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*Attribution of radiation health effects
and inference of radiation risks*

Considerations for application of the IAEA safety standards

FOREWORD

[to be drafted at the end]

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1. INTRODUCTION

1.1 BACKGROUND

The IAEA safety standards are based on the scientific knowledge on the levels and health effects associated with radiation exposure that have been studied over decades by the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) and on the recommendations of international expert bodies, notably the International Commission on Radiological Protection (ICRP).

UNSCEAR was established by the United Nations General Assembly on 3 December 1955. Its mandate is to undertake broad assessments of sources of ionizing radiation and of the effects of ionizing radiation on human health and the environment. In pursuit of this mandate, UNSCEAR thoroughly reviews and evaluates exposures to radiation at the global and regional levels and evaluates evidence for radiation induced health effects in exposed groups. UNSCEAR also reviews advances in the understanding of the radiobiological mechanisms by which radiation induced effects on human health or on non-human biota can occur.

In its resolution 62/100 of 17 December 2007, the United Nations General Assembly requested UNSCEAR “to clarify further the assessment of potential harm owing to chronic low-level exposures among large populations and also the attributability of health effects”, and encouraged UNSCEAR “to submit a report on that issue at its earliest convenience”.

In 2015, the UNSCEAR 2012 Report to the General Assembly and its Annexes on attribution of health effects and inference of risk (A/67/46) was published [1]. The UNSCEAR 2012 report raised questions about understanding among experts and communication with the public regarding issues such as radiation exposure, health effects and future risks, and set out in clear language the concepts of retrospective attribution of radiation health effects to past radiation exposures and prospective inference of health risks from radiation exposures. The report focused on “the sum of the relevant incremental exposures above that from normal background exposure to natural sources, because that is usually the characteristic considered in epidemiological studies (and is also of interest to those who might use the Committee’s information as the basis for policy and decision-making).” [1].

The ICRP was established in 1928 at the Second International Congress on Radiology in Stockholm, Sweden. The Board of Governors of the IAEA first approved health and safety measures in March 1960, when it was stated that “The Agency’s basic safety standards ... will be based, to the extent possible, on the recommendations of the International Commission on

Radiological Protection (ICRP)”. The ICRP’s latest recommendations on radiation protection were published in 2007 as ICRP Publication 103 [2].

In its response to the UNSCEAR 2012 report, the Commission on Safety Standards¹ requested that a Safety Report be prepared on how to apply the concepts of:

- Retrospective attribution of radiation health effects to past radiation exposures;
- Prospective inference of health risks from radiation exposures;
- Prediction of notional health effects for comparative purposes (e.g. use of collective dose).

1.2 OBJECTIVE

The objective of this Safety Report is to explain how the concepts of attribution of health effects and inference of risks, as set out in UNSCEAR 2012 [1], can be taken into account in understanding the key concepts of the IAEA safety standards and in applying the standards.

The Safety Report also describes how an understanding of the concepts of attribution and inference can improve the communication of radiation risks in different circumstances.

The target audience of this Safety Report is experts on safety in regulatory bodies, other relevant authorities, operating organizations, technical support organizations and international organizations. It is also expected to be of wider interest among the scientific community.

1.3 SCOPE

This Safety Report addresses protection against harmful effects of ionizing radiation as addressed in the IAEA safety standards, i.e. it covers all circumstances that give rise to radiation risks, for the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes, and protective actions to reduce existing or unregulated radiation risks.

Although this Safety Report summarizes the scientific aspects of attribution of health effects to radiation exposure, as set out in UNSCEAR 2012 [1], it does not provide guidance on assessing prospective cancer risks from exposure to radiation, nor on assessing the

¹ The Commission on Safety Standards is a standing body of senior government officials, appointed by the IAEA Director General, holding national responsibilities for establishing standards and other regulatory documents relevant to nuclear, radiation, transport and waste safety, and to emergency preparedness and response

attributability of health effects to radiation exposure for purposes of determining legal liability in compensation programmes for cancer.²

Terms in this Safety Report are to be understood as they are defined in the IAEA Safety Glossary³ [5].

1.4 STRUCTURE

[to be prepared at the end]

² Such matters are addressed in Refs [3, 4].

³ The purpose of the IAEA Safety Glossary is to define and explain the usage of terms in the safety standards as a whole, and as such some of the definitions are necessarily inconsistent with the definitions included in UNSCEAR 2012 [1], which are for the purposes of that report alone.

2. RISK-RELATED CONCEPTS

2.1 RETROSPECTIVE ATTRIBUTION OF RADIATION HEALTH EFFECTS TO PAST RADIATION EXPOSURES

Harmful health effects of radiation exposure can be categorized in two groups, namely:

- Deterministic effects, which are described as injury in populations of cells, , and are also termed tissue reactions;
- Stochastic effects, which includes malignant disease and heritable effects.

2.1.1 Deterministic effects

2.1.1.1 Characteristics of deterministic effects

As the human body is exposed to ionizing radiation, a process of ionization occurs that alters atoms in molecules, at least transiently, and thus might alter the structure of molecules in cells. If molecules within a living cell are affected, components of cells might be damaged. This damage might kill the cell, or it might result in a viable but modified cell or affect the capacity of the cell for reproduction. If a critical number of cells in a living organ or tissue is killed, or if a critical number of cells is prevented from reproducing and functioning normally, there might eventually be a loss of function of the organ or tissue, resulting in detrimental health effects.

Deterministic effects are usually acute and occur early (usually within hours or a few days) in individuals exposed to radiation at high doses. Examples of deterministic effects include erythema (i.e. skin burns), damage to the haemopoietic system, acute radiation syndrome (i.e. radiation sickness), epilation (i.e. hair loss) and death of the exposed individual.

Deterministic effects can occur only in an individual if the radiation dose exceeds a certain threshold level of dose. Below the threshold level of dose, no deterministic health effect is caused. Above the threshold level of dose, however, a deterministic effect is more severe for a higher dose. The level of the threshold dose is different for different deterministic effects. It is also related to the length of time of exposure, and it may depend, to a limited extent, on the individual who is exposed.

2.1.1.2 Attribution of deterministic effects

As stated in UNSCEAR 2012 [1], a deterministic effect in an individual can be unequivocally attributed to radiation exposure by means of a differential pathological diagnosis that eliminates possible alternative causes.

2.1.2 Stochastic effects

2.1.2.1 Characteristics of stochastic effects

Exposure to ionizing radiation can also induce the non-lethal modification of cells, which may still be viable and may still retain their functional capacity. The human body's immune system is very effective at detecting and destroying abnormal cells. If somatic cells in a tissue or organ are modified by exposure to radiation, they might survive but modify or lose their functionality. If germ cells are modified by exposure to radiation, they might survive and still retain their reproductive capacity, but either perform cell division and give rise to defective descendant cells, or not be able to retain control over cell division. This might eventually lead to the development of malignant diseases such as leukaemia and solid cancers.

Reproductive cells of an organism have the function of transmitting genetic information to the descendants of an exposed individual. Modified reproductive cells hypothetically might transmit altered genetic information (mutation) to the descendants of an exposed individual and thus cause hereditary effects to the descendants. Such random health effects and hereditary effects, which might originate from a single modified cell, are termed stochastic effects.

The latency period for the manifestation of stochastic effects might be from a few years in the case of leukaemia to tens of years for other malignant conditions such as solid cancers.

The probability of occurrence of a stochastic effect is greater for a higher radiation dose and the severity of the effect (if it occurs) is independent of dose.

2.1.2.2 Attribution of stochastic effects

At present, it is not possible to attribute a stochastic effect in an individual to radiation exposure. This is the case because, even in the absence of radiation exposure, similar effects that are indistinguishable from stochastic effects of radiation exposure might occur, such as those effects that are due to other carcinogens. Even the discovery of a biological indicator or biomarker specifically for effects of radiation exposure at low levels of dose and low dose rates would not change this, because it is unlikely or, at present, not possible that effects of a

particular exposure to radiation could be differentiated from the effects of exposure to natural background radiation. Unlike for deterministic effects, therefore, in the case of stochastic effects of radiation exposure, unequivocal differential pathological diagnosis on individuals is not possible at present.⁴

However, by means of epidemiological studies of populations of people, it is sometimes possible to attribute an increase in the frequency of occurrence of stochastic effects to radiation exposure. Such attribution at the population level might be possible provided that, among other things, the change observed in the base level incidence of the stochastic effect is high enough to overcome the inherent epistemic uncertainties of epidemiological data and the uncertainties due to statistical limitations of epidemiology.

An example is the incidence of thyroid cancer among children. Thyroid cancer generally has a very low incidence in children, but it is greatly affected by radiation exposure (i.e. the radio-sensitivity for the effect is high). Results from some epidemiological studies have shown increased frequency of thyroid cancer among children that can be attributed with confidence to radiation exposure. But even if an increase of the frequency of thyroid cancer in an exposed population is observed, a particular case of thyroid cancer in an individual still cannot be attributed unequivocally to radiation exposure.

However, in many other situations, for example where the change observed in the frequency of a stochastic effect is small or when the dose is low, it is not possible to attribute an increase in frequency of a stochastic effect in a population to radiation exposure.

2.1.2.3 Uncertainties in attributing stochastic effects

Estimates of stochastic effects are intrinsically uncertain, particularly at low doses. There are two types of uncertainty: statistical or aleatory uncertainties, which are due to the random variation of the magnitudes of the estimates and are inherent in a phenomenon; and epistemic uncertainties, which are those due incomplete knowledge about a phenomenon [5]

UNSCEAR [7] has identified a large number of sources of uncertainty in the epidemiological estimates of radiation effects

⁴ That is, stochastic effects are not provable for a single individual. See Ref. [6] for further discussion.

The more dominant uncertainty in the case of stochastic effects due to radiation exposure is the statistical or aleatory uncertainty, due to the impact of dose levels and the sample size of the epidemiological study on statistical power..

As a result of the uncertainties, “It is extremely difficult to detect excess frequency of occurrence of cancer by studying population exposures limited to low dose and very low doses. This is because, at low doses and, in particular, at very low doses, the plausible increased frequency of occurrence of stochastic effects is normally dwarfed by statistical and other variations in the baseline frequency of their occurrence. As a result, extremely large sample sizes (typically millions of people) would theoretically be required in these dose ranges for a statistically significant increase in frequency to be observed” [1].

2.1.3 The dose-response relationship

For the purposes of facilitating the discussion of health effects of radiation exposure, UNSCEAR has adopted a terminology to indicate bands of exposure, expressed as approximate ranges of total absorbed dose. The terminology is intended to foster consistent interpretation of the terms ‘high’, ‘moderate’, ‘low’ and ‘very low’ total doses of low linear energy transfer (LET) radiation (e.g. gamma radiation). Table 1 [1] indicates, in approximate ranges, bands of total absorbed dose (to the whole body or to a specific organ or tissue of an individual) received in addition to the total from normal background exposure to natural sources of radiation. The dose bands do not account for the rate at which the dose is delivered.

TABLE 1. TERMINOLOGY FOR BANDS OF ABSORBED DOSE [1]

Terminology for dose bands	Range of absorbed dose for low-LET radiation ⁵	Scenarios
High	Greater than about 1 Gy	Typical dose to individuals after severe radiation accidents or from radiotherapy
Moderate	About 100 mGy to about 1 Gy	Doses to about 100,000 of the recovery operation workers after the Chernobyl accident, doses to 173 Fukushima Daiichi recovery workers.

⁵ For low-LET radiation, 1 mGy absorbed dose is equivalent to 1 mSv effective dose.

Low	About 10 to about 100 mGy	Dose to an individual from multiple whole body computerized tomography (CT) scans, some occupational workers
Very low	Less than about 10 mGy	Most public and occupational exposure situations

UNSCEAR 2012 [1] made a distinction between three different regions of the dose–response relationship (see Fig. 1) in relation to the observation of effects, namely:

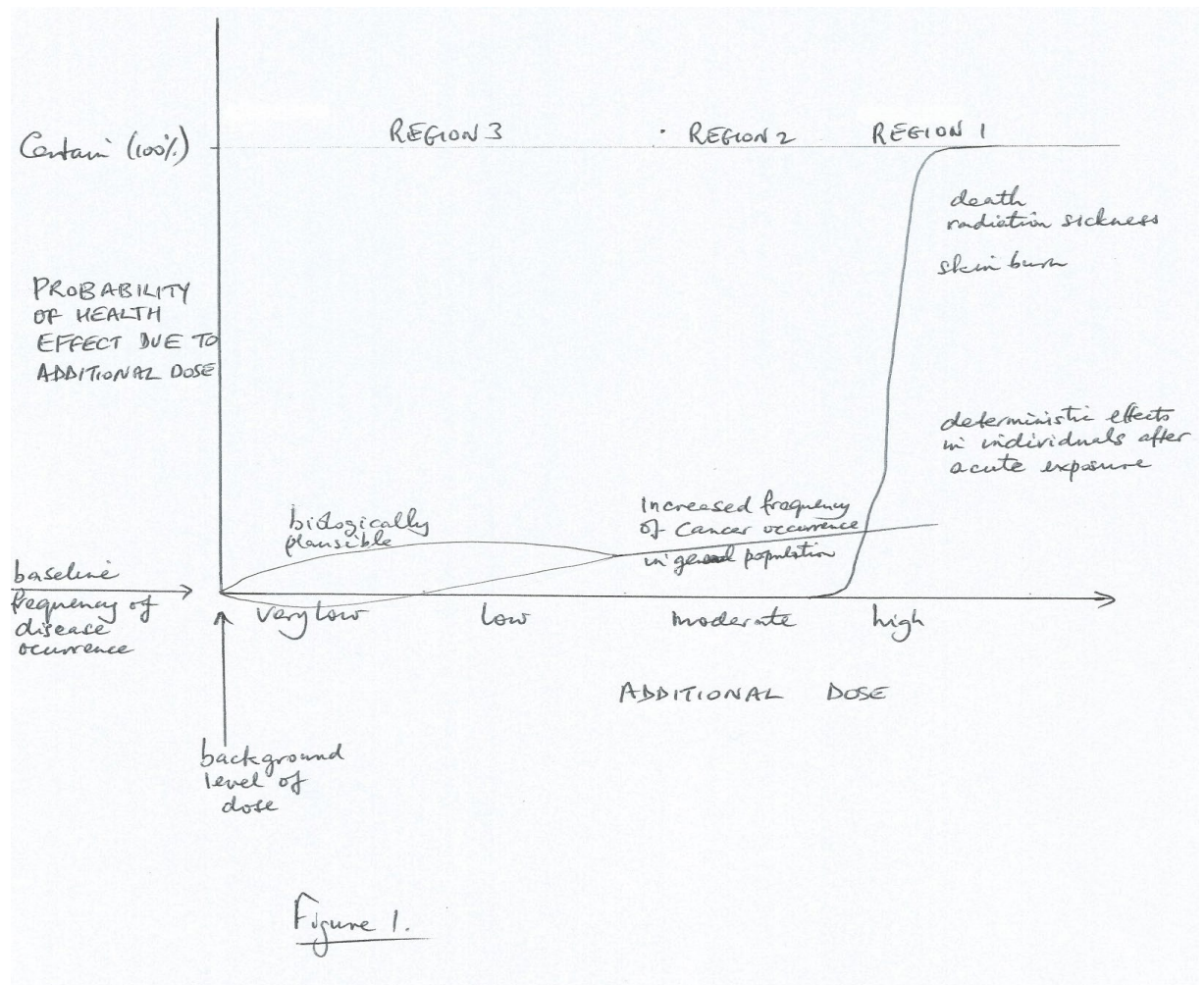


FIG. 1. Relationship of radiation doses and health effects. (Adapted from Ref. [8]).

Region 1: The high-dose region for which health effects are clinically observable in individuals by means of a diagnosis (deterministic effects). The dose response relationship for deterministic effects in large populations follows a sigmoid function (red line in Fig. 1), but in practice, at the individual level, it is assumed to be a threshold function: below the dose threshold for the

occurrence of a particular deterministic effect, the radiation risk is taken to be zero; above the threshold it is assumed to be one.

Region 2: The moderate-dose region for which effects are observable only statistically among populations, and for individuals are not attributable to radiation exposure, by means of epidemiological estimates (stochastic effects). The dose response relationship for stochastic effects observed in large populations forms a roughly linear function (blue line in Fig. 1).

Region 3: The low and very low-dose region for which effects may be scientifically plausible but are not observable in individuals or in the collective incidence in an exposed population.

2.2 PROSPECTIVE INFERENCE OF HEALTH RISKS FROM RADIATION EXPOSURES

2.2.1 Frequentist risk and subjective risk

The concept of risk has to do with a likelihood of some adverse consequences occurring in the future. In the context of radiation-related health effects, risk is defined as “The probability of a specified health effect occurring in a person or group as a result of exposure to radiation” [5]⁶.

The quantification of risk (or probability) was originally founded on the retrospective analysis of factual frequencies of past occurrences of events. In the context of radiation-related health effects, frequentist probabilities can be stated if which direct epidemiological data exist, which is generally only in the moderate and high dose regions (see Section 2.1.2.2) The concept of risk later evolved to include also subjective probability based on expert judgement. In the context of radiation-related health effects, expert judgement has mainly involved extrapolation of epidemiological knowledge from the moderate and high dose region, using appropriate modifying and adjustment factors, and biological insight. Circumstances for which no direct epidemiological data exist and for which judgements needs to be made include: “(i) extrapolation of risks over lifetime, (ii), transference to another population; (iii) transference

⁶ In UNSCEAR 2012 [1], the term ‘risk’ is defined in a manner that is consistent for the purposes of this Safety Report, but is somewhat more precise, namely “risk refers to the probability that an event of interest (e.g. onset of cancer) will occur (i.e. it is prospective) during a given time period (e.g. the rest of life following an exposure)”.

from one type of radiation to another; (iv) inferring risks from low-dose-rate exposure; and (v) inferring risks from low and very low doses” [1].

Although frequentist probabilities and subjective probabilities are quite different from an epistemological point of view, mathematically they are handled the same way, which has contributed to the lack of distinction between these two types of probabilities in practice. In particular, in inferring radiation risks for purposes of radiation protection (see Section 2.2.3), which needs to cover situations of high dose and high dose rate, as well as situations of low dose and low dose rate, the distinction between frequentist risk and subjective risk is not normally made explicit. The frequentist probabilities arising from the epidemiological studies of populations exposed to relatively high doses and high dose-rates are extrapolated to propose subjective radiation risk estimates for low-dose, low-dose-rate situations.

2.2.2 Inferring radiation risks for purposes of estimating health effects

For exposure to high doses, received in a short period of time, there is sufficient evidence to be able to estimate (predict) whether or not there will be a deterministic effect in an exposed individual, and the likely severity of the effect (see Section 2.1.1 and 2.1.3).

For exposure to moderate to high doses, there is epidemiological evidence to be able to estimate (predict) with some confidence of an increased risk of stochastic effects in a population similar to that for which the evidence exists (see Section 2.1.2 and 2.1.3). Epidemiological estimates are generally performed using data on frequencies of actual health effects that occurred in the aftermath of past radiation exposure situations. These studies usually involved relatively high doses and high dose-rates (such as the Life Span Study (LSS) of the survivors of the atomic bombings in Hiroshima and Nagasaki). UNSCEAR latest major evaluations of epidemiological studies radiation induced cancer were issued were finalized in 2006 and 2010 [7, 9]. These evaluations provided a statistically significant estimate of the excess lifetime risk of mortality for doses in the moderate to high dose regions. That is, the risk of a health effect occurring following a dose in the moderate to high range could be considered a frequentist risk.

For exposures in the ranges of very low and low doses, UNSCEAR states that “there have been no studies that unequivocally indicate statistically significant increases in the frequency of occurrence of cancer in epidemiological studies of the general population” [1]. UNSCEAR notes that there are several plausible dose-response relationships for the very low and low regions (i.e. region 3 of Fig. 1), and it “considers that risks are unlikely to change

dramatically just below the dose levels at which a statistically significant increased frequency of occurrence has been established” [1].

The prospective inference of risk from radiation exposure depends on the conceptual models that have been used to project doses due to exposures and the possible consequences of those doses for individuals. It also depends on the simplifying assumptions made, and on the factors for modification and adjustment used in these models. The conceptual models used may be mechanistic models (i.e. models that are intended to simulate the relevant scientific and medical mechanisms of the phenomena concerned), or they may just be mathematical ‘curve fitting’ models. Cumulatively, uncertainties and margins of error in the values derived from the use of conceptual models — and especially, various conceptual models in aggregation — may be significant.

Figure 2 shows some possible dose response relationships for the risk of cancer from exposures at very low, low and moderate doses, all of which are plausible in terms of known mechanisms for cancer induction. The risk presented by any of these relationships would be considered subjective risk, i.e. based on expert judgement and not on actual epidemiological data.

Figure I. Schematic presentation of plausible dose–response relationships for the risk of cancer in the ranges of very low, low and moderate doses

The doses in the figure are in addition to the total background exposure to natural sources of radiation. The data points and confidence intervals* marked on the graph represent observations of increased frequency of occurrence of a specific cancer type in populations exposed to moderate doses. The various lines represent the following plausible dose–response relationships for inferred risk of cancer for exposures in the ranges of low and very low doses: (a) supralinear; (b) linear non-threshold (LNT); (c) linear–quadratic; (d) threshold; and (e) hormetic. These relationships are discussed in more detail in paragraph A82

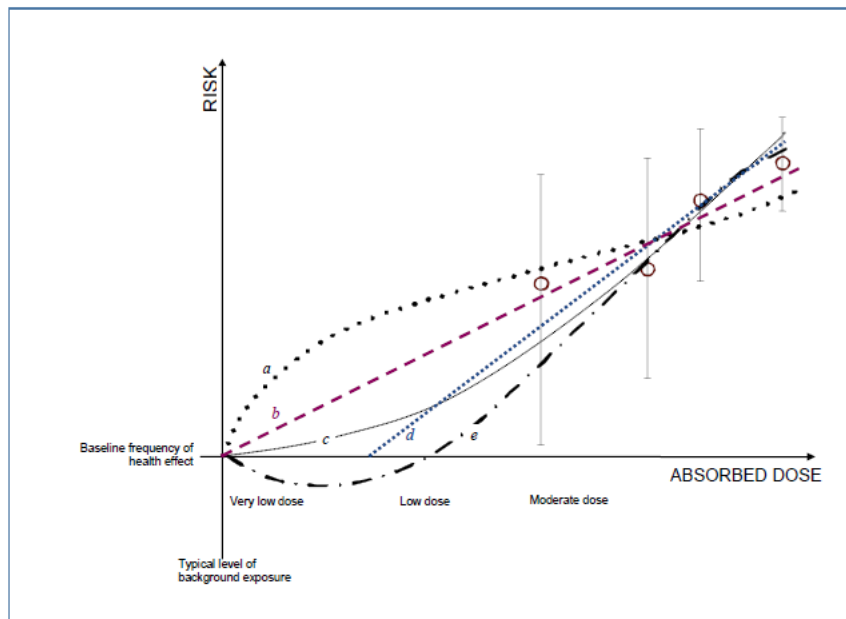


FIG. 2. Schematic presentation of plausible dose-response relationships for the risk of cancer in the ranges of very low, low and moderate doses [1].

These relationships are:

- (a) The cancer risk at very low and low doses is substantially greater than expected from an LNT relationship (a supralinear relationship – curve ‘a’ in Fig. 2).
- (b) The response observed in the moderate dose range is extrapolated linearly down to zero additional dose to the background radiation (linear non-threshold (LNT) relationship – curve ‘b’ in Fig. 2). This linear relationship is used in modelling the risk of cancers other than leukemia [10] and is also the model used for purposes of radiation protection (see Section 2.2.3). The cancer risk at very low and low doses is substantially lower than expected from an LNT relationship (a threshold or hermetic relationship – curves ‘d’ and ‘e’ in Fig. 2 respectively).

These possible plausible doseresponse relationships demonstrate why it is not possible to provide any objective estimation of the level of cancer in populations exposed to very low and low doses of radiation. UNSCEAR states that these relationships in Fig. 2 “cannot be convincingly verified or falsified at the moment” [1].

2.2.3 Inferring radiation risks for purposes of radiation protection

The ICRP first used the linear no-threshold (LNT)⁷ theory in its recommendations published in 1966 [11]. The LNT is a conceptual model in which the risk of stochastic effects is assumed to increase in direct proportion to the radiation dose. The model applies for all levels of dose, i.e. the LNT makes no distinction between how it handles moderate doses that lead to attributable stochastic effects (at a population level) and how it handles low and very low doses for which one cannot attribute effects. Moreover, the LNT model does not allow for any dependence on the dose rate or on the rate of change of dose-rate. Within this model, any additional dose above background levels implies a non-zero risk of stochastic effects. The risk coefficient in the LNT (i.e. the slope of line ‘c’ in Fig. 2), is taken to be 5% per sievert.

The ICRP stated at that time “the Commission sees no practical alternative, for the purposes of radiological protection, to assuming a linear relationship between dose and effect, and that doses act cumulatively. The Commission is aware that the assumptions of no threshold and of complete additivity of all doses may be incorrect, but is satisfied that they are unlikely to lead to the underestimation of risks” [11].

In its most recent recommendations ICRP continues to assume the LNT model for purposes of practical radiation protection: “The central assumption of a linear dose–response relationship for the induction of cancer and heritable effects, according to which an increment in dose induces a proportional increment in risk even at low doses, continues to provide the basis for the summation of doses from external sources of radiation and from intakes of radionuclides” [2].

In developing its most recent recommendations, ICRP also reviewed the latest biological and epidemiological studies on the health effects of ionizing radiation. ICRP found that “The distribution of risks to different organs/tissues is judged to have changed somewhat since Publication 60, particularly in respect of the risks of breast cancer and heritable disease. However, assuming a linear response at low doses, the combined detriment⁸ due to excess cancer and heritable effects remains unchanged at around 5% per Sv” [2].

⁷ UNSCEAR uses the term ‘linear non-threshold model’ in its reports [1].

⁸ ICRP defines detriment as “The total harm to health experienced by an exposed group and its descendants as a result of the group’s exposure to a radiation source. Detriment is a multidimensional concept which principal components are: the stochastic quantities: probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and length of life lost if the harm occurs” [ICRP 103 ??].

ICRP has expressed certain provisos in calculating the risk coefficient of 5% per Sv. It has noted that the experimental results in animals and other biological organisms, and even limited human experience, indicate that cancer induction at low doses and low dose rates is likely to be less than that observed at high doses and high dose rates [12], i.e. that the relationship between dose and response at low doses is not purely linear and that the LNT in fact leads to an overestimate of radiation risk for such doses and dose rates. A dose and dose-rate effectiveness factor (DDREF) has been used to compensate for this overestimation. ICRP used a factor of 2 for DDREF in ICRP 60 [12]. ICRP also noted that as cancer survival rates are expected to rise, the nominal risk coefficients may be an overestimate of risks in the future.

In addition to these scientific concerns regarding the extrapolation of the risk coefficient of 5% per Sv to low and very low doses in the mSv range, it also needs to be recalled that the LNT is not based on objective observation of health effects (i.e. it does not represent a frequentist risk estimate in the low and very low dose range). It is a model (i.e. it represents a subjective risk estimate, based on expert judgement) and indeed it is one of only several plausible possible models for what could happen at low and very low doses (see Fig. 2). It has been selected from among these possible plausible models not because it is the most likely model to be scientifically correct; in fact, given what is known about cellular repair mechanisms following exposure to radiation, it is less likely to be scientifically correct than some of the other models shown in Fig. 2. Rather, the main purpose of adopting the LNT is to facilitate the practical application of the approach to radiation protection. The LNT provides the basis for assuming the appropriateness of summing or aggregating doses from external sources of radiation and doses from intakes of radionuclides, while maintaining a simple approach to calculations for radiation protection.

2.3 ESTIMATION OF HEALTH EFFECTS FOR COMPARATIVE PURPOSES

Possible health effects that might result from situations of exposure, even for very low doses, sometimes need to be estimated for comparative purposes. For example, authorities with responsibilities for public health have to allocate resources for measures for radiation protection appropriately and effectively. This might involve making projections of theoretical numbers of postulated stochastic effects for comparative purposes.

The concept of ‘collective dose’ [12, 13] was introduced as a tool for use in optimization, namely for comparing protection and safety options (see Section 3.4.2). The collective dose is

calculated as the sum of all individual doses over the time period of exposure being considered. The concept of collective dose assumes the LNT model, because only on this basis is it possible to add doses. Collective dose due to occupational exposure for a group of workers is used in the optimization of protection and safety in some facilities when assessing various options to carry out a maintenance task in a nuclear power plant for example [14]. Collective dose is also used for comparing alternative options for managing discharges from facilities [15] and as one of the criteria for allowing emergency workers to receive an exposure in excess of 50 mSv is “when undertaking actions to avoid a large collective dose” [16, 17].

Great care needs to be taken in considering ‘collective dose’ to a large number of people (i.e. by multiplying low doses and very low doses for large populations). The calculation of collective dose conceals large biological and statistical uncertainties. The assumptions that underpin any such calculations, as well as the associated uncertainties in the information and the limitations on its applicability, have to be made explicit and have to be taken into account. UNSCEAR 2012 [1] states that “The Scientific Committee notes that public health bodies need to allocate resources appropriately, and that this may involve making projections of numbers of health effects for comparative purposes. This method, though based upon reasonable but untestable assumptions, could be useful for such purposes provided that it were applied consistently, the uncertainties in the assessments were taken fully into account, and it were not inferred that the projected health effects were other than notional.”

Specifically, the computation of cancer deaths based on collective effective doses involving trivial exposures to large populations is not reasonable and ICRP, UNSCEAR and the IAEA have all strongly advocated that such use of collective dose be avoided [1, 2, 15]

UNSCEAR 2012 [1] stated quite clearly that “the Scientific Committee does not recommend multiplying very low doses by large numbers of individuals to estimate numbers of radiation-induced health effects within a population exposed to incremental doses at levels equivalent to or lower than natural background levels.”

3. BASIS OF THE SAFETY STANDARDS

3.1 PURPOSE, DEVELOPMENT AND USE OF THE SAFETY STANDARDS

The IAEA is authorized, under Article III.A.6 of its Statute “To establish or adopt, in consultation and, where appropriate, in collaboration with the competent organs of the United Nations and with the specialized agencies concerned, standards of safety for protection of health and minimization of danger to life and property (...), and to provide for the application of these standards”.

The safety standards provide principles, requirements and recommendations that are based on the possibility and likelihood of the occurrence of incidents and other events, as well as on expert judgement, and they are intended to be used prospectively, with the objective of protecting people and the environment. The safety standards are regulatory in nature, and their purpose is to provide instructive advice, for cooperative, constructive and collaborative use, and to support decision making.

The safety standards reflect an international consensus on what constitutes a high level of safety for protecting people and the environment from harmful effects of ionizing radiation. They are based on the practical experience of Member States and are produced through a process of international consensus building, through consultation with the cosponsoring organizations and Member States by means of a system of standing bodies of senior representatives of both Member States and selected intergovernmental organizations and international non-governmental organizations, respectively. Many safety standards are sponsored jointly by several agencies of the United Nations system. As such, the safety standards are intergovernmental, international safety standards.

The safety standards are part of the global nuclear safety regime. The regime establishes a consistent and comprehensive internationally agreed basis for the proper protection of people and the environment from harmful effects of ionizing radiation. The global nuclear safety regime encompasses:

- States’ legally binding obligations in protection and safety, which are expressed as international conventions, as well as voluntary obligations expressed as declarations of diplomatic conferences and codes of conduct;
- The safety standards, together with provisions for their application, which support those legally binding and voluntary obligations. The safety standards form a basis for

these legal instruments and also serve as a global reference in order to help parties meet their obligations.

The regulation of safety is a national responsibility and safety standards are not legally binding on States; however, they are widely applied and many States decide to adopt these standards for use in national regulations. The standards are also applied by designers, manufacturers and operating organization around the world to enhance nuclear and radiation safety in power generation, medicine, industry, agriculture, research and education. The safety standards are binding on the IAEA in relation to its own operations, and also on States in relation to IAEA assisted operations.

The safety standards are issued in the IAEA Safety Standards Series, which comprises three categories of publications — Safety Fundamentals, Safety Requirements and Safety Guides:

- The Safety Fundamentals present the fundamental safety objective and principles for protection and safety [18]. The Safety Fundamentals are formulated in language that is understandable to the non-specialist reader and they convey the basis and rationale for the safety standards to those at senior levels in government and regulatory bodies.
- The Safety Requirements establish the requirements that must be met to ensure the protection of people and the environment, both now and in the future. The requirements are governed by the objective and principles of the Safety Fundamentals. They are formulated in a manner that facilitates their use in establishing a national regulatory framework. The requirements represent the international benchmark for protection and safety, and thus they have major implications for regulatory policy and for decision making.
- The Safety Guides provide recommendations and guidance on how to comply with the safety requirements. They present international good practices to help users striving to achieve high levels of safety.

The safety standards are not intended for attributing health effects, either individually or collectively, to radiation exposure as their cause, and the models used in the safety standards to assign risk are not intended to be used in attributing health effects. Moreover, the safety standards are not drafted as legal documents and they do not contain statements that are intended to be contested in court (e.g. in the context of occupational compensation claims).

3.2 SCOPE OF THE SAFETY STANDARDS

The safety standards cover all circumstances that give rise to radiation risks and are applicable for the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes, and protective actions to reduce unregulated radiation risks. The safety standards are concerned with both radiation risks that exist in normal circumstances and radiation risks that arise as a consequence of incidents.

The safety standards cover radiation protection and nuclear safety (also termed ‘protection and safety’), i.e. the protection of people and the environment against radiation risks, and the safety of facilities and activities that give rise to radiation risks. Protection and safety includes the safety of nuclear installations, radiation safety, the safety of radioactive waste management and safety in the transport of radioactive material, and emergency preparedness and response⁹. The safety standards also address protection of the environment, and the interface between nuclear security and safety¹⁰.

It is with regard to radiation protection, i.e. protection of humans against harmful effects of radiation, that the concepts of attribution and inference, as set out in UNSCEAR 2012 [1], can be most helpful.

For radiation protection of humans, three basic categories of exposure have been considered, namely occupational exposure, public exposure and medical exposure. For the purpose of establishing practical requirements for protection and safety, the safety standards also distinguish between three different types of exposure situation: planned exposure situations, emergency exposure situations and existing exposure situations.

There are some situations involving radiation exposure that are considered not to be amenable to control¹¹ (see GSR Part 3 [16], para. 1.42). These are excluded from the scope of the safety standards.

The safety standards are intended to be applied for situations where radiation exposure could occur. Such situations involve exposures that can certainly be anticipated (i.e. the

⁹ Safety standards in the area of emergency preparedness and response apply for preparedness and response for a nuclear or radiological emergency irrespective of the initiator of the emergency, whether the emergency follows a natural event, a human error, a mechanical or other failure, or a nuclear security event.

¹⁰ Measures that are specific to nuclear security (e.g. measures of physical protection) are not included the safety standards, although both safety and nuclear security have the common aim of protecting people, society and the environment. The IAEA issues guidance on nuclear security in the IAEA Nuclear Security Series.

¹¹ It is generally accepted that it is not feasible to control ⁴⁰K in the body, or cosmic radiation at the surface of the earth.

exposures expected to occur in normal operation), and ‘potential’ exposures (i.e. exposures that are not expected to be delivered with certainty but that might result from an incident or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors).

The standards apply for situations in which exposures could lead to health effects that can be attributed at an individual level (deterministic effects), situations in which exposures could lead health effects that can be attributed at a population level (stochastic effects), and situations in which risks can only be inferred (i.e. situations involving exposures in all three regions of Fig. 1). However, the safety standards are not formulated in terms of the various types of health effect, either individually attributable or at attributable at a population level, to which exposures might give rise. Rather, the requirements and recommendations in the safety standards are provided on the basis of an inference of the risk associated with different levels of exposures that will or might occur in the future.

3.3 ETHICAL BASIS OF THE SAFETY STANDARDS: THE LINEAR NO-THRESHOLD MODEL AND THE PRECAUTIONARY PRINCIPLE

The safety standards are regulatory in nature, and as such they need to be practical and to be able to provide requirements and recommendations on protection for a broad range of exposures to both high doses of radiation (e.g. ‘potential’ exposures following an accident) and to very low doses at levels typical of the global average background levels of radiation (e.g. exposures in normal operation of a facility).

SF-1 notes that “The most harmful consequences arising from facilities and activities have come from the loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or other source of radiation.” The safety standards require that measures be taken to make sure that the likelihood of such a loss of control is extremely low. The intended outcome is that high doses and deterministic health effects, as well as moderate doses and possible stochastic health effects, will be avoided providing the safety standards are met.

“For the regulation of low and very low doses, the safety standards assume “that there is no threshold level of radiation dose below which there are no associated radiation risks” [18] Therefore, there is no distinction made in the safety standards between the regulation of moderate doses, for which stochastic effects could be attributed at a population level, and the regulation of low and very low doses at levels below which stochastic effects can be attributed

at a population level. In practice, then, the safety standards make use of the LNT hypothesis for the inference of risk at very low, low and moderate doses.

In addition to being a very effective tool for practical purposes in establishing coherent, consistent and above all workable standards for radiation protection and safety (see Section 2.2.3), the LNT hypothesis is also commensurate with the ‘precautionary principle’ [19] and therefore is a prudent and ethical basis for prevention and protection. The precautionary principle is an approach for dealing with possible risks in undertaking activities that could plausibly lead to morally unacceptable harm in cases where scientific understanding is incomplete or uncertain. The principle is applied by policy makers to justify discretionary decisions taken in situations where there is a possibility of harm arising from making a certain decision. The precautionary principle is predicated on the belief that there is a social duty and responsibility to protect the public from harm in situations for which scientific investigation has found a plausible risk. These protections can be relaxed only if further scientific findings emerge that provide sound evidence that no harm will result.

UNSCEAR 2012 [1] has noted that the LNT with associated risk coefficients is “coherent with radiobiological knowledge, adhere[s] to epidemiological information and incorporate[s] ethical judgements on the relative harm associated with different health effects”.

Therefore, it seems that the use of LNT for the inference of risk at moderate, low and very low doses remains the most plausible approach to regulatory control.¹²

3.4 THE PRINCIPLES OF RADIATION PROTECTION

Many of the fundamental concepts used throughout the IAEA safety standards are set out in the Safety Fundamentals [18]. The intention is to convey the basis and rationale for the IAEA safety standards to those at senior levels in government and regulatory bodies. The Safety Fundamentals establish the fundamental safety objective of protecting people and the environment, and a coherent set of ten fundamental principles that represent a common safety philosophy and ethics across all areas of application of the standards. Although the fundamental safety principles are applicable in their entirety, four of the fundamental safety principles are

¹² In addition, any alternative model for the dose–response relationship for radiation exposure that is intended for practical operational use for purposes of radiation protection would have to be developed and agreed internationally with the approval of interested parties.

directly related to the protection of people, to UNSCEAR 2012 [1] and to the purpose of this Safety Report, as follows:

- Two principles in SF-1 relate to justification, namely Principle 4 on *justification of facilities and activities*, which states that “facilities and activities that give rise to radiation risks must yield an overall benefit” [18] and Principle 10 on *protective actions to reduce existing or unregulated radiation risks*, which states that “protective actions to reduce existing or unregulated radiation risks must be justified and optimized” [18];
- Principle 5 on *optimization of protection*, which states that “protection must be optimized to provide the highest level of safety that can reasonably be achieved” [18];
- Principle 6 on *limitation of risks to individuals*, which states that “measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm” [18];

3.4.1 The concepts of attribution and inference and the principle of justification

Justification involves a balancing of benefits and harm to determine prior to taking an action whether the action is expected to yield a net benefit to the exposed individuals or to society. Justification has to be applied in making decisions on whether to introduce a new facility or activity in a State, on whether to take actions to reduce radiation exposures in an emergency exposure situation or in an existing exposure situation. Decisions on justification may fall within the authority of a broad spectrum of stakeholders, depending on the issue, from the highest levels of government to day-to-day practitioners, thus the concept needs to be well-understood by all.

Justification of the operation of facilities or the conduct of activities means that the detriments that might be caused by the introduction of a new source of radiation or by the reduction of an exposure would be outweighed by the individual and societal benefits that are expected to accrue. In some cases, the detriments and the benefits are to the same group of people, while in other cases, the detriments will be to a different group of people from those who accrue the benefits. The comparison of the benefits and detriments of nuclear and radiation technologies often goes beyond the consideration of protection and safety, and entails the consideration of economic, societal, environmental and other factors.

Medical radiation exposure of patients, whether for diagnosis or for treatment, is a special case, in that the benefit is primarily to the patient. The justification for such a procedure is

therefore considered first with regard to the specific procedure to be used. The justification decision for individual patients is a clinical decision made by medical practitioners.

In all cases justification involves the prospective inference of risks as a key element in assessing the detriment side of the equation of benefits and harm.

The introduction of new facilities or activities, or the development of protective strategies and preventive actions need to be justified in all situations, whether the radiation risks associated with projected doses for which health effects are attributable, either at an individual level or at a population level, or whether the radiation risks associated with low doses and very low doses, for which health effects are not attributable and where risks can only be inferred. This consideration is likely to be of particular importance in decision making on justification of protective actions in an emergency (e.g. if projected or received doses are below the appropriate generic criteria provided in the safety standards [17], and thus in the low and very low dose range, particular care is needed that protective actions to be undertaken in all circumstances indeed do more good than harm). It is also important for existing exposure situations, in which the doses due to radiation exposure might be in the moderate, low or very low range.

3.4.2 The concepts of attribution and inference and the principle of optimization of protection and safety

Optimization of protection and safety is defined as the process for determining what level of protection and safety would result in the magnitude of individual doses, the number of individuals (workers and members of the public) subject to exposure and the likelihood of exposure being as low as reasonably achievable (ALARA), economic and social factors being taken into account [5].

Optimization of protection and safety is a prospective, iterative process that examines the available options for protection. Depending upon the circumstances, the process can include the use of a variety of quantitative and qualitative techniques, for example the use of ‘collective dose’ (see Section 2.3).

Optimization is conducted within a set of boundary conditions on the range of available protection options. These boundary conditions are referred to as dose constraints or risk constraints in the case of planned exposure situations and as reference levels in the case of emergency exposure situations or existing exposure situations.

Dose constraints and reference levels are not dose limits. Exceeding a dose constraint or a reference level does not represent non-compliance with regulatory requirements; rather they are regarded as values that are not to be exceeded for planning purposes.

Table 2 summarizes the values for dose constraints and for reference levels applicable for each exposure situation, as established in GSR Part 3 [16]. It can be seen that the values for dose constraints and reference levels all lie in the range of very low and low dose bands of Table 1. The intention is that, if protection and safety is optimized, the dose received by workers and members of the public will be in the region below which health effects could be attributed at an individual or population level.

TABLE 2. FRAMEWORK FOR SOURCE RELATED DOSE CONSTRAINTS AND REFERENCE LEVELS [20]

Range in which the value for a dose constraint or reference level is set	Category of exposure and type of exposure situation
20 to 100 mSv ^{13, 14, 15}	● Reference level for public exposure in an emergency exposure situation
1 to 20 mSv per year	● Dose constraint for occupational exposure in a planned exposure situation ● Dose constraint for medical exposure of carers and comforters in a planned exposure situation ● Reference level for workers in an existing exposure situation ● Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radon in dwellings, areas with residual radioactive material
Not greater than 1 mSv per year	● Dose constraint for public exposure in planned exposure situations ● Reference level for public exposure in specific existing exposure situations, e.g. exposure due to radionuclides in commodities such as food, drinking water or construction materials

¹³ Acute dose or annual dose.

¹⁴ In exceptional situations, informed volunteer workers may receive doses above this band of values to save lives, to prevent severe deterministic health effects or to prevent the development of catastrophic conditions.

¹⁵ Situations in which the dose threshold for deterministic effects in relevant organs or tissues could be exceeded always require action.

In certain situations, decisions might need to be taken regarding the application of limited resources in optimizing protection for different groups of individuals, some of whom might be subject to higher doses than others. This consideration is likely to be of particular importance when optimizing the protective actions in an emergency (e.g. if doses are below the generic criteria provided in the safety standards [17], and thus in the low and very low dose range, particular care is needed that protective actions to be undertaken in all circumstances are properly optimized). It is also important for existing exposure situations, where the doses due to radiation exposure might be in the moderate, low or very low range.

3.4.3 The concepts of attribution and inference and the principle of limitation of risks to individuals

Justification and optimization of protection and safety do not in themselves guarantee that no individual bears an unacceptable risk of harm. Consequently, doses and radiation risks must be controlled within specified limits. Conversely, because dose limits represent a legal upper bound of acceptability, they are insufficient in themselves to ensure the best achievable protection under the circumstances, and they have to be supplemented by the optimization of protection and safety. Thus, both the optimization of protection and safety and the limitation of doses and risks to individuals are necessary to achieve the desired level of safety.

The ICRP has recommended the dose limits that have been adopted into the safety standards. The selection of the dose limit for workers has been based on expert judgement on what level of dose above which the consequences for the worker would be widely regarded as unacceptable. The dose limits are for annual effective dose of 20 mSv for occupational exposure and of 1 mSv for exposure of members of the public. Dose limits do not apply for medical exposure of patients.

The dose limits only apply for planned exposure situations i.e. from the planned operation of a source or from a planned activity that results in exposure from a source. Dose limits do not apply for emergency exposure situations or for existing exposure situations. This complexity could lead to misunderstandings (see Section 5).

The dose limits are set in the very low and low dose bands shown in Table 1. The dose limits are less than the dose levels at which health effects could be attributed at an individual or population level; indeed the attributability of health effects is not used as a criterion for limitation of doses.

4. PRACTICAL APPLICATION OF RISK-RELATED CONCEPTS FOR DIFFERENT CIRCUMSTANCES

4.1 EXPOSURE OF THE PUBLIC

4.1.1 Doses and health effects associated with public exposure

Members of the public are continuously exposed to natural and artificial sources of radiation, resulting in doses in the range of very low to low doses. UNSCEAR periodically summarizes radiation exposure of the public due to natural and artificial sources of radiation [21, 22, 23, 24]. The global average annual effective dose received by the public is approximately 2.4 mSv [22]. Table 4 and Fig. 3 summarize the doses associated with public exposure from different natural and artificial sources.

The largest component of this exposure arises from the indoor inhalation of naturally occurring radon gas and the short-lived decay products of radon (1.26 mSv). Other natural sources of radiation include cosmic radiation (high-energy protons, X rays and gamma-rays produced in space and arriving at the surface of the Earth) and terrestrial sources (rocks and soil) or any other material whose radioactivity is due only to radionuclides of natural origin such as in food. Average annual public exposure to natural radiation sources has not changed significantly over time, although individual exposures, particularly to radon, can differ significantly spatially and temporally.

The public is also exposed to artificial sources of radiation from present and past activities. Examples of artificial sources of radiation include nuclear power plants, research reactors, sources used in medical and veterinary facilities (X rays and radionuclides used in nuclear medicine) and in education and research facilities, sources used for industrial purposes such as industrial radiography and radiation gauges, consumer products and non-medical human imaging. Exposure may also result from episodic events due to human activities, such as atmospheric nuclear weapons testing. These contributions are all included under ‘other’ in Fig. 3.

From Table 3 and Fig. 3 it can be seen that the exposure to the large majority of the members of the public from natural and artificial sources of radiation results in the range of very low levels of doses..

TABLE 3. GLOBAL AVERAGE ANNUAL DOSES, AND RANGES OF DOSES, ASSOCIATED WITH PUBLIC EXPOSURE TO ENVIRONMENTAL SOURCES OF RADIATION [22]

Source of radiation	Average annual effective dose and typical range of individual doses in brackets (mSv)
Radon and thoron gas	1.26 (0.2 – 10)
Terrestrial	0.48 (0.3 – 1)
Ingestion	0.29 (0.2 – 1)
Cosmic	0.39 (0.3 – 1)
Nuclear energy generation	0.0002 (doses of up to 0.02 mSv for critical groups at 1 km from some nuclear reactor sites)
Atmospheric testing	0.005
Chernobyl accident	0.002 (globally dispersed radionuclides)
Fukushima accident	Less than 0.01 (first year, countries outside Japan)
Total from all environmental sources	2.44 (1 – 13)

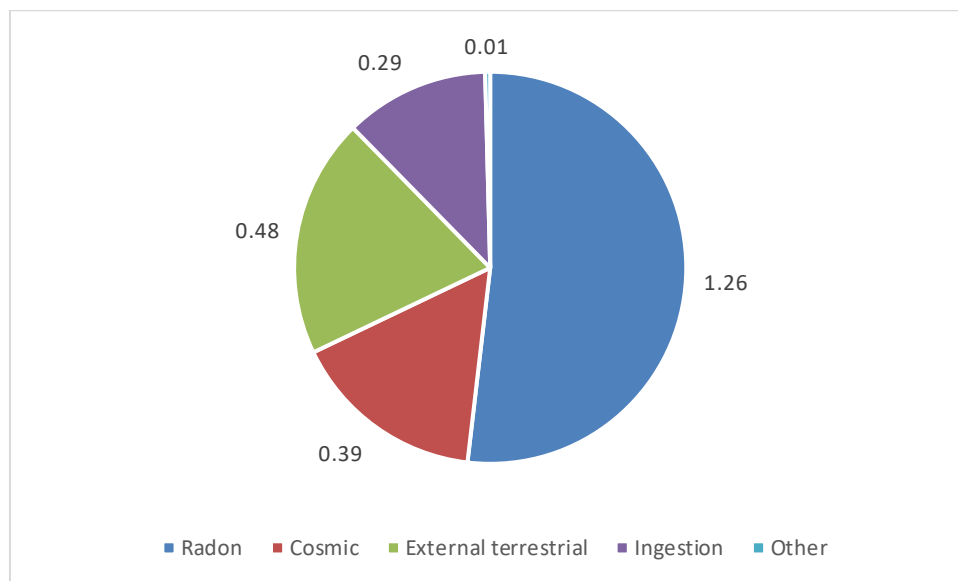


FIG. 3. Estimated contributions to public exposure from different sources, in mSv. (Adapted from Ref. [22]).

UNSCEAR has published several reviews of the health effects associated with public exposure. UNSCEAR has published a review of epidemiological studies of cancer risk due to low dose rate radiation from environmental sources in Ref. [25]. This includes reviews of the Techna River cohort (TRC) studies in the Russian Federation and studies of environmental exposure to high natural background radiation (HNBR) in Karunagappally, Kerala, India and Yangjiang, Guandong Province, China. UNSCEAR concluded that “the TRC study has demonstrated dose-dependent increases in occurrence of solid cancer and leukaemia, though associations with radiation exposure were also found for cancer types that have not been commonly increased following radiation exposure in other studies. No discernible increases were reported for solid cancer or leukaemia in the Karunagappally or Yangjiang HNBR studies, though the low precision of the risk estimates does not rule out either absence of an excess risk of cancer or substantially higher risks per dose unit than those reported in high-dose and dose-rate studies”.

However, there are cases where health effects in members of the public are indeed attributable at the population level. UNSCEAR published a review of the health effects from exposure to radon in Ref. [7]. The studies reviewed indicate a significant association between the risk of lung cancer and exposure to radon in homes, i.e., lung cancers due to radon in homes are attributable at the population level. UNSCEAR concluded that the excess relative risk for lifetime exposure for residential exposure to radon is 0.16 per 100 Bq/m³. The World Health Organization has concluded that “Recent studies on indoor radon and lung cancer in Europe, North America and Asia provide strong evidence that radon causes a substantial number of lung cancers in the general population. Current estimates of the proportion of lung cancers attributable to radon range from 3 to 14%, depending on the average radon concentration in the country concerned and the calculation methods” [26].

UNSCEAR also included a case study on lung cancer from exposure to radon in 117 homes in Winnipeg, Canada in Ref. [1]. UNSCEAR concluded that an “increased frequency of lung cancer is unlikely to be observable among people living in the Winnipeg homes sampled because of the small numbers involved; however, if the size of the population exposed at the same levels were large enough, then the predicted increase frequency is potentially observable”. UNSCEAR concluded that “an observed lung cancer in an individual cannot be unequivocally attributed to radon exposure”.

However, some individuals and groups have also been exposed to radiation resulting from accidents at nuclear power plants and from exposure to orphan sources [22, 23]. These

exposures have ranged from high doses for a few individuals, moderate doses for groups of individuals to low and very low doses for some population groups. UNSCEAR summarized the doses and health effects for members of the public from the Chernobyl accident in Ref. [22]. More than 300,000 individuals received doses in excess of 10 mSv. The average thyroid dose to evacuees was about 500 mGy, while the average thyroid dose to 6 million people living in contaminated areas was about 100 mGy. UNSCEAR concluded that “the contamination of milk with ^{131}I , for which prompt countermeasures were lacking, resulted in large doses to the thyroids of members of the general public; this led to a substantial fraction of the more than 6000 thyroid cancers observed to date among people who were children or adolescents at the time of the accident (by 2005, 15 cases had proved fatal). To date, there have been no persuasive evidence of any other health effect in the general population that can be attributed to radiation exposure” [22]. UNSCEAR also included a case study on thyroid cancer after the Chernobyl accident in Ref. [1]. UNSCEAR concluded that there was “strong support for attributing, at least in part, the observed increase frequency to radiation exposure” in this population. UNSCEAR also concluded that “in the absence of a biomarker to distinguish radiation-related thyroid cancer from one that occurs due to other causes, an observed thyroid cancer in an individual among the population of those exposed as children or adolescents at the time of the accident cannot be equivocally attributed to radiation exposure from the accident”.

UNSCEAR summarized the doses and health effects from the Fukushima accident in Ref. [23, 24]. In the first year following the Fukushima Daiichi nuclear power plant accident, for adult evacuees the average thyroid dose ranged from 16 to 35 mGy, for adults living in Fukushima prefecture the average thyroid dose ranged from 7.8 to 17 mGy, and for adults living in the rest of Japan the average thyroid dose ranged from 0.5 to 0.9 mGy [23]. UNSCEAR concluded that “No radiation-related deaths or acute diseases have been observed among the workers and general public exposed to radiation from the accident. The doses to the general public, both those incurred during the first year and estimated for their lifetimes, are generally low or very low. No discernible increased incidence of radiation-related health effects are expected among exposed members of the public or their descendants” [23]. UNSCEAR also addressed the matter that “the rates of diagnosed, suspected or confirmed thyroid cancer among the approximately 300,000 individuals who were children or adolescents (ages 0–18) at the time of the [Fukushima Daiichi] accident were found to be much higher than those documented in the cancer registries of other prefectures of Japan” but noted several pieces of evidence that led to UNSCEAR’s conclusion that “the increased incidence rates may be due to over-diagnosis

(i.e., detection of thyroid cancer that would not have been detected without the screening and would not have caused symptoms or death during a person's lifespan)" [24].

Members of the public have also been exposed to radiation from exposure to orphan sources. There have been situations in which members of the public suffered deterministic health effects, which are attributable at an individual level. For example, following an accident with an abandoned device containing a caesium source in Goiânia, 21 people received doses in excess of 1 Gy [22]. UNSCEAR has summarized accidents involving orphan sources that lead to exposure of members of the public to high doses in Ref. [22]. UNSCEAR summarized information on 34 accidents involving orphan sources, which resulted in 42 early deaths and in disfiguring injuries to both children and adults. The details of many of these accidents have been published by the IAEA [27, 28, 29, 30, 31].

4.1.2 Control of public exposure in the safety standards

Requirements for establishing governmental, legal and regulatory systems for the control of radiation sources are established in GSR Part 1 (Rev. 1) [32]. Requirements for control of public exposure are established in GSR Part 3 [16] and GSR Part 7 [17]. Detailed guidance for control of public exposure is provided in many IAEA Safety Guides: for planned exposure situations [15, 20, 33, 34]; for emergency exposure situations [35]; for existing exposure situations [20, 36, 37]; and for regaining control over orphan sources [38] and on control of orphan sources in the metal recycling industry [39].

Exposure of the public due to some sources of radiation are excluded from the scope of the safety standards. These exposures are unamenable to control, e.g. exposure due to natural radionuclides in food, exposure due to cosmic rays at the surface of the earth, exposure due to radionuclides due to fallout from atmospheric testing and globally dispersed due to accidents. Excluded exposures in fact make up a significant fraction of those exposures shown in Table 3 and Fig. 3.

4.1.2.1 Control of public exposure at low and very low levels of dose

For planned exposure situation, the control of public exposures at low and very low levels of dose is to be achieved thorough optimization of protection and safety, and by applying a dose limit to the representative person. The safety standards establish criteria in the form of dose limits (i.e. 1 mSv in a year), dose constraints (i.e. 0.1 to less than 1 mSv in a year) to be used in optimization of protection and safety, and exemption and clearance criteria (of the order of 10 μ Sv in a year), i.e. all values that are in the range of very low doses (region 3 of Fig. 1). The

government or the regulatory body establishes or approves the actual value of the dose constraint, taking into account the characteristics of the site and of the facility or activity, the scenarios for exposure, and the views of interested parties. The setting of the dose constraint needs to be considered with other health and safety provisions and the technology available and it is applied at the design stage. In practice, through optimization of protection and safety, members of the public receive doses due to the operation of facilities and the conduct of facilities that are significantly lower than the annual dose limit of 1 mSv.

For emergency exposure situations and existing exposure situations, the safety standards require that exposures of members of the public above the reference level be reduced, through the application of optimized protection strategies and protective actions. For emergency exposure situations, the reference level is in the range from 20 to 100 mSv, while for existing exposure situations, the reference level is in range of 1 to 20 mSv, i.e. values that are in the range of low doses (region 3 of Fig. 1). The actual value of reference level within these ranges is established or approved by the government, regulatory body or another relevant authority, and it will depend on the prevailing circumstances for the exposures under consideration (see Section 3.4.2).

4.1.2.2 Control of public exposure at moderate and high levels of dose

The safety standards require that protection strategies be “developed, justified and optimized at the planning stage, by using scenarios based on the hazard assessment, for avoiding deterministic effects and reducing the likelihood of stochastic effects due to public exposure.” [16].

For facilities and activities that are within the scope of the safety standards, the avoidance of high and moderate doses to the public in planned exposure situations is to be achieved through proper design. Risk constraints are required to be applied in the design to ensure that safety measures are optimized.

In existing exposure situations, moderate doses to the public might occur. In an emergency, the full range of doses to the public, including high doses and moderate doses, might occur. GSR Part 7 groups the hazards associated with emergency exposure situations into five emergency preparedness categories: facilities in category I are those for which an emergency could give rise to severe deterministic effects in members of the public. Appendix II of GSR Part 7 sets out generic criteria taking for protective actions and other response actions to avoid or minimize severe deterministic effects. Such actions are expected to be undertaken

under any circumstances. Appendix II of GSR Part 7 also sets out generic criteria for taking protective actions and other response actions to reduce the risk of stochastic effects. Such actions are expected to be undertaken only if they can be undertaken safely.

4.2 OCCUPATIONAL EXPOSURE

Occupational exposure is the exposure of workers to radiation incurred during their work. Occupational exposure is additional to the exposure that workers receive as members of the public i.e. the natural and artificial sources of radiation as the public discussed in Section 4.1. Workers may also incur medical exposure (Section 4.3).

4.2.1 Doses and health effects associated with occupational exposure

Several international organizations have conducted surveys to gain insight into occupational radiation exposure. These organizations include UNSCEAR [22], the IAEA [40] Nuclear Energy Agency [41]. The occupations in which workers are monitored individually are those associated with the nuclear fuel cycle and some industrial and medical specialties. Many workers exposed to natural sources of ionizing radiation are not individually monitored, due to the nature of the work. These workers include underground and surface miners, for whom it is not practical to wear air sampling equipment, and aircrew, for whom potential exposures are not possible..

Between the years 2000 and 2002 the average annual individual effective dose of monitored workers was around 0.4 mSv per year [22]. This annual dose is lower than, and in addition to, the normal background dose coming from natural sources [22]. Table 4 show the global average annual doses for occupational exposure for different industries. Comparison with Table 1 shows that for almost all sectors (except for interventional cardiology), the average annual effective dose lies within the very low region.

TABLE 4. GLOBAL AVERAGE ANNUAL DOSES ASSOCIATED WITH OCCUPATIONAL EXPOSURE FOR DIFFERENT INDUSTRIES [22]

Industry	Average annual effective dose (mSv)
Nuclear fuel cycle	1.0
Uranium mining	2.1 – 2.3
Uranium milling	1.1
Fuel fabrication	1.6
Reactor operations	1.0 (2% > 10 mSv)
Fuel reprocessing	0.9
Decommissioning	1.9
Aircrew	2.5
Industrial radiography	1.5 (1% > 15 mSv)
Industrial irradiators	0.63 (1% > 15 mSv)
Luminizing	0.72
Radioisotope production	2 (2% > 15 mSv)
Well logging	0.96
Accelerator operators	0.74
All other industrial uses	0.26
Veterinary medicine	0.15
Educational	0.08
Coal mining	2.4
Other mining	3.0
Medical	0.5
Diagnostic radiology	1.2 (0.3 - 3.1)
Interventional cardiology	3.1 (0.4 – 29.5)
Dental	0.06
Nuclear medicine	0.7
Radiotherapy	0.5

The sections below provide some additional detail for certain groups of workers for which detailed studies of doses and health effects have been performed.

4.2.1.1 *Nuclear fuel cycle workers*

Nuclear fuel cycle workers include those involved in the mining and processing of uranium and thorium ores, enrichment of uranium, manufacturing of nuclear fuel, operation of nuclear reactors (including research and test reactors), reprocessing nuclear fuel, and waste management and decommissioning activities relating to operations associated with the production of nuclear energy. Average exposures range from 1 to 2 mSv per year, with about 2% of workers receiving doses above 10 mSv, and a few individual exposures approaching 20 to 30 mSv per year for exceptional necessary work situations in high dose-rate work areas. The average annual occupational exposures tend to lie within the range of very low and low doses.

UNSCEAR published a review of the Mayak worker study, which covered 21,500 people who worked at the Mayak nuclear complex in the Soviet Union between 1948 and 1972 [7]. The average cumulative external dose among those monitored was 0.8 Gy. Some workers had the potential for significant internal exposure from inhaled plutonium. UNSCEAR noted that the risk estimates are somewhat lower than those from the LSS cohort, but that the authors of the study cautioned that any comparison has to be regarded as tentative in view of the dosimetric uncertainties.

[

The international worker study is also described in Annex A of Ref. [7] is based on 407,391 workers from 15 countries working in 154 nuclear facilities, who were monitored for external photon exposure with personal dosimeters. UNSCEAR concluded that “there are substantial uncertainties in the risk estimates derived from 15-country study, consequently not too much should be made of the apparent discrepancies with risks observed in other studies such as the LSS” [7].

UNSCEAR has summarized accidents at nuclear facilities that lead to exposure of workers to high doses in Annex C of UNSCEAR 2008 [22]. There have been 35 serious radiation accidents reported: 24 were in facilities related to nuclear weapons research, development and production, and to the reprocessing of nuclear fuel for weapons programmes. Other accidents occurred in power reactor research, development and operation, and in the reprocessing of nuclear fuel. Excluding the 1986 accident at Chernobyl, 32 deaths are known to have occurred as a result of radiation exposure in accidents at nuclear facilities, and 61 workers suffered radiation injuries requiring medical care. The incidence of accidents in these facilities has fallen; most of the deaths and injuries occurred in the early years of research and

development in the context of nuclear weapons programmes. Only one criticality accident, with the death of two workers, has occurred in the past 20 years.

UNSCEAR has summarized the health effects from the Chernobyl accident in Annex D to UNSCEAR 2008 [22]. UNSCEAR concluded that “the observed health effects currently attributable to radiation exposure are as follows:

- 134 plant staff and emergency workers received high doses of radiation that resulted in acute radiation syndrome (ARS), many of whom also incurred skin injuries due to beta radiation.
- The high radiation doses proved fatal for 28 of those people.
- Skin injuries and radiation-induced cataracts are major impacts for the for the ARS survivors.
- Other than this group of radiation workers, several hundred thousand people were involved in recovery operations, but to date, apart from indications of an increase in the incidence of leukaemia and cataracts among those who received higher doses, there is no evidence of health effects that can be attributed to radiation exposure”.

Regarding emergency workers involved in the Fukushima Daiichi accident, UNSCEAR concluded that “No deterministic health effects or deaths have been observed among workers engaged in emergency work that could be attributed to radiation exposure” and that it “expects no discernible increase in health effects among the overall group of emergency workers that could be attributed to their radiation exposure” [24]. Regarding the 174 workers who received effective doses within the first year above 100 mSv or more, UNSCEAR “considers that it is unlikely that an increased incidence of cancer due to irradiation would be discernible, because the normal variability in baseline rates of cancer incidence is much larger than the inferred radiation-associated cancer rates” [24].

4.2.1.2 Miners

The worldwide level of exposure for workers exposed to natural sources of radiation is estimated to be 2.9 mSv for approximately 13 million workers [22]. The level of exposure in mines depends on several factors, including the type of mine, the geology and the working conditions, particularly the ventilation. For coal mines, the average effective dose is 2.4 mSv for an estimated 6.9 million workers [22]. For non-coal mines, the average effective dose is 3 mSv for an estimated 4.9 million workers. [22] The average annual radiation doses are very low, especially for those underground mines with good ventilation.

UNSCEAR published a review of the health effects from exposure to radon in Annex E of UNSCEAR 2006 [7], including studies of exposure of miners to radon. UNSCEAR reviewed 11 miner cohorts and prepared a qualitative evaluation of considerations such as the number of excess lung cancers, the quality of the exposure data and confounders such as smoking and exposure to arsenic. UNSCEAR combined the estimated excess relative risks for the studies and obtained values that compares remarkably well with values from pooled residential radon studies (see Section 4.1.1).

4.2.1.3 Medical workers

Radiological medical practitioners, medical radiation technologists, medical physicists and nurses constitute the largest single group of workers occupationally exposed to human-made sources of radiation. For conventional diagnostic imaging techniques, the average annual effective dose is about 1.2 mSv (range 0.33 - 3.14 mSv) for measurably exposed workers. For interventional procedures, the average annual effective dose is about 3.1 mSv for measurably exposed workers with a range of 0.4 - 29.5 mSv.

Annex A of UNSCEAR 2006 [7] also describes the United States medical radiologic workers study, involving a cohort of 146,022 United States ‘radiologic technologists’ certified between 1926 and 1982. There were no radiation dose estimates for the cohort; the radiation effect was derived from those entering the profession prior to and after 1940. UNSCEAR notes that the authors of the study found that “as with most working populations, the rates of death from all cancers were lower than expected in the general population, for both. No specific cancer type showed an overall excess risk”. UNSCEAR also noted that there were substantial methodological concerns with the data sets.

A study of Chinese radiologists and technologists is also set out in Annex A of UNSCEAR 2006 [7]. This cohort consisted of 27,011 medical diagnostic workers, including both radiologists and technicians, employed between 1950 and 1980 in 24 provinces of China. A control group consisted of 25,782 workers from other medical specialties who did not use X-ray equipment in their work. Retrospective dose assessment was performed. An excess of total cancers and a significant excess of leukaemia was found. UNSCEAR concluded that “The reported statistical significance of the results in this study, however, should be treated

cautiously, as it appears that calculations were performed without taking into account the variance contributed by the control group” [7].

4.2.1.4 Workers in industrial facilities

There are many uses of radiation sources in industry, including industrial radiography, industrial irradiators, radioisotope production, well logging, thickness gauges, soil moisture gauges, and the use of accelerators. The average annual dose to workers in these industries is less than 1 mSv except for industrial radiography with 1.5 mSv and radioisotope production with 2 mSv. There is also a wide range of doses received in some of these industries. For example, 30% of industrial radiography workers receive doses over 1 mSv and 1 % or receive dose over 15 mSv; 55% of radioisotope production workers receive more than 1 mSv and 2% receive more than 15 mSv; and 29% of industrial irradiator workers receive more than 1 mSv and 1 % receive more than 15 mSv [22].

Annex C of UNSCEAR 2008 [22] “lists 80 accidents at industrial facilities. Nine deaths were reported in these accidents. They all occurred at industrial irradiation facilities using high-activity sealed sources, primarily because of improper entry into the hot cell, and a lack or failure of safety mechanisms. At least 84 other people were excessively overexposed in these facilities. In other industries, 36 workers were injured during the use of radiography sources, X-ray devices and accelerators, and during manufacturing procedures” [22]. The details of several industrial accidents affecting workers have also been published by the IAEA [42, 43, 44, 45].

4.2.2 Control of occupational exposure in the safety standards

The requirements for control of occupational exposure are established in GSR Part 3 [16]. Recommendations on meeting the requirements for control of occupational exposure are provided in GSG-7 [14]. Recommendations specific to control of occupational exposure in medical facilities are provided in SSG-46 [46].

4.2.2.1 Control of occupational exposure at low and very low levels of dose

As stated in GSR Part 3 [16], “For occupational exposure of workers over the age of 18 years, the dose limits are:

- (a) An effective dose of 20 mSv per year averaged over five consecutive years¹⁶ (100 mSv in 5 years) and of 50 mSv in any single year;
- (b) An equivalent dose to the lens of the eye of 20 mSv per year averaged over five consecutive years (100 mSv in 5 years) and of 50 mSv in any single year;
- (c) An equivalent dose to the extremities (hands and feet) or to the skin¹⁷ of 500 mSv in a year.”

Dose constraints are used in the optimization of protection and safety in planned exposure situations. Dose constraints are established by the employer, and subject to the approval of the regulatory body. The value of the dose constraint is less than the applicable dose limit. The hierarchy of preventive measures used in optimization are (i) engineered controls; (ii) administrative controls; and (iii) use of personal protective equipment.

For many workplaces, optimization of protection and safety is met at the design stage, through engineered controls. For example, in conventional radiography and dental radiography, the X ray apparatus needs to meet design requirements, and the design of the X ray room includes the installation of shielding and operator screens to protect the worker. Workers in such workplaces receive very low annual doses, often less than 1 mSv in a year. Over the working lifetime, their occupational doses are in the low dose region of Table 1.

However, in some workplaces, the additional use of administrative controls and personal protective equipment are required, as engineering controls are not sufficient to optimize protection and safety. For example, workers using interventional radiological equipment need to stand next to the patient, and are required to undergo training in radiation protection measures, to wear personal protective equipment (lead aprons, glasses) and to use ceiling mounted screens. Failure to use the protective screens and to wear personal protective equipment might result in effective doses, and doses to the lens of the eye, that exceed the dose limits. In nuclear power plants, workers who carry out maintenance might need to work in high

¹⁶ “The start of the averaging period shall be coincident with the first day of the relevant annual period after the date of entry into force of these Standards, with no retrospective averaging.”

¹⁷ “The equivalent dose limits for the skin apply to the average dose over 1 cm² of the most highly irradiated area of the skin. The dose to the skin also contributes to the effective dose, this contribution being the average dose to the entire skin multiplied by the tissue weighting factor for the skin.”

dose rate environments and the process of optimization of protection and safety for each maintenance task is performed prior to it being carried out. The annual doses received some of these workers can exceed 10 mSv in a year.

4.2.2.2 Control of occupational exposure at moderate and high levels of dose

While these annual doses in a single year can be considered to be low, in accordance with the terminology of Table 1, over a working life of 30-40 years, the lifetime effective dose of some workers might be several hundred millisievert and are in the moderate region of Table 1. In addition, the dose to the lens of the eye for workers in interventional radiology might exceed the threshold for deterministic effects if personal protective equipment is not worn. The purpose of the safety standards is to ensure that these radiation protection arrangements are in place so that workers do not receive lifetime occupational exposures that are in the moderate dose region of Table 1.

For emergency workers, GSR Part 3 and GSR Part 7 require that the relevant requirements for occupational radiation protection in planned exposure situations be applied, except for the requirement relating to dose limits. Requirement 45 of GSR Part 3 and Requirement 11 of GSR Part 7 state:

“The operating organization and response organizations shall ensure that no emergency worker is subject to an exposure in an emergency that could give rise to an effective dose in excess of 50 mSv other than:

- (1) For the purposes of saving human life or preventing serious injury;
- (2) When taking actions to prevent severe deterministic effects or actions to prevent the development of catastrophic conditions that could significantly affect people and the environment; or
- (3) When taking actions to avert a large collective dose”

Guidance values for restricting the exposure of emergency workers are set out in GSR Part 7 and in GSR Part 3, and it is only for lifesaving actions that an individual dose of 500 mSv to an emergency worker may be exceeded. As stated in GSR Part 7, the value of 500 mSv may be exceeded only “under circumstances in which the expected benefits to others clearly outweigh the emergency worker’s own health risks, and in which the emergency worker volunteers to take the action and understands and accepts these health risks”. Further

recommendations for the protection of workers in an emergency are provided in Section 4 of GSG-7.

4.3 MEDICAL EXPOSURE

4.3.1 Doses and health effects associated with medical exposure

Medical exposure is that exposure incurred by patients for the purposes of medical or dental diagnosis or treatment; exposure of individuals as part of health screening programmes; by carers and comforters; and by volunteers subject to exposure as part of a programme of biomedical, diagnostic or therapeutic research [5]. Medical exposure is the largest human-made source of exposure to ionizing radiation: the global average annual effective dose received by the public due to medical exposure is approximately 0.6 mSv [22]. In 2008, the estimated worldwide annual number of diagnostic and interventional radiological procedures (including dental) was 3.6 billion, the estimated number of nuclear medicine procedures was over 30 million, and the estimated number of radiation therapy procedures was over 5 million [22].

Diagnostic medical procedures contribute significantly to the global average annual public exposure of 0.6 mSv. There has been a significant increase in medical exposures over the past decades, mainly due to the rapid expansion in the use of computed tomography (CT) scanning. In several countries, this has meant that medical exposure has displaced exposure due to natural sources of radiation as the largest overall component of the annual average effective dose.

The average doses from diagnostic procedures are very low. The average dose for chest radiography and for radiography of the extremities are less than 0.1 mSv. The average dose from CT of the abdomen and interventional procedures such as percutaneous transluminal coronary angioplasty (PTCA) are low (i.e. more than 10 mSv). Table 5 shows global average dose and range of doses for some medical procedures. As can be seen from Table 5, CT scans contribute the largest population dose from diagnostic procedures.

TABLE 5. GLOBAL AVERAGE ANNUAL DOSES ASSOCIATED WITH MEDICAL EXPOSURE [22]

Medical application	Global average effective dose (mSv) per examination (range of values in brackets)
Diagnostic and international procedures	
Chest X ray	0.07
Limbs and joints	0.07
Pelvis and hips	1.1
Abdomen	0.8
Upper GI	3.4
Lower GI	7.4
Mammography	0.26
Head CT	2.4 (0.8-7.8)
Thorax CT	7.8 (1.7-11.5)
Abdomen CT	12 (3.7-20)
Percutaneous Transluminal Coronary Angioplasty (PTCA)	12 (6-19)
Nuclear Medicine	
Bone (^{99m}Tc)	(3.1 – 9)
Cardiovascular (^{99m}Tc)	(4.7-14.1)
Lung Perfusion (^{99m}Tc)	(1.2 – 4)
Thyroid scan (^{99m}Tc)	(0.8-3.5)
Renal	(0.4-3.8)
Brain	(2 – 7.5)
PET	(5.6-10.8)

As the dose to the patient from diagnostic medical procedures is in the very low to low dose range, it is very difficult to attribute any adverse health effect to a single radiation exposure from diagnostic medical procedures UNSCEAR included a case study relating to CT scans in UNSCEAR 2012, which demonstrates the difficulty in attributing adverse health effects from diagnostic procedures.

The case study (Case Study V, in Appendix B to UNSCEAR 2012 [1] describes a case study from the USA published in 2007. There were 72 million CT scans performed in the USA

in that year, and the task was to infer risks for future cancer from radiation exposure due to CT scanning in that specific year. UNSCEAR noted that “the published case study made conditional predictions of the risk to the population taking account of the doses to individual organs and tissues, age at exposure and the inferred risks for each cancer type for people exposed at moderate or high doses”. UNSCEAR concluded that “the inferred increase in the number of cancers would be of the order of 2% above the normal frequency in the general population, although more than 2% of the population [are] subjected to CT. An epidemiological study to demonstrate such an increase would involve following hundreds of thousands of people over many years, and a similar-sized, match control group”.

The doses from interventional procedures are also in the low dose region. However, for some patients, the interventional procedure may not be straightforward, and the dose to the skin of the patient may be in the high region, and the patient can receive a skin burn [46]. A case study is set out in Appendix A to UNSCEAR 2012 [1] regarding a 69-year-old, 140 kg man with long standing heart disease who underwent a fourth cardiac catheterization that included several attempts at coronary angioplasty and stenting. The fluoroscopy recorded time was 34 minutes and there were 50 cine runs with a total of about 6,200 frames. About three weeks after the procedure, the subject noticed intense itching, pain and blistering lesions in a square pattern on his back. About seven months after the procedure, there was a chronic eschar with marked induration and inflammation that was extending out from a central necrotic area. The analysis set out in UNSCEAR 2012 leads to the conclusion that the “the subject’s lesion on his back was confidently attributed to the radiation exposure”.

Therapeutic procedures are associated with high doses. In radiation therapy, the intent is to kill (shrink or eradicate) the tumour while sparing the normal surrounding tissue. This killing of the tumour is an observable, deterministic health effect that can be directly attributed to the radiation exposure. Depending on the area being irradiated, deterministic side effects, such as nausea, vomiting and diarrhea, can also occur.

Unintended and accidental exposures also occur during medical procedures. There have been occasions when patients have been accidentally exposed to enough external radiation from diagnostic procedures to cause deterministic effects, particularly skin reddening and loss of hair. For example, 206 patients treated at Cedars-Sinai Medical Center in Los Angeles received

eight times the normal dose of radiation during a specific type of brain scan. Forty percent of the affected patients experienced skin redness and hair loss [48].

UNSCEAR reviewed accidents from medical procedures and considers that accidents associated with the medical use of radiation in diagnosis and treatment may have been under-reported [22]. UNSCEAR reviewed 32 accidents with 46 deaths that had occurred since 1967, and noted that “there have been a large number (623) of persons who developed early acute (deterministic) health effects as a result of these accidents. Delays in recognizing errors led to greater numbers of persons being injured. The 32 accidents considered here involved serious overexposures to radiation, but underexposures can also have serious consequences for patients” [22].

The IAEA has reviewed accidental exposures in radiotherapy [49]. This report reviewed 92 accidental exposures, and provides a short account of what happened in each case, including the initiating event and the relevant contributing factors, as well as the remedial action taken, if known. The IAEA also provides a reporting system for radiotherapy and radionuclide therapy incidents and near misses, which currently includes over 1300 incident reports [49].

4.3.2 Control of medical exposure in the safety standards

Requirements for control of medical exposure are set out in GSR Part 3 [16]. Detailed guidance for control of medical exposure is provided in SSG-46 [46].

There are no dose limits for medical exposure. For medical exposure, the optimization of protection and safety is the management of the radiation dose to the patient commensurate with the medical purpose. The optimization of protection and safety for medical exposure necessitates a special approach. Too low a radiation dose could be as bad as too high a radiation dose, in that the cancer is not cured or the images taken are not of suitable diagnostic quality. The medical exposure always has to lead to the required clinical outcome.

In X ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, diagnostic reference levels (DRLs) are a tool used in the optimization of protection and safety. Periodic assessments are required to be performed of typical patient doses or, for radiopharmaceuticals, of activities administered in a medical radiation facility. If comparison with established DRLs shows that the typical doses or activities to patients are either unusually high or unusually low, a local review is required to be initiated to ascertain whether protection and safety has been optimized and whether any corrective action is required. DRLs are not dose limits.

Other tools used in the optimization of protection and safety applied to medical exposure include design of medical radiological equipment and facilities, the use of operational protocols and programmes of quality assurance.

The doses from all diagnostic medical imaging procedures are in the very low and low range, in accordance with the terminology of Table 1.

5. THE IMPLICATIONS OF THE CONCEPTS OF ATTRIBUTION OF HEALTH EFFECTS AND INFERENCE OF RISK FOR COMMUNICATION

5.1 COMMUNICATION ABOUT THE SAFETY STANDARDS

5.1.1 Purpose of the safety standards

As described in Section 2, there is a distinction between actual data relating to actual health effects that can be attributed either in individuals (deterministic effects) or in a population (stochastic effects) (see Section 2.1), models used for estimating health effects (see Section 2.2.2), and models used for the regulatory purpose of radiation protection (see Section 2.2.3). The models used in the safety standards for purposes of radiation protection are not intended to be used in estimating health effects, neither retrospectively nor prospectively.

Moreover, the safety standards are not drafted as legal documents and they do not contain statements that are intended to be contested in court (e.g. in the context of occupational compensation claims).

5.1.2 Use of reference levels

With regard to optimization of protection and safety, the safety standards set out a framework for source related dose constraints and reference levels, which are presented as ranges of values (see Table 2). It might be assumed that the selection of a dose constraint or a reference level at the lower end of that range would provide ‘better’ protection than selection of a value at the upper end. However, that is not the case. Both the highest and the lowest values within the ranges of dose constraints and reference levels lie within region 1 of Fig. 1, i.e. irrespective of the value selected for a dose constraint or reference level within the range given in Table 2, there will be no attributable health effects, neither at an individual level nor at a population level. Rather, it is the process of optimization, which takes into account economic and social factors, including other non-radiation risks present, that provides overall protection to individuals. That is, optimization ensures that the level of protection will be the best possible under the prevailing circumstances; it will not necessarily be the option with the lowest risk or dose.

In addition, the values in Table 2 are, mainly, annual values. If individuals are exposed to radiation over many years, and even if protection and safety is optimized in accordance with the framework set out in Table 2, the total lifetime dose of such an individual could possibly

reach into the ‘moderate’ range of doses and therefore health effects could be attributable at a population level (i.e. for a large group of such individuals).

5.1.3 Use of dose limits

With regard to limitation of risks, the safety standards set out dose limits for public and occupational exposure in planned exposure situations. The dose limit for the public is 1 mSv per year, which is lower than the dose limit for workers, and also lower than the lower bound of the range of reference levels recommended for use for optimization of protection and safety in emergency exposure situations and existing exposure situations (see Table 2). It might be assumed that any dose above 1 mSv would be dangerous to an individual. However, this would be a misunderstanding of the purpose of a dose limit: a dose limit is a restriction on ‘additional’ doses from planned activities; exceeding the dose limit would cause some form of legal sanction but would not be expected to lead to any health effects. As set out in UNSCEAR 2012 [1], if an individual were to receive a dose far in excess of 1 mSv, up to about 100 mSv, this dose would still be in the very low or low range of doses and would not lead to any health effect observable in the individual themselves, nor in the collective incidence in an exposed group of individuals.

5.1.4 Use of collective dose

The proper use of collective dose is described in Section 2.3, i.e. its use in comparing options for purposes of optimization of protection and safety. It might be assumed that the health effects used for such calculations are in fact real health effects that will actually occur in individuals and populations, rather than notional health effects derived on the basis of a model, i.e. the LNT. Particularly in the case of situations involving low and very low doses, where health effects cannot be attributed, this would lead to a significant misunderstanding: unreasonable conclusions could be drawn regarding the computation of deaths following trivial exposures of large populations. ICRP, UNSCEAR and the IAEA have all strongly advocated that such use of collective dose be avoided [1, 2, 15].

5.2 COMMUNICATION ABOUT RISK

The public rightly expects “to have access to reliable, comprehensive and easily understandable (plain, unambiguous and jargon-free) information about safety and regulatory issues in order to form opinions and make fully informed decisions” [51]. Moreover, the public in general has a great deal of uncertainty regarding any issue involving nuclear and radiation

safety, and such uncertainties can influence the public's perception of radiation risk [51]. Table 7 of Ref. [52] sets out some influences on the public's perception of risk.

5.2.1 Requirements for communication about risk

Regarding the responsibilities of the regulatory body and the authorized party, para. 4.68 of GSR Part 1 (Rev. 1) [32] states:

“The authorized party shall inform the public about the possible radiation risks (arising from operational states and accidents, including events with a very low probability of occurrence) associated with the operation of a facility or the conduct of an activity. This obligation shall be specified in the regulations promulgated by the regulatory body, in the authorization or by other legal means.”

The extent of public information activities is required to reflect the “risks associated with facilities and activities, in accordance with a graded approach” [32] i.e. more extensive public communication is expected for those facilities and activities with which a higher risk is associated.

GSR Part 3 [16] establishes several requirements regarding communication about risk to the public. Requirement 50 of GSR Part 3 [16] states:

“The government shall provide information on levels of radon indoors and the associated health risks and, if appropriate, shall establish and implement an action plan for controlling public exposure due to radon indoors.”

Regarding the provision of information to the public for emergency preparedness and response, Requirement 10 of GSR Part 7 [17] states:

“The government shall ensure that arrangements are in place to provide the public who are affected or are potentially affected by a nuclear or radiological emergency with information that is necessary for their protection, to warn them promptly and to instruct them on actions to be taken.”

Requirement 13 of GSR Part 7 [17] states:

“The government shall ensure that arrangements are in place for communication with the public throughout a nuclear or radiological emergency.”

There are also requirements in the safety standards for proper communication of radiation risks to workers. Paragraph 3.110 of GSR Part 3 [16] states:

“Employers, in cooperation with registrants and licensees: (a) Shall provide all workers with adequate information on health risks due to their occupational exposure in normal operation, anticipated operational occurrences and accident conditions, adequate instruction and training and periodic retraining in protection and safety, and adequate information on the significance of their actions for protection and safety;”

Information on radiation risks is also required to be communicated to emergency workers. Paragraph 4.18 of GSR Part 3 [16] states:

“Response organizations and employers shall take all reasonable steps to assess and record the doses received in an emergency by emergency workers. Information on the doses received and information concerning the associated health risks shall be communicated to the workers involved.”

In medicine, there are also requirements for communication about radiation risks. Requirement 36 of GSR Part 3 [16] states:

“Registrants and licensees shall ensure that no person incurs a medical exposure unless there has been an appropriate referral, responsibility has been assumed for ensuring protection and safety, and the person subject to exposure has been informed as appropriate of the expected benefits and risks.”

5.2.2 Communication about risk using the concepts of attribution and inference

GSG-14 [53] sets out an example system for putting radiological health hazards in perspective, which has been derived on the basis of the findings of the 2012 UNSCEAR [1] report and which can be used by the relevant authorities in communicating with the public, workers and patients. The system comprises three levels:

- ‘Dangerous to health’: this corresponds to situations in which an individual might develop a deterministic effect, i.e. doses in region 1 of figure 1
- ‘Possible health effects’: this corresponds to situations in which there is a possibility that epidemiological studies would reveal an increase in the frequency of occurrence in cancers in a large population, i.e. doses in region 2 of figure 1
- ‘No observable health effects’: this corresponds to situations in which there is no possibility that current epidemiological studies would reveal an increase in the frequency of occurrence in cancers in a large population, i.e. doses in region 3 of figure 1

During and following an emergency, some communities might receive doses in the moderate or high range (i.e. region 1 or 2 of Fig. 1). Residents of these affected areas will be urged to follow the safety and protective instructions issued by the relevant authorities. As noted in [54], experience has shown that the public follow instructions best when they understand how the actions provide for their protection. Appendix II of GSG-2 [54] sets out a plain language explanation of the various operational intervention levels, which can be used when explaining instructions to the public. These plain language explanations can be enhanced with reference to the three-level system above, so as to explain to the public that the objective of the protection actions is to prevent exposures that could lead to deterministic effects or observable increase in the incidence of cancer.

There are also existing exposure situations where communities might receive doses in the moderate range (i.e. region 2 of Fig. 1). GSG-15 [37] recommends that the conclusions of UNSCEAR 2012 [1] be referred to when communicating about radiation risks to the public in remediating areas affected by past activities or events, and notes “the importance of avoiding unnecessary anxiety, while appropriately recognizing relevant inferred risks and detriments, in order to facilitate people to make their own informed decisions”. As noted in the IAEA report on the Fukushima-Daiichi accident: “The risks of radiation exposure and the attribution of health effects to radiation need to be clearly presented to stakeholders, making it unambiguous that any increases in the occurrence of health effects in populations are not attributable to exposure to radiation, if levels of exposure are similar to the global average background levels of radiation” [55].

Paragraph 3.14 of SSG-32 [36] recommends that informational material be provided to the public on “scientific evidence on the health risks from long term exposure due to radon indoors”. The three-level system set out above, which is based on the scientific findings of UNSCEAR 2012 [1], can be used to communicate to the public the radiation risk due to radon, for example for individuals exposed to radon in their home over the course of their lifetime, and therefore incurring doses in the ‘moderate’ region of Fig. 1, for which studies have indicated a statistically significant increased risk of lung cancer (see Section 4.1.1).

For most workers, even over the course of a working lifetime, the dose they receive will lie within the low region of Fig. 1 (see Table 4). However, the three-level system can be used for communicating the risks in areas such as coal mining, so that employers and workers are able to take informed decisions about their work, and also lifestyle choices such as smoking.

In medicine, where patients are required to be informed of the expected benefits and risks of any medical exposure, the three-level system above can also be used to communicate the risks. Similarly, the three-level system can support a medical practitioner who “has the responsibility to ensure that the carer or comforter is correctly informed about radiation protection and the radiation risks involved” [46]. Although the dose associated with a single instance of a diagnostic medical imaging procedure will be in the very low and low range (see Section 4.3.1), if certain procedures are undertaken successively over many years, the cumulative dose could reach into the ‘moderate’ region of Fig. 1, in which there could be an increase in the incidence of health effects that is attributable at the population level. This information, when presented in the context of the three-level system above, can be used to support decision making by patients and medical practitioners.

APPENDIX: A PLAIN LANGUAGE EXPLANATION OF THE CONCEPTS OF ATTRIBUTION AND INFERENCE TO SUPPORT PUBLIC COMMUNICATION AND IN PARTICULAR MEDIA OUTREACH

This Safety Report seeks to describe whether cancer can be caused by exposure to ionizing radiation and how the risk of such exposure can be estimated. It does this by speaking of ‘attribution of radiation health effects’ and ‘inference of radiation risk’. Sometimes even technical people do not use the concepts appropriately, which can lead to over-estimation of the effects, causing confusion among the public regarding the risks. In short, ‘attribution of radiation health effects’, means estimating whether a cancer could have been caused by exposure to radiation and ‘inference of radiation risk’ means estimating whether an exposure to radiation could lead to future cancers. Both of these are difficult to do, particularly for low levels of radiation.

Exposure to high doses of radiation, such as happened at Hiroshima and Nagasaki, can lead to death or serious health damage for individuals. For moderate doses, such happened after the Chernobyl accident, there can be an increase in the rates of cancer evident in a population. However, the situation for low doses, such as we encounter every day, is much less clear because our bodies respond very differently to high doses and low doses; low doses stimulate our defence and repair mechanisms whereas high doses overwhelm them.

Clinical studies into health effects caused by occupational and medical radiation exposures have produced an estimate of the increased risk of cancer of around 5% per 1000 mSv. That is to say that if we were to follow one hundred people who received a dose of 1000 mSv over their lifetime, we could expect to find that, on average, five more had developed cancer than a similar number of people who had not received such a dose. Bear in mind too that the lifetime risk of developing cancer for a member of the public is approximately 40% and that it is not possible to be certain that a cancer developed by a person who received a dose of 1000 mSv was caused by the radiation or by some other factor.

The safety standards aim to protect people from harmful effects of radiation. The safety standards have to be both ethical (i.e. they have to be precautionary) and practical (i.e. they have to be usable). The approach that is used in the standards that is both ethical and practical is the ‘linear no-threshold’ (LNT) model. This model assumes that any exposure to radiation may cause health effects, with no cutoff at low levels and with damage increasing as the level of radiation increases. However, it is only a model, and does not represent reality. Incorrect understanding of this could lead to over-estimation of the damage to health and life from very

low levels of radiation incurred by large numbers of people, and then to decisions being taken that actually put people at risk from other dangers that are not related to radiation.

The key message of this report is that it is appropriate to use the safety standards to infer risks of health effects for purposes of protection and safety (of the public, of workers and of patients) but it is not appropriate to use the standards to attribute health effects to radiation exposures.

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