such as with sunbeds).

In such circumstances, strict adherence to quantitative limits and their practical implementation may be neither appropriate nor possible and additional strategies are required to limit exposure.

C4.2.4 Advice on limiting exposure to UVR and health promotion

Adherence to the limits on exposure as advised above will avoid short-term adverse health effects and reduce the risk of developing long-term adverse health effects. The degree to which the potential for damage to health will be reduced is difficult to quantify in the current state of scientific knowledge about dose–response relationships, although evidence for an effect is clear (AGNIR, 1995, 2002). Hence, there is a need to minimise the possible increase in risk of long-term adverse health effects which result from long-term exposure to UVR by taking additional measures that can be described qualitatively, and provide protection of the skin and eyes. The measures include:

a avoiding needless exposures to UVR,

b limiting exposure to UVR whenever exposure will exceed the ELV,

c avoiding repetitive exposure up to the ELV.

Practical strategies for controlling UVR exposures in a wide range of different circumstances are discussed in detail elsewhere (NRPB, 2002). Where exposure is unintentional and to workers, appropriate control and/or personal protective measures are recommended. Where exposure of the general public is to the sun, advice on protective measures is given. Where exposure is to artificial sources, including suntanning devices, protective measures are essential. The use of devices for elective tanning is discouraged. However, if such devices are used, adherence to published standards on usage is essential.

Individual sensitivity to UVR varies considerably. Risks of skin cancer are greatest in people with fair complexions (light skin, red or blonde hair, and blue eyes) and sun-sensitive skins, and melanoma risks are

Ten ways to minimise sun-induced skin and eye damage (AGNIR, 2002)

1	Take sensible precautions to avoid sunburn, particularly in children.
2	Remember that a suntan offers only modest protection against further exposure. It is not an indication of good health.
3	Limit unprotected personal exposure to solar radiation, particularly during the four hours around noon, even in the UK.
4	Seek shade wherever possible, but remember sunburn can occur even when in partial shade or when cloudy.
5	Remember that overexposure of skin and eyes can occur while swimming and is more likely when there is a high level of reflected UVR, such as from snow and sand.
6	Wear suitable head wear, such as a wide-brimmed hat, to reduce exposure to the face, head and neck.
7	Cover skin with clothing giving good protection – examples are long-sleeved shirts and loose clothing with a close weave.
8	Sunglasses should exclude both direct and peripheral exposure of the eye, ie be of a wrap-around design.
9	Apply sunblocks, or broadband sunscreens with high sun protection factors (at least SPF*15) to exposed skin. Apply generously and reapply frequently†.
10	Remember that certain individuals have abnormal skin responses to UVR exposure and may need medical help. Certain prescribed drugs, medicines, foods, cosmetics and plant materials can make people more sensitive to sunlight.

* The sun protection factor (SPF) is the ratio of the UVR exposure to produce minimal erythema on a skin site protected by sunscreen to the UVR exposure to produce a comparable erythema on unprotected skin. For example, an SPF of 20 would reduce exposure to 5% of that of unprotected skin.

† The SPF is assessed after phototesting *in vivo* at an internationally agreed application thickness of 2 mg cm^{-2}. However, a number of studies have shown that consumers apply much less than this, typically between 0.5 and 1.5 mg cm^{-2}. Application thickness has a significant effect on protection, with most users probably achieving a mean value of between 20 and 50% of that expected from the product label as a result of common application thickness. In other words, to achieve the required degree of protection, it is important that the sunscreen is applied generously and reapplied frequently.

raised in those with many and atypical naevi. The erythemal and tanning responses are commonly used to group sensitivity into different skin types and these need to be taken into account in determining appropriate protective measures.

The AGNIR has advised on ten ways to minimise sun-induced damage by the public. These approaches are to be considered in educational and awareness programmes for UVR and solar protection (see the table on page 57).

C4.3 Future development of exposure guidelines

The ICNIRP standing committee on optical radiation has prepared a detailed report on protecting workers from UVR. This report was published in collaboration with the WHO and ILO (ICNIRP et al, 2007) and will be reviewed by the HPA RPD.

C5 Guidance on Limiting Exposure to Laser Radiation

Laser radiation is considered to be monochromatic optical radiation but many laser devices may emit laser radiation at a number of discrete wavelengths. The range of devices covers most of the optical wavelength spectrum from 100 nm to 1 mm. Many, but not all, laser products emit a laser beam that is well collimated.

The laser was first successfully demonstrated in 1960. Applications for laser technology have multiplied since then but, until the late 1990s, they remained within the professional domain. However, lasers are now widely available to the public in consumer products.

The irradiance (W m^{-2}) within the laser beam may be very high over a considerable part of the laser beam path, due to the achievable high radiant power and small beam area. Under such conditions, the probability of human exposure to the beam may be very small, but the consequences should such an exposure occur, could be quite serious.

They key organ of concern is the eye. At high irradiance levels, even very short duration exposure could result in complete destruction of vision. The skin may also be at risk, and usually presents a larger target area.

C5.1 Summary of scientific evidence on health effects

The broad range of possible laser beam wavelengths means that there is a range of potential health effects following exposure of either the eye or the skin. Concerns over potential chronic effects due to long-term, low level exposures to monochromatic radiation have not been realised over the 45 years of potential and actual exposures.

For both the eye and the skin, the depth of penetration of optical radiation is wavelength dependent. For the eye, optical radiation is transmitted through to the retina for wavelengths between 400 and 1400 nm, although the boundaries do not represent sharp cut-offs in practice. A visual stimulus is

produced by optical radiation from approximately 400 to 780 nm peaking at about 550 nm, although, again, these boundaries do not represent sharp cut-off points.

Of particular concern is the wavelength region from 780 to 1400 nm. These wavelengths are focused by the cornea and lens on to the retina but produce no visual stimulation, apart from fluorescence at the damaged site. Between 700 and 780 nm it is possible to exceed the exposure limits with radiation appearing to be just a dull red glow. Above 1400 nm and below 400 nm the anterior parts of the eye tend to absorb the laser radiation. The peak transmission of optical radiation in the skin is at about 1000 nm.

ICNIRP has reviewed the scientific literature on the effects of laser radiation and has published guidelines for exposure limits (ICNIRP, 1996, 2000a). The exposure limits have been determined by a review of experimental data from a range of laboratories, taking into account uncertainties in dosimetric parameters. In general, a probit analysis has been used to determine the ED_{50} for observable lesions. A comparison of data from different laboratories showed that microscopic injuries did not occur below one-tenth of the ED_{50}, and usually appeared at between 25 and 50% of this value. The revision of the exposure limits in 2000 (ICNIRP, 2000a) recognised the development of laser technology to be able to produce sub-nanosecond pulses and the potential for intrabeam viewing of laser radiation in the retinal hazard region (400 to 1400 nm). Long-term viewing will result in different parts of the retina being exposed due to natural eye movements and other physiological factors.

C5.2 Advice on protection

To address the complexity of potential exposure conditions from laser sources, a laser classification scheme was developed to provide guidance to users. The current version, produced by the International Electrotechnical Commission, is published in a British Standard (BSI, 2007). The classification scheme takes account of the exposure limits published by ICNIRP and makes some assumptions about exposure conditions. These assumptions have been based on occupational exposure and do not take account of use of laser products in the domestic environment, particularly by children. The NRPB gave advice to the Department of Trade and Industry in December 1998 suggesting that only Class 1 or Class 2 laser products should be generally available to the public. However, it is recognised that Class 2 laser products are not without risk. Staring into the beam from a Class 2 laser product may result in a retinal injury. Even Class 1 laser products may produce sub-damage-threshold effects, such as dazzle, distraction and after-images. The safety implications will usually depend on the task being carried out by the recipient of the laser beam.

C5.3 Future development of exposure guidelines

Laser technology continues to develop and present new challenges for exposure guidelines. Issues that continue to be considered by the ICNIRP standing committee on optical radiation include: lasers that produce extremely short (sub-picosecond) pulses and wide-wavelength-spectrum lasers, due to uncertainties on the exposure limits for such sources; exposure limits for human tissues other than the eye and the skin – for example, when laser beams are used for non-surgical applications inside the body;

whether exposure limits should be extended below 180 nm; and the complexities of sources which produce large retinal images.

C6 Guidance on Limiting Exposure to Broadband Optical Radiation other than Ultraviolet Radiation

Optical radiation from 380 nm to 1 mm, that is not laser radiation, is termed either incoherent optical radiation or broadband optical radiation, to distinguish it from laser radiation. Radiation with wavelengths from approximately 380 to 780 nm produces a visual sensation in the eye. Radiation with wavelengths longer than 700 nm is termed infrared (IR) radiation and is subdivided into IRA 700–1400 nm, IRB 1400–3000 nm and IRC 3000 nm – 1 mm. It should be noted that there is some overlap with the ultraviolet region and between visible wavelengths and infrared radiation.

Potential sources of broadband optical radiation include the sun, general lighting, signal and indicator systems, heating systems, and medical/aesthetic and security applications. ICNIRP issued a statement in 2000 suggesting that light emitting diodes (LEDs) should not be considered as laser devices, so these are also included here (ICNIRP, 2000b).

C6.1 Advice on protection

Although health effects are possible across the whole wavelength spectrum, the retinal hazard region from 380 to 1400 nm is considered the most important. It should also be recognised that some sources will emit optical radiation in the ultraviolet region in addition to the required wavelengths.

In contrast to wavelengths outside the 380–780 nm region, for wavelengths in the visible region, it is not necessarily appropriate to reduce the level of exposure to the lowest practicable level. An obvious example is where the optical radiation is used for task illumination. The response of the eye to optical radiation across the visible region is not constant. It peaks at about 550 nm under high illumination levels and shifts to about 510 nm under low illumination levels. Over the range 380–780 nm, the relative response ranges over a factor of about 7000. Even at the lower limits of the eye's wavelength response, the optical radiation may be perceived if there is sufficient radiance. However, it is possible that the optical radiation may present a risk of injury at these levels.

Exposure to light sources that are bright, ie induce a large visual response, may cause sub-damage-threshold effects, such as dazzle, distraction, glare and after-images. The body has a number of systems to manage such high level light sources, including the aversion response and variation of the diameter of the pupil. However, the ambient light level before the insult can affect the ability of an individual to continue with a task post-exposure.

Exposure limit values are published by ICNIRP for broadband incoherent optical radiation (ICNIRP, 1997). Consideration is taken of the risk of retinal thermal hazards (300–1400 nm), blue-light photochemical retinal hazards (300–700 nm), infrared radiation hazards to the eye (780–3000 nm) and thermal injury to the skin. Guidance is also given for the retinal photochemical hazard to the aphakic and infant eye (300–700 nm).

In contrast to laser radiation, where the risk of exposure is generally small but the health consequence could be large, with non-laser radiation sources, the risk of exposure is usually higher with lower consequences. This higher risk of exposure means that consideration needs to be given to individuals who may be particularly sensitive. These will include people who may be taking drugs or applying topical lotions that may make them particularly photosensitive.

The ICNIRP guidance does not provide ELVs for wavelengths between 3000 nm and 1 mm. Until relatively recently, non-laser sources in this wavelength region were rare. However, the development of terahertz sources for a range of applications, including medical and security applications (Davies at al, 2004), means that this region now needs to be considered. ICNIRP considers that the key health issue at wavelengths from 3000 nm to 1 mm is heat stress and refers to work in this area by the ACGIH (2001). ICNIRP published a statement on far-infrared radiation in 2006 (ICNIRP, 2006).

The CIE has published a standard with a lamp classification scheme similar to that for laser products (CIE, 2002). This was adopted as an IEC standard during 2006 (IEC, 2006).

C6.2 Future development of exposure guidelines

The ICNIRP standing committee on optical radiation continues to review the biological data. It is important that any difference between exposure limits for laser and non-laser optical radiation can be justified. LEDs have been removed from the scope of IEC 60825-1 (BSI, 2007), except for LEDs used for communication purposes, in Edition 2. It is also proposed within the IEC to produce a manufacturing safety standard for products containing non-laser optical radiation sources to support IEC 62471 (IEC, 2006).

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Acronyms

ACGIH	American Conference of Governmental Industrial Hygienists
ACHS	Advisory Committee on Hazardous Substances
ACP	Advisory Committee on Pesticides
ACTS	Advisory Committee on Toxic Substances
ADI	Acceptable daily intakes
AEGLS	Acute exposure guideline levels
AGIR	Advisory Group on Ionising Radiation
AGNIR	Advisory Group on Non-ionising Radiation
ALARA	As low as reasonably achievable
ALARP	As low as reasonably practicable
AQS	Air quality standards
CERRIE	Committee Examining Radiation Risks of Internal Emitters
CHaPD	Chemical Hazards and Poisons Division (of the HPA)
CHM	Commission on Human Medicines
CICAD	Concise International Chemical Assessment Document
CIE	International Commission on Illumination
CNS	Central nervous system
COC	Committee on Carcinogenicity of Chemicals in Food, Consumer Products and the Environment
COM	Committee on Mutagenicity of Chemicals in Food, Consumer Products and the Environment
COMARE	Committee on Medical Aspects of Radiation in the Environment
COMEAP	Committee on Medical Effects of Air Pollutants
COT	Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment
DDREF	Dose and dose rate effectiveness factor
Defra	Department for Environment, Food and Rural Affairs
DH	Department of Health
DTI	Department of Trade and Industry
DTLR	Department for Transport, Local Government and the Regions
DWI	Drinking Water Inspectorate
DWP	Department of Work and Pensions
EA	Environment Agency
EC	European Commission/Council
ED_{50}	Effective dose, 50% (dose of a toxic substance or radiation required to produce a specified effect in 50% of the exposed population)
EFSA	European Food Safety Authority
EHC	Environmental Health Criteria
ELF	Extremely low frequency
ELVs	Exposure limit values

EMF	Electromagnetic field
EMEA	European Medicines Agency
EPAQS	Expert Panel on Air Quality Standards
EU	European Union
FAO	Food and Agriculture Organization
FSA	Food Standards Agency
HPA	Health Protection Agency
HSC	Health and Safety Commission
HSE	Health and Safety Executive
IAEA	International Atomic Energy Agency
IARC	International Agency for Research on Cancer
ICNIRP	International Commission on Non-Ionizing Radiation Protection
ICRP	International Commission on Radiological Protection
IEC	International Electrotechnical Commission
IEGMP	Independent Expert Group on Mobile Phones
IEH	Institute of Environment and Health
IGHRC	Interdepartmental Group on Health Risks from Chemicals
ILO	International Labour Organization
INIRC	International Non-Ionizing Radiation Committee
IPCS	International Programme on Chemical Safety
IR	Infrared
IRPA	International Radiation Protection Association
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticide Residue
LD_{50}	Lethal dose, 50% (dose of a toxic substance or radiation required to cause death in 50% of the exposed population)
LED	Light emitting diode
LET	Linear energy transfer
LOAEL	Lowest observed adverse effect level
MHRA	Medicine and Healthcare Products Regulatory Agency
NEA	Nuclear Energy Agency
NOAEL	No observed adverse effect level
NRPB	National Radiological Protection Board
OECD	Organisation for Economic Co-operation and Development
PSD	Pesticides Safety Directorate
PF	Power frequency (50 Hz in the UK)

RF	Radiofrequency
RPD	Radiation Protection Division (of the HPA)
SAGE	Stakeholder Advisory Group on ELF EMFs
SAR	Specific energy absorption rate
SCOEL	Scientific Committee on Occupational Exposure Limits
SPF	Sun protection factor
TDI	Tolerable daily intake
UN	United Nations
UNEP	United Nations Environment Programme
UNSCEAR	United Nations Scientific Committee on the Effects of Atomic Radiation
UV	Ultraviolet
UVR	Ultraviolet radiation
VMD	Veterinary Medicines Directorate
VPC	Veterinary Products Committee
WATCH	Working Group on Action to Control Chemicals
WHO	World Health Organization

Quantities and Units

Quantity	Units	Notes
Ionising radiation		
Absorbed dose	gray (Gy) joules per kilogram	
Equivalent dose	sievert (Sv)	Absorbed dose (Gy) multiplied by radiation weighting factor for the type of radiation
Effective dose	sievert (Sv)	Sum of equivalent doses (Sv) to organs and tissues multiplied by tissue weighting factors
Committed effective dose	sievert (Sv)	Total effective dose delivered over a lifetime from radionuclides taken into the body
Non-ionising radiation		
Electromagnetic fields		
Frequency	hertz (Hz)	EMFs 0 to 300 GHz Radiofrequencies 100 kHz to 300 GHz
Wavelength	metres (m)	
Electric field strength	volts per metre (V m^{-1})	
Magnetic flux density Magnetic field strength	tesla (T) amperes per metre (A m^{-1})	
Current density	amperes per square metre (A m^{-2})	
Specific energy absorption rate (SAR) (heat load)	watts per kilogram (W kg^{-1})	Exposure measure for restricting exposure to EMFs of frequencies between 100 kHz and 10 GHz
Power density	watts per square metre (W m^{-2})	Exposure measure for restricting exposure to EMFs of frequencies between 10 GHz and 30 GHz
Ultraviolet radiation		
Wavelength	metres (m)	UVA 315–400 nm UVB 280–315 nm UVC 100–280 nm
Irradiance	watts per square metre (W m^{-2})	Exposure measure for continuous exposure of eye or skin
Spectral irradiance	watts per square metre per metre (wavelength) (W m^{-2} m^{-1})	Irradiance for UVR wavelengths within a specified band
Effective irradiance	watts per square metre (W m^{-2})	Irradiance multiplied by a wavelength-dependent effectiveness (weighting) factor
Radiant exposure	joules per square metre (J m^{-2})	Exposure measure for time-integrated (or pulsed) exposure of eye or skin
Effective radiant exposure (exposure limit value (ELV) defined in terms of effective radiant exposure within fixed periods)	joules per square metre (J m^{-2})	Radiant exposure multiplied by a wavelength-dependent effectiveness (weighting) factor