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No. 122

Attribution of Radiation Health Effects and Inference of Radiation Risks

Considerations for Application of the IAEA Safety Standards

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ATTRIBUTION OF RADIATION HEALTH EFFECTS AND INFERENCE OF RADIATION RISKS

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SAFETY REPORTS SERIES No. 122

ATTRIBUTION OF RADIATION HEALTH EFFECTS AND INFERENCE OF RADIATION RISKS

CONSIDERATIONS FOR APPLICATION OF THE IAEA SAFETY STANDARDS

INTERNATIONAL ATOMIC ENERGY AGENCY
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FOREWORD

In 2012, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) presented a report to the United Nations General Assembly in which it clarified the scientific knowledge regarding the attribution of health effects to radiation exposure and the inference of risks from a radiation exposure that has been received. The UNSCEAR 2012 report distinguished between three types of radiation exposure: (i) radiation exposure at a high level, for which a health effect in an individual can be attributed to the exposure; (ii) radiation exposure at a moderate level, for which an increased incidence of health effects in a population can be attributed to the exposure; and (iii) radiation exposure at low and very low levels, where effects — either at an individual or at a population level — cannot be attributed to the exposure, and instead the risks can only be inferred.

The IAEA safety standards provide principles, requirements and recommendations that are intended to be used to protect people and the environment from harmful effects of ionizing radiation. They do this on the basis of inferred risks — both risks that exist in normal circumstances and risks that could arise as a consequence of an accident — but they are generally not formulated in terms of health effects that could be attributed to radiation exposure.

This Safety Report explains how the concepts of attribution of health effects and inference of risks can be taken into account in the application of the safety standards, so as to implement them more effectively. In particular, this publication explains the relevant provisions of the safety standards for high and moderate levels of exposure, where health effects might be able to be attributed to the exposure, and for low and very low levels of exposure, where risks can only be inferred. This Safety Report also supports more effective communication by clarifying the proper use of certain concepts relating to radiation risks and by providing a plain language explanation of the concepts of attribution of effects and inference of risks.

The IAEA is grateful for the contributions of all those who were involved in the drafting and review of this report. The IAEA officer responsible for this publication was K. Asfaw of the Office of Safety and Security Coordination.

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1. INTRODUCTION

1.1. BACKGROUND

The IAEA safety standards are based on the scientific knowledge of the health effects associated with radiation exposure that has been gained over decades by the studies of 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 by its resolution 913 (X). 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 reviews and evaluates exposures to radiation at global and regional levels and evaluates evidence for radiation induced health effects in exposed persons. 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 (A/RES/62/100), 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 it "to submit a report on that issue at its earliest convenience". This was subsequently provided by UNSCEAR in its 2012 Report to the General Assembly (A/67/46), in particular in annex A to that report [1]. The report sets out the concepts of retrospective attribution of radiation health effects to past radiation exposures and the prospective inference of health risks from radiation exposures. UNSCEAR 2012 [1] also raises questions about understanding among experts and communication with the public regarding issues such as radiation exposure, health effects and risks. The report focuses 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. Its purpose is to advance for the public benefit the science of radiological protection, in particular by providing recommendations and guidance on all aspects of protection against ionizing radiation. The ICRP's

latest recommendations for a system of radiological protection were published in 2007 as ICRP Publication 103 [2].

Following the issue of UNSCEAR 2012 [1], the IAEA Safety Standards Committees and the Commission on Safety Standards (CSS)[1] considered whether the report could have implications for the IAEA safety standards — both those published and those still under development. The CSS did not identify any safety standards that warranted revision as a result of UNSCEAR 2012 [1]; however, there was general consensus in the CSS that a better understanding among users of the safety standards of the concepts of attribution of health effects and inference of risks could enhance the application of the standards and communication on radiation risks. Consequently, the CSS requested that a Safety Report be prepared on how to apply the concepts of: (a) retrospective attribution of radiation health effects to past radiation exposures; (b) prospective inference of health risks from radiation exposures; and (c) prediction of notional health effects for comparative purposes (e.g. the 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 applying the safety standards and in more effectively communicating concepts relating to radiation risks in the safety standards.

The safety standards are not intended to be used in estimating health effects, either retrospectively or prospectively. This Safety Report also explains that it is appropriate to use the safety standards to infer risks for the purposes of protection and safety (of the public, workers and patients), but it is not appropriate to use them to attribute health effects to radiation exposures, in particular after exposure to low and very low doses.

The target audience of this Safety Report comprises experts on radiation protection and safety and individuals who might need to communicate on matters

[1] The five Safety Standards Committees are standing bodies of senior representatives in the areas of emergency preparedness and response, nuclear safety, radiation safety, transport safety and waste safety. They are open to all IAEA Member States and were established to make recommendations on the IAEA's programme for the development, review and revision of safety standards and on activities to support the use and application of these standards. 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.

of radiation protection and safety in regulatory bodies, other relevant authorities, operating organizations, technical support organizations and international organizations.

1.3. SCOPE

This Safety Report addresses matters relating to radiation health effects, radiation risks and radiation protection. It is relevant for all circumstances covered by the safety standards that give rise to radiation risks, including the entire lifetime of all facilities and activities — existing and new — utilized for peaceful purposes, as well as existing or unregulated radiation risks (see Section 3.3).

This Safety Report does not address nuclear safety, nuclear security or the protection of the environment.

This Safety Report does not provide guidance on assessing prospective cancer risks from exposure to radiation, or on assessing the attributability of health effects to radiation exposure for purposes of determining legal liability in compensation programmes for individuals who have cancer.[2]

The terms used in this Safety Report are to be understood as they are defined in the IAEA Nuclear Safety and Security Glossary [5]. The purpose of the IAEA Nuclear Safety and Security 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 intentionally not consistent with the definitions included in UNSCEAR 2012 [1], which are for the purposes of that report alone.

The terms ‘attribution’ and ‘inference’ are defined in UNSCEAR 2012 [1]. Attribution is: “The ascribing of an actual or manifest outcome to a cause. In the context of this report, attribution refers to the ascribing of an outcome—in particular a health effect—to radiation exposure” [1]. The health effect might be a deterministic effect evident in an individual or a stochastic effect evident via observation of an increase of the incidence of that effect in a population. Inference is: “The process of drawing conclusions from scientific observations, evidence and reasoning in the presence of uncertainty” [1].

The use of the term ‘risk’ warrants some additional explanation. In the safety standards, ‘risk’ is used in different ways depending on the context. For the purposes of this Safety Report, the relevant definition is: “The probability of a specified health effect occurring in a person or group as a result of exposure to radiation” [5]; the health effect could be, for example, skin reddening or cancer (see Section 2.1). In UNSCEAR 2012 [1], “risk refers to the probability that an event of interest (e.g. onset of cancer) will occur (i.e. it is prospective) during a

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

TABLE 1. TERMINOLOGY FOR BANDS OF RADIATION DOSE *(adapted from table 1 of annex A of UNSCEAR 2012 [1])*

Terminology for dose bands	Range of absorbed dose for low LET radiation	Scenarios
High	Greater than ~1 Gy	Typical dose (whole or partial body) to individuals after severe radiation accidents or from radiotherapy
Moderate	~100 mGy to ~1 Gy	Doses to about 100 000 of the recovery operation workers after the Chernobyl accident
Low	~10 to ~100 mGy	Dose to an individual from multiple whole body computed tomography (CT) scans
Very low	Less than ~10 mGy	Dose to an individual from conventional radiology (i.e. without CT or fluoroscopy)

given time period (e.g. the rest of life following an exposure)". This is considered consistent with the definition used in this Safety Report. More general meanings of the word 'risk' as used in the safety standards, such as the risk of an accident occurring or the risk to ecosystems in the environment, are not intended here.

For the purposes of discussing health effects, UNSCEAR has adopted a terminology to indicate bands of radiation exposure, expressed as approximate ranges of total absorbed dose. The terminology is intended to foster a consistent interpretation of the terms 'high', 'moderate', 'low' and 'very low' with reference to total doses of low linear energy transfer (LET) radiation (e.g. gamma radiation). Table 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 that from normal background exposure to natural sources of radiation. The dose bands do not account for the rate at which the dose is delivered.

1.4. STRUCTURE

Sections 2 and 3 summarize the relevant concepts from UNSCEAR 2012 [1] and the safety standards. Section 2 draws a clear distinction between three concepts that are not always distinguished clearly in practice: data on actual effects; models used to estimate the occurrence of health effects; and models used for purposes of radiation protection. Section 3 addresses the basis of the IAEA safety standards

and sets out their purpose (i.e. protection of people and the environment from harmful effects of ionizing radiation) and also makes connections between the fundamental principles of justification, optimization and limitation of risks and the concepts of attribution and inference.

Section 4 considers doses that have occurred in the past and whether health effects were able to be attributed to these doses, either at an individual or at a population level, for each of the three categories of exposure (occupational exposure, public exposure and medical exposure). For each exposure category, it also considers how exposure is to be controlled, in accordance with the IAEA safety standards, in dose ranges where individual effects can be attributed, where effects can be attributed at a population level and where risks can only be inferred.

Section 5 provides suggestions on how the concepts of attribution and inference can support communication about certain concepts in the safety standards that are sometimes misunderstood and also sets out an approach that can be applied to communicate with the public about radiation risks.

The Appendix provides a plain language explanation of the concepts of attribution and inference to support public communication.

2. RISK RELATED CONCEPTS

2.1. ATTRIBUTION OF HEALTH EFFECTS TO PAST RADIATION EXPOSURES

Basic aspects of radiation health effects are set out in UNSCEAR 2012 [1]. In the context of radiation protection, harmful health effects of radiation exposure are categorized into the following two groups[3]:

— Deterministic effects, which are described as injury in populations of cells and are also termed ‘tissue reactions’;
— Stochastic effects, which include malignant disease, benign tumours and heritable effects.

[3] There are some health effects, such as circulatory diseases and cataracts, that have not been possible to classify as either deterministic or stochastic effects. For the purposes of UNSCEAR 2012 [1], such effects are included in the term ‘tissue reactions’.

2.1.1. Deterministic effects

2.1.1.1. Characteristics of deterministic effects

When the human body is exposed to ionizing radiation, a process of ionization occurs that might alter the structure of molecules in cells. If such molecules are affected, cells might be damaged. This damage might kill the cell, or it might result in a viable but modified cell, including a cell in which the capacity for reproduction is affected. If a critical number of cells in an 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, which are termed 'deterministic effects'.

Deterministic effects are, with few exceptions (e.g. fibrotic processes), acute and occur early in individuals exposed to radiation at high doses. Examples of deterministic effects include hair loss, skin burns, damage to the haematopoietic system, acute radiation syndrome (i.e. radiation sickness) and death.

A deterministic effect can occur only if the individual radiation dose exceeds a certain threshold. At increasing doses above this threshold level, the deterministic effect becomes more severe. The level of the threshold dose is different for different deterministic effects. The threshold is also related to the duration of exposure, and it depends (to some extent) on the individual who is exposed.

2.1.1.2. Attribution of deterministic effects

As stated in annex A of UNSCEAR 2012 [1]:

> "In the context of deterministic effects, one can very often observe many characteristics (e.g. damage evolution and severity) in a differential pathological diagnosis, so that a health effect in an individual can be unequivocally attributed to a radiation exposure."

2.1.2. Stochastic effects

2.1.2.1. Characteristics of stochastic effects

Exposure to ionizing radiation can also induce a modification of the genetic material in a cell in such a way that the cell remains viable. If the damaged cell is not killed by the body's immune system, this might eventually lead to the development of cancer or benign tumours in the exposed tissue or organ. If the cell that is modified by exposure to radiation is a reproductive cell, it might

transmit altered genetic information to the descendants of an exposed individual and thus cause health effects in those descendants. Radiation induced heritable effects have been demonstrated in animal studies but have not been demonstrated for human populations exposed to any level of radiation [1]. Such health effects, including heritable effects, are termed 'stochastic effects'.

The latency period for the manifestation of stochastic effects might be a few years (e.g. in the case of most types of leukaemia) to tens of years (e.g. for other malignant conditions, such as solid cancers). The probability of occurrence of a stochastic effect increases with increasing radiation dose; 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 with certainty a stochastic effect in an individual to radiation exposure. This is because similar health effects also occur in the absence of radiation exposure (i.e. due to other carcinogens), and there are currently no specific biomarkers for stochastic radiation health effects. Even if such a biomarker were discovered, it would not be possible to distinguish between the effects of exposure to low levels of radiation from artificial sources and 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 of individuals is not currently possible.[4]

By means of epidemiological studies of populations of exposed persons, it is possible, under certain conditions, to attribute an increase in the incidence of stochastic effects to radiation exposure. Such attribution at the population level is possible only where the observed change in incidence of the stochastic effect is high enough to be clearly distinguished from the normal incidence of such effects, taking into account the inherent uncertainties in epidemiological studies.

An example is the incidence of thyroid cancer among children. Thyroid cancer has a very low normal incidence in children, and the high radiosensitivity of the thyroid makes this radiation induced effect easier to attribute. Therefore, epidemiological studies have shown an increased frequency of thyroid cancer among children that can be attributed with confidence to radiation exposure [7]; however, thyroid cancer in an individual still cannot be attributed unequivocally to radiation exposure.

In many other situations — for example, where the change in the incidence of a stochastic effect is small or where the dose is low — it is not possible to attribute such effects to radiation exposure, either for individuals or for a population.

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[4] See Ref. [6] for further discussion.

2.1.2.3. Uncertainties in attributing stochastic effects

Estimates of the incidence of stochastic effects are uncertain, particularly at low doses. There are two types of uncertainty: aleatory uncertainties (also called statistical uncertainties), which are due to the random variations of the estimates (i.e. in comparison with the 'true' value) and are inherent to a phenomenon; and epistemic uncertainties, which are due to incomplete knowledge about a phenomenon, which affects the ability to produce a reliable estimate [5].

Annex B of UNSCEAR 2012 [1] addresses uncertainties in risk estimates for radiation induced cancer. The dominant uncertainty is the statistical (or aleatory) uncertainty, due to the dose distributions and the sample size considered in epidemiological studies. For low and very low doses, these statistical variations are normally large enough to obscure any small increase in the incidence of stochastic effects. As stated in annex A of UNSCEAR 2012 [1]:

> "It is extremely difficult to detect excess frequency of occurrence of cancer by studying population exposures limited to low dose and very low doses" [8]. "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."

In other words, as a consequence of these uncertainties, it might never be possible to demonstrate the effects of low and very low doses using epidemiological studies.

2.1.3. The dose–response relationship

The dose–response relationship presents the increase in probability of health effects for an increase in radiation dose. UNSCEAR 2012 [1] notes "the current limitations to knowledge…regarding health effects from radiation exposure" and highlights the distinctions between the attributability of effects for three different ranges of dose (see Fig. 1), as follows:

— The high dose range (i.e. above 1 Gy; see Table 1), for which deterministic effects are clinically observable in individuals by means of a diagnosis. The dose–response relationship for deterministic effects in a population follows a sigmoid function distribution (the 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 probability of that effect is taken to be zero; above the threshold, it is assumed to be one.

— The moderate dose range (i.e. about 100 mGy to about 1 Gy; see Table 1), for which radiation induced stochastic effects are observable (i.e. statistically) only in populations by means of epidemiological studies; such effects cannot be unequivocally attributed to radiation exposure of individuals. The dose–response relationship for stochastic effects observed in large populations forms a roughly linear function (the blue line in Fig. 1). Therefore, it is important to note that the extent to which health effects in this dose range can be observed depends not only on the dose received but also on the size of the exposed population.
— The low dose and very low dose range (i.e. less than about 100 mGy; see Table 1), for which health effects might be scientifically plausible but are not observable in either individuals or an exposed population.

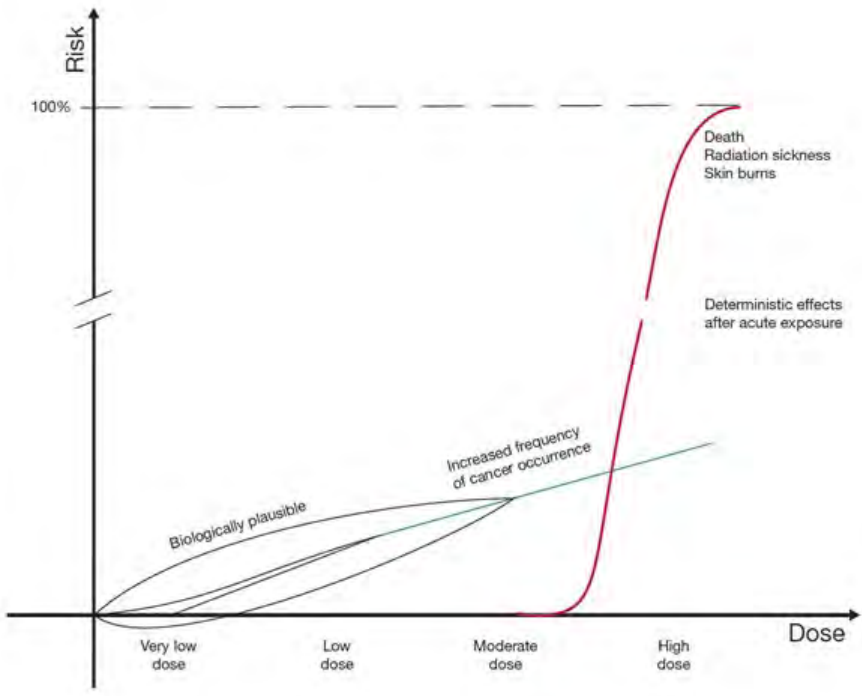

FIG. 1. Relationship between radiation dose and risk of health effects. (Adapted with permission from figure A–VI of annex A of UNSCEAR 2012 [1].)

2.2. INFERENCE OF HEALTH RISKS FROM RADIATION EXPOSURES

2.2.1. Frequentist risk and subjective risk

The mathematical quantification of risk (or probability) was originally based on retrospective analysis of the frequencies of past occurrences. The concept of risk later evolved to also include subjective risks estimated on the basis of expert judgement. The distinction between frequentist risk and subjective risk, and the fact that risk estimates in radiation protection are generally derived values based on expert judgement, are not always made explicit, and an expression such as 'estimated increased risk of cancer of 5% per sievert' (see Section 2.2.3) could refer either to a frequentist risk or a subjective risk.

In the context of radiation induced health effects, a frequentist risk can be derived from the results of epidemiological studies. This is generally the case only in the moderate and high dose ranges (see Section 2.1.3). Such epidemiological studies have also usually involved moderate to high dose rates (e.g. the Life Span Study of the survivors of the atomic bombings in Hiroshima and Nagasaki [1]).

Subjective risks in the context of radiation induced health effects are generally derived from a consensus opinion of experts. Such expert judgement has mainly involved extrapolation of the results of epidemiological studies of populations exposed to moderate and high doses, and moderate and high dose rates, to derive subjective risk estimates for situations in which the inherent uncertainties make obtaining frequentist risk estimates impossible (see Section 2.1.2.3). Such extrapolation involves the use of appropriate modifying factors and is also based on knowledge of the biological mechanisms that underly such effects. There are various situations in which expert judgement is necessary to extrapolate epidemiological data, including: "*(i)* extrapolation of risks over lifetime, *(ii)* transference to another population; *(iii)* transference 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].

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 normally sufficient evidence "to be able to predict relatively accurately whether or not there will be a deterministic effect in an exposed individual and, if so, the likely severity of that health effect" [1] (see Sections 2.1.1 and 2.1.3).

For exposure to moderate doses or to high doses, there is epidemiological evidence "to be able to predict with some confidence an increased risk of stochastic effects in an exposed population similar to that for which evidence

exists" [1] (see Sections 2.1.2 and 2.1.3). UNSCEAR's latest major evaluations of epidemiological studies of radiation induced cancer were issued in annex A of UNSCEAR 2006 [9] and in UNSCEAR 2010 [10]. These evaluations provided a statistically significant estimate of the excess lifetime risk of mortality for doses in the moderate to high dose ranges. Therefore, the risk of a health effect occurring following a dose in the moderate or high dose range could be considered a frequentist risk.

For exposures in the ranges of very low and low doses, annex A of UNSCEAR 2012 [1] 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". Therefore, only subjective risks can be inferred for very low and low doses, and the values derived will depend on the models and assumptions used to project and predict the possible consequences of these doses for individuals. The cumulative uncertainties and margins of error in the values derived from the use of models may be significant.

Annex A of UNSCEAR 2012 [1] notes that there are several plausible dose–response relationships for the very low and low dose ranges, although 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". In particular, the risks in the upper part of the low dose range in Fig. 1 (i.e. where no population level data are available) are unlikely to be higher than the risks in the lower part of the moderate dose range in Fig. 1 (where population level data are available).

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 values for risks obtained from any of these relationships are subjective risks — that is, they are based on expert judgement and not on actual epidemiological data.

The plausible dose–response relationships illustrated in Fig. 2 are as follows:

(a) The risk of radiation induced cancer from exposure in the very low and low dose range is substantially greater than expected from a linear no threshold (LNT) relationship (a supralinear relationship — curve *a* in Fig. 2).
(b) The risk of radiation induced cancer from exposure in the moderate dose range is extrapolated linearly down to zero additional dose (line *b* in Fig. 2). A linear relationship is commonly used in modelling the risk of cancers other than leukaemia [11] and is also the model used for purposes of radiation protection (see Section 2.2.3).
(c) The risk of radiation induced cancer is lower than that predicted by the linear dose–response relationship at very low doses and follows a quadratic

relationship (curve *c* in Fig. 2). Such a linear–quadratic relationship is generally preferred for estimating the risk of leukaemia [11].

(d) The risk of radiation induced cancer from exposure in the very low and low dose ranges is substantially lower than expected from a linear dose–response relationship and is a threshold relationship or a hormetic relationship (line *d* and curve *e* in Fig. 2, respectively).

The relatively large uncertainties in determining whether stochastic effects occur at low and very low doses (see Section 2.1.2.3) are such that all of these dose–response relationships are scientifically plausible. Annex A of UNSCEAR 2012 [1] states that the relationships in Fig. 2 "cannot be convincingly verified or falsified at the moment".

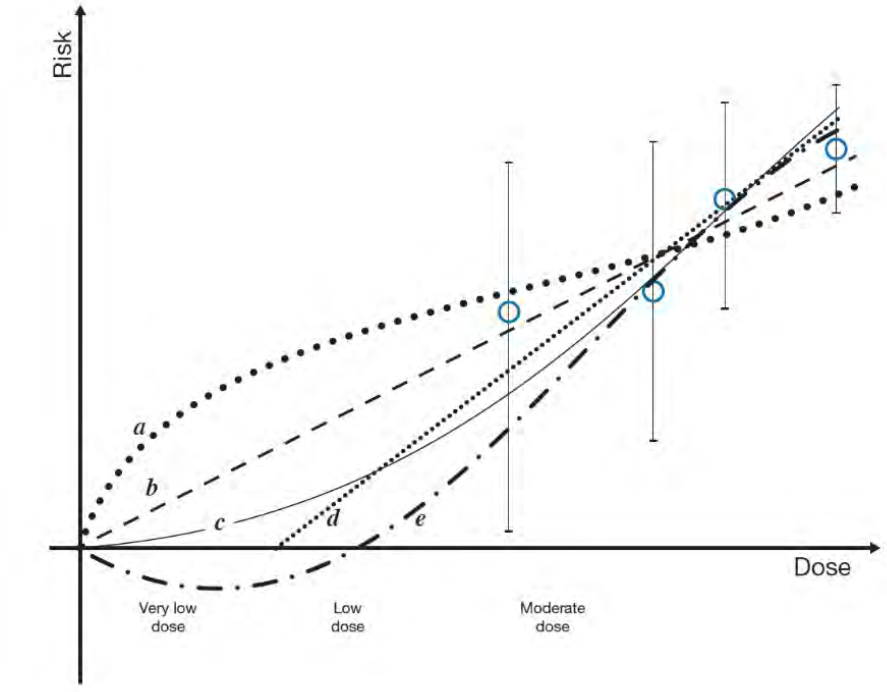

FIG. 2. Schematic presentation of plausible dose–response relationships for the risk of radiation induced cancer in the ranges of very low, low and moderate doses (see text for definitions of curves a–e*). The data points and confidence intervals marked on the graph represent observations of increased frequency of occurrence of a specific cancer type in populations exposed to moderate doses. (Reproduced with permission from figure 1 of annex A of UNSCEAR 2012 [1].)*

2.2.3. Inferring radiation risks for purposes of radiation protection

The inference of radiation risks for the purposes of radiation protection needs to consider exposure to high doses and high dose rates, exposure to low doses and low dose rates, as well as acute exposures and chronic exposures. It is also necessary to provide a system of protection that is workable in practice. On the basis of these considerations, the model used for inferring risks for the purposes of radiation protection is based on the LNT hypothesis. This is the hypothesis that the risk of stochastic effects is assumed to increase in direct proportion to the radiation dose (i.e. as per line *b* in Fig. 2). The LNT model is designed to be applied for all levels of dose below the relevant threshold values at which deterministic effects occur; that is, the LNT hypothesis makes no distinction between moderate doses that lead to attributable stochastic effects (at a population level) and low and very low doses for which health effects due to radiation exposure cannot be attributed. The LNT model also does not take into account the dose rate or the rate of change of dose rate. Within the LNT model, any additional dose above background levels implies a non-zero risk of stochastic effects.

The ICRP first used the LNT model in its recommendations published in 1966 [12]. In Ref. [2], the ICRP continues to apply and promote the LNT model for the purposes of radiation protection and states:

> "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."

In Ref. [2], the ICRP also reviews the latest biological and epidemiological studies on the health effects of ionizing radiation and states:

> "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 detriment due to excess cancer and heritable effects remains unchanged at around 5% per Sv."[5]

The LNT hypothesis is not based on objective observation of health effects; that is, it does not represent a frequentist risk estimate at low and very low doses. Instead, it represents a subjective risk estimate, based on extrapolation from the high and moderate dose ranges and on expert judgement. Although the LNT hypothesis is consistent with known mechanisms for induction of cancer (see para. A82 of annex A of UNSCEAR 2012 [1]), it is only one of several possible models for what could be assumed to happen at low and very low doses (see Fig. 2). Nevertheless, it is still considered by the ICRP to be scientifically the best model for the purposes of radiation protection [2].

The purpose of adopting the LNT hypothesis is to facilitate the practical application of the system of radiation protection. The LNT hypothesis provides the basis for the aggregation and summation of equivalent and effective doses from external radiation and from intakes of radionuclides while maintaining a simple approach to calculations.

In addition, the LNT hypothesis is considered an ethical approach to radiation protection. With regard to this, Ref. [2] states:

"The LNT model is not universally accepted as biological truth, but rather, because we do not actually know what level of risk is associated with very-low-dose exposure, it is considered to be a prudent judgement for public policy aimed at avoiding unnecessary risk from exposure."

Therefore, the LNT hypothesis may be considered to be commensurate with the 'precautionary principle'[6] [14] and is a prudent basis for prevention and protection [15].

Annex A of UNSCEAR 2012 [1] also states that the LNT and the associated radiation risk coefficients are "coherent with radiobiological knowledge, adhere to epidemiological information, and incorporate ethical judgements on the relative harm associated with different health effects".

---

[5] The ICRP defines detriment as "The total harm to health experienced by an exposed group and their descendants as a result of the group's exposure to a radiation source. Detriment is a multi-dimensional concept. Its principal components are stochastic quantities: probability of attributable fatal cancer, weighted probability of attributable non-fatal cancer, weighted probability of severe heritable effects, and potential years of life lost if the harm occurs" [13].

[6] See http://www.precautionaryprinciple.eu/

In conclusion, it is considered that the use of LNT for the inference of risk at low and very low doses remains the most reasonable and practical approach to radiation protection.

2.3. ESTIMATION OF HEALTH EFFECTS FOR COMPARATIVE PURPOSES

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

The concept of collective dose [16, 17] 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 is consistent with the use of the LNT model, which enables the summation of doses. For example, the collective dose due to occupational exposure of a group of workers is sometimes used in the optimization of protection and safety when assessing various options to carry out a maintenance task in a nuclear power plant [18]. Collective dose is also used for comparing alternative options for managing discharges from facilities [19]. The use of collective dose is described in more detail in Ref. [20].

Care needs to be taken when multiplying low doses with a large number of exposed persons to derive a collective dose. Such a calculation conceals large uncertainties: for example, the increased uncertainties in modelling both individual doses and the size of the exposed population (especially far into the future) mean that the concept of collective dose cannot be used to reliably infer the risks that might be associated with the post-closure period of a waste disposal facility [21].

The assumptions that underpin calculations of collective dose, as well as the associated uncertainties and limitations on its applicability, have to be made explicit and taken into account. Annex A of UNSCEAR 2012 [1] states:

> "[P]ublic health bodies need to allocate resources appropriately, and… 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."

The estimation of cancer deaths on the basis of collective effective doses involving trivial exposures to large populations is not reasonable, and the ICRP, UNSCEAR and the IAEA have all strongly recommended that such use of collective dose is scientifically not justified and should be avoided [1, 2, 19]. Specifically, UNSCEAR 2012 [1] states:

"[T]he 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 normal natural background levels."

3. BASIS OF THE SAFETY STANDARDS

3.1. PURPOSE OF THE SAFETY STANDARDS

Article III.A.6 of the IAEA Statute [22] states:

"[The IAEA is authorized 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 intended to be used to protect people and the environment from harmful effects of ionizing radiation. The safety standards are regulatory in nature, and as such, they need to be practical and provide requirements and recommendations for a broad range of facilities and activities. As well as including measures for protection — namely, for controlling exposures to both high doses of radiation (e.g. exposures following an accident) and very low doses at levels typical of the global average background levels of radiation (e.g. exposures from the normal operation of a facility or normal use of a radioactive source) — the safety standards also include measures for safety, that is, for the prevention of incidents or accidents.

The safety standards are not intended to be used for attributing health effects to radiation exposure, either individually or collectively, or retrospectively or prospectively. Moreover, the safety standards are not intended to be cited in court (e.g. in the context of occupational compensation claims).

3.2. DEVELOPMENT AND USE OF THE SAFETY STANDARDS

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 Member States by means of a system of standing bodies of senior representatives of Member States, selected intergovernmental organizations and international non-governmental organizations. Many safety standards are sponsored jointly by several agencies of the United Nations system and other intergovernmental organizations. As such, the IAEA safety standards are intergovernmental, international standards for safety. The regulation of safety is a national responsibility, and the 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 and manufacturers of nuclear and radiation technologies and by licensees 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.

3.3. SCOPE OF THE SAFETY STANDARDS

The safety standards cover all situations that give rise to radiation risks and are applicable for the entire lifetime of all facilities and activities — both existing and new — utilized for peaceful purposes and protective actions to reduce unregulated radiation risks.

The safety standards are concerned with both risks that exist in normal circumstances and risks that could arise as a consequence of incidents, including loss of control over a nuclear reactor core, nuclear chain reaction, radioactive source or any other source of radiation. The risks addressed in the safety standards are intended to include both risks to persons and risks to the environment.

The IAEA Safety Standards Series is based on a hierarchy of three types of publication: Safety Fundamentals, Safety Requirements and Safety Guides, as explained below:

— The Safety Fundamentals present the fundamental safety objective and principles for protection and safety [23]. They are formulated in a way that is understandable to non-specialist readers, and they convey the basis and rationale for the safety standards to those at senior levels in government and regulatory bodies (see Section 3.4).
— The Safety Requirements establish the requirements that shall 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. The requirements 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 are based on internationally recognized good practices to help users to achieve high levels of protection and safety.

The safety standards cover radiation protection and nuclear safety (also termed 'protection and safety'), namely the protection of people and the environment against risks and the safety of facilities and activities that give rise to 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 response[7]. The safety standards also address the interface between nuclear security and safety.[8]

For the purpose of establishing practical requirements for protection and safety, the safety standards distinguish between three different types of exposure situation: planned exposure situations, emergency exposure situations and existing exposure situations. In addition, for the protection of persons, three basic

[7] Safety standards for preparedness and response for a nuclear or radiological emergency apply irrespective of the cause of the emergency, including a natural event, human error, mechanical or other failure, or a nuclear security event.

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

categories of exposure have been considered: occupational exposure, public exposure and medical exposure.

There are some situations involving radiation exposure that are considered not to be amenable to control[9] (see para. I.42 of IAEA Safety Standards Series No. GSR Part 3, Radiation Protection and Safety of Radiation Sources: International Basic Safety Standards [24]). 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 are anticipated (e.g. the exposures expected to be incurred in normal operation) and 'potential exposures' (i.e. that are not expected to be incurred with certainty, but that may potentially result from an incident involving a source of radiation or owing to an event or sequence of events of a probabilistic nature, including equipment failures and operating errors [5]).

In accordance with the risk related concepts presented in Section 2 of this Safety Report, it can be seen that the safety standards apply to 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 to health effects for which an increase in incidence of the effect in a population can be attributed to exposure (stochastic effects) and situations in which risks can only be inferred. Notwithstanding this, the safety standards are generally not formulated in terms of health effects, either individually attributable or attributable at a population level. Instead, the requirements and recommendations in the safety standards are more generally aimed at the restriction of risks, from facilities and activities and from unregulated or existing situations.

3.4. THE FUNDAMENTAL SAFETY PRINCIPLES

Many of the fundamental concepts used throughout the IAEA safety standards are set out in IAEA Safety Standards Series No. SF-1, Fundamental Safety Principles [23]. SF-1 [23] is presented in language that is understandable to the non-specialist reader, and the intention is to convey the basis and rationale for the IAEA safety standards to those at senior levels in government and regulatory bodies.

SF-1 [23] states 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

[9] It is generally accepted that it is not feasible to control ^{40}K in the body or cosmic radiation at the surface of the Earth.

safety standards require that measures be taken to make sure that the likelihood of such a loss of control is extremely low. The intention is that high doses and deterministic effects, as well as moderate doses and possible stochastic health effects, will be avoided.

SF-1 [23] also states that: "For the purposes of the IAEA safety standards, it is assumed that there is no threshold level of radiation dose below which there are no associated radiation risks." Therefore, the safety standards make use of the LNT hypothesis for the inference of risk at very low and low doses.

SF-1 [23] establishes the fundamental safety objective of protecting people and the environment, as well as a coherent set of ten fundamental principles that represent a common safety philosophy 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 directly related to the protection of people, and hence to the purpose of this Safety Report, as follows:

(a) Principle 4 on justification of facilities and activities states that: "**Facilities and activities that give rise to radiation risks must yield an overall benefit**".

(b) Principle 5 on optimization of protection states that: "**Protection must be optimized to provide the highest level of safety that can reasonably be achieved**". Paragraph 3.23 of SF-1 [23] states:

> "The optimization of protection requires judgements to be made about the relative significance of various factors, including:
>
> — The number of people (workers and the public) who may be exposed to radiation;
> — The likelihood of their incurring exposures;
> — The magnitude and distribution of radiation doses received;
> — Radiation risks arising from foreseeable events;
> — Economic, social and environmental factors."

(c) Principle 6 on limitation of risks to individuals states that: "**Measures for controlling radiation risks must ensure that no individual bears an unacceptable risk of harm**". Paragraph 3.25 of SF-1 [23] states that: "Consequently, doses and radiation risks must be controlled within specified limits".

(d) Principle 10 on protective actions to reduce existing or unregulated radiation risks states that: "**Protective actions to reduce existing or unregulated radiation risks must be justified and optimized**".

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

Justification involves a balancing of benefits and harm to determine whether an action is expected to yield a net benefit to the exposed individuals or to society. Justification has to be applied, for example, in making decisions on whether to introduce a new facility or activity in a State and 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, from the highest levels of government to day to day practitioners; therefore, the concept needs to be well understood by all. The main aim of justification is "to do more good than harm" [2].

Justification means that the detriments that might be caused by the introduction of a new source of radiation or by the reduction of an existing or emergency exposure would be outweighed by the benefits. In some cases, the potential detriments and benefits are to the same person(s); in other cases, the detriments and benefits are received by different (groups of) persons. The comparison of the benefits and detriments often goes beyond the consideration of protection and safety and entails a consideration of economic, societal, environmental and other factors. Medical exposures, whether for diagnosis or for treatment, are a special case, in that the benefit is primarily to the patient. The justification for such exposures 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 possible detriments.

Justification needs to be performed in all exposure situations, irrespective of whether or not radiation exposures are at a level for which health effects might be attributable. This is of particular importance in the justification of protective actions and the protection strategy in a nuclear or radiological emergency. Protective actions are almost always justified in situations involving high and moderate doses (e.g. when projected doses are above the generic criteria provided in annex II of IAEA Safety Standards Series No. GSR Part 7, Preparedness and Response for a Nuclear or Radiological Emergency [25]). However, in emergency exposure situations and in existing exposure situations involving low and very low doses, particular care is needed to ensure that protective actions, which could have significant societal, economic or environmental impacts, do more good than harm.

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

Optimization of protection and safety is 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 [2, 5]. The goal is to achieve the best protection under the circumstances and with the resources available, which does not necessarily mean achieving the lowest dose.

Optimization of protection and safety is a prospective, iterative process that examines the available options for protection [2]. 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 [2].

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

Table 2 summarizes the ranges of values for dose constraints and for reference levels applicable for each exposure situation, as established in GSR Part 3 [24]. The values in Table 2 all lie in the very low and low dose ranges shown in Table 1. This means that if protection and safety is optimized, the dose received by workers and members of the public will not be in the ranges in which health effects could be attributed at an individual or population level.

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 may be of particular importance in emergency exposure situations and in existing exposure situations. In optimizing protection and safety in planned exposure situations and optimizing protection strategies and protective actions in emergency exposure situations and in existing exposure situations, particular consideration needs to be given to those groups of individuals that receive higher doses, particularly if such doses could be in the moderate or even high dose ranges, where health effects can be attributed to exposure at the population or even the individual level.

TABLE 2. DOSE CONSTRAINTS AND REFERENCE LEVELS [26]

Range in which the value for a dose constraint or reference level is set	Category of exposure and type of exposure situation
20–100 mSv[a,b,c]	Reference level for public exposure in an emergency exposure situation
1–20 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)

[a] Acute dose or annual dose.

[b] In exceptional situations, informed volunteer workers may receive doses above this range to save lives, to prevent severe deterministic effects or to prevent the development of catastrophic conditions.

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

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

Paragraph 3.25 of SF-1 [23] states: “Justification and optimization of protection 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.”

In addition, para. 3.26 of SF-1 [23] states:

> “Conversely, because dose limits and risk limits represent a legal upper bound of acceptability, they are insufficient in themselves to ensure the

best achievable protection under the circumstances, and they therefore have to be supplemented by the optimization of protection. Thus both the optimization of protection and the limitation of doses and risks to individuals are necessary to achieve the desired level of safety."

The dose limits that have been adopted in the safety standards (i.e. in GSR Part 3 [24]) were originally recommended by the ICRP [17]. The dose limit for exposure of workers is an annual effective dose of 20 mSv, and for exposure of members of the public it is an annual effective dose of 1 mSv. Dose limits do not apply for medical exposure of patients. The selection of the dose limit for workers was based on expert judgement on the level of dose above which the consequences for the worker would be widely regarded as unacceptable [17]. The dose limit for the public, in contrast, was set at a similar order of magnitude to natural background levels, based on uncertainties, the lack of measurement and the lack of direct benefit from the radiation [17].

Dose limits apply only for planned exposure situations, namely from the planned operation of a source or from a planned activity that results in exposure from a source.[10] Dose limits do not apply for emergency exposure situations or for existing exposure situations, where reference levels are used as criteria. This complexity could lead to misunderstandings (see Section 5).

The dose limits are in the very low and low dose bands shown in Table 1. Thus, the dose limits are lower than the dose levels at which health effects could be attributed at an individual or population level to radiation exposure; indeed, the attributability of health effects is not a criterion for limitation of doses.

[10] In some cases, dose limits for workers for planned exposure situations are applied to emergency exposure situations (see para. 4.21 of GSR Part 3 [24]) and to existing exposure situations (see paras 5.26 and 5.29 of GSR Part 3 [24]).

4. PRACTICAL APPLICATION OF RISK RELATED CONCEPTS FOR DIFFERENT CATEGORIES OF EXPOSURE

4.1. PUBLIC EXPOSURE

4.1.1. Doses and health effects associated with public exposure

Members of the public are continuously exposed to radiation, resulting in very low or low doses. UNSCEAR periodically summarizes the radiation exposure of the public due to natural and artificial sources of radiation [7, 9, 27–31]. The global average annual effective dose received by the public is approximately 2.4 mSv [7]. Table 3 and Fig. 3 summarize the doses associated with public exposure from different natural and artificial sources.

TABLE 3. GLOBAL ANNUAL DOSES [7, 28]

Source or mode	Average annual effective dose (typical range) (mSv)
Inhalation (radon gas)	1.26 (0.2–10)
External terrestrial	0.48 (0.3–1)
Ingestion	0.29 (0.2–1)
Cosmic radiation	0.39 (0.3–1)
Nuclear fuel cycle	0.0002 (<0.02 mSv for critical groups at 1 km from some nuclear reactor sites)
Atmospheric testing of nuclear weapons	0.005
Chernobyl accident	0.002 — globally dispersed radionuclides
Fukushima Daiichi accident	<0.01 — first year, countries outside Japan
Total from all sources	2.44 (1–13)

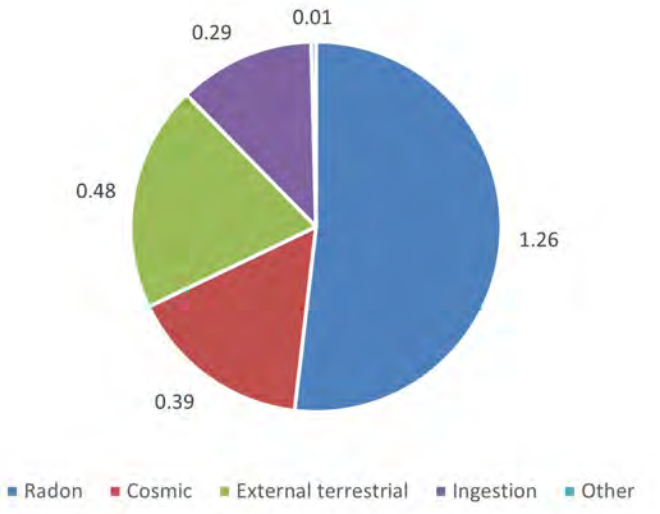

FIG. 3. Estimated contributions to public exposure from different sources, in millisievert. (Data taken from table 1 of UNSCEAR 2008 [7].)

The largest component of the global average annual effective dose arises from the indoor inhalation of naturally occurring radon gas and its short lived decay products (on average 1.26 mSv in a year). 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), terrestrial sources (rocks and soil) and other materials containing radionuclides of natural origin, such as food. The average annual exposure to natural radiation sources has not changed significantly over time, although individual exposures, particularly to radon, can differ significantly, both spatially and temporally. Annex B of UNSCEAR 2008 [7] provides information on the global range of exposures to each of these components, which tends to follow a log-normal distribution.

The public is also exposed to artificial sources of radiation from current and past facilities and activities. Examples include nuclear power plants; research reactors; radioactive waste disposal facilities; releases into the air and into the groundwater from installations; 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 nuclear gauges; consumer products; and non-medical human imaging. Exposure also results from 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 of the large majority of members of the public due to natural and artificial sources of radiation falls in the range of very low levels of dose.

UNSCEAR has published several reviews of the health effects associated with public exposure, including a review of epidemiological studies of cancer risk due to low dose rate radiation exposure from environmental sources (see annex B of UNSCEAR 2017 [29]). This includes reviews of the Techa River cohort (TRC) studies in the Russian Federation and studies of environmental exposure to high natural background radiation (HNBR) in Karunagappally, India, and Yangjiang, China. UNSCEAR 2017 [29] concludes:

> "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."

UNSCEAR's reviews of epidemiological studies of people living near nuclear installations have not shown an increase in attributable effects [9]. For disposal of low and intermediate level solid waste, UNSCEAR 2008 [7] estimates that the worldwide average annual individual effective dose is minimal, at about 1 nSv per year for each facility. UNSCEAR 2006 [9] also reviews studies of groups of persons exposed to atmospheric nuclear weapons testing and does not identify an increased incidence of leukaemia among such groups.

There are cases where radiation induced health effects in members of the public are attributable at the population level; for example, reviews of the health effects from exposure to radon are published in annex E of UNSCEAR 2006 [9] and annex B of UNSCEAR 2019 [30]. These studies indicated a significant association (at a population level) between the risk of lung cancer and exposure to radon in homes. The World Health Organization concludes [32]:

> "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."

UNSCEAR 2012 [1] also considers a case study on lung cancer from exposure to radon in 117 homes in Winnipeg, Canada, and concludes:

> "[I]ncreased frequency of lung cancer is unlikely to be observable among the 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 increased frequency is potentially observable."

UNSCEAR 2012 [1] concludes that: "An observed lung cancer in an individual cannot be unequivocally attributed to exposure to radon".

Some persons have also been exposed as a result of accidents at nuclear power plants or with orphan sources [7, 28]. These exposures range from high doses for a few individuals to moderate doses for groups of individuals and low and very low doses for some population groups. Annex D of UNSCEAR 2008 [7] summarizes the doses and health effects for members of the public from the Chernobyl accident. More than 300 000 individuals received effective doses in excess of 10 mSv. The average thyroid dose to evacuees was about 500 mGy; that is, in the moderate range of doses as shown in Table 1, whereas the average thyroid dose to 6 million people living in contaminated areas was about 100 mGy. UNSCEAR 2008 [7] concludes:

> "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 has been no persuasive evidence of any other health effect in the general population that can be attributed to radiation exposure."

UNSCEAR 2012 [1] also includes a case study on thyroid cancer after the Chernobyl accident and concludes that there is "strong support for attributing, at least in part, the observed increased frequency to radiation exposure" in this population. UNSCEAR also states:

> "In the absence of a biomarker to distinguish a 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 unequivocally attributed to radiation exposure from the accident" [1].

UNSCEAR summarizes the doses and health effects from the Fukushima Daiichi nuclear power plant accident in annex A of UNSCEAR 2013 [28] and annex B of UNSCEAR 2020/2021 [31]. In the first year following the 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 [28]. UNSCEAR 2013 [28] concludes:

> "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."

UNSCEAR 2020/2021 [31] states:

> "[T]he 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.
>
> …….
>
> "[T]he 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)."

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 effects, which are attributable at an individual level. For example, following an accident with an abandoned teletherapy device in Goiânia, Brazil, containing a ^{137}Cs source, 21 people received doses in excess of 1 Gy [7]. Annex C of UNSCEAR 2008 [7] summarizes accidents involving orphan sources that led to the exposure of members of the public to high doses, with information on 34 accidents involving orphan sources that resulted in 42 early deaths and disfiguring injuries to both children and adults. The details of many of these accidents have been published by the IAEA, for example in Refs [33–37].

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 IAEA Safety Standards Series No. GSR Part 1 (Rev. 1), Governmental, Legal and Regulatory Framework for Safety [38]. Requirements for control of public exposure are established in GSR Part 3 [24] and GSR Part 7 [25]. Detailed guidance for control of public exposure is provided in many IAEA Safety Guides: for planned exposure situations [19, 26, 39, 40]; for emergency exposure situations [41–43]; for existing exposure situations [26, 44, 45]; for regaining control over orphan sources [46]; and for control of orphan sources in the metal recycling industry [47].

Exposure due to some sources of radiation is excluded from the scope of the safety standards because the sources are not amenable to control; examples include exposure due to cosmic rays at the surface of the Earth and exposure due to globally dispersed artificial radionuclides, such as from atmospheric testing of nuclear weapons. Excluded exposures in fact make up a certain fraction of those exposures incurred by the public, shown in Table 3 and Fig. 3.

4.1.2.1. Control of public exposure at low and very low doses

For planned exposure situations, the control of public exposures is generally focused on low and very low doses and is achieved through optimization of protection and safety and by applying dose constraints and the public dose limit to representative persons.

GSR Part 3 [24] establishes various criteria for the control of public exposures, such as the dose limit for public exposure (i.e. an effective dose of 1 mSv in a year), dose constraints (i.e. 0.1 to less than 1 mSv in a year) or risk constraints to be used in optimization of protection and safety, and exemption and clearance criteria (of the order of 10 μSv in a year). All these values are very low doses.

The government or the regulatory body is required to establish or approve dose constraints (see para. 3.222 of GSR Part 3 [24]) and is expected to take into account the characteristics of the facility or activity, the scenarios for exposure and the views of interested parties. The government or regulatory body is also required to ensure that the dose limit is not exceeded in case members of the public are exposed to several sources of radiation from different authorized practices; see footnote 25 of GSR Part 3 [24]. In practice, through optimization of protection and safety, the actual doses that members of the public receive as a result of the operation of facilities and the conduct of activities are expected to be significantly lower than the annual effective dose limit of 1 mSv.

Dose limits are not applied in emergency exposure situations and existing exposure situations. Rather, the safety standards require that the protection of all individuals be optimized; this applies to persons incurring doses above the reference level, as well as doses below the reference level, with the priority given to those persons who receive doses above the reference level. Indeed, para. 5.8 of GSR Part 3 [24] states that: "All reasonable steps shall be taken to prevent doses from remaining above the reference levels".

As shown in Table 2, for emergency exposure situations, the reference level specified in GSR Part 3 [24] is in the range 20–100 mSv in a year, whereas for existing exposure situations, the reference level is in the range of 1–20 mSv in a year; that is, values that are in the low dose range in Fig. 1. The actual value of the reference level within these ranges is required to be established or approved by the government, regulatory body or another relevant authority (see paras 4.8 and 5.8 of GSR Part 3 [24]), and it will depend on the prevailing circumstances for the exposure situation under consideration.

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

For emergency exposure situations, para. 4.7 of GSR Part 3 [24] states:

> "The government shall ensure that protection strategies are 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."

In emergency exposure situations, high doses and moderate doses to the public might occur. Generic criteria for use in emergency preparedness and response are specified in appendix II of GSR Part 7 [25]. On the basis of a hazard assessment, a protection strategy and associated emergency arrangements are required to be established at the preparedness phase [25]. The higher the expected doses, the more comprehensive the strategy and associated arrangements need to be to ensure effective response, with priority given to taking protective actions aimed at avoiding or minimizing severe deterministic effects and reducing the risk of stochastic effects. Table II.1 of GSR Part 7 [25] sets out generic criteria for doses received within a short period of time and for which protective actions and other response actions are expected to be taken under any circumstances in an emergency to avoid or minimize severe deterministic effects. Table II.2 of GSR Part 7 [25] sets out generic criteria for protective actions and other response actions to reduce the risk of stochastic effects. Such actions are expected to be undertaken only if this can be done safely.

In existing exposure situations, it is possible that moderate doses to the public might occur, for example, in an area that has been contaminated by a past activity or event. To prevent such exposures, the safety standards recommend that the planning and implementation of remediation be such that greater efforts are directed to areas where the highest contributions to doses and risk might be expected [45]. This might be accomplished through the removal of a source and/or the reduction of its magnitude, such as through engineered barriers, restrictions or other mechanisms that disrupt exposure pathways [45].

4.2. OCCUPATIONAL EXPOSURE

4.2.1. Doses and health effects associated with occupational exposure

UNSCEAR [7], the IAEA [48] and the OECD Nuclear Energy Agency [49] have conducted studies on occupational exposure. Typical occupations in which workers are monitored individually to assess their occupational exposure are those associated with the nuclear fuel cycle and research, as well as industrial and medical facilities involving radiation sources. However, there are other workers, especially those exposed to natural sources of ionizing radiation, who are not individually monitored.

TABLE 4. GLOBAL AVERAGE ANNUAL OCCUPATIONAL EXPOSURE FOR DIFFERENT PRACTICES [7]

Practice	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

TABLE 4. GLOBAL AVERAGE ANNUAL OCCUPATIONAL EXPOSURE FOR DIFFERENT PRACTICES [7] (cont.)

Practice	Average annual effective dose (mSv)
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 facilities	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

Table 4 shows the global average annual doses for occupational exposure for different practices. Apart from interventional cardiology, annual effective occupational exposures lie within the very low dose range.

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) and reprocessing of spent nuclear fuel, as well as those involved in waste management and decommissioning activities relating to operations associated with the production of nuclear energy. Average exposures are 1–2 mSv per year, with about 2% of workers receiving doses above 10 mSv [7]; consequently, occupational exposures tend to lie within the range of very low and low doses.

Annex A of UNSCEAR 2006 [9] contains a review of a study of 21 500 workers at the Mayak nuclear complex in the former Soviet Union between 1948 and 1972. 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 2006 [9] notes that the estimates of radiation induced risks from this study are lower than those derived from other studies, but that any comparisons have to be regarded as tentative in view of the dosimetric uncertainties.

An international worker study is also described in annex A of UNSCEAR 2006 [9] and is based on over 400 000 workers from 15 countries working in 154 nuclear facilities, who were individually monitored for external exposure. UNSCEAR 2006 [9] concludes that "there are substantial uncertainties in the risk estimates derived from the 15-country study. Consequently, not too much should be made of the apparent discrepancies with risks observed in other studies".

Annex C of UNSCEAR 2008 [7] summarizes accidents at nuclear facilities that led to high doses to workers as follows:

> "Of the 35 reported accidents, 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" (in the period 1988 to 2008).

Annex D of UNSCEAR 2008 [7] summarizes the radiation induced health effects from the Chernobyl accident and concludes the following:

> "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 irradiation;
> — The high radiation doses proved fatal for 28 of these people;
>
> …….
>
> — Skin injuries and radiation-induced cataracts are major impacts for the ARS survivors;
> — Other than this group of emergency 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 2020/2021 [31] concludes 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 UNSCEAR "expects no discernible increase in health effects among the overall group of emergency workers that could be attributed to their radiation exposure". Regarding the 174 workers who received effective doses above 100 mSv within the first year, UNSCEAR 2020/2021 [31] states 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".

4.2.1.2. Miners

The worldwide average annual exposure of the approximately 13 million workers exposed to natural sources of radiation is estimated to be 2.9 mSv [7]. 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 estimated average effective dose is 2.4 mSv; for non-coal mines, it is estimated to be 3 mSv [7]. Thus, the average annual radiation doses

are in the very low dose range, especially for those underground mines with good ventilation.

Annex E of UNSCEAR 2006 [9] contains a review of the health effects from exposure to radon. UNSCEAR reviewed 11 miner cohorts and evaluated the number of excess lung cancers, the quality of the exposure data and confounding factors such as smoking and exposure to arsenic. UNSCEAR combined the estimated excess relative risks for miners and obtained values close to those from pooled studies of exposure to radon in homes.

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 [7]. For conventional diagnostic imaging techniques, the average annual effective dose is about 1.2 mSv (range 0.33–3.14 mSv) for medical workers subject to individual monitoring [7]. For interventional procedures, the average annual effective dose is about 3.1 mSv (range of 0.4–29.5 mSv) for individually monitored workers [7].

Annex A of UNSCEAR 2006 [9] also describes a study involving a cohort of 146 022 'radiologic technologists' in the United States of America certified between 1926 and 1982. UNSCEAR 2006 [9] notes: "As with most working populations, the rates of death from all cancers were lower than expected in the general population, for both sexes. No specific cancer type showed an overall excess risk." UNSCEAR 2006 [9] also notes that there were substantial methodological concerns with the epidemiological data.

A study of Chinese radiologists and technologists is also described in annex A of UNSCEAR 2006 [9]: "The study group 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 2006 [9] concludes:

> "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."

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, nuclear gauges and accelerators. The average annual dose to workers in these industries is less than 1 mSv, except for industrial radiography (average annual dose of 1.5 mSv) and radioisotope production (average annual dose of 2 mSv). There is also a wide range of individual doses received in some industries. For example, 30% of industrial radiography workers receive annual doses over 1 mSv and 1% receive annual doses over 15 mSv; 55% of radioisotope production workers receive annual doses over 1 mSv and 2% receive annual doses over 15 mSv; and 29% of industrial irradiator workers receive annual doses over 1 mSv and 1% receive annual doses over 15 mSv [7].

Annex C of UNSCEAR 2008 [7] lists 80 accidents at industrial facilities and states:

> "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."

Details of several industrial accidents affecting workers have also been published by the IAEA, for example in Refs [50–53].

4.2.2. Control of occupational exposure in the safety standards

Requirements for control of occupational exposure are established in GSR Part 3 [24] and in GSR Part 7 [25]. Recommendations on meeting the requirements for control of occupational exposure are provided in IAEA Safety Standards Series No. GSG-7, Occupational Radiation Protection [18]. Recommendations specific to control of occupational exposure in an emergency, with a focus on the transition to an existing exposure situation, are provided in IAEA Safety Standards Series No. GSG-11, Arrangements for the Termination of a Nuclear or Radiological Emergency [43], and those specific to control of occupational exposure in medical facilities are provided in IAEA Safety Standards Series No. SSG-46, Radiation Protection and Safety in Medical Uses of Ionizing Radiation [54].

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

For planned exposure situations and existing exposure situations, the same requirements for control of occupational exposures apply, and the control of occupational exposures is generally focused on low and very low doses.

Dose limits (i.e. an effective dose of 20 mSv per year averaged over five consecutive years and of 50 mSv in any single year) are part of the requirements for the control of occupational exposure in planned exposure situations and existing exposure situations. To the extent practicable and if circumstances allow, dose limitation is applied also for emergency workers in emergency exposure situations (see also Section 4.2.2.2).

Dose constraints are used in the optimization of protection and safety. Dose constraints for occupational exposure are established by operating organizations (see footnote 25 of GSR Part 3 [24]). The value of the dose constraint is less than the applicable dose limit, and occupational exposures are required to be optimized below the dose constraint (see paras 1.22–1.28 of GSR Part 3 [24]). As a result, most occupational exposures are a small fraction of the dose limits (typically below 1 mSv in a year), namely in the very low dose range.

However, in some workplaces, occupational exposures might still not be as low as this, even after options to optimize protection and safety have been implemented. For example, workers using interventional radiological equipment need to stand next to the patient and even with radiation protection measures in place might receive certain exposures, especially to the extremities and to the lens of the eye. Workers who carry out certain maintenance activities in nuclear power plants might need to work in high dose rate environments. As a result, the annual effective doses received by some of these workers can exceed 10 mSv in a year, namely a dose within the low dose range.

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

Although doses from occupational exposure in a single year can be considered to be low, over a working life of 40 or more years, the lifetime effective dose of some workers might be several hundred millisievert: this is in the moderate dose range in Table 1. However, it may still not be possible to attribute stochastic effects to such exposures owing to the small numbers of workers who receive doses in this range.

For emergency workers, GSR Part 3 [24] and GSR Part 7 [25] require that the relevant requirements for occupational radiation protection in planned exposure situations be applied, unless there are exceptional circumstances. The exceptional circumstances are defined in para. 5.55 of GSR Part 7 [25], which states (see also para. 4.15 of GSR Part 3 [24]):

"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;
(3) When taking actions to avert a large collective dose."

For emergency workers carrying out such actions, guidance values are required to be applied to restrict the exposure of emergency workers. These guidance values are set out in appendix I of GSR Part 7 [25] and are in the range of moderate doses (see Table 1), as the benefit to an individual and the society from carrying out these actions significantly outweighs the risks to which emergency workers are subjected while taking assigned actions. It is only for lifesaving actions that an individual dose to an emergency worker may exceed these doses (possibly even entering the high dose range in Table 1), and only "under circumstances in which the expected benefits to others clearly outweigh the emergency worker's own health risks, and the emergency worker volunteers to take the action and understands and accepts these health risks" [25]. Because of this, it is of paramount importance that risks associated with the radiation exposure of emergency workers be factored into the justification and optimization of the protection strategy. Further recommendations for the protection of workers in an emergency are provided in section 4 of GSG-7 [18] and in section 4 of GSG-11 [43].

4.3. MEDICAL EXPOSURE

4.3.1. Doses and health effects associated with medical exposure

Medical exposure is the 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 type of exposure to ionizing radiation, although the increases in annual effective dose per caput due to medical exposure that had been seen in previous decades appear to have levelled off [31]. According to UNSCEAR 2020/2021, the global average annual individual effective dose received by the public in 2020/2021 from medical

TABLE 5. WEIGHTED DOSE PER PROCEDURE FOR VARIOUS PROCEDURES [31]

Medical application	Typical effective dose per procedure (mSv)
Diagnostic procedures	
Conventional radiology (excluding dental)	0.37
Dental radiology	0.01
Computed tomography	6.4
Interventional radiology	14.9
Nuclear medicine procedures	6.8

exposure was approximately 0.6 mSv [31]. The estimated worldwide annual number of medical radiological procedures was 4.2 billion, the estimated number of nuclear medicine procedures was 40 million, and the estimated number of radiation therapy procedures was over 6 million [31].

Table 5 shows the weighted effective dose per examination for some diagnostic and interventional medical procedures. The average effective doses from most diagnostic procedures are very low. As can be seen from Table 5, computed tomography (CT) scans deliver significantly higher doses, but these still fall within the low dose range as defined in Table 1.

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 2012 [1] provides a case study of 72 million CT scans performed in the United States of America in 2007. The report states 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” [1]. UNSCEAR 2012 [1] concludes:

> “[T]he 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, matched-control group.”

The doses from interventional procedures are also in the low dose range. However, for some patients, the interventional procedure might not be straightforward, and the dose to the skin of the patient might be in the high dose range — in some cases high enough for the patient to receive a skin burn — which can be attributed with confidence to the particular exposure [55].

Therapeutic medical 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 itself an observable, deterministic effect that can be directly attributed to the radiation exposure. Depending on the area being irradiated, deterministic side effects, such as nausea, vomiting and diarrhoea, can also occur.

Unintended and accidental exposures might also occur during medical procedures. There have been occasions when patients have been accidentally exposed during diagnostic procedures to cause deterministic effects, particularly skin reddening and loss of hair. For example, Ref. [56] describes a case in which over 200 patients received eight times the normal dose of radiation during a specific type of brain scan. Forty per cent of the affected patients experienced skin redness and hair loss, which could be attributed to the exposure they had incurred [56].

Annex C of UNSCEAR 2008 [7] reviews accidents from medical procedures and considers that accidents associated with the medical use of radiation in diagnosis and treatment may have been underreported. The IAEA has also reviewed accidental exposures in radiotherapy [57]. The IAEA provides a reporting system called Safety in Radiation Oncology (SAFRON) for radiotherapy and radionuclide therapy incidents and near misses, which at the time of this publication includes over 1300 incident reports [58]. Further accidental overexposures are also documented in Refs [59–61]. In many of the accidents documented, the dose was sufficiently high that deterministic effects occurred, which could be attributed to the overexposure.

4.3.2. Control of medical exposure in the safety standards

Requirements for control of medical exposure are established in GSR Part 3 [24]. Recommendations for control of medical exposure are provided in SSG-46 [54].

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 (or to comforters and carers or medical volunteers, as appropriate) commensurate with the medical purpose. The optimization of protection and safety for medical exposure necessitates a special approach because in most cases it is necessary to deliver a dose that is sufficient to achieve the desired clinical

outcome. As such, too low a radiation dose is to be avoided as much as too high a radiation dose.

In X ray medical imaging, image guided interventional procedures and diagnostic nuclear medicine, diagnostic reference levels are the main tool used in the optimization of protection and safety. As stated in para. 1.31 of GSR Part 3 [24]:

> "Periodic assessments are performed of typical doses or activity of the radiopharmaceuticals administered in a medical facility. If comparison with established diagnostic reference levels shows that the typical doses or activity of the radiopharmaceuticals administered are either too high or unusually low, a local review is to be initiated to ascertain whether protection and safety has been optimized and whether any corrective action is required."

Other tools used in the optimization of protection and safety applied to medical exposure include the design of medical radiological equipment and facilities, the use of operational protocols and programmes of quality assurance and training of personnel. As a result of the optimization of medical exposure, the expectation is that doses from diagnostic and interventional medical procedures will be in the very low and low dose range, as described in Section 4.3.1. In addition, the intention is that unintentional radiation induced health effects associated with therapeutic medical procedures are avoided.

5. 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 are distinctions between data relating to 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 safety standards apply the models used for the regulatory purpose of radiation protection, and as such, they are

not intended to be used in estimating health effects, either retrospectively or prospectively.

5.1.2. Use of dose constraints and 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). There are two considerations in Table 2 that could lead to misunderstandings or misapplication of the framework.

First, 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. 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.

The recommended ranges of values for dose constraints and reference levels all lie within the low and very low dose range. Consequently, 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, either at an individual level or at a population level. In many cases, it is other non-radiation-related risks that could be considered more important in the process of optimization, particularly when limited resources are available, to avoid inequitable outcomes in optimizing the protection of groups that receive different levels of dose, or when the protection measures could have significant social or environmental cost.

Second, the 1–20 mSv dose range in Table 2 is usually applied to annual dose constraints or reference levels. If persons were to receive a dose at the upper end of this range over many years, the total exposure could possibly reach into the moderate range of doses. Consequently, if a large enough population were exposed, health effects could be attributable. The most prominent example where such a situation might arise (i.e. the exposure of a large population reaching the moderate dose range) is in relation to radon in homes. As described in Section 4.1.1, studies have indicated a significant association (at a population level) between the risk of lung cancer and exposure to radon in homes. As such, it is possible that compliance with the reference level for radon in homes might still result in attributable health effects at a population level.

5.1.3. Use of dose limits

The safety standards set out dose limits for public exposure and occupational exposure (see Sections 4.1.2.1 and 4.2.2.1), and these limits are in the range of very low and low doses. As such, no radiation induced health effects can be attributed to radiation exposure at an individual or population level.

It might be possible for some workers to repeatedly receive doses close to the dose limit for occupational exposure. They could thereby receive a lifetime effective dose in the moderate dose range in Table 1. However, as noted in Section 4.2.2.2, it may still not be possible to attribute stochastic effects to such workers owing to the small size of the exposed population.

Dose limits are sometimes assumed to demarcate the boundary between what is 'safe' and 'unsafe'. As such, a dose above 1 mSv to a member of the public could even be assumed to lead to attributable health effects. However, as shown in Table 1, doses up to 100 mSv are within the very low or low range of doses and would not lead to any health effect observable in either an individual or an exposed group of individuals.

5.1.4. Use of generic criteria for emergency exposure situations

As described in Section 4.1.2.2, GSR Part 7 [25] provides generic criteria for use in emergency preparedness and response. These criteria are used to help in determining the need for taking protective actions and other response actions and are given in terms of doses that are within the moderate and high dose ranges in Fig. 1, as they aim to avoid severe deterministic effects and reduce the risk of stochastic effects. Thus, an effective response is expected to ensure that doses are kept below the generic criteria, thereby also ensuring that there are no radiation induced health effects that could be attributed at an individual or population level.

5.1.5. Use of collective dose

The proper use of collective dose, namely its use in comparing options for purposes of optimization of protection and safety, is described in Section 2.3. It might be incorrectly assumed that the health effects used for such calculations are actual health effects that can be attributable at an individual or a population level, rather than notional health effects derived on the basis of the LNT model. Particularly in the case of situations involving low and very low doses, where health effects cannot be attributed to radiation exposure, this could lead to significant misunderstanding whereby unreasonable conclusions could be drawn about the expected health effects following trivial exposures of large populations.

The ICRP, UNSCEAR and the IAEA have all strongly advocated against such use of collective dose [1, 2, 19]; for example, GSG-9 states that: "Collective dose must not be used to predict health effects" [19].

5.2. COMMUNICATION ABOUT RISK AND HEALTH EFFECTS

Paragraph 1.1 of IAEA Safety Standards Series No. GSG-6, Communication and Consultation with Interested Parties by the Regulatory Body [62], states:

> "Members of the public usually have incomplete knowledge and a great deal of uncertainty regarding any issue involving nuclear and radiation safety because of the complexity of the topic. Such incomplete knowledge and uncertainty influence the public's perception of the radiation risk associated with nuclear energy, radioactive waste and the use of radiation sources. 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."

Table 7 of Ref. [63] sets out some influences on the public's perception of risk in relation to a nuclear or radiological emergency.

5.2.1. Safety requirements for communication about risk and health effects

Regarding the responsibilities of the regulatory body and the authorized party, para. 4.68 of GSR Part 1 (Rev. 1) [38] 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."

Paragraph 4.69 of GSR Part 1 (Rev. 1) [38] states that: "Public information activities shall reflect the radiation risks associated with facilities and activities, in accordance with a graded approach". Thus, more extensive public communication is required for those facilities and activities with a higher risk.

GSR Part 3 [24] establishes several requirements regarding communication about risk to the public. Requirement 50 of GSR Part 3 [24] 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 [25] 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 [25] states:

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

As part of these arrangements, para. 5.71 of GSR Part 7 [25] states that: "Arrangements shall be made so that in a nuclear or radiological emergency information is provided to the public in plain and understandable language." Paragraph 5.72 of GSR Part 7 [25] states:

> "The government shall ensure that a system for putting radiological health hazards in perspective in a nuclear or radiological emergency is developed and implemented with the following aim:
>
> — To support informed decision making concerning protective actions and other response actions to be taken;
> — To help in ensuring that actions taken do more good than harm;
> — To address public concerns regarding potential health effects."

There are also requirements in the safety standards for proper communication of radiation risks to workers. Paragraph 3.110(a) of GSR Part 3 [24] states:

> "Employers, in cooperation with registrants and licensees…[s]hall 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 [24] 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."

There are also requirements for communication about radiation risks associated with medical exposure. Requirement 36 of GSR Part 3 [24] 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 and health effects using the concepts of attribution and inference

IAEA Safety Standards Series No. GSG-14, Arrangements for Public Communication in Preparedness and Response for a Nuclear or Radiological Emergency [64], provides recommendations on putting radiological health hazards in perspective that take into account the concepts of attribution of health effects and the inference of risks. In particular, the appendix to GSG-14 [64] describes an example system for putting radiological health hazards in perspective in relation to a nuclear or radiological emergency. This system was derived on the basis of

the findings of UNSCEAR 2012 [1] and the generic criteria described in Sections 4.1.2.2 and 5.14 of this Safety Report. The system comprises three levels:

(1) 'Dangerous to health': This corresponds to situations in which an individual might develop a deterministic effect, that is, the high dose range in Fig. 1.
(2) '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 of cancers in a large population, namely the moderate dose range in Fig. 1.
(3) '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 of malignant diseases in a large population, that is, the low and very low dose range in Fig. 1.

During and following an emergency, some members of the public might receive doses in the moderate dose or high dose ranges in Fig. 1. Such persons will be urged to comply with instructions in protective actions and other response actions issued by the relevant authorities. As noted in para. II.26 of GSG-2 [42], experience has shown that the public follow instructions best when they understand how the actions provide for their protection. Paragraphs II.29–II.38 of GSG-2 [42] provide a plain language explanation of the various operational intervention levels that are used to trigger specific protective actions and other response actions and that can be used in 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 the health effects that can be prevented if the instructions are followed and emergency response actions are taken in a timely manner (see also the Appendix to this Safety Report).

There are also existing exposure situations where members of the public might receive doses in the moderate dose range in Fig. 1 (see Section 4.1.2.2). GSG-15 [45] 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. Paragraph 2.59(e) of GSG-15 notes that "the importance of not creating unnecessary anxiety, while appropriately recognizing relevant inferred risks and detriments, in order to enable people to make their own informed decisions".

The three level system set out above can also be used to communicate to the public the health effects and radiation risks associated with high, moderate, low and very low doses. As stated in Ref. [65]:

> "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."

Paragraph 3.14 of IAEA Safety Standards Series No. SSG-32, Protection of the Public against Exposure Indoors due to Radon and Other Natural Sources of Radiation [44], recommends that informational material be provided to the public on "scientific evidence on the health risks arising from long term exposure due to radon indoors". The three level system set out above can also be used to communicate to the public the radiation risk due to radon, especially for individuals exposed to radon in their homes over the course of their lifetime and who are in the moderate dose range in Fig. 1, for which there could be attributable health effects at a population level (see Section 4.1.1 of this Safety Report).

For most workers, their lifetime occupational exposure will be within the low and very low dose range (see Table 4). The three level system set out above can also be used for communicating the associated health effects and radiation risks associated with their occupational exposure. An example that uses the three level system in explaining health effects and radiation risks associated with exposures of emergency workers in a nuclear or radiological emergency and the associated medical actions is provided in table I–15 of Ref. [66].

With regard to medical exposure, Requirement 36 of GSR Part 3 [24] requires that "**the person subject to exposure has been informed as appropriate of the expected benefits and risks**". Although the dose associated with a single diagnostic procedure will be in the very low and low dose range in Fig. 1, if certain procedures are undertaken repeatedly, the cumulative dose could reach into the moderate dose range. In that range, there could be an increase in the incidence of health effects that could theoretically be attributable at a population level, although — given the small sizes of the populations involved — in practice this will not be able to be seen. 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

Exposure to high levels of radiation, such as were received by some workers during the Chernobyl accident, can quickly lead to serious health effects, including death. For moderate exposures, such as were received by some members of the public after the accident, there can be a detectable increase in the rates of diseases such as cancer and leukaemia in the population many years after the exposure. However, the situation for low levels of radiation exposure, such as are received by workers and members of the public in daily life, is much less clear. This raises two important questions:

— Is it possible to know whether a specific health effect could have been caused by an exposure to radiation?
— Is it possible to estimate whether an exposure to radiation could lead to future health effects?

Both of these questions are often difficult to answer, particularly for low levels of radiation.

Studies of radiation exposures received by large groups of people have concluded that radiation can cause diseases such as cancer and that the risk that such effects will occur is higher if a higher exposure has been received. These effects occur many years after the exposure and are medically the same as those that occur because of other causes. Because of this, it is generally not possible to be certain whether a disease that occurs in a person was caused by exposure to radiation or by another factor. A noticeable difference in the numbers of people with cancer can only be seen in large groups of people who have received moderate or high exposures. No difference in the numbers of people with cancer can be seen if the levels of exposure were low.

Nevertheless, just because a difference in the number of people with cancer cannot be seen for low levels of exposure, it is not assumed that there is no risk at all. The safety standards aim to protect people from harmful effects of radiation and are based on a precautionary approach that is both ethical and practical. To achieve this, it is assumed that any exposure to radiation might possibly cause health effects (even if these are not detected) and that the risk of these effects increases as the level of radiation increases.

It is important to understand that any risks associated with low levels of radiation exposure are also low. This is especially important when decisions are taken that might put people at risk from other dangers. For example, the evacuation of people from areas where there are low levels of radiation can do more harm than good overall, considering the physical and psychological challenges associated with evacuating people from their homes.

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This Safety Report explains how the concepts of attribution of health effects and inference of risks can be taken into account in the application of IAEA safety standards, so as to implement them more effectively. In particular, this publication demonstrates explicitly what the relevant provisions of the safety standards are for high and moderate levels of exposure, where health effects might be able to be attributed to the exposure, and for low and very low levels of exposure, where risks can only be inferred. This Safety Report also aims to support more effective communication by clarifying the proper use of certain concepts detailed in the safety standards and providing plain language explanations of the concepts of attribution of effects and inference of risk.

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