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Principes van stralingsbescherming

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the Dutch policy document ‘Radiation protection and risk management’

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Advies van een commissie van de Gezondheidsraad
Report of a committee of the Health Council of the Netherlands

to

the Minister of Health, Welfare and Sports

the Minister of Housing, Spatial Planning and Environment

the Minister of Social Affairs and Employment

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Contents

Executive summary

In this report a committee of the Health Council of the Netherlands with experts from the Netherlands, Sweden and the US compares the principles for radiological protection of the International Commission on Radiological Protection (ICRP) with those of the Netherlands Government. The report responds to a request from the Minister of Housing, Spatial Planning and Environment.

The ICRP system of protection has been defined most recently in the '1990 Recommendations of the ICRP'. The principles for protection of the public against ionising radiation in the Netherlands, denoted by 'OmRS' in this report, are described in the policy document 'Radiation protection and risk management' of 1990 and further clarified in a follow-up document published in 1993 and in subsequent letters of the Government to Parliament.

The committee has restricted its report to non-accident situations. On request of the President of the Health Council it also discusses occupational exposure, but only summarily.

Protection systems

The ICRP system for protection of the public against ionising radiation is part of a coherent system of radiological protection, that also includes protection against occupational and medical exposure. The ICRP aims at protecting health against the harmful effects of ionising radiation without unduly hampering the beneficial uses of radiation sources. The OmRS policy document sets out a policy for radiological

protection as part of the environmental risk management policy of the Netherlands government. Health protection should be realised by restricting the probability of death attributable to radiation sources below defined limits (environmental quality objectives). Protection against occupational exposure is only treated summarily in the OmRS-document.

Justification, optimisation and limits

Some human activities may increase the radiation exposure of the population and should therefore be subject to control. For such activities, called practices, ICRP recommends, as a first stage in deciding on their tolerability for society, to investigate whether the benefits outweigh the economic and social costs. Only practices that produce a net benefit, and are thus justified, should be adopted or continued, provided that the radiological protection measures are optimised. This implies that individual doses, the number of people exposed and the potential (accidental) exposures should be as low as reasonably achievable (ALARA), taking social and economic factors into account. Dose constraints should be used as boundary values in the optimisation process to prevent that justification and optimisation would lead to an intolerable degree of inequity in individual risk. They reflect criteria for ‘good radiological protection practice’ and may therefore differ between broad categories of practices or groups of exposed persons. The individual dose limit on public exposure is set by ICRP to 1 millisievert of effective dose per year and serves as a reference point (and upper limit) for deriving dose constraints related to the exposure of the general public. It refers to the total exposure from all practices within the scope of the protection system.

OmRS also uses the concepts of justification, optimisation and limits, but with a different meaning. From the environmental policy point of view, activities are unjustified if they are counterproductive in reaching the objectives of environmental policy. Furthermore the probability of death attributable to one year of exposure (the so-called ‘individual risk’) should not exceed the maximum permissible risk level of 1 per 1 000 000 per year. This level is derived from the maximum permissible risk level of 1 per 100 000 per year, related to the exposure from all radiation sources within the scope of the system, by division by a factor of 10. The maximum permissible risk level for one source is considered by OmRS to correspond to an effective dose of 0,04 millisievert per year and the maximum permissible risk level for all sources to a dose of 0,4 millisievert per year. Below the maximum permissible risk level optimisation should be applied and, in principle, further constraints may be set by the authorities as part of the licensing process.

The basis for justification of a practice proposed by ICRP differs fundamentally from that of OmRS. According to the ICRP the benefits of a practice are an essential part of the justification equation. In OmRS the maximum permissible risk level is the primary justification criterion, and benefits are not taken into account.

The maximum permissible risk level for one source of OmRS may also be viewed as a first step in limiting individual radiation exposures associated with a given practice. In the ICRP approach application of reasonable dose constraints in the optimisation of protection may be considered to be such a first step. Whereas the maximum permissible risk level of OmRS has an equal value for all sources, the ICRP dose constraints may differ between groups of practices.

One of the aims of the environmental risk management policy of the Netherlands Government is to provide equal levels of protection against different environmental agents. It tries to realise that purpose by setting identical maximum permissible risk levels for different agents. However, setting equal limits on the probability of death does not guarantee equal levels of protection, given the different nature of agents, such as radiation, carcinogenic and non-carcinogenic substances and the possibility of industrial accidents, with their possible differing health effects.

Depending on how the protection systems of the ICRP and OmRS are worked out, both may lead to levels of protection that are considered to be sufficient by the parties involved. The committee points out that both the ICRP and the OmRS protection system, as far as public or environmental exposure is concerned, pertain to a small part of the radiation dose that individuals or groups in the general population may receive. The largest contribution to the dose of the population stems from natural sources and is essentially uncontrollable.

Magnitude of limits

ICRP provides two arguments for its dose limit of 1 millisievert per year for public exposure. The first is related to the estimated harm in people continuously exposed to levels up to the dose limit. It is argued that the possible harm, given its nature and distribution in the course of time, could probably not be considered intolerable on an individual basis. The second argument is related to the natural background radiation. Geographical variations in background radiation (excluding inhaled radon decay products) have an order of magnitude of one millisievert per year and have not led to observable harm in large population groups.

In OmRS the ‘individual risk’ (per year) is related to lifelong, chronic radiation exposure. This implies that this concept does not represent the excess mortality rate later in life due to exposure in a given year, as in the ‘external safety’ policy. One might say that OmRS establishes a limit on the excess probability of dying from

cancer, associated with lifelong exposure from all functional applications of radiation sources and non-nuclear industries, of 1 per 1000 and with radiation exposure from a single source of 1 per 10 000. These 'lifetime risk' limits then correspond to dose limits of 0,4 millisievert per year and 0,04 millisievert per year, respectively, using a value for the human lifespan of 100 years. (If the relationship between dose and increase in cancer mortality, the so-called nominal probability coefficient, derived by ICRP had been used the corresponding values would have been 0,2 and 0,02 millisievert per year.)

OmRS states that for any radiation source the individual dose should be lower than 0,04 millisievert per year. Further guidelines state that below 0,0004 millisievert per year further optimisation to reduce radiation exposure has no priority for the Government.

The setting of dose constraints, as recommended by ICRP, leaves a larger degree of flexibility than the OmRS approach, because there is more room for deciding on the appropriate technical means to obtain a balance between health benefits of exposure reduction and costs of that reduction.

Risk and cancer

The committee has also assessed the differences between the two systems of protection against the background of new insights on the concept of risk and on the relationship between radiation dose and the incidence of cancer, obtained during the last two decades. 'Risk', as used in deciding on the tolerability of human activities, is a multi-attribute concept. Narrowing it to, *e.g.*, the probability of death associated with an activity, is an oversimplification and might mask elements that are important in policy decisions.

A relevant health effect associated with radiation exposure is cancer. It is assumed, for radiological protection purposes, that even low radiation doses increase the probability of cancer later in life in proportion to the dose. The present view is that radiation is not a direct cause of cancer, but that it is one of the factors that, together, may lead to the development of a malignant tumour. Radiation may be described as an environmental factor that increases the susceptibility to cancer, an illness that predominantly manifests itself at older ages. The excess cancer mortality in an exposed population appears to have an age distribution that does not differ appreciably from that of the 'normal' cancer mortality.

The committee concludes that ICRP takes these views explicitly into account, whereas OmRS does not.

Overview

In the table below the committee has summarised the differences between the two systems for protecting the general public against ionising radiation.

In this table the committee lists the main differences between the system of radiological protection of the general public recommended by the ICRP in 1990 and that of the Netherlands Government. The numbers in the fourth column refer to the section in this report where the subject is treated in more detail.

	ICRP	Netherlands Government (OmRS)	
objective	protection of the public against risks associated with radiation exposure[a]	protection of the public against risk associated with industrial accidents and environmental agents, including radiation	2.5, 8.2
	beneficial uses of radiation sources should not be unduly hampered	exposure to be limited by environmental quality objectives	
basic principles[b]	practice is justified if it produces a net benefit, *i.e.* if its benefits exceed its costs	practice is only justified if the radiation exposure is below a dose limit, corresponding to a maximum permissible risk limit for one source	4
	optimisation of radiological protection (ALARA)	optimisation of radiological protection (ALARA) below a dose limit for a single source	
	individual dose limit as a final safeguard to avoid intolerable individual exposure from all practices		
assumed excess cancer mortality per unit (effective) dose	5 per cent per sievert	2,5 per cent per sievert	5
method of dose limitation	optimisation with dose constraints, depending on the nature of the practice	equal dose limit for a each source, below which optimisation with possibly further constraints should be applied	4, 5
magnitude of the dose limit	1 millisievert per year for all practices together; practice related dose constraints are less than this value	0,04 millisievert per year for each source[c]	5
rationale for the dose limit	1 millisievert per year does not lead to intolerable risk according to model calculations and is less than the geographical variation in the dose from natural radiation sources	0,04 millisievert per year is supposed to correspond to an excess cancer mortality 1 per 1 000 000 per year of exposure (population average, chronic exposure)	5, 8.3

[a] The ICRP system of protection of the public is part of a general, coherent system of protection against risk associated with occupation, medical and public radiation exposure.

[b] For activities that increase the radiation exposure of the public, called practices by the ICRP and functional applications and non-nuclear industries in the 'Radiation protection and risk management' document of the Netherlands Government.

[c] This should guarantee that the effective dose from all functional applications and non-nuclear industries does not exceed 0,4 millisievert per year, the effective dose corresponding to a maximum permissible risk level for all sources of 1 per 100 000 per year.

Chapter 1

Introduction

1.1 'Omgaan met risico's van straling' ('Radiation protection and risk management')

Similar to developments in other countries, in the Netherlands interest in protection against ionising radiation goes back to the 20s. As early as 1926 the Health Council advised the Netherlands Government on radiological protection standards (GR26). In 1969 the 'Kernenergiewet' (Nuclear Energy Act) came into force and subsequently all regulations for protection against ionising radiation have been based on this act. The regulations have, up until now, followed closely the Euratom Basic Safety Standards, an European Union directive.

In 1987 the Government discussed its radiological protection policy with the Lower House of Parliament in relation to changes in the Radiation Protection Decree that were necessary to accommodate modifications of the Euratom Basic Safety Standards. These modifications incorporated recommendations of the International Commission on Radiological Protection (ICRP) that were published in 1977 (ICRP77). In the debate the Government promised to review its radiological protection policy and to relate it to its environmental policy as applied to external safety and environmental agents. The result was the policy document 'Omgaan met risico's van straling' (OmRS; Radiation protection and risk management), that was published in 1990 (TK90). The document does not deal with medical exposures. A policy document on medical applications of ionising radiation was published in 1989 (TK89b).

1.2 Policy debate and request for advice

The OmRS-document presents a policy framework for protection against occupational and environmental exposure to ionising radiation. The new radiological protection policy for environmental exposure, *i.e.* exposure not related to medical examination or treatment of the exposed and outside the premises of an 'inrichting' (establishment)*, was based on the principles described in the policy document 'Omgaan met risico's' (OmR; Premises for risk management; TK89a).

The environmental risk management policy of the Netherlands Government, including the policy on radiological protection, was debated both inside and outside Parliament. In the course of this debate the Government has published documents with clarifications and modifications. As far as protection against ionising radiation in the environment is concerned the so-called OmRS follow-up document is of relevance (TK93a).

With respect to occupational radiation exposure the OmRS-document refers to established principles of protection of workers that are based on the 'Arbeidsomstandig- hedenwet' (Working Environment Act).

In Parliament the question of the relationship between the Dutch environmental radiological protection policy and internationally accepted regulations and radiological protection principles was repeatedly raised. The OmRS follow-up document offered some comparison between the Dutch policy and the system of radiological protection recommended by the ICRP, but this did not satisfy all politicians. Subsequently the Minister of Housing, Spatial Planning and Environment requested the Health Council

> to report (...) on the scientific aspects of major differences identified by the Council between the system of radiological protection of the 1990 Recommendations of the ICRP and the environmental radiological protection policy that was formulated in the 'Radiation protection and risk management' documents.

The letter with the minister's request for advice is published in annex A.

1.3 Health Council report on radiation risk

The Health Council has published several reports on the possible health effects of exposure to ionising radiation and on principles and methods of radiological protection. The most recent report in this series dates from 1991 (GR91). In that report

* Environmental exposure in Dutch policy differs from public exposure as defined by ICRP. See chapter 2.

the scientific data on radiation health effects are reviewed. Also quantities to characterise risk in assessing and managing radiation risks are discussed.

1.4 Committee and report

To answer the minister's request for advice, the President of the Health Council established a committee of experts from the Netherlands, Sweden and the United States. He asked the committee not to exclude worker protection from its deliberations and report. The members of the committee are listed in annex B.

In the next chapter (2) the committee outlines some general concepts in health physics. In the subsequent chapters (3 - 6) several aspects of protecting the public against health effects associated with exposure to ionising radiation are reviewed and the approaches of the ICRP and of the Netherlands Government are compared.* In a separate chapter (7) occupational exposure is discussed. The final chapter (8) presents some overall conclusions.

ICRP and OmRS

The committee will use the acronym 'ICRP' to denote the '1990 Recommendations of the International Commission on Radiological Protection' (ICRP Publication 60; ICRP91). If the Commission itself is meant ('the ICRP'), this will be clear from the context. Some general information on the mission of the Commission and on the historic development of its recommendations are presented in annex C.

'OmRS' denotes the present radiological protection policy of the Netherlands Government as described in the 'Radiation protection and risk management document' (TK90), and the 'Radiation protection and risk management follow-up document' (TK93a), and with the modifications introduced after the discussions between Government and Parliament, especially with respect to the abolishment of the concept of negligible risk in radiological protection policy (TK93b). Parts of this policy are not formally in force as this necessitates changes of the Radiation Protection Decree (Nuclear Energy Act) which are not realised as yet.

* The committee has taken note of the comparison of both approaches in the OmRS follow-up document, but has refrained from referring to it explicitly.

Chapter 2

General concepts

Radiological protection is concerned with protecting man against the harmful effects of ionising radiation. In this chapter the committee reviews some general concepts in radiological protection. For more details the committee refers to publications of the Health Council (GR91) and of the ICRP (ICRP91).

2.1 Health effects

Much is known about the interaction between ionising radiation and biological tissue and about the mechanisms that lead to injury and health damage, although our present day knowledge is far from complete. Notwithstanding this, national and international committees of experts in radiobiology and health physics have used the available data for recommending protection principles and protection measures.

Given the complexity of the interaction between radiation and biological tissue it has been necessary to adopt models to describe the interaction and its consequences. These models are based on assumptions for assessing possible health effects from radiation exposure. One assumption is that it is possible to classify the response of the organism into two categories.

The first category comprises:

- the increase of the probability that the exposed individuals get leukaemia or any other form of cancer
- the increase of the probability of hereditary disorders in the progeny of the exposed individuals.

With this type of response of the organism the probability of occurrence of the effect, cancer or a hereditary disorder, is related to the radiation exposure. The effects are called ‘stochastic’. The stochastic effects of radiation do not differ from similar effects induced by other causes: they are not identifiable as being ‘radiogenic’.

At present there is not sufficient evidence to accept the hypothesis that there would be an exposure threshold, below which the probability of an exposure-related stochastic effect would be zero. Therefore it is assumed that the response is linearly related to the radiation exposure down to zero exposure. As many exposures of the population, with the exception of those in radiotherapy, do not result in more than a moderate increment of the natural exposure, a linear relationship is an adequate approximation for radiological protection purposes.

The second type of response of the organism to radiation exposure comprises the so-called deterministic effects. This response is characterised by an effect-related exposure threshold; only above the threshold the (deterministic) health effect manifests itself. Its severity will increase with increasing radiation exposure. Examples of deterministic effects are: so-called radiation sickness, cataract, temporal and permanent infertility, and developmental effects after exposure of the fetus.

It has also been reported that radiation exposure of the fetus may negatively influence the mental capacity of the later child. Whether this effect can be classified as stochastic or deterministic is not clear.

Deterministic effects occur at relatively high exposure levels that normally will not be found at the workplace or in the environment. As in the majority of situations such high exposures can be avoided, radiological protection at work or at home is primarily concerned with limiting the probability of stochastic effects.

2.2 Quantities for describing exposure

Absorbed dose

The absorbed dose is the fundamental exposure measure for expressing exposure-response relationships. For radiological protection purposes, that is for exposure to *low dose, low dose rate* radiation*, it suffices to use the organ absorbed dose, which is defined as the radiation energy absorbed in the organ divided by the organ mass. After uniform exposure of the body the absorbed dose in all organs and in the body as a whole is approximately the same. The SI-unit of absorbed dose has got the special name gray (Gy).

* Doses and dose rates that are normally found in the workplace and in the environment; absorbed doses less than 200 milligray and absorbed dose rates less than 3 milligray per hour (UN88).

Equivalent dose

The absorbed dose-response relationship depends on the physical properties of the radiation. For radiological protection purposes it is usually deemed acceptable to add the absorbed doses of different types of radiation after multiplication with a factor (equal to or larger than 1) related to the relative biological effectiveness of the radiation. The resulting quantity is called equivalent dose. The SI-unit of equivalent dose has got the special name sievert (Sv).

Effective dose

The ICRP has recommended the quantity of effective dose for use in radiological protection (ICRP91). In the case of homogeneous irradiation of the body the effective dose is equal to the whole body equivalent dose. In the case of inhomogeneous irradiation ICRP has defined the effective dose as a weighted sum of equivalent organ doses (see annex E). The effective dose is based on a comparison of the organ sensitivities and the seriousness of the different health effects (cancer and hereditary disorders). The special name of the SI-unit of effective dose is the same as that of equivalent dose: sievert. The committee will use ‘effective dose’ as the primary quantity for expressing exposure. For radiological protection purposes, the stochastic response is assumed to be linearly related to the effective dose, throughout the range of low dose and low dose rate exposure of importance in radiation protection.

Collective dose

The harm to the population is considered to be linearly related to the collective effective dose, *i.e.* the sum of the individual effective doses of the exposed population. The unit of collective dose is the sievert (often written as person-sievert).

2.3 Risk

Cause-effect chains and probability of harm

‘Risk’ concerns the probability of harm to human health, to ecosystems and to goods, in relation to the severity and magnitude of the harm. It is a multi-attribute concept that closely resembles the concept of detriment introduced by the ICRP in its most recent recommendations (ICRP91; for a discussion of risk and risk attributes see Vle90, Nor92).

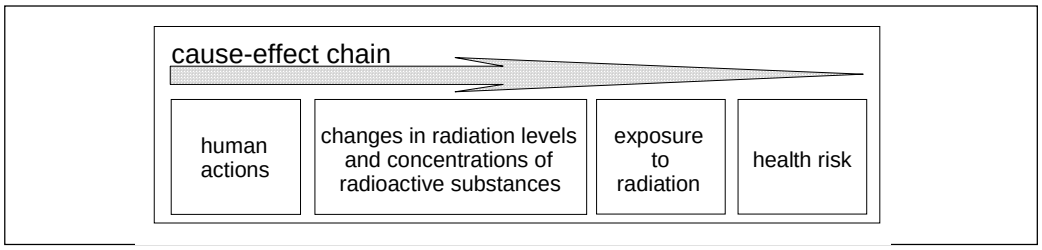

Figure 1 Cause-effect chain of radiation risk.

To assess risks and to identify possibilities for risk reduction and risk management cause-effect chains have to be analysed. The general form of a cause-effect chain is given in figure 1. Radiological risk originates in human activities that may modify radiation levels and concentrations of radioactive substances from natural sources and increase existing radiation levels by using radiation sources and by introducing man-made radioactive substances in the environment. People are exposed after the radiation and the radioactive substances have passed through pathways, that may be simple in a workplace, but very complex in the natural environment. Some of the pathways, *e.g.* transport of radioactive substances in air or surface water, may be common to various activities, *i.e.* to various cause-effect chains. On the other hand, the committee stresses that the (total) risk associated with the cause-effect chain of a given practice is related to more factors than radiation exposure alone.

As is done in the ICRP recommendations and in the radiological risk policy document of the Netherlands Government, the committee will limit itself to the health detriment caused by radiation exposure due to past, present and future human actions.

Quantifying radiation risk

In most practices deterministic effects from radiation exposure will not occur (an exception is radiation therapy where deterministic effects, *i.e.* the destruction of malignancies, are induced purposely). Therefore the stochastic effects of radiation exposure get most attention. The excess probability of getting cancer due to radiation exposure depends on the age at exposure, the duration of the exposure, the magnitude of the exposure and the age at which the effect is studied. In annex D the committee presents examples of the relation between the excess probability of cancer and exposure.

2.4 Exposure of workers, patients and the general population

Generally, three exposure situations are distinguished:

- occupational exposure
- medical exposure
- public or environmental exposure.

Occupational exposure occurs in the course of performing occupational duties. Because of the ubiquity of radiation, this definition would mean that all workers are 'occupationally exposed' and would be subject to the provisions of control of occupational exposure. The ICRP and also regulatory authorities have therefore restricted the application of the system of radiological protection at the workplace to exposures that are to be regarded as the responsibility of the operational management.*

Medical exposure is confined to irradiation of people in the course of their own medical examination or treatment. Exposure of medical personnel is considered to be occupational exposure.

ICRP defines public exposure as all exposures other than those classified as occupational or medical. These encompass not only exposure from licensed and unlicensed radiological practices, but also exposure to radiation from natural sources that may have been modified by human activities, exposure from past nuclear weapons testing and enhanced environmental exposures resulting from accidental releases of radioactive substances. The main part is unavoidable and stems from natural radiation sources.

The environmental radiological protection policy of OmRS is concerned with environmental exposures. These are largely equivalent with the public exposures of ICRP. However, exposure of people on the premises of an 'inrichting' (establishment)** is not considered to be environmental exposure.

Most medical examinations cause relatively small individual doses but with a high dose rate: generally the exposure occurs within seconds or minutes. To be effective, radiation therapy involves much higher doses at a high dose rate. Dose rates in occupational exposure are much lower; doses are commonly spread out over months and years. The exposure of the population from natural and man-made sources in the environment is lower still, in terms of dose and of dose rate.

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* Discussion on the boundary between occupational and non-occupational radiation exposure will remain. ICRP has recommended to include exposure during work from the storage of materials containing natural radioactive substances and during work in jet aircraft in the definition of occupational exposure.

** The concept of 'inrichting' is difficult to translate. It pertains to a plant or a group of installations, under the jurisdiction of a single corporate body, in general situated at one location with physical and organisational connections.

Regular and potential exposures

Regular exposures are by definition expected and may be considered as unavoidable or as being sufficiently limited. They also include doses due to foreseeable deviations from normal practices and incidents. Infrequent, unwanted occurrences, like the accidental emission of radioactive substances, and especially those with potentially high consequences, are assessed separately. These types of exposures are denoted by ICRP as potential exposures. The committee will not deal with radiological accidents and potential exposures in this report.

2.5 Other concepts

ICRP uses some concepts that are not to be found in OmRS and vice versa. The more important ones are discussed in this section.

ICRP

Detriment

ICRP uses the concept of detriment to denote the possible harm induced by exposure to radiation. Detriment is considered to be a multidimensional concept with attributes related to the magnitude and the severity of the induced harm, and to the probability of its occurrence. Only after introducing simplifications the concept of detriment can be quantified and, with even more assumptions, its dimensions can be aggregated into a single measure. ICRP limits the elaboration of the concept of detriment to *health* detriment. It was already introduced by the ICRP in 1977 (ICRP77), but in the latest recommendations (ICRP91) it has been redefined as given above. The concept of detriment is very close to the concept of risk discussed in 2.3.

As already mentioned effective dose is considered to be related to the individual health detriment: increasing the effective dose will increase the detriment. For a population exposed to low dose, low dose rate radiation ICRP relates the health detriment to the collective effective dose.

System of protection

The aim of the system of radiological protection of ICRP is to limit the health detriment associated with the radiation exposure to an appropriate level without unduly limiting the beneficial practices causing the radiation exposure. The system is intended to prevent the occurrence of deterministic effects by keeping doses below the relevant

thresholds and to ensure that all reasonable steps are taken to reduce the induction of stochastic effects.

OmRS

'Individual risk'

OmRS bases its approach to limiting harmful health effects of environmental exposure to ionising radiation on the notion of 'individual risk', which was already introduced in the OmR-document (TK89a; see also TK85). Individual risk is defined as: "the likelihood that a person will suffer a given harmful effect as a result of exposure to an agent". The harmful effect primarily considered in the case of radiation exposure is cancer death and individual risk is expressed on an annual basis.

System of protection

The principles of protection of OmRS refer to the environmental and occupational protection policy objectives: to protect humans against the harmful effects of their activities. Environmental policy objectives also include the protection of other organisms, ecosystems and property. The environmental policy objectives are further specified as: to save resources and reduce emissions and waste streams through integrated chain management, to reduce total energy use and strive for quality improvement of products, production processes, waste streams and emissions into the environment. Individual risk associated with radiation exposure should be kept below defined limits. OmRS presents only the latter criterion in an operational form.

Comparison

In the past the ICRP has considered the possibility of basing its system of protection on a 'risk' concept, *i.e.* on taking the probability of the occurrence of certain harmful effects instead of effective dose as the fundamental quantity of the system. However, in its latest recommendations (ICRP91) the ICRP explicitly refrains from doing so. This position takes account of the results of scientific research in the last two decades: the relationship between dose and risk is less simple and straightforward than was originally thought. This is also true for occupational exposure, but deserves even more emphasis for exposure of the general public, as estimates of the detriment have to be derived from data on exposure situations that are quite different in terms of dose, dose rate, and personal characteristics and life style.

ICRP therefore starts with the concepts of individual and collective effective dose which are considered to be the relevant exposure measures and which can be approximately interpreted in terms of health detriment using the best available scientific data. In contrast, the Dutch environmental radiological protection policy is based on individual risk, generally expressed as the probability of death due to the exposure.

With respect to the system of protection the committee notes important differences. ICRP aims at protection of health against the detrimental effects associated with radiation exposure without unduly hampering the beneficial uses of radiation sources. OmRS places radiological protection of the general population in the framework of Dutch environmental policy and considers radiation and radioactive substances as environmental pollutants which should, as far as possible, be eliminated from the environment. Health protection should be realised by restricting the probability of death attributable to radiation exposures from certain sources and practices below defined limits.

ICRP focuses on protection against radiation and does not make a connection with risk from other sources. OmRS establishes equal risk limits in terms of the probability of death due to different environmental factors that are considered to be a health hazard, with the objective to offer equal levels of protection against each of these factors.*

OmRS does not give an exact definition of individual risk as related to radiation exposure. The OmRS policy document indicates that the quantity individual risk refers to the excess probability that an individual dies from cancer due to chronic, lifelong radiation exposure. The individual risk level (per year) that is used in risk limit comparison, is found by dividing this probability by the human lifespan expressed in years. The OmRS quantity individual risk (per year) should not be confused with the excess probability of dying from cancer later in life due to one year of radiation exposure (which would correspond to the original definition of ‘individual risk’ in the OmR-document). As is illustrated in annex D the latter quantity is dependent on the age at exposure whereas the individual risk of OmRS depends only on the effective dose (and the characteristics of a reference population).

* The Health Council Committee on Risk measurement and risk assessment will discuss the protection system of the Dutch environmental risk policy in more detail. Its report is expected to be published in early 1995.

Chapter 3

Scope

ICRP

ICRP recommends that as part of the system of radiological protection both source-related and individual-related assessments should be carried out. Source-related assessments are necessary to decide on the tolerability of a given practice and take into account the occupational and public radiation exposure from only that source. Individual related assessments take into account the contributions of several or of all practices to the individual effective dose.

ICRP states that it is necessary to limit the scope of the system of radiological protection by defining categories of practices and sources that are brought under the system. It gives guidelines how to define the scope of the system in terms of controllability of sources and exposures. This leads to two broad categories (see also figure 2):

- human activities that increase the radiation exposure - practices
- human activities that aim at decreasing the radiation exposure - interventions.

Examples of practices are research using radiotracers and generating electricity from nuclear energy. Mitigating measures to reduce radon exposure in existing dwellings is an example of intervention (ICRP classifies the construction of new dwellings as a practice). Another example of intervention are actions to reduce exposures after radiological accidents.

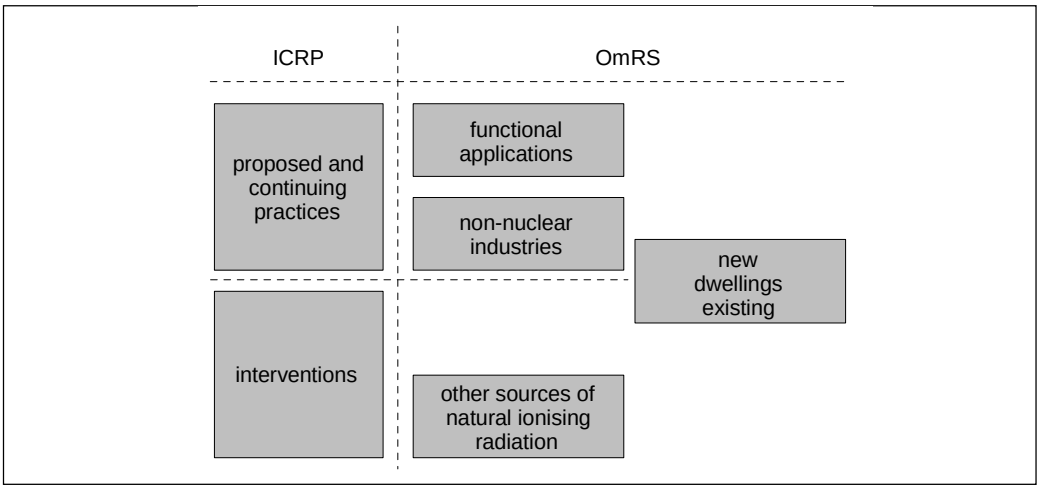

Figure 2 The approximate relationship between the classification of ICRP of human actions that change radiation exposure (practices and intervention) and the four groups of sources of radiation exposure considered by OmRS.

OmRS

OmRS distinguishes four categories of 'sources' (see figure 2):

- functional applications, *i.e.* practices that specifically use radiation sources or radioactivity
- non-nuclear industries, *i.e.* activities in which large quantities of raw materials containing natural radionuclides are processed
- dwellings*
- other sources of natural ionising radiation.

Comparison

Both ICRP and OmRS propose to limit the combined radiation exposure from given categories of sources. However, if the health detriment is linearly related to the effective dose, the contributions of different practices or sources to the health detriment are mutually independent. In that case limiting the probability of harm from each single practice or source might suffice. A reason for limiting the combined radiation exposure could be the prevention of deterministic effects, but given the levels of protection offered by both the ICRP and the OmRS system that would hardly be of relevance. Another reason might be to avoid that an individual accumulates too high a

* called 'bouwen en wonen' (building and lodging) in the OmRS-document

probability of stochastic effects (cancer and hereditary disorders). In the view of the committee that argument would logically lead to considering the combined contribution of all environmental factors to that probability and not of radiation alone.

The classification of sources in OmRS does not fully match with that of ICRP. Dwellings are considered to be a special category in OmRS. It is not subject to the risk limitation criterion, neither for existing, nor for new dwellings. The approach of OmRS for dwellings is ‘stand still’, *i.e.* keeping the exposure at existing levels.*

* However, in a recent policy paper the Government announced changes in the Building Code, that would reduce radon concentrations in new dwellings. Also, mitigating measures are proposed to reduce radon concentrations in existing dwellings (TK94).

Chapter 4

Protection by prevention

In this chapter the committee discusses the protection approach for proposed and continuing practices of ICRP, respectively functional applications and non-nuclear industries of OmRS. The key words of both systems are: prevention and control. Cause-effect chains (figure 1) provide models for control, that should primarily be effectuated close to the source. In controlling radiation exposures also long term effects, *e.g.* related to the release of long-lived radionuclides into the environment, should be taken into account.

ICRP

For proposed and continuing practices the ICRP system of protection consists of three principles:

- justification of the practice
- optimisation of protection
- individual dose limits.

Decisions concerning the adoption or continuation of any human activity involve, at the first stage, the identification and examination of different options which can be expected ‘to do more good than harm’. The justification principle refers to this first stage in the decision making process. It encompasses a consideration of all benefits and social and economic costs of the practice, including the health detriment associated with the radiation exposure. ICRP considers a practice to be justified if it

produces a net benefit: no human activity involving exposure to radiation should be adopted unless it produces sufficient benefit to the exposed individuals or to society. ICRP states that justification is a general principle and not specifically related to radiation practices.

For a justified practice ICRP recommends optimisation of radiological protection: in relation to any particular source within a practice, the magnitude of the individual doses, the number of people exposed, and the likelihood of potential exposures should all be kept as low as reasonably achievable, economic and social factors being taken into account (ALARA). Optimisation implies that any further reduction of radiation exposure is only warranted if the benefits associated with the reduction of the health detriment outweigh the social and economic costs of the extra reduction measures.

Finally the effective dose of the exposed individuals should be less than the dose limit recommended for those individuals. ICRP introduces dose limits to prevent intolerable individual exposure from all practices within the system of protection. The dose limit has the effect of constraining the optimisation of protection. Because the limit pertains to exposure from all sources within the system of protection ICRP recommends the use of so-called dose constraints below the dose limit. Dose constraints should be set by the authorities in relation to broad categories of practices or groups of exposed persons and leave sufficient room for exposure from other justified practices, in order to prevent exceeding the individual dose limit.

OmRS

OmRS permits the application of radiation sources if it is not counterproductive in reaching the objectives of environmental policy, *i.e.* reduction of resource use, pollution and waste streams, reduction of energy use, and quality improvement, *and* if the associated individual risk of any member of the public does not exceed the maximum permissible risk level. The former criteria are applied in a qualitative and implicit way in the licensing process. Only the latter criterion has been operationalised in a quantitative form. An (annual) individual risk limit, the maximum permissible risk level, is set on the cancer mortality associated with the radiation exposure from all functional applications and non-nuclear industries. A source related individual risk limit, the maximum permissible risk level for one source, has been established that is a factor of 10 below the maximum permissible risk level. The same limit applies to all sources. In the original OmRS-document (TK90) it was stated that the risk of existing practices should be below the maximum permissible risk level and new practices should not result in individual risk levels above the so-called negligible risk level, that was set at 1 per cent of the maximum permissible level.

If the application of a radiation source is thus permitted, the individual risk has to be lowered by applying optimisation or the ALARA principle. In the original OmRS-document (TK90) it was stated that after a given period of time the optimisation should result in an individual risk below the negligible level. In later discussions between Government and Parliament the policy was modified. The negligible risk level has been abolished as far as exposure to radiation is concerned (TK93b).* The primary principle is that practices with associated 'individual risks' above the maximum permissible level can not be allowed and further reduction of risk should be achieved by applying the ALARA principle. Through the licensing process the authorities may define levels of individual risk or related dose levels below the maximum permissible level for one source in order to (further) constrain the optimisation. For licensing purposes a so-called secondary risk level has been introduced, which is equal in magnitude to the former negligible risk level. Below the secondary level risk reduction has no priority for the authorities, although the ALARA-obligation for the licensee remains (see VROM93).

Comparison

The approaches of ICRP and OmRS are fundamentally different, although, depending on the way they are worked out, both may lead to levels of protection that are considered to be sufficiently high. Both ICRP and OmRS, use the concepts of justification, optimisation and dose limits, but the meaning of these concepts in both systems differ.

ICRP starts from a utilitarian point of view: no practice should be adopted or continued unless it produces a net benefit. Instead of looking for a net benefit OmRS presents the maximum permissible (individual) risk level per source as a justification criterion. This implies that the role of the maximum permissible risk level is conceptually different from that of the individual dose limit in the ICRP system of protection. In the latter case it is a final safeguard to protect the individual against excessive radiation exposure from a cumulation of practices, that would each be justified from a societal point of view. In OmRS the maximum permissible risk level is related to environmental quality objectives and overrides any consideration of benefit associated with a practice.

The notion of optimisation or the ALARA principle in both approaches is similar.** As the negligible risk level, as a fixed and final goal of ALARA-efforts, is indeed abolished, the OmRS approach now amounts to finding an optimum below a maximum permissible risk level. However, the OmRS maximum permissible risk level

* Also with respect to protection against industrial accidents ('external safety').

** Much effort is put into bringing the ALARA principle to practice. For a recent overview, see CEC94.

for one source has the same fixed value for each source and, given its restrictive magnitude, leaves appreciably less room for optimisation than the ICRP system, at least in principle, allows. This conclusion follows from a comparison of the effective dose that is equivalent to the maximum permissible level and the ICRP dose limit; see chapter 5.

In the ICRP system of protection optimisation is to be subject to dose constraints. These constraints are related to broad categories of practices or categories of exposed people; the values are not necessarily the same for each source or practice. They take account of operational experience and reflect ‘good radiological protection practice’: their choice will depend on the circumstances. The notion of ‘constraint’ is not found in OmRS, although the authorities may set further restrictions below the maximum permissible risk level for one source. The latter is the same for all sources; OmRS does not allow to apply different levels for different types of sources.

These differences between ICRP and OmRS are apparently related to a difference in viewpoint. OmRS wants to guarantee equal protection against environmental factors (‘environmental quality’) for any member of the public, and bases the protection level in terms of the individual risk concept only on the magnitude of the radiation exposure. The primary principle of ICRP is that exposure of people should not be higher than is justified by the net benefit of a particular practice and the reasonably available technical means.

Chapter 5

Individual limits for dose and risk

Discussions about systems of radiological protection often focus on the magnitude of dose or risk limits. In this chapter the committee discusses some aspects of the magnitude of the dose and risk limits in both systems.

ICRP

For public exposure ICRP recommends an annual limit on the effective dose of 1 millisievert. In special circumstances a higher effective dose could be allowed, as long as the 5 year average is less than 1 millisievert per year.* ICRP presents two lines of thought in discussing the value of the dose limit. It estimates the health detriment associated with doses near the limit and it also compares the dose limit with the natural background radiation level and with its geographical variations.

In order to interprete dose limits in terms of health effects, ICRP applies conversion coefficients for stochastic effects, called nominal probability coefficients. Numerical values of these coefficients are presented in table 1. An estimate of a given form of health detriment in a population of all ages is obtained by multiplying the collective dose of the population with the appropriate nominal probability coefficient. ICRP restricts the use of these values to estimating the health detriment associated with chronic, low dose, low dose rate exposure needed for the discussion of radiological protection principles and measures. The coefficients are not intended to be

* For the lens of the eye, the skin and the hands and feet additional limits are set to avoid deterministic effects.

Table 1 Coefficients used by ICRP in estimating the health detriment associated with radiation exposure, so-called nominal probability coefficients for stochastic effects (from ICRP91, table 3).

exposed population	nominal probability coefficient per sievert effective dose		
	all cancer	all fatal cancer	severe hereditary effects
adult workers	$4{,}8 \times 10^{-2}$	$4{,}0 \times 10^{-2}$	$0{,}8 \times 10^{-2}$
whole population	$6{,}0 \times 10^{-2}$	$5{,}0 \times 10^{-2}$	$1{,}3 \times 10^{-2}$

used for accurate predictions of the actual health detriment in exposed populations. Using these data and information about the age distribution of cancer patients ICRP reviews several dimensions of health detriment. It assesses the health detriment associated with life time exposure to a variety of effective dose values in terms of changes in the age specific mortality curves.

In the second approach, ICRP compares the recommended individual dose limit with the geographical variation in the natural background radiation level (excluding the contribution from inhaled radon decay products), that amounts to more than a factor of two. The argument is that if large groups of people are exposed to an extra effective dose of one millisievert per year during their whole lifetime without any observable harm, no intolerable detriment is to be expected if small groups of people are exposed to a similar effective dose for a limited number years.

From this assessment ICRP concludes that exposure up to the limit, which only applies to a small part of the total public exposure, in general, would not lead to intolerable radiation risk in the exposed population.

New and more detailed knowledge on radiation effects may lead to a change in the nominal probability coefficients. The committee concludes that in the ICRP approach a change in the nominal probability coefficients necessitates adaptation of the dose limits only if it affects the rationale for the dose limit.

OmRS

OmRS establishes individual (mortality) risk limits. The maximum permissible individual (mortality) risk level for exposure to all relevant sources of radiation, *i.e.* functional applications and non-nuclear industries, is set equal to 1 per 100 000 or 10^{-5} per year and the maximum permissible individual risk level for one source to 1 per 1 000 000 or 10^{-6} per year (year refers to the year of exposure). In an appendix to a policy document published in 1985 the Government provided some insight in the rationale of these values (TK85). For acute fatalities from accidents with individual industrial installations a maximum permissible (individual) risk level was defined of 1

Table 2 Conversion coefficients used by OmRS for estimating health effects associated with radiation exposure for stochastic effects (TK90).

exposed population	coefficient per sievert effective dose		
	all cancer	all fatal cancer[a]	severe hereditary effects
adult workers	-[b]	$2{,}5 \times 10^{-2}$	-[b]
whole population	-	$2{,}5 \times 10^{-2}$	-

[a] in 1991 the Health Council derived a value of $(4\text{-}7) \times 10^{-2}$ per sievert (GR91)

[b] not stated

per 1 000 000 per year and of 1 per 100 000 per year for the risk of all installations together. The 10^{-6}-level was shown to be 1 per cent of the lowest value of the age specific mortality in the Dutch population (at that time 1 per 10 000 per year for the 12-16 years old). It was also argued that a 10^{-5}-level was not out of line with the individual dose limit for exposure of the public of 1 millisievert used in radiological protection, given the nominal probability coefficient for cancer death of about 1×10^{-2} per sievert that was used by the ICRP in its 1977 recommendations (ICRP77).

For the control of radiation exposure the individual risk limits have to be converted into effective dose by devision with a conversion coefficient. The conversion coefficients used by OmRS are given in table 2. In the original OmRS-document a mortality coefficient of $2{,}5 \times 10^{-2}$ per sievert was introduced awaiting a recommendation of the Health Council. In 1991 the Health Council recommended a value in the range of $(4\text{-}7) \times 10^{-2}$ per sievert (GR91), which is in line with the evaluations of the UNSCEAR (UN88, UN93) and the ICRP (ICRP90). In the OmRS follow-up document the conversion coefficient was not adjusted and the derived dose limits were left unchanged. This means that an effective dose of 0,4 millisievert is supposed to correspond to the 10^{-5} risk limit for all sources and an effective dose of 0,04 millisievert to the 10^{-6}-limit of a single radiation source.

In chapter 2 the committee already mentioned that the OmRS quantity ‘individual risk’ refers to lifetime exposure and should not be interpreted as the risk to an individual associated with a given year of exposure. One might say that the maximum permissible risk level for all sources (1 per 100 000 per year) roughly corresponds to a limit of 1 per 1000 on the excess probability of dying of cancer after lifelong, chronic exposure to radiation. This limits the lifetime individual effective dose to about 40 millisievert using the conversion coefficient of table 2. The latter value is reached with an annual exposure of 0,4 millisievert, year after year, if the lifespan is assumed to be 100 years.

The individual risk limits of $10^{-5}/10^{-6}$ per year that originated from the field of 'external safety' have been transferred to the field of radiological protection in the OmR- and OmRS-documents. Although the committee acknowledges that defining a level of protection has to be the result of a political decision, it wants to point out that equating the individual mortality risk of industrial accidents and that of radiation exposure, does not necessarily imply equal levels of protection. The risk from industrial accidents differs, both in its probability component and in its health effect component, from the risk associated with radiation exposure. The committee mentions the following differences:

- radiation affects the exposed individuals by increasing their susceptibility to cancer; in case of industrial accidents the 'exposed' persons are either affected and incur harm, or they are not affected at all*
- industrial accidents lead to acute health effects and death and possibly to long term health effects; radiation exposure of the low dose, low dose rate type only induces long term health effects (primarily cancer and hereditary disorders)
- the acute health effects of industrial accidents do not depend on individual characteristics, like age and sex, at least not to a large extent; as the committee pointed out before, the stochastic response to radiation exposure is dependent on the age at exposure.

The committee concludes that the notion of individual risk, introduced in the environmental policy documents, has a different meaning in the case of 'external safety' as compared to radiological protection. A consequence of this conclusion is that setting equal limits on 'individual risk' associated with industrial accidents and that associated with radiation exposure does not guarantee equal levels of protection in both situations. The committee is of the opinion that these observations are also relevant outside the 'domains' of external safety and radiation.

More detailed knowledge on the health effects of radiation exposure that would lead to changes in the conversion coefficient, would 'automatically' change the values of the dose limits associated with the maximum permissible risk limits. If not, it implies a new policy decision on how to choose the value of the conversion coefficient within its range of uncertainty.**

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* The committee neglects here psychological contributions to the detriment.

** The committee refers to the 1991 Health Council report on radiation risk (GR91) in which assumptions and uncertainties in deriving these coefficients were discussed. Important sources of uncertainty are: the transfer of epidemiological data from one population (*e.g.* the Japanese bomb survivors) to another (*e.g.* the present Dutch population) and the assumptions used to obtain an excess cancer probability at low dose and low dose rate radiation exposure from that observed at high dose and dose rate.

Comment

The committee ends this chapter with a comment on the use of the nominal probability coefficients or conversion coefficients. Those coefficients have been derived, as ICRP points out, for discussing systems of radiological protection. They are not intended to be used for accurate estimates of the actual health detriment in an exposed population by simply multiplying the coefficients with the estimated or measured effective doses.

Chapter 6

Protection by intervention

There is another broad category of human activities which aim to decrease the overall radiation exposure. Such activities remove existing sources, modify pathways, or reduce the number of exposed individuals, and are described as intervention. The radiation sources concerned are often difficult to control. Examples are natural sources, possibly modified by human action, like radon in dwellings, and man-made sources due to past practices, like the fall-out of atomic bomb tests. See also figure 2. The committee will not discuss intervention related to radiological accidents.

ICRP

The principles for intervention according to ICRP are: justification and optimisation. Here again justification means a positive answer to the question: does intervention produce a net benefit? A net benefit implies that the benefits, especially the health benefits, of the intervention actions outweigh the associated economic and social costs, or, more simply: intervention should do more good than harm. The decrease in radiation exposure or the effective dose averted is the primary benefit to be obtained by the intervention. If intervention is justified then the action should be optimised, *i.e.* the extra social and economic costs of further measures should be balanced against the extra reduction in radiation exposure. (See also ICRP93.)

Individual dose limits do not play a role in the ICRP approach to intervention. For specific situations intervention levels may be derived and have been recommended by the ICRP as practical decision tools, but these are fundamentally different from the

individual dose limits to be applied for practices and should only be based on justification and optimisation considerations. The dose limits are designed for different purposes (see chapter 4).

OmRS

OmRS considers the maximum permissible risk level as an environmental quality objective. Exceeding this level (or the associated exposure level) should lead to intervention. However, OmRS states that the so-called other sources of natural ionising radiation, like potassium-40 in the body and cosmic radiation, are essentially uncontrollable and no risk reduction is possible. In the case of existing dwellings intervention is considered, at least in principle, necessary to reduce the radon concentration.

Comparison

It is difficult to compare the ICRP and OmRS approaches to intervention. ICRP stresses the balancing of the costs and benefits in a broad sense. OmRS does not explicitly mention such considerations. In principle, the maximum permissible risk level of OmRS functions as a trigger level for intervention, whereas ICRP explicitly states that the recommended dose limit cannot, by definition, play such a role.

Chapter 7

Occupational exposure

7.1 Limitations

The President of the Health Council asked the committee to also discuss the systems for protection against occupational radiation exposure. This discussion necessarily has to be of a limited nature as OmRS deals with occupational exposure only summarily. A comparison between the ICRP and the Dutch principles of protection in occupational radiation exposure would have meant a study of many documents apart from the OmRS-documents and of the Euratom Basic Safety standards as well. The committee only reviews the most important aspects and, furthermore, refrains from dealing with operational details.

7.2 System of protection

ICRP

The development of the ICRP system of protection can only be understood by realising that it is rooted in protection of the worker. The protection against public exposure was modelled after the approach for worker protection. As occupational exposure is always related to practices, the same principles as discussed in chapter 4, *i.e.* justification of a practice, optimisation of radiation protection with dose constraints as boundary conditions and individual dose limits to protect individual workers to a sufficient degree, apply. The effective dose limit recommended is 20 millisievert per year

averaged over 5 years (100 millisievert in 5 years) with the further provision that the effective dose should not exceed 50 millisievert in any year.

OmRS

The original OmRS-document summarily deals with protection against occupational exposure. It refers to the general principles of protection of workers which are different from the environmental policy principles. According to OmRS the usual approach adopted for protecting workers against harmful agents at the workplace in the Netherlands, *viz.* keeping exposure below regulatory limits to prevent harm to the worker and his or her progeny, is not feasible for ionising radiation because it is assumed that any exposure entails a certain probability of harm. As exposure can not be avoided in all circumstances it should be restricted to a level "as low as possible" (quotation). The principles for achieving this are laid down in the 'Arbeidsomstandighedenwet' (Working Conditions Act). These are:

- the reasonableness principle
- the accepted technology principle.

Measures to reduce exposure should be taken after consultation between employer and employees, and should be tested for effectiveness as well as result in exposures below regulatory exposure limits. Exposure reduction implies both reducing individual exposures as well as the number of the exposed persons.

OmRS also establishes dose limits as a means to achieve a sufficient level of protection. It offers several arguments for such limits:

- limits result from a balancing of costs and benefits
- limits should be set at a level to avoid deterministic effects
- limits should correspond to a risk level that exists in comparable industries as far as 'exposed' workers are concerned and to a risk level comparable to that of 'safe' industries as far as 'non-exposed' workers are concerned.*

OmRS establishes the annual dose limit for 'exposed' workers at 20 millisievert and the annual dose limit for 'non-exposed' workers at 2 millisievert.

Comparison

The committee concludes that the approaches of protection in occupational radiation exposure of ICRP and of OmRS have much in common. Both put forward optimisation

* 'Exposed' workers in OmRS terminology are workers that are officially registered as radiation workers. The other workers fall into the 'non-exposed' category. Exposure of these workers cannot always be fully avoided.

and dose limits as protection tools, be it that OmRS emphasises dose limits more than ICRP does. The notion of dose constraints is not mentioned in OmRS. With respect to 'justification' the earlier comments of the committee in chapter 4 apply. The individual dose limit recommended by ICRP provides somewhat more flexibility than that of OmRS, but in the opinion of the committee in actual practice in the Netherlands the difference will be not of much importance.

7.3 Magnitude of dose limits

A worker would receive an effective dose of about 1000 millisievert if he or she would be exposed up to the ICRP dose limit during the whole working life. Such an exposure is considered by ICRP to be the lower bound of exposure regimes that would be considered as giving rise to intolerable health detriment. ICRP reaches this conclusion after assessing the detriment associated with lifetime exposure to a variety of effective doses in terms of excess mortality, shortening of life expectancy and of hereditary effects in later generations.

As mentioned above OmRS presents some consideration for the dose limits, the most relevant of which are the prevention of deterministic effects and the comparison with the risk in other industries. Such a comparison is not easy, given the differences in nature of occupational risks between one industry and another. In its 1977 recommendations (ICRP77) the ICRP also motivated its recommended dose limit with such a comparison*, but in its new report (ICRP91) explicitly chooses not to do so.

* See also the Health Council report on these ICRP recommendations (GR84).

Chapter 8

Evaluation

In the preceding chapters the committee has compared the systems of protection against ionising radiation of ICRP and OmRS. It has noted some fundamental differences between the two systems. The committee discusses the implications of these differences in this chapter.

8.1 Scientific understanding

Research efforts in the last two decades have broadened our knowledge of radiation exposure and its associated risk. The committee wants to draw attention to the following aspects:*

- the concept of risk
- the mechanism of tumour formation and growth
- the relative nature of excess cancer risk.

Concept of risk (see also chapter 2)

In western society there has been an increasing awareness that technological developments may threaten the health of individual people. As a consequence governments and other authorities were pressed to limit such risks and looked for possibilities to quantify risks in order to develop regulatory standards. This led to

* These aspects have been discussed more extensively in the 1991 Health Council report on 'Radiation risk' (GR91).

scientific analysis of the concept of risk and to the development of models and methods to estimate possible health effects of concrete activities or situations. Gradually it has become clear that risk should be considered as a concept with a variety of attributes. Narrowing the risk concept to, *e.g.*, the probability of death is an oversimplification, may lead to misunderstanding and might mask important elements that play a role in policy decisions.

ICRP is more explicit in recognising and reflecting the multidimensionality of the concept of health risk (or health detriment), and in that respect more in accordance with the results from 'risk research' than OmRS.

Cancer

For low dose, low dose rate exposure one of the relevant biological responses to radiation exposure is the increased probability of getting cancer. Until about 20 years ago radiation was considered to be a direct cause of cancer. At present there is an impressive body of scientific evidence, obtained by the co-ordinated efforts of clinical researchers and molecular biologists showing that the development of a malignant tumour requires several mutations in one tissue cell together with a proliferation of the mutated cells. Radiation appears to be one of the many factors that, together, may lead to cancer. Therefore it is inaccurate to state that 'radiation induces cancer'. It would be rather more correct to describe radiation as an environmental factor increasing the susceptibility to cancer. Cancer is an illness that predominantly manifests itself at older ages and is caused by processes and agents that stimulate cell proliferation or bring about specific mutations in genes involved in cell division.

The practical significance of this scientific insight obtained during the last two decades is that after exposure of a population to radiation an increased incidence of cancer is mainly observed after the exposed persons have reached the older ages at which cancer most frequently occurs. The study of cancer mortality among the survivors of the atomic bomb explosions above Hiroshima and Nagasaki has demonstrated that the excess cancer mortality in this population has an age distribution that does not differ appreciably from the 'normal' cancer mortality (Shi90).*

A second implication is that children are more sensitive to radiation, because in several organs intensive cell proliferation is taking place in connection with natural growth. This is also borne out by epidemiological studies, *inter alia* by the recent finding of an increased incidence of thyroid cancer in areas in Belarus, Ukraine and

* The committee stresses that this is an empirical finding, not the result of a preference to analyse the data with a relative risk model. In Shi90 it is stated: "Further observations on the effects of age ATB (at time of bomb) confirm earlier suggestive evidence that radiation-induced cancers increase significantly when the survivors reach those ages at which cancers normally develop."

Russia, that were affected by fall-out from the Chernobyl reactor accident. (Analysis of these observations shows that, given the estimates of the thyroid doses incurred, the increase in thyroid cancer incidence is compatible with the risk factors that are used in the system of radiological protection.) In estimating the probability of health effects from radiation exposure this should be taken into account by assigning a greater sensitivity to children.

Relative cancer risk

Important for radiation protection philosophy is the scientific finding, mentioned in the preceding section, that the excess probability of getting cancer after exposure to radiation is, for most cancers, predominantly of a relative nature, although there are notable exceptions. After exposure to radiation the excess probability of dying from cancer is a given fraction of the age specific probability of cancer incidence that appears to be, for most cancers, almost constant or to decline only slowly during further life. The excess probability of cancer death does depend on the age at exposure, being highest at young exposure age. See also annex D.

The committee is of the opinion that the rationale for the ICRP system of protection is more directly connected to recent scientific findings that were referred to in the present section, than the rationale given in OmRS. However, it should be noted that the ICRP system of protection specifically refers to radiological protection, whereas OmRS aims at establishing a system of radiological protection that is part of a general, uniform system of protection against environmental agents.

8.2 Tolerability of radiological risk

The models and rules for deciding on the tolerability of radiological risk recommended by ICRP differ from those of OmRS. ICRP implicitly supposes that a single corporate body, *e.g.* a licensing authority, takes into account all possible benefits and all possible harm associated with a practice or with intervention and decides on the tolerability of a practice of the appropriateness of the intervention for society. Dose limits are not to be used as decision criteria but as basic quantities for constraining exposures in operational practice.

OmRS on the other hand sets out from the objective of safeguarding environmental quality and reducing environmental pollution. Ionising radiation is considered as a harmful agent and environmental pollutant. OmRS is only concerned with part of the justification process (in the ICRP sense), *viz.* with the extent to which an activity does not hamper reaching to the objectives of environmental policy and with the question if

risk limits are exceeded. Therefore the maximum permissible risk level of OmRS is a primary decision criterion for the tolerability of the radiological risk associated with an activity, and thereby of the (environmental) tolerability of the activity itself.

A consequence of this difference in approach is that ICRP purposely leaves room for tolerating different radiological risks from different practices taking into account the benefits associated with the practice. OmRS applies the same risk limit to all sources. The principles of OmRS do not allow to take into consideration the benefits associated with practices and may in this way hamper beneficial practices.*

8.3 Comparing limits in terms of dose

In chapter 5 (table 1 and table 2) the committee presented the coefficients for converting effective dose into health detriment as used by ICRP and by OmRS. These coefficients have been derived from a model of lifelong exposure to low dose, low dose rate radiation.

Dose constraints

The ICRP limit for exposure of individual members of the public from all 'artificial' sources and practices (excluding medical diagnosis and treatment) is set equal to an annual effective dose of 1 millisievert. OmRS converts its maximum permissible risk level of 1 per 100 000 per year into an effective dose limit of 0,4 millisievert per year (see chapter 5). Both values can be considered to reflect the order of magnitude of the variation of the background radiation exposure, excluding the effective dose contribution from inhaled radon decay products. Because they differ only by somewhat more than a factor of 2, one could argue that they are not appreciably different given the inaccuracies in the estimation of health effects.**

However, the different interpretation of the limits has large practical consequences. OmRS establishes a dose limit of 0,04 millisievert per year, related to the maximal permissible risk level for one source as a first step in constraining the exposure from a single source; below this limit dose levels might be specified as further constraints for the optimisation of protection measures. ICRP does not specify source related dose limits and recommends against setting a fixed, general constraint for a single practice. It proposes to establish dose constraints for general groups of practices or groups of exposed people, taking into account the distribution of

* Of course, exceptions can always be made by explicit decisions. This has been done for the exposure of relatives of patients treated with radioactive substances.

** However, the committee is aware of the fact that in policy discussions the consequences of choosing a dose limit of either 1 or 0,4 may be large.

exposures due to that type of practices among the exposed population in question. A dose constraint may be appreciably higher than 0,04 millisievert per year (but is always less than 1 millisievert per year).

Influence of the conversion coefficient

The limiting dose values of 0,4 and 0,04 millisievert per year were derived in OmRS by applying a conversion coefficient of $2{,}5 \times 10^{-2}$ per sievert (table 2) to, respectively, the 1 per 100 000 and 1 per 1 000 000 maximum permissible risk levels. In a system of protection based on individual risk scientific information should, in so far available, be used to interpret risk attributes, such as mortality, in terms of effective dose. According to the committee, given the lack of explicit guidance in OmRS on how to deal with uncertainties in the scientific data, an appropriate coefficient to convert mortality risk to effective dose is the one recommended by ICRP in table 1, *viz.* 5×10^{-2} per sievert. This value is within the range of $(4\text{-}7) \times 10^{-2}$ per sievert given in the Health Council report on radiation risk (GR91).

Using this conversion coefficient the OmRS maximum permissible risk level (all sources) would result in an effective dose of 0,2 millisievert per year, which differs significantly from the 1 millisievert per year recommended by ICRP. The source related individual risk limit of OmRS converts to an effective dose of 0,02 millisievert per year and dose constraints for optimisation, if applied, would be less than this value.

To put these values into perspective they might be compared with the background radiation. In the Netherlands the effective dose from natural radioactive substances in the body (excluding inhaled radon decay products) amounts to about 0,4 millisievert per year, the effective dose from cosmic radiation varies between 0,1 and 0,3 millisievert per year and the effective dose from natural radioactivity in soil from 0,02 to 0,4 millisievert per year (CCRX91). These sources and the resulting effective doses are essentially uncontrollable.

Relative risk limitation

Given the scientific insights in the origins and occurrence of cancer and excess cancer associated with radiation exposure and if one would opt for the inclusion of a limitation of the probability of dying from cancer in the system of protection, establishing a relative mortality risk limit is a feasible approach. The committee has verified that lifelong exposure to an annual effective dose of a few millisievert would increase the age specific cancer mortality by not more than one per cent (*cf.* ICRP91, table C-4a). If the excess probability of cancer death should be limited to 1 per cent per year, this would require restricting the public exposure to an effective dose of 2 to 3

millisievert per year. ICRP has used similar calculations in deriving the values of the recommended dose limits (ICRP91, figure C.7 and C.8). The committee points out that such a limitation differs from that in the OmR- and OmRS-documents. In the latter case the individual risk limit appears to refer to the overall probability of death attributable to an environmental agent, incurred in a given year of exposure. For radiation this definition is than further modified by averaging over all ages.

8.4 Final remarks

The ICRP system of radiological protection has not been static over the years. In the course of time the emphasis shifted from dose limits to justification and optimisation as the primary tools of radiological protection. The dose limits were lowered stepwise in the past, both because additional scientific data on radiation health effects became available and because radiation practices expanded and became more diversified in nature. The stability and coherence of the system together with its prudent evolution has led to its acceptance both by international and national authorities, as well as by radiological protection advisers and officers at an operational level.

It is not within the mission of the committee to recommend a choice between the two systems of protection compared in this report. Also, such a choice could not be made on scientific grounds alone. As far as the level of exposure is concerned, one may argue that, given the more strict limitation, the OmRS system might lead to lower effective doses. However, on a population level the differences would be marginal given the relatively small fraction of the collective public or environmental exposure controlled by the system. If one takes the point of view that protection levels should also be related to resource use many more factors should be taken into account. The committee considers such a study of importance, but outside the scope of the present report.

The Hague, December 31, 1994,
for the committee,

Dr WF Passchier, Prof Dr L Ginjaar,

scientific secretary chairman

Literature

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TK85 Indicatief Meerjarenprogramma Milieubeheer 1986-1990. TweedeKamer, vergaderjaar 1985-1990, 19204, nrs 1, 2.

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TK89b Medische stralingstoepassingen doorgelicht. Tweede Kamer, vergaderjaar 1989-1990, 21439, nrs 1, 2.

TK90 Omgaan met risico's van straling. Normstelling ioniserende straling voor arbeid en milieu. Tweede Kamer, vergaderjaar 1989-1990, 21483, nrs 1, 2 (19 maart 1990).

TK93a Vervolgnotitie Omgaan met risico's van straling. Tweede Kamer, vergaderjaar 1992-1993, 21439, nr 15. (3 februari 1993).

TK93b Risicobenadering in het milieubeleid (verslag van een mondeling overleg op 8 december 1993). Tweede Kamer, vergaderjaar 1993-1994, 22666, nr 5.

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Annexes

Annex **A**

Request from the Minister of the Environment to the President of the Health Council

reference: DGM/SVS/18394009, letter of April 6, 1994 of the Minister of the Environment to the Minister of Health (the letter was sent by the Minister of Health to the President of the Health Council with an accompanying letter, dated April 22, 1994, DGVgz/BMO94679)

In 1991 the Health Council published the advisory report 'Radiation risks' (report 1991/22). In the same year I asked the Health Council to evaluate the premises of the environmental risk management policy of the Netherlands Government (DGM/DS/MBS nr 23o91005). Up until now the Health Council did not issue the requested advisory report.

From 1991 onwards the Lower House of Parliament has debated several times the further development of the environmental risk management policy. In my consultations with the House I have proposed to discontinue the use of the notion of a negligible risk level as a lower bound in applying the ALARA-principle (consultation on the risk management policy of December 8, 1993).

The topic of the aforementioned consultation was the follow-up document on 'Radiation protection and risk management' (Tweede Kamer, 1992-1993, 21 483, nr. 15) in which the radiological protection policy, which was presented in the policy document 'Radiation protection and risk management' (Tweede Kamer, 1989-1990, 21 483, nr. 2), has been further developed. In section 2.6 of the follow-up document a limited comparison between the principles of the Dutch policy and the 1990 Recommendations of the International Commission on Radiological Protection (ICRP 60, April 1991) is presented.

I herewith request the Health Council to report separately, in addition to the other advisory reports mentioned, on the scientific aspects of major differences identified by the Council between the system of

radiological protection of the 1990 Recommendations of the ICRP and the environmental radiological protection policy that was formulated in the ‘Radiation protection and risk management’ documents.

I would be pleased to receive your report not later than November 1994.

(signed)
Minister of Housing, Spatial Planning and Environment,
JGM Alders

Annex **B**

Members of the Committee on Principles of radiological protection

The following experts participated in the committee:

- Prof Dr L Ginjaar, chemist, President of the Health Council of Netherlands - *chairman*
- Prof Dr Joh Blok, emeritus professor of molecular biophysics
- Drs JAG Davids, radiobiologist
- Mrs Prof Dr JCM van Eijndhoven, chemist, Director Rathenau Instituut and University of Utrecht
- Prof Dr JMA van Engelshoven, radiodiagnost, Academic Hospital, University of Limburg
- Ir ChrJ Huyskens, radiation physicist, Director Radiation protection department, Technical University of Eindhoven
- Prof Dr B Lindell, radiation physicist, emeritus Chairman of the International Commission on Radiological Protection
- Dr CB Meinhold, health physicist, President of the US National Council on Radiation Protection and Measurements and Vice-Chairman of the International Commission on Radiological Protection
- Dr CE Rasmussen, radiation physicist, Director of Radiation Protection Department, Interfaculty Reactor Institute, Technical University of Delft
- Dr WF Passchier, physical chemist, secretariat of the Health Council of the Netherlands - *scientific secretary*

Mrs MFC van Kan of the Health Council staff served as the committee's secretary. Editorial assistance was provided by Dr WM Becker of the staff of the National Council on Radiation Protection and Measurements and by Drs AB Leussink of the Health Council staff.

Annex **C**

ICRP and its recommendations

A The Commission

The International Commission on Radiological Protection was established in 1928 with the name International X ray and Radium Protection Committee, following a decision by the Second International Congress of Radiology. In 1950 the commission was restructured and renamed. It is an independent body and appoints its own members, but has a special relationship with the four-yearly Radiology Congress meetings and with the International Society of Radiology.

The mission of the ICRP is contained in its name: to provide data and recommendations for the protection of man against the harmful effects of exposure to ionising radiation. Since there is little direct evidence of harm in human beings at levels of annual dose at or below the various dose limits recommended by the commission, a good deal of scientific judgement is required in predicting the probability of harm at low doses. Most of the observed data have been obtained at higher doses and usually at high dose rates. The ICRP presents estimates that it considers not likely to underestimate the consequences of exposures. Estimating these consequences and their implications necessarily involves social and economic judgements as well as scientific judgements in a wide range of disciplines. The ICRP has aimed to make the basis of such judgements as clear as possible, and recognises that others may wish to reach their own conclusions on many of these issues (ICRP91, para 6).

The ICRP intends its recommendations to be of help to regulatory authorities at national and supranational levels, mainly by providing guidance on the principles of radiological protection. Authorities will need to develop their own structures of legislation and regulation in line with the prevailing policies and practices. As the ICRP itself also states (ICRP91, para 8), its recommendations have been used as basis for national and international radiological protection regulations, which has helped to provide a consistent basis for national and supranational regulatory standards. For its part the commission has been concerned to maintain stability in its recommendations.

The Euratom Basic Safety Standards, issued in the form of European Union directives, have always referred to the ICRP recommendations as an important basis for the regulations, as have, at least by implication, the radiological protection regulations issued in European Union Member States.

B The historic development of the ICRP recommendations

In the Health Council report 'Radiation risk' (GR91) the recommendations of the ICRP are put into a historical perspective (section 3.2). That part of the report is reproduced below.

Soon after the discovery of the phenomenon of ionising radiation also its deleterious effects were uncovered. This resulted in the establishment in 1928 of the 'International X-ray and Radium Commission' by the Second International Congress on Radiology in Stockholm. This commission was the predecessor of the ICRP. The task of the ICRP is to formulate recommendations for the protection of man against the harmful effects of ionising radiation.

Until shortly after World War II the knowledge on the effects of the exposure to ionising radiation was limited. It was known that radiation could damage the substance of tissue cells and cause permanent damage in an individual or, after exposure of the gonads, cause defects in the offspring. Already at that date the ICRP discussed a problem that is still subject of debate: what is to be considered a negligible risk. In 1954 the ICRP wrote (British Journal of Radiology 1955, Supplement 6): "Since no radiation level higher than the natural background can be regarded as absolutely 'safe', the problem is to choose a practical level that, in the light of present knowledge, involves a negligible risk." The commission proposed exposure limits in the form of a maximum permissible dose per week. It assumed that, given the low dose rates to which workers would be exposed in practice, permanent damage like skin cancer would not occur during life (ICRP59).

In its 1958 recommendations (ICRP59) the ICRP also mentioned the increased leukaemia incidence among radiologists. The recommended maximum permissible dose of 50 milligray (5 rad) per year was based on that observation and on the consideration that, if a threshold for leukaemia existed, it might be lower than 7500 milligray (750 rad), the maximum bone marrow dose to be received in a 50 year period (the then recommended exposure limit for bone marrow was 150 milligray per year). In 1958 the ICRP

also took into consideration damage to other organs than the skin and the bone marrow and the possibility of genetic defects from irradiation of the gonads.

In 1965 knowledge about the effects of ionising radiation had increased, *inter alia* from the studies among the Japanese atomic bomb survivors. In its Publication 9 the ICRP wrote: “It must be recognised that sufficient information is not available as to the possible forms of injury that may results from irradiation of various tissues. Nevertheless, apart from the acute effects of large doses, it appears likely that the most important effects will be carcinogenesis, the production of degenerative effects such as cataracts, developmental abnormalities in foetal tissue, and hereditary defects.” (ICRP66, para 27). Furthermore, the ICRP concluded that any exposure to radiation may carry some risk for the development of somatic and hereditary effects. Therefore, the commission recommended not only to apply maximum permissible doses but also to avoid unnecessary exposure to radiation and to keep radiation doses as low as is readily achievable (ALARA).

Given the discussion on radiological protection standards in the Netherlands, the following statement of the ICRP is relevant. If the dose-effect relationship were known an acceptable dose might be derived from an acceptable degree of risk. (ICRP66, para 36).

In 1977 more data had become available from the atomic bomb survivor studies. However, the dose-effect relationship for low dose, low dose rate exposures was still not well known. The ICRP stated: “For human populations in particular, knowledge of dose-response relationships is too limited to enable confident prediction of the shapes and slopes of the curves at low doses and low dose rates.” (ICRP77, para 28). However, the ICRP was of the opinion that it was possible to estimate globally the radiation risk associated with a given radiation dose for radiological protection purposes. Such an estimate was used to argue that the recommended system of radiological protection, including the maximum permissible doses (called dose limits in 1977), would lead to risks that would socially be acceptable. The commission compared the probability of radiation induced fatal cancer and the probability of genetic defects in the first two generations of offspring with the probability of fatal accidents in non-radiation practices (ICRP78).

The ICRP proposed to leave the 1965 recommendations essentially unchanged. The acronym ALARA was now interpreted as ‘as low as reasonably achievable’. With the word ‘reasonably’ the ICRP expressed the notion that in striving for dose reduction the cost of reduction measures should be balanced against the amount of reduction achieved (optimisation). According to the ICRP economic and social factors play a role in finding the optimum.

The dose limits for workers were interpreted stricter as the quarterly limit and the limit for the accumulated dose were replaced by an annual dose limit. The value of the annual limit, 50 millisievert (5 rem), was put equal to the former limit for the dose accumulated over working life divided by the number of working years. The dose limitation for inhomogeneous exposure differed more fundamentally from the earlier recommendations. Using data on effects in several organs the ICRP proposed to convert organ doses after inhomogeneous exposure into equivalent radiation doses after homogeneous exposure; in later publications this new quantity was denoted by effective dose equivalent and more recently by effective dose (ICRP77, ICRP78, ICRP91).

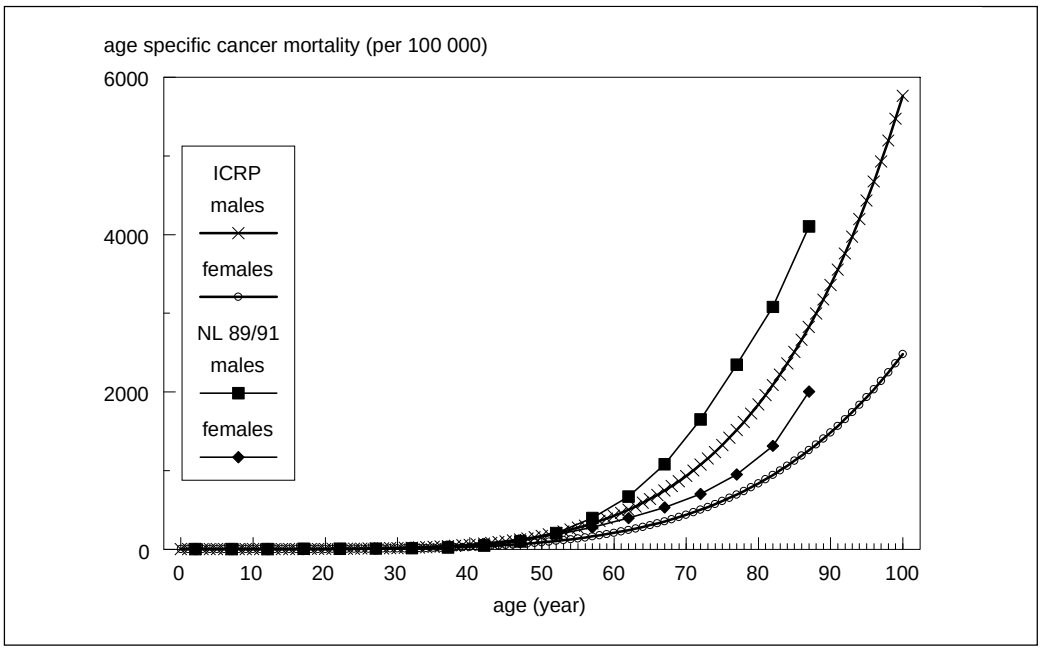

Figure 3 The age specific cancer mortality used in the computations in this appendix (from ICRP91) and the age specific mortality in the Netherlands population in 1989/1991 (Vis94).

Table 3 The excess cancer mortality (per 100 000) associated with exposure to an effective dose of 1 millisievert at a given age. Demographic data: Swedish males, 1991.

age at exposure (year)	life expectancy after age at exposure (year)	excess cancer mortality (per 100 000)		
		total lifetime	at age (year)	
			30	70
0	75	12	0,03	0,5
20	55	6	0,01	0,3
40	36	2	-	0,1
60	19	1	-	0,1

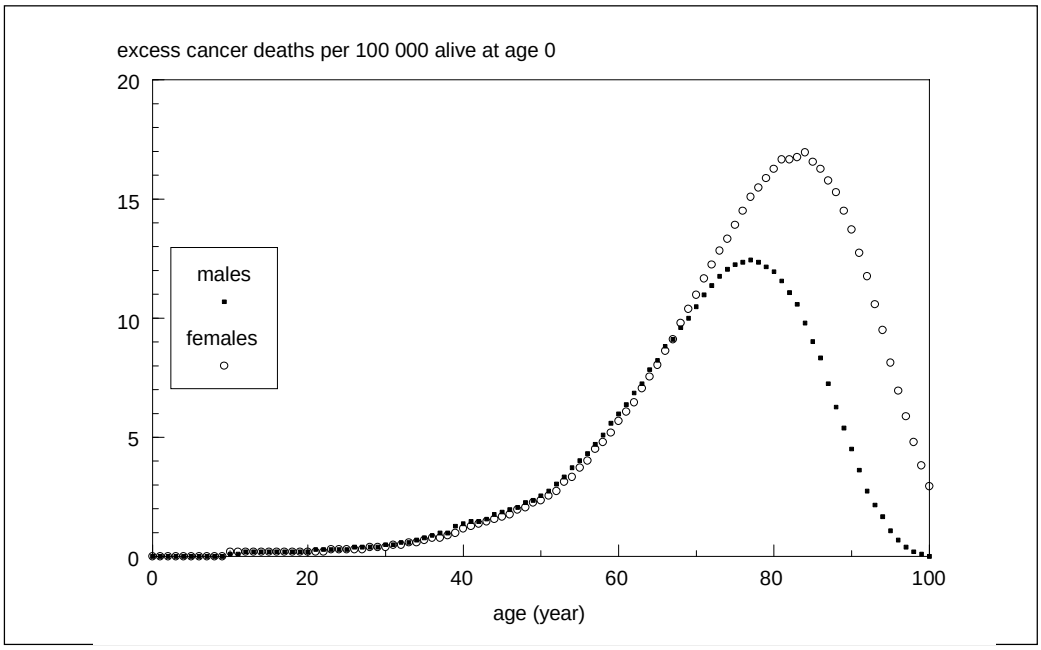

Figure 4 The distribution with age of the probability of excess cancer death associated with continuous, lifelong exposure to an effective dose of 1 millisievert per year as a function of age. The probability is given as the excess deaths at a given age in a group of 100 000 people all alive at age 0.

Annex **D**

Quantifying radiation risk

In this annex the results of calculations of the extra cancer mortality associated with exposure to ionising radiation are presented. The calculations haven been performed using a computer program developed by committee member Lindell. They are given to illustrate the relationship between radiation exposure and cancer mortality and should not be used to estimate health effects in actual exposure situations.

The calculations are based on the risk projection models in ICRP Publication 60 (ICRP91), appendix C. In this annex a relative risk projection model is used together with the ICRP standard data for the age specific 'normal' cancer mortality. The latency period, *i.e.* the lapse of time between a radiation exposure and the associated increase in the probability of getting cancer, is assumed to be 2 years for leukaemia and 10 years for solid tumours. Demographic data of the Swedish population in 1991 have been used.

In figure 3 the age specific cancer mortality as used in the model is compared with that of the Netherlands population in 1989/1991 (Vis94). The figure demonstrates that the mortality rises strongly with age. The standard curves used by ICRP are somewhat below the most recent data from the Netherlands, but such a difference does not seriously affect the outcome of the computations.

For different exposure ages the excess cancer mortality associated with a (single) effective dose of 1 millisievert has been calculated. The results are given in table 3. The figures in the table show that with increasing age of exposure the excess cancer mortality decreases, but also that the excess mortality predominantly manifests itself at old age. Figure 4 shows the age distribution of the excess cancer deaths in a group of individuals who are subject to a lifelong exposure of 1 millisievert per year starting at age 0. Above the age of 80 the excess cancer mortality decreases with age as the overall number of survivors then rapidly decreases.

Table 4 Values of the tissue weighting factor w_T for effective dose (ICRP91, table 2).

organ T	w_T	organ T	w_T
gonads	0,2	bone marrow (red)	0,12
colon	0,12	lung	0,12
stomach	0,12	bladder	0,05
breast	0,05	liver	0,05
oesophagus	0,05	thyroid	0,05
skin	0,01	bone surface	0,01
remainder	0,05		

ICRP91, table 2 also presents guidance on the applicability of the weighting factors and on the interpretation of the 'remainder'

Annex **E**

Effective dose

In this section the committee discusses the concept of effective dose. For more information the reader is referred to the 1990 Recommendations of the ICRP (ICRP91) and the Health Council report on radiation risk (GR91, appendix H).

The quantity effective dose, *E*, is defined by

$$E = \sum_T w_T H_T$$

in which H_T denotes the equivalent dose in organ T and w_T is the so-called tissue weighting factor. The weighting factors are normalised to 1, *i.e.*

$$\sum_T w_T = 1$$

The weighting factors recommended by ICRP are given in table 4. The weighting factor for each organ, with the exception of the gonads, is directly related to the probability of fatal cancer in the organ per unit organ equivalent dose multiplied by a factor related to the lethality of the given cancer and by a normalisation constant. For the gonads the weighting factor is equal to the probability of a hereditary effect in the progeny of the exposed person per unit gonad equivalent dose multiplied by a normalisation constant. Subsequently the weighting factors are rounded to either 0,01, 0,05, 0,12 or 0,2.

In defining effective dose ICRP has aggregated the different forms of detriment taking into account cancer incidence, cancer lethality and hereditary effects. The practical use of effective dose in radiological protection is in deriving limits for intake of radionuclides, where the resulting equivalent doses are usually not equally distributed among the various organs and tissues.

OmRS expresses strong reservations about aggregating different radiation health effects. It states that each effect (*i.e.* fatal cancer, non-fatal cancer, teratogenic effects and hereditary effects) should be weighted equal and that limiting fatal cancer also reduces the risk of other forms harms to a sufficient degree. It is not clear if OmRS suggests methods for the calculation of the risk from the intake of radionuclides that differ from those of ICRP. In practice it appears that effective dose calculations using the factors recommended by ICRP for the conversion of activity intake to effective dose are accepted by the Dutch authorities.