Commission on Radiological Protection (SSK)

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Proposals of the SSK for the revision of ICRP 103

Statement by the German Commission on Radiological Protection (SSK)

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Preface

The current internationally practised system of radiological protection is based on the recommendations of Publication 103 of the International Commission on Radiological Protection (ICRP), published in 2007. For some years it has been the declared intention of ICRP to open up the discussion on the problems of radiological protection beyond the inner circle of the Main Commission and its four Committees and give radiological protection experts around the world more opportunities to participate. At the end of 2021, ICRP held a highly regarded workshop under the heading The Future of Radiological Protection, which can be seen as the starting point for a broad global debate on shaping the future system of radiological protection.

The Federal Environment Ministry asked the SSK to join in this discussion and determine whether the list of topics and aspects proposed for revision by ICRP is complete. If necessary, the SSK should make additional proposals for clearly justifying and prioritising the topics and aspects selected to date, and where relevant indicate how, in its view, these may need to be supplemented.

This statement is the product of the advisory mandate and was drawn up by an SSK working group comprised of the following members:

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1 Introduction

Just a few years after W.C. Röntgen discovered x-rays in 1895 (Röntgen 1896) and A.H. Becquerel discovered nuclear radiation in 1896 (Becquerel 1896), the first observations were made of the damage this form of radiation can cause (e.g. Drury 1896, Frieben 1902). It soon became clear that measures to protect against this damage had to be taken. National and international bodies and associations were established at the time to put forward recommendations for protective measures and suggestions for their implementation. As a rule, these bodies were composed of medical professionals who were beginning to apply these new forms of radiation for diagnostic and therapeutic purposes in the emerging field of radiology.

In 1925, the International Congress of Radiology took place in London. It was one of the first international meetings of radiologists and can be viewed as the beginning of international radiological protection. The second such congress in 1928 in Stockholm established the International X-Ray and Radium Protection Committee (IXRPC). This is considered the forerunner of today's ICRP. The body was renamed several times in subsequent years, in part to highlight that radiological protection no longer related solely to medicine, but had a much broader relevance. The Commission was given its current name, International Commission on Radiological Protection (ICRP), in 1950. The ICRP is an independent international organisation that advances the science of radiological protection for the public benefit. Specifically, it provides recommendations and guidance on all aspects of protection against ionising radiation. Legally, it is a registered charity. A detailed history of ICRP can be found in Clarke and Valentin (Clarke und Valentin 2009).

Originally, ICRP published its recommendations and statements as articles in various medical and physics journals. Since 1959, ICRP has had its own numbered series of papers which has been published as *Annals of the ICRP* since 1977.

Traditionally, ICRP sees its main task as drawing up recommendations on general issues of radiological protection. These provide the principle and conceptual basis for the system of radiological protection, which is then enshrined in countries' national provisions. A range of other key international institutions monitor, support and supplement the work of ICRP. For example, the United Nations Scientific Committee on the Effects of Atomic Radiation (UNSCEAR) collects and scrutinises findings from the various areas of radiation research, from which it then provides an up-to-date scientific basis. The International Atomic Energy Agency (IAEA) focuses primarily on the application of radiological protection in nuclear engineering, while the International Radiation Protection Association (IRPA) is an umbrella association representing radiological protection bodies and practitioners.

Since its inception, the global influence of ICRP on the discussion and development of general radiological protection standards has been remarkably great. The overall system developed by ICRP, and hence the fundamental concept of radiological protection, have informed practically all legal provisions in this field. Throughout the world, national legislation to regulate radiological protection is essentially based on ICRP recommendations. As a result, legal regulation of radiological protection has, to an astonishing degree, evolved in a uniform way worldwide. It is therefore not surprising that ICRP recommendations are very highly respected in the radiological protection community.

The first international agreement on radiological protection standards was drawn up in 1934 (IXRPC 1934). It can be seen as the basic recommendation of ICRP (or the then IXRPC) and included the first recommended dose limits. Its main focus was on proposals for preventing deterministic effects for occupationally exposed persons (in today's terminology). The first "modern" basic recommendation was the 1977 ICRP Publication 26 (ICRP 1977a), which can

be considered the first complete system of radiological protection. That report formulated the principles of radiological protection that still apply today – justification, optimisation and limitation. These are the pillars of the overall system of radiological protection. ICRP Publication 26 is also the basis for the effective dose with the radiation and organ weighting factors (consequently also the detriment concept) and for the distinction between stochastic and deterministic effects.

ICRP Publication 60, produced in 1990 (1990 Recommendations of the International Commission on Radiological Protection, ICRP 1991b), was another major step forward in expanding and refining the system. In the preceding years, the Japanese-US research group Radiation Effects Research Foundation (RERF), which conducts the Life Span Study (LSS) on Japanese survivors of the nuclear bombs, had published a series of reports with new comprehensive data and analyses on the LSS cohorts (e.g. Preston et al. 1987). Together with the revision of the LSS dosimetry DS86 (e.g. Fry und Sinclair 1987), this led to improved, more robust risk estimates which formed the basis for recommending lower dose limits. The dose limits recommended in ICRP Publication 60 (ICRP 1991b) still apply today.

The current international radiological protection system is based on the basic recommendation presented as ICRP Publication 103 from the year 2007 (The 2007 Recommendations of the International Commission on Radiological Protection, ICRP 2007a). Alongside numerous expansions and reforms, Publication 103 further defines the three fundamental principles of radiological protection – justification, optimisation and limitation. These principles have since been adopted in many international and national rules and laws. Taking various forms, they apply to planned, existing and emergency exposure situations. Dose limits are laid down for planned occupational exposure situations and for exposure of the public, but not for patients. In existing and emergency exposure situations for which a general dose limit is not appropriate, dose constraints and ranges of reference levels are defined instead. These serve as a tool for the optimisation principle, allowing a flexible and practical approach for keeping radiation exposure generally as low as reasonably achievable. Referred to as the ALARA principle, this approach has become a part of the general system of radiological protection (ICRP 2007a).

For some years it has been the declared intention of ICRP to open up the discussion on the problems of radiological protection beyond the inner circle of the Main Commission and its four Committees and give radiological protection experts around the world more opportunities to participate. This intention is pursued in the wide range of workshops offered on relevant radiological protection issues, in congresses and meetings and in the call for cooperation on drawing up draft recommendations in ICRP Task Groups. Increasingly, draft recommendations are also released for comments prior to their adoption.

At the end of 2021, ICRP held a highly regarded workshop under the heading The Future of Radiological Protection, which can be seen as the starting point for a broad global debate on shaping the future system of radiological protection. The workshop was preceded by two publications outlining ICRP's intention of opening up a broad, frank and transparent discussion (Laurier et al. 2021, Clement et al. 2021). ICRP sees this as the start of a long-term (probably more than ten years), international discussion on developing new recommendations to replace ICRP Publication 103 (ICRP 2007a). While the system of radiological protection has performed well, met basic ethical principles and proven robust in practical application, it must adapt to changes in science and society and be revised accordingly.

These circumstances prompted the Federal Environment Ministry to ask the SSK to also participate in this discussion. The advisory mandate of 23 September 2021 tasked the SSK with determining whether the list of topics and aspects proposed for revision by ICRP is complete. The SSK was requested to make any necessary proposals for clearly justifying and prioritising

the topics and aspects selected to date, and where relevant indicate how, in its view, these may need to be supplemented. As part of its response, the SSK was asked to determine how far relevant national and international scientific research activities are covered. This review was to encompass research activities completed since ICRP Publication 103 (ICRP 2007b) as well as commenced or planned research projects such as UNSCEAR initiatives. Concluded and ongoing deliberations of the SSK should also be included in the review.

This statement represents the results of the work on the advisory mandate.

2 Areas addressed by ICRP since ICRP Publication 103

2.1 Introduction

The following section presents the topic areas addressed by ICRP since Publication 103 (ICRP 2007a) and gives an overview of its publications on radiological protection up to the end of November 2022. The respective publications are summarised under relevant thematic headings. In addition, the annex contains a list of all ICRP task groups that had not completed their deliberations or published the results of them by 30 November 2022. Section 2.3 describes the areas where the system of radiological protection needs to be further optimised and kept fit for purpose. This is based on the publications of Laurier et al. (Laurier et al. 2021) and Clement et al. (Clement et al. 2021).

2.2 ICRP publications since Publication 103

2.2.1 Basic principles

An important part of ICRP publications is the focus on general questions and applications of radiological protection. For instance, ICRP Publication 104 (Scope of Radiological Protection Control Measures, ICRP 2007c) recommends approaches to national authorities for defining the scope of radiological protection measures based on the general principles of justification and optimisation, and advises on different radiation exposure situations.

ICRP Publication 147 (Use of Dose Quantities in Radiological Protection, ICRP 2021b) consolidates and builds on the concepts set out in ICRP Publication 103 (ICRP 2007a). It clarifies the different dose quantities in relation to their health risk, and from this derives guidance that goes beyond the recommendations to date. Effective dose and collective dose are valuable tools for protecting against stochastic effects (e.g. cancer). Effective dose is generally used in doses below 100 mSv, but in specific cases effective dose can be up to 1 Sv. In low doses or dose rates, effective dose can be used as an approximate indicator for radiation risk. However, it is not a substitute for specific, individual risk analysis. Absorbed dose is used to lay down dose limits for organs and tissue (deterministic effects and tissue effects).

ICRP Publication 138 (Ethical Foundations of the System of Radiological Protection, ICRP 2018b) is aimed at establishing the foundations and common language for discussing ethics in the context of radiological protection. The core ethical values – “do good, avoid doing harm”, “exercise prudence by making informed and carefully considered choices, also in the presence of scientific uncertainties”, “ensure justice by avoiding unfairness in the distribution of risks” and “safeguard dignity, by according every person unconditional respect” – support the principles of the system of radiological protection, namely justification, optimisation and individual dose limitation. The procedural values accountability, transparency and inclusiveness are intended as aids for the practical implementation of radiological protection.

ICRP Publication 122 (Radiological Protection in Geological Disposal of Long-lived Solid Radioactive Waste, ICRP 2013b) contains recommendations for radioactive waste management and updates previous ICRP reports on this topic. The recommendations relate specifically to geological disposal of long-lived solid radioactive waste. The publication describes the different stages in the life time of a geological disposal facility and addresses the application of relevant radiological protection principles for all possible stages, depending on the various exposure situations. The publication particularly looks at the distant future stage, when memory of the disposal facility may be lost and future generations unwittingly expose themselves to great danger.

2.2.2 Medicine

2.2.2.1 General

ICRP Publication 105 (Radiological Protection in Medicine, ICRP 2007b) contains recommendations relating to medical exposure of patients, their comforters and carers, and of volunteers in biomedical research. The publication makes it clear that in this context too, the fundamental principles of radiological protection apply: justification, dose limitation, dose optimisation.

No dose limits are applied to medical exposure of patients. Such dose limits can do more harm than good to patients with chronic, severe or life-threatening medical conditions, because they restrict the informative value of the examination and hinder access to urgently needed information. In this case, the emphasis is on justification of the medical use of radiation and optimisation of radiological protection. In diagnostic and interventional procedures, justification of the procedure and management of the patient dose are the appropriate mechanisms to avoid unnecessary radiation exposure. The ICRP is of the opinion that "in radiation therapy, the avoidance of accidents (equipment and procedures) is a predominant issue."

ICRP Publication 113 (Education and Training in Radiological Protection for Diagnostic and Interventional Procedures, ICRP 2009e) deals with education and training of medical personnel. This is necessary because the steady increase in the number of diagnostic and interventional medical procedures with ionising radiation, has led to higher patient and staff doses. Building on the recommendations in ICRP Publications 103 and 105 (ICRP 2007a; Radiological Protection in Medicine, ICRP 2007b), Publication 113 sets out extended recommendations for different categories of doctors and other healthcare professionals who perform or support diagnostic and interventional procedures that use ionising radiation and nuclear medicine therapies. ICRP Publication 113 (ICRP 2009e) provides guidance on the necessary radiological protection education and training.

ICRP Publication 139 (Occupational Radiological Protection in Interventional Procedures, ICRP 2018a) addresses the protection of patients and personnel during interventional procedures. Radiological protection measures and trained personnel are needed to ensure this. The publication gives guidance on exposure monitoring strategies, use of protective garments, education and training and quality assurance. It gives advice on assessing the effective dose from dosimeter readings, estimating exposure of the lens of the eye, on extremity doses, selection and testing of protective garments and auditing interventional procedures.

2.2.2.2 Diagnostic applications

ICRP Publication 106 (Radiation Dose to Patients from Radiopharmaceuticals – Addendum 3 to ICRP Publication 53, ICRP 2008b) provides biokinetic and dosimetric models for 33 radiopharmaceuticals, absorbed doses and effective doses, and recommendations related to

breastfeeding for mothers who have undergone a nuclear medicine investigation. ICRP Publication 128 (Radiation Dose to Patients from Radiopharmaceuticals: A Compendium of Current Information Related to Frequently Used Substances, ICRP 2015a) draws together information relating to radiation dose in nuclear medicine examinations. It includes biokinetic models, biokinetic data, dose coefficients (organs and tissue) and effective doses for diagnostic radiopharmaceuticals.

Diagnostic reference levels (DRL) were already introduced in ICRP Publication 73 (Radiological Protection and Safety in Medicine, ICRP 1996b). Over the years, the concept was further developed, most recently in ICRP Publication 135 (Diagnostic Reference Levels in Medical Imaging, ICRP 2017c). That publication serves to explain the terminology, recommend DRLs for various imaging procedures and provide information for interventional therapy and paediatric radiology.

ICRP Publication 121 (ICRP 2013c) is intended to provide referring clinicians and clinical staff performing diagnostic imaging and interventional procedures for paediatric patients with guidelines for radiological protection in specific modalities – radiography and fluoroscopy, interventional radiology and computed tomography. One of the unique aspects of paediatric imaging is the wide range in patient size (and weight). This requires special attention to optimisingand modifying equipment, technique, and imaging parameters. Major paediatric interventional procedures should be performed by experienced operators trained in radiological protection (in some countries, such training is mandatory). For computed tomography, dose reduction should be optimised by the adjustment of scan parameters (such as mA, kVp, and pitch) according to patient weight or age, region scanned, and clinical question.

ICRP Publication 129 (Radiological Protection in Cone Beam Computed Tomography (CBCT) ICRP 2015b) describes radiological protection in the application of Cone Beam Computed Tomography (CBCT). CBCT offers more application options compared to conventional CT, but the clinical benefit should always be weighed against the radiation risk to patient and operator. Optimising protection applies not only to whole-body CT, but also to exposures to specific tissues, especially the lens of the eye, the cardiovascular and the cerebrovascular system.

As more and more fluoroscopic procedures are being performed outside radiology departments, there is a risk that radiological protection is being neglected. ICRP Publication 117 (Radiological Protection in Fluoroscopically Guided Procedures outside the Imaging Department, ICRP 2010b) stresses that patient dose monitoring is essential whenever fluoroscopy machines are used. The report recommends that manufacturers develop systems to indicate patient dose indices and to produce patient dose reports that can be transferred to the hospital network. It furthermore recommends shielding screens that can be effectively used for the protection of workers using fluoroscopy machines in operating theatres without hindering the clinical task.

2.2.2.3 Therapeutic application

ICRP Publication 140 (Radiological Protection in Therapy with Radiopharmaceuticals, ICRP 2019b) deals with radiological protection in nuclear medicine therapy. This requires administration protocols that justify and optimise the treatment. Treatment planning should include individual estimates of doses, and verification of doses to both tumours and normal tissues. Pregnant women and children should be given particular consideration. Breastfeeding should be discontinued for the duration of the therapy. Radiopharmaceuticals, especially in therapeutic doses, can result in exposure of personnel. Therefore, suitable protective measures must be taken. Patients should be hospitalised and their individual situation taken into account.

Brachytherapy is another form of radiation therapy and is addressed in ICRP Publication 149 (Occupational Radiological Protection in Brachytherapy, ICRP 2021c). If not disposed of properly, sources used in brachytherapy can lead to environmental contamination and exposure of the public. Patients may develop unwanted tissue reactions. Clinical procedures should be optimised and suitable measures implemented wherever possible during transport, storage and therapy in order to reduce the dose for the environment and the public. Staff should be sufficiently trained. They are responsible for providing patients with relevant information. Personal dosimetry for staff, dose management and quality assurance are essential for the safe application of brachytherapy; a medical physics expert (MPE) should be available at all times.

ICRP Publication 127 (Radiological Protection in Ion Beam Radiotherapy, ICRP 2014a) looks at radiological protection in ion beam radiotherapy. Careful treatment planning is required to ensure precise dose localisation in the treatment volume of the target while ensuring minimal damage to the surrounding tissue. The patient group must be selected with a view to maximising the advantage for the patients.

ICRP Publication 120 (Radiological Protection in Cardiology, ICRP 2013d) deals with radiological protection in imaging and inverventional procedures in cardiology, as these can entail high radiation exposure of staff and patients. This report provides guidance to assist cardiologists with justification and the optimisation of protection in cardiac CT examinations, nuclear medicine investigations and fluoroscopic interventions.

Alongside recommendations on specific therapeutic applications, ICRP Publication 112 (Preventing Accidental Exposures from New External Beam Radiation Therapy Technologies, ICRP 2009f) also generally examines the potential for human error and problems in the use of new radiotherapy technologies. Information on the circumstances that led to incidents or near misses in the past can play an important role in preventing future accidents. Sharing findings from serious incidents is necessary, but not sufficient when dealing with new technologies. It is of the utmost importance to be proactive.

2.2.3 Dose calculation

2.2.3.1 General

ICRP Publication 107 (Nuclear Decay Data for Dosimetric Calculations, ICRP 2008a) is an electronic database of nuclear physics data for calculating radionuclide-specific radiological protection quantities. The database supersedes the data in ICRP Publication 38 (Radionuclide Transformations - Energy and Intensity of Emissions, ICRP 1983). It will be the basis for future ICRP publications of dose coefficients for the intake of or exposure to radionuclides in the workplace and the environment. The database contains information on half-lives, decay chains and yields and energies of radiations emitted in nuclear transformations of 1,252 radionuclides of 97 elements.

ICRP Publication 116 (Conversion Coefficients for Radiological Protection Quantities for External Radiation Exposures, ICRP 2010a) contains conversion coefficients for effective dose and organ absorbed dose for various types of external exposure. These coefficients were calculated using the official ICRP/ICRU computational phantoms representing the Reference Adult Male and the Reference Adult Female. The transport of radiation within the human body was simulated with the Monte Carlo codes using idealised whole-body irradiation geometries. The simulations were used to determine the absorbed dose for each organ in the reference phantoms. The effective dose conversion coefficients were derived from the obtained organ absorbed dose, the radiation weighting factor w_R and the tissue weighting factor w_T in accordance with the procedure set out in ICRP Publication 103 (ICRP 2007a).

ICRP Publication 119 (Compendium of Dose Coefficients based on ICRP Publication 60, ICRP 2012b) is a compilation of dose coefficients for intakes of radionuclides by workers and members of the public. It also contains conversion coefficients to apply occupational radiological protection against external radiation as set out in ICRP Publications 68 (Dose Coefficients for Intakes of Radionuclides by Workers, ICRP 1994), 72 (Age-dependent Doses to the Members of the Public from Intake of Radionuclides – Part 5 Compilation of Ingestion and Inhalation Coefficients, ICRP 1995) and 74 (Conversion Coefficients for use in Radiological Protection against External Radiation, ICRP 1996a). It is a comprehensive reference work for dose coefficients based on the previous recommendations of ICRP 60 (ICRP 1991b).

ICRP Publication 133 (The ICRP Computational Framework for Internal Dose Assessment for Reference Adults: Specific Absorbed Fractions, ICRP 2016c) focuses on the specific absorbed fraction (SAF). The SAF is one of the steps in calculating dose coefficients for internal exposure to radionuclides (alongside biokinetic models and decay scheme data). SAFs are defined as the fraction of particle energy emitted in a source tissue region that is deposited in a target tissue region per mass of target tissue. They are expressed in units of kg^{-1}.

2.2.3.2 Computer models

ICRP Publication 110 (Adult Reference Computational Phantoms, ICRP 2009d) describes the development and intended use of computational phantoms of the Reference Male and Reference Female. The phantoms are based on medical image data of real people, but are consistent with the data and anatomical and physiological reference parameters given in ICRP Publication 89 (Basic Anatomical and Physiological Data for Use in Radiological Protection Reference Values, +ICRP 2002) for both male and female subjects.

ICRP Publication 145 (ICRP 2020b) describes mesh-type reference computational phantoms (MRCPs) for the Reference Adult Male and Reference Adult Female, in contrast to the voxel-type reference phantoms of ICRP Publication 110 (ICRP 2009d). The MRCPs were constructed by converting the Publication 110 phantoms into a mesh format and adding tissue layers that are at particularly high risk of radiogenic cancer. The MRCPs contain all the sources and target organs or tissues required for calculating the effective dose. The organ and tissue masses are consistent with those given in ICRP Publication 89 (ICRP 2002). The masses differ slightly from those of ICRP Publication 110 because they include the blood content of the individual organs or tissues. Effective doses calculated with this model correspond closely to those of earlier publications, with only slight differences observed for small tissue structures and weakly penetrating radiations. Previous publications thus remain valid.

ICRP Publication 143 (Paediatric Computational Reference Phantoms, ICRP 2020a) describes the development and use of ten computational phantoms for Reference Male and Reference Female newborns and children aged 1, 5, 10 and 15 years. These phantoms use the same structure as that given for adults in ICRP Publication 110.

2.2.3.3 Occupational exposure

A series of publications aimed at replacing ICRP Publications 30 (Limits for Intakes of Radionuclides by Workers, ICRP 1979) and 68 (Dose Coefficients for Intakes of Radionuclides by Workers, ICRP 1994) address occupational exposure to radionuclides. They provide revised dose coefficients for occupational intakes of radionuclides by inhalation or ingestion. They also describe methods of individual and workplace monitoring and general aspects of retrospective dose estimation. Part 1 (ICRP Publication 130, Occupational Intakes of Radionuclides: Part 1, ICRP 2015c) describes the biokinetics, the dosimetric methodology and the use of data from

experiments on animals. The main changes are a revision of the Human Respiratory Tract Model and biokinetic models using more recent and physiologically more realistic assumptions.

Part 2 (ICRP Publication 134, Occupational Intakes of Radionuclides: Part 2, ICRP 2016a), Part 3 (ICRP Publication 137, Occupational Intakes of Radionuclides: Part 3, ICRP 2017b), Part 4 (ICRP Publication 141, Occupational Intakes of Radionuclides: Part 4, ICRP 2019a) and Part 5 (ICRP Publication 151, Occupational Intakes of Radionuclides: Part 5, ICRP 2022) of the series present data for individual elements and radioisotopes, including information on chemical form, physical parameters, reference levels for biokinetic models and monitoring techniques. Data on inhalation, ingestion, and direct input to blood are provided for various elements[1].

ICRP Publication 150 (Cancer Risk from Exposure to Plutonium and UraniumICRP 2021d) deals with the cancer risk from exposure to plutonium and uranium. It supplements ICRP Publication 115 (Lung Cancer Risk from Radon and Progeny and Statement on Radon, ICRP 2010c). Due to the limitations of dose reconstruction, epidemiological studies on workers in uranium mining do not allow a completely reliable risk estimate. The Mayak worker cohort shows an increased risk of lung cancer, liver and bone cancers, but not of leukaemia. In the Sellafield cohort, only increased risk of lung cancer was observed. The lifetime excess risk of lung cancer mortality is similar to that for exposure to radon and its progeny nuclides. Compared to external gamma radiation, an increased biological effectiveness of alpha particles was found for the risk of lung cancer due to plutonium or radon progeny, which is consistent with a radiation weighting factor of 20.

2.2.3.4 Natural exposure

ICRP Publication 144 (Dose Coefficients for External Exposures to Environmental Sources, ICRP 2020d) provides reference organ and effective dose-rate coefficients for external exposures of the general public resulting from contamination of soil, air and water. Coefficients for the radionuclides listed in ICRP Publication 107 (Nuclear Decay Data for Dosimetric Calculations, ICRP 2008a) are given for newborns, children, adolescents and adults. The data shows that the smaller body mass of young children will result in higher dose-rate coefficients. This is because the smaller masses of tissues shielding the organs puts them closer to the external source. However, age-related differences are generally minor for the most important radionuclides.

ICRP Publication 142 (Radiological Protection from Naturally Occurring Radioactive Material (NORM) in Industrial Processes, ICRP 2019c) deals with exposures resulting from NORM. NORM nuclides are controllable, with protection achieved through justification of actions taken and optimisation of protection. The main focus is on long-term exposures. Reference levels (excluding radon and thoron) should reflect the distribution of exposures. In the majority of cases, they would be less than a few mSv annual effective dose.

2.2.4 Radon

ICRP Publication 115 (Lung Cancer Risk from Radon and Progeny and Statement on Radon, ICRP 2010c) reviews recent epidemiological studies of the association between lung cancer and exposure to radon and its progeny. Residential and miner epidemiological studies provide consistent estimates of lung cancer risk with statistically significant associations. According to ICRP (ICRP Publication 115), these associations were observed from average annual

[1] https://journals.sagepub.com/doi/suppl/10.1177/ANIB_48_2-3/suppl_file/OIR_Data_Viewer_for_P134-P137-P141.zip

concentrations of about 200 Bq m^{-3} and cumulative occupational levels of about 50 working level months (WLM). Based on recent results from combined analyses of epidemiological studies of miners, a lifetime excess absolute risk of 5×10^{-4} per WLM (14×10^{-5} per mJ h m^{-3}) should now be used as the nominal probability coefficient for radon-induced and radon-progeny-induced lung cancer. ICRP concludes that radon and its progeny should be treated in the same way as other radionuclides within the ICRP system of protection; that is, doses from radon and its progeny should be calculated using ICRP biokinetic and dosimetric models. The ICRP provides dose coefficients per unit exposure to radon and radon progeny for different reference conditions of domestic and occupational exposure, with specified equilibrium factors and aerosol characteristics.

ICRP Publication 126 (Radiological Protection against Radon Exposure, ICRP 2014c) provides guidance on radiological protection against radon exposure. Radon concentration in buildings is subject to wide regional variations. Outdoor radon exposure is generally not an issue. Radon exposure is the second leading cause of lung cancer after smoking. Radon exposure is an existing exposure situation for which national authorities should develop a protection strategy which includes a commitment to reduce exposure. For this, the Commission recommends a reference level of 300 Bq m^{-3}, applicable to both workplaces and habitable rooms.

The problem of radon is dealt with further in Section 0.

2.2.5 Emergency preparedness

ICRP Publication 146 (Radiological Protection of People and the Environment in the Event of a Large Nuclear Accident, ICRP 2020c) deals with protection of the public and the environment from exposure after a serious nuclear accident. It updates ICRP Publications 109 (Application of the Commission's Recommendations for the Protection of People in Emergency Exposure Situations, ICRP 2009b) and 111 (Application of the Commission's Recommendations to the Protection of People Living in Long-term Contaminated Areas after a Nuclear Accident or a Radiation Emergency, ICRP 2009c). A large nuclear accident will affect all aspects of daily life. In order to take protective actions, it is essential to characterise the on-site and off-site radiological situation as quickly as possible. Reference levels should be laid down that make suitable actions possible also during the early and intermediate phases of an accident. The goal here is to mitigate radiological consequences for people and the environment while at the same time ensuring suitable working conditions for the responders. Responders should be provided with appropriate personal protection. Preparedness planning is essential for dealing with large nuclear accidents.

2.2.6 Flora and Fauna

ICRP Publication 108 (Environmental Protection - the Concept and Use of Reference Animals and Plants, ICRP 2008b) summarises current knowledge of the radiation effects on various biotic types and derives reference levels to help optimise the level of effort needed to protect the environment and its organisms.

The Commission first addressed environmental protection in Publication 103 (ICRP 2007a). ICRP Publication 114 (Environmental Protection: Transfer Parameters for Reference Animals and Plants, ICRP 2009a) further develops the approach to this complex subject. The Commission describes a set of reference animals and plants (RAPs) as the basis for relating exposure to dose and dose to radiation effects for different types of animals and plants.

In Publication 124 (Protection of the Environment under Different Exposure Situations, ICRP 2014d), the Commission describes its framework for environmental protection and how to apply it within the system of radiological protection. The report explains the objectives relating

to the protection of animals and plants in their natural environment. Through the use of RAPs, Derived Consideration Reference Levels (DCRLs) can be determined which relate radiation effects to necessary doses for different potential pathways of exposure.

ICRP Publication 136 (Dose Coefficients for Non-human Biota Environmentally Exposed to Radiation, ICRP 2017a) describes the Commission's revised and extended dosimetric framework for non-human biota. The current dose coefficients (DCs) apply to body masses ranging from 1 mg to 1,000 kg, to heights above the ground surface from 0.1 m to 500 m and to different sources in soil and in ambient air. A software tool (BiotaDC) allows DCs to be assessed for user-defined applications.

ICRP Publication 148 (Radiation Weighting for Reference Animals and Plants, ICRP 2021a) reviews data on relative biological effectiveness (RBE) for one low-energy beta emitter (tritium) and for alpha-emitting radionuclides. No patterns were observed between different species. For tritium, RBE stands at 1.5 to 2 (compared to x-rays), 2 to 2.5 (compared to gamma rays) and 10 for alpha particles. Therefore, for all animals and plants, weighting factors of 1 (low-linear energy transfer, LET) and 10 (alpha particles) were assumed.

2.2.7 Radiobiology

ICRP Publication 118 (ICRP Statement on Tissue Reactions / Early and Late Effects of Radiation in Normal Tissues and Organs – Threshold Doses for Tissue Reactions in a Radiation Protection Context, ICRP 2012a) contains an overview of the early and late effects of radiation in normal tissues and organs and updated estimates of "practical" threshold doses for tissue reactions defined at the level of 1% incidence. It gives estimates for morbidity and mortality endpoints in all organ systems following acute, fractionated, or chronic exposure. It considers the haematopoietic and endocrine systems, the immune, reproductive, circulatory, respiratory, musculoskeletal, and nervous systems, the digestive and urinary tracts, the skin and the eye.

Tissue stem cells are considered target cells for carcinogenesis, and ICRP Publication 131 (Stem Cell Biology with Respect to Carcinogenesis Aspects of Radiological Protection, ICRP 2015d) therefore addresses this topic. As well as tissue stem cells, there are progenitor cells in the haematopoietic system, intestinal mucosa and the epidermis. The premise that a single stem cell can be the origin of radiation-induced cancer is consistent with an LNT model approach (cf. Section 4.1.1) However, low doses give rise to non-linear effects, making extrapolations problematic and application to radiological protection difficult. Radiation carcinogenesis is age dependent, with a low to moderate risk for embryo and foetal stages, high risk for children and low risk for adults.

2.2.8 Other topics

ICRP Publication 123 (ICRP 2013a) deals with the exposure of astronauts to radiation. During their occupational activities in space, astronauts are exposed to ionising radiation from natural radiation sources present in this environment. However, they are not usually classified as being occupationally exposed in the sense of the general ICRP system of radiological protection of workers applied on Earth. The exposure assessment and risk-related approach described in ICRP Publication 123 are clearly restricted to the special situation in space and should not be applied to other exposure situations on Earth.

ICRP Publication 132 (ICRP 2016b) deals with radiological protection from cosmic radiation in aviation. Exposure to cosmic radiation is classified as an existing exposure situation in which the dose rate increases with flight altitude and latitude. The 11-year solar cycle is also an influencing factor. Exposure of aircraft pilots and crew is classified as occupational exposure,

that of the passengers as public exposure. Exposures should be kept as low as reasonably achievable (ALARA).

ICRP Publication 125 (Radiological Protection in Security Screeing ICRP 2014b) looks at protecting people against radiation during security screenings. The use of ionising radiation to screen individuals for security purposes requires careful justification and adequate optimisation of protection. Optimisation measures are aimed in particular at dose reduction and protection in the vicinity of the screening. The use of ionising radiation for security screening purposes is not generally justified and is regarded as planned public exposure. In light of the rapid evolution in technologies and potential threats, justification for screening should be regularly reviewed.

2.3 Topic areas identified by ICRP for further treatment

Based on the publications of Laurier et al. (Laurier et al. 2021) and Clement et al. (Clement et al. 2021), members of ICRP have identified and described topics to be dealt with in future. While these do not represent an official ICRP position, they draw on the experiences of the members and on discussions with experts from around the world.

The system of radiological protection must be adapted in line with changes in science and society in order to remain fit for purpose. To this end it is recommended that the research necessary to support radiological protection be identified and encouraged. Three main research areas were named: risk assessment, dosimetry and application/implementation.

In risk assessment, the classification into the two categories, tissue reactions and stochastic effects, should be reconsidered. This is especially true for the concept of detriment, which should be updated and improved to reflect the latest scientific findings. Gaining a better understanding of tissue reactions and the individual response to radiation exposure in humans and improving knowledge of the effects of radiation on animals and plants are considered equally necessary. With regard to environmental protection in particular, recommendations should be formulated that also take into consideration sustainable development, quality of life and the impacts of implementing protective actions. Further studies on the mechanisms of low doses of radiation at the molecular, cellular and tissue levels are a recommended focus for the long term.

In the case of dosimetry, more data on various factors that influence relative biological effectiveness (RBE) should be collected. In this way, dosimetric phantoms could be adjusted to the size and dimensions of patients in order to calculate an individual-specific dose. Given that the objective of the ALARA principle is to optimise and protect, it should not necessarily seek the lowest possible exposure, but find a balance between factors such as dose, risk and societal, environmental, economic and general well-being. In future, environmental protection should be given greater attention. Equally, biokinetic models for radionuclides in human tissue should be (further) developed, especially in relation to transfer from mother to foetus or to an infant via breast milk.

For the application and implementation of radiological protection, Laurier et al. consider it necessary to develop dose registries that can be made available to epidemiologists. The aim is to enable the detrimental effects of ionising radiation to be better weighed against the benefits of the respective use. Protection of animals during veterinary applications of ionising radiation should also be addressed. To this end, simplified dosimetric models could be developed. The use of NORM, studies on natural sources of radiation, upgrades to existing buildings and space tourism are further areas of application that should be examined in more detail in future. The definitions of the current categories of exposure situations (planned, existing, emergency) must be clarified and their application reviewed.

Radiological protection faces major challenges in the future. The use of artificial intelligence, for instance in selecting patients or in radiation treatment planning, raises new questions, including ethical issues. New tasks include communicating with the lay public and ensuring appropriate public participation. The psychological consequences of emergencies and their management must be taken into account, as people's responses to unanticipated situations can be widely different to their normal behaviour.

3 Relevant SSK recommendations since ICRP Publication 103

Since ICRP Publication 103 (ICRP 2007a), the SSK has drawn up over 150 recommendations and statements, as well as numerous publications on a range of radiological protection topics. These cover an extremely broad spectrum, ranging from specific questions on individual aspects of radiological protection (Section 4.2) and their practical implementation (Section 3.2) to more general questions relating to key elements of the system of radiological protection or its basic concept (Sections 3.1 and 4.1). Some of these recommendations and statements support and strengthen parts of the ICRP system, justifying the continuation or consolidation of the corresponding recommendations. Others see a justified reason to supplement, extend or modify the existing system. The following sections set out the results and statements from the SSK consultations.

3.1 Issues relating to the conceptual basis of radiological protection

3.1.1 Dose and dose rate effectiveness factor (DDREF)

Information on the dose-response relationship is indispensable for assessing radiological risk and therefore an essential basis for radiological protection as a whole. For practical radiological protection purposes, it is generally assumed that in principle stochastic radiation effects are proportional to the dose, including when low doses are involved. This assumption is known as the linear no-threshold (LNT) model, one of the basic concepts with major consequences for the entire field of radiological protection (cf. Section 4.1.1). It is also assumed that at low doses, the risk is not generally dependent upon radiation exposure over time, i.e. that it is not contingent upon the dose rate.

However, it was noted that radiobiological and radioepidemiological studies have indicated there may be deviations from "pure" linearity at low doses ("dose effect") and, moreover, dependencies on the dose rate ("dose-rate effect"). This would mean that for low doses and low-dose rates, the actual risk is over-estimated by a certain factor if the risk values are extrapolated in linear fashion from high doses and high-dose rates to low doses and low-dose rates. For this reason, even in its earlier recommendations ICRP developed a concept that takes all these influences into account in one common factor, the DDREF. For low doses and low-dose rates, the risk coefficients calculated through linear extrapolation are divided by the DDREF. ICRP Publication 103 (ICRP 2007a) confirms the previously introduced DDREF of 2 for the induction of solid tumours in the case of photon exposures (sparsely ionising radiation).

The DDREF is a conceptually subtle quantity. The method used to determine the DDREF does not involve a single "factor" in the sense of a constant parameter for estimating risk coefficients. Instead, the DDREF value depends on the respective dose and dose rate used to extrapolate low doses and low dose rates. There could also be further influences, such as dependence on the energy of the radiation (Trabalka und Kocher 2007). However, there is not enough information available about the type and magnitude of all these dependencies. That is why the DDREF – irrespective of the value assigned to it – is rather of general importance for radiological

protection and less relevant for specific aspects. The effects of all these dependencies are combined in a single constant "factor", the DDREF.

Since its introduction, the scientific basis for justifying a DDREF has increasingly become a controversial subject of debate. In 2006, the SSK recommended (SSK 2006a) setting a DDREF of 1. BEIR VII (BEIR 2006) proposed a DDREF of 1.5. UNSCEAR (UNSCEAR 2010) and WHO (WHO 2013) subsequently stopped using the DDREF. In its later recommendation on the DDREF (SSK 2014a), the SSK refined its earlier position and justified it in greater detail based on recent scientific findings.

In the opinion of the SSK, radiobiological and radioepidemiological studies on the effect of exposures to a low-dose rate do not, overall, clearly point to tumour risk being dependent on the dose rate, i.e. they do not indicate the presence of a dose-rate effect (SSK 2014a). Neither do studies, especially those on the LSS cohort of atomic bomb survivors (e.g. Ozasa et al. 2012), provide any clear distinction between various types of dose-response relationship, e.g. linear or linear-quadratic. It is therefore currently not possible to derive a dose-effect value. Dose effects and dose-rate effects actually seem to be largely independent of each other. Overall, based on current scientific findings, the SSK no longer sees sufficient justification for the DDREF used in radiological protection (SSK 2014a). However, the SSK does not consider the available knowledge sufficient to justify an immediate need for action as regards abolishing the DDREF.

The most important factors for radiological protection are damage associated with exposure (carcinogenesis and genetic mutations) and their likelihood of occurrence. These factors are quantified by the "detriment" (damage to health), a weighted probability of damage that factors in, e.g. risk coefficients, including a DDREF, (cf. Section 4.1.2). However, the detriment also includes a number of other parameters, such as probability of survival, quality of life and loss of life expectancy. The values that are the basis for these parameters have changed over time (Breckow et al. 2018). Improved living conditions and medical progress could, for example, lead to an increase in probability of survival in the case of developing cancer, an improvement in quality of life and a reduction in loss of life expectancy. All these parameters need to be taken into account when further assessing the health effects of a certain exposure. In the opinion of the SSK, an isolated view of the risk coefficient and/or DDREF does not sufficiently take account of the overall situation (SSK 2014a).

Conclusion: In its publication (SSK 2104b), the SSK recommends possibly "abolishing the DDREF or adjusting it to bring it into line with more recent findings." Due to its importance for risk evaluation and impact on radiological protection, the SSK further recommends that any general adjustment of the DDREF should include adapting all other parameters pertaining to detriment (i.e. to radiation-related damage) to current scientific findings.

3.1.2 Radon dose coefficients

Quantitative variables and radon protection measures generally refer to exposure levels, i.e. the activity concentration or cumulative activity concentration (activity concentration multiplied by time) in the ambient air. The reference level for Radon-222 in dwellings and the workplace, for example, is an activity concentration of 300 $Bq\,m^{-3}$ (Euratom 2014). The activity concentration is directly used in relevant studies (e.g. Darby et al. 2005) to determine lung cancer risk resulting from inhalation of radon and its progeny. It is therefore appropriate to base radon protection on this easily measured quantity. The stipulations then do not relate to a dose quantity (e.g. to the effective dose) as in other areas of radiological protection. Accordingly, relevant radiological protection measures based on activity concentrations do not require explicit dose levels.

However, risk assessments and radiological regulations on radon exposures, which lack references to dose quantities, are difficult to link to assessments in other areas of radiological protection. Moreover, it is necessary to be able to refer to dose levels in a number of situations and issues. In particular, occupational radiological protection regulations for radon exposure require a reference to the effective dose. Such reference is also envisaged in the ICRP recommendations (ICRP 2007a) and national regulations. In these cases, radon exposures occurring in workplaces are treated like planned exposure situations.

Generally, dose coefficients can be used to convert an exposure quantity to a dose quantity. In the case of a radon exposure, the exposure quantity can be expressed in units of working level months (WLM), cumulative alpha energy concentration in mJ h m^{-3} or cumulative Rn-222 activity concentration in MBq h m^{-3}. The organ dose of the lungs or the effective dose, expressed in mSv, serves as the reference dose quantity. Converting the exposure to a dose, referred to as dose conversion, is based on a set of assumptions and models. A number of parameters and factors, such as radiation and tissue weighting factors, are also included in the calculation.

Initially, ICRP had linked the risk per exposure resulting from the epidemiological studies available at the time to the (then current) risk coefficients for the total detriment (ICRP 1993). This epidemiological approach yielded radon dose coefficients that could be used to calculate a value for the effective dose (in mSv) using the cumulative activity concentration (in MBq h m^{-3}).

In parallel to the epidemiological approach, ICRP developed a biokinetic lung dose model based on a dosimetric approach. A model of the respiratory tract that was developed and updated multiple times was the basis for calculating the dose distribution in the various lung regions. This model, known as the Human Respiratory Tract Model (HRTM), considers in detail the deposition, length of stay, transport, exchange and release of the radionuclides in question in the individual compartments of the lungs (ICRP 2015c).

In general, the ICRP approach for all radionuclides uses biokinetic models to describe how they behave in the body over time following their incorporation, including their excretion (ICRP 2017b). These models are used to calculate the number of nuclear transformations and resulting energy transmission in the individual parts of the body. Multiplying the respective absorbed dose with the radiation weighting factors w_R enables the organ dose values to be calculated. The effective dose is calculated by totalling the organ dose values which are then multiplied by the tissue weighting factors w_T. Radon is treated differently than other radionuclides in that the effective dose is not only expressed per incorporated activity (Sv per Bq, separately for radon and its short-lived progeny), but also per exposure (mSv per (Bq h m^{-3})) for radon including its progeny. In its most recent publications on radon dose coefficients (ICRP 2010c, ICRP 2014c, ICRP 2017b), ICRP generally prefers the dosimetric approach, mainly to be consistent with the approach taken for the incorporation of other radionuclides.

In general, ICRP provides dose coefficients for reference persons without taking individual characteristics and/or behaviour patterns into account. In particular, no differentiated dose coefficients for smokers and non-smokers are provided. Where modifying factors are provided for special situations (impacts due to smoking, air pollution, respiratory diseases), their influence remains nonetheless largely unclear. The radon dose coefficients developed by ICRP using the dosimetric approach are therefore values for reference persons with standardised environmental conditions. In addition to the individual variability and variability of the environmental conditions, the reference levels include a number of uncertainties (SSK 2017). Potential sources of these uncertainties include

– deposition values of the radon progeny in the lung regions directly related to the dose;

- the mechanical transport rates of deposited radon progeny for mucociliar clearance from the bronchial region to the extrathoracic region and clearance from the extrathoracic region to the gastrointesinal tract;
- absorption rates from the respiratory tract to the blood, particularly the Pb-214 fraction retained in the walls of the airways in a bound state; and
- the definition and location of radiosensitive cells of particular relevance in terms of alpha radiation.

ICRP has published a series of recommendations on radon dose conversion in past years, which essentially aim to change the dose coefficients previously used (ICRP 2010c, ICRP 2014c, ICRP 2017b). In its recommendation on radon dose coefficients, the SSK engages critically with the data and conceptual basis of the ICRP recommendations (SSK 2017, Müller et al. 2016). In the view of the SSK, the radon exposure conversions to effective dose values are currently unclear, irrespective of whether they are based on the dosimetric approach or the epidemiological approach. The radon dose coefficients resulting from both of these approaches exhibit significant uncertainties within which it is difficult to determine a specific value. UNSCEAR (UNSCEAR 2019) also highlights this situation in its discussion of radon dose coefficients. The new radon dose coefficients proposed by ICRP, mainly in its Publications 115 (ICRP 2010c) and 126 (ICRP 2014c), are in fact based on dosimetric and epidemiological findings from recent years, but the derivation of these values still presents a number of design flaws. The SSK therefore considers this to be an ongoing issue that may well require quantitative amendments in the foreseeable future along with, probably to a lesser extent, design adjustments. The SSK finds that both the old and new dose coefficients appear to be reconcilable with the epidemiologic data within the existing uncertainties. For these reasons, the SSK recommended (SSK 2017) leaving the radon dose coefficients in Germany unchanged until the ICRP provides definitive recommendations on the issue and until international regulatory agreement has been reached on the basis of in-depth scientific discussions.

ICRP finds a common dose coefficient for workplace and dwelling exposure feasible (ICRP 2017b). In this regard, the SSK finds that the uncertainties in the epidemiological studies and the many assumptions necessary to compare the risks of mine workers with those of the general public in dwellings currently preclude a definitive statement on equating or differentiating the risk coefficients in cases of equivalent activity concentration and exposure duration (SSK 2017). The SSK does not rule out the possibility that the risk coefficients differ for miners and the general public. In contrast to occupational exposure, exposure of the public in dwellings lasts a lifetime and can vary significantly over time. In the underlying studies, weighted average activity concentrations in all dwellings the participants had inhabited up to some decades before diagnosis were calculated. The resulting risk estimates were therefore expressed per activity concentration, not cumulatively (i.e. without reference to duration of exposure).

In order to gain an overview of how other European countries are implementing Directive 2013/59/Euratom, particularly with regard to the issue of new radon dose coefficients on the basis of ICRP Publications 103 (ICRP 2007a) and 115 (ICRP 2010c), the SSK interviewed experts from 15 EU countries, who are involved in implementing the directive in their respective country, about the current situation and progress of discussions into the introduction of new dose coefficients in their countries (SSK 2017).

The responses failed to provide a clear picture of current progress made and the next steps to be taken in the individual countries. Discussions on whether and how to address the results of ICRP Publications 115 (ICRP 2010c) and 103 (ICRP 2007a) are still under way or have only just begun. Most of the experts surveyed assume that the existing models will be amended to reflect the new ICRP recommendations. However, only very few countries have actually

proceeded to do this, as is the case in Switzerland where the revised radiation protection ordinance (federal level) introduced a reference level of 300 Bq m^{-3} without providing a radon dose coefficient to calculate the dose to the population. Switzerland has only provisionally introduced a radon dose coefficient in the subordinate dosimetric ordinance (departmental level) for workplace dose calculation.

In most other countries, the radon dose coefficient stipulations have been retained, with the introduction of new coefficients contingent upon an explicit ICRP recommendation. The dose coefficients in this recommendation should be subsequently introduced in corresponding ordinances and regulations. The stipulation of a certain value should generally be enshrined in subordinate rather than superordinate ordinances/directives, as is the case in Switzerland, so as to make it easier to amend the dose coefficients at a later date.

Conclusion: A reassessment of all available findings on dose calculation, including new analysis of the Wismut data and PUMA (Pooled Uranium Miners Analysis) study (Rage et al. 2020) should result in a consensus-worthy and workable ICRP recommendation on radon dose coefficients. Beyond this, the goal for the future should generally be recommendations on radon protection based on activity concentrations or exposure values rather than dose values, so that dose conversions can be largely avoided.

3.1.3 Radiation-induced skin cancer

Skin, the largest organ of the human body with a variety of possible types of exposure, plays a special role in radiation protection in many ways.

Currently, the general assumption is that ionising radiation can mainly cause basal cell carcinoma, a subtype of skin cancer. There is a weak association with the occurrence of squamous cell carcinoma, while malignant melanoma is considered not inducible by ionising radiation.

In determining the effective dose, as for other organs, the contribution of radiation-induced skin cancer risk to the total stochastic risk is expressed in the organ weighting factor w_R. The organ weighting factor is based on the incidence risk coefficients for the respective organ and the subsequent calculation of the detriment. For almost all organs, the risk coefficient differs from the detriment, which mainly includes lethality, by no more than a factor of 2. In contrast, skin cancer not only has by far the highest incidence risk coefficients of all organs (higher than all others together) but also, due to the assumed very low lethality of the prevalent basal cell carcinoma, a very low detriment. This leads to a difference between detriment and risk coefficient by the remarkably high factor of 250, i.e. more than 100 times the difference for other organs. Although the contribution of the skin risk coefficient to the total risk coefficient is around 60%, the skin detriment makes up only about 0.7% of the total detriment (ICRP 2007a). This situation mainly has far-reaching significance when comparing radiation-induced risk for skin cancer to skin cancer risk due to other agents. In this regard, ionising radiation is attributed significance that is 250 times lower than, for example, UV radiation.

In determining the risk coefficients of the individual tissues or organs, ICRP Publication 103 (ICRP 2007a) relies heavily on the incidence studies of the Life Span Study, LSS, based on Preston et al. (Preston et al. 2007). This work and Ron et al. (Ron et al. 1998) provide detailed information on melanoma and the non-melanocytic cancers basal cell carcinoma and squamous cell carcinoma. However, ICRP Publication 103 does not consider these data robust enough for determining risk coefficients. Rather than drawing on the then quite new LSS incidence data, ICRP uses the unchanged risk coefficients from ICRP Publication 60 (ICRP 1991b), which are based, in turn, on ICRP Publication 59 (ICRP 1991a). The data underlying the recommendations of ICRP Publication 103 therefore date back in part to studies from the 1990s. Due

to the special significance of radiation-induced skin cancer, the scientific data basis needs to be updated and subsequently reviewed with respect to whether the currently accepted qualitative and quantitative claims about skin cancer risk are still applicable.

To transfer risk from one population group to another (e.g. from the LSS cohorts to the world population), ICRP (ICRP 2007a) uses a mixed model to take into account multiplicative (relative risk model) and additive (absolute risk model) aspects of the background risk. For most organs, a mix of 50% excess relative risk (ERR) to 50% excess absolute risk (EAR) is used. In contrast, for skin cancer, ERR alone is used. This choice and the decision not to use the LSS data are both due to the large uncertainties when transferring risk to other populations. In Japan, the incidence rate of basal cell carcinoma (as well as other skin cancers) is very low, while the incidence rates, particularly in Europe, Australia and the US are extraordinarily high, the highest of all types of cancer. The percentage of absolute risk and relative risk selected for a mixed model strongly influences the resulting risk coefficients. If, instead of the relative risk model (100% ERR to 0% EAR) favoured in ICRP Publication 103, the absolute risk model (0% ERR to 100% EAR) were used and transferred to populations with significantly higher background rates of skin cancer, the value of the risk coefficient for the skin would be exponentially lower. This difficulty in transferring risk between populations with very different and also difficult-to-determine background rates for non-melanocytic skin cancers led ICRP (ICRP 2007a) to leave the risk estimates unchanged from ICRP Publication 60 (ICRP 1991b).

Skin cancer, defined by the subtype basal cell carcinoma, is only attributed a very limited impact on quality of life with the assignment of "minimal impairment of quality of life" $q_{min} = 0$ and a very low lethality factor *k* in the detriment. In ICRP Publication 103 (ICRP 2007a), skin cancer is the only tissue assigned $q_{min} = 0$. Changes in the selection of q_{min} would have extreme impacts on the detriment values for skin cancer.

In the current radiological protection system (ICRP 2007a), the following characteristics distinguish skin cancer from all other types of cancer:

- The incidence risk coefficient for skin cancer is by far the highest for all types of cancer. It is higher than all others added together.
- However, the detriment for skin cancer is the lowest of all types of cancer due to the low lethality.
- Skin cancer is the only type of cancer with no mixed model used to transfer risk between populations. The multiplicative risk model (relative risk model) is used exclusively.
- Skin cancer is the only cancer assigned $q_{min} = 0$ (minimal impairment of quality of life).

Sugiyama et al. (Sugiyama et al. 2014) is by far the most important recent study analysing the LSS cohorts with regard to skin cancer for the observation period 1958 to 1996. The study confirms the assumption that basal cell carcinoma (BCC) is the defining subtype of skin cancer. In agreement with all previous analyses of the LSS cohorts, no statistically significant dose-response relationships were found for squamous cell carcinoma (SCC) and malignant melanoma (MM).

Sugiyama et al. (Sugiyama et al. 2014) explores how various models fit the dose-response relationship for BCC. Of the models, a linear threshold model with a threshold dose at 0.63 Gy was found to be the best fit. This puts the threshold dose in a range higher than most exposures encountered in practical radiological protection settings. Although a less ideal fit, a pure LNT model yields a very conservative estimate with a value that is around half that given in ICRP Publication 103 (ICRP 2007a).

The selection of the parameters to calculate the risk coefficients and the detriment prove much more critical for skin cancer than for all other types of cancer (SSK 2023 in preparation). Assuming a threshold model providing the best fit according to Sugiyama et al. (Sugiyama et al. 2014) would mean that skin cancer would play no role at all in the stochastic risk and would therefore be entirely excluded from the list of risk coefficients and organ weighting factors. This would also be the case if using an LNT model with a risk transfer model based on the absolute risk model. However, if an LNT model with exclusively relative risk transfer and a $q_{min} = 0.1$ is used, as with other cancers, it would result in the second highest detriment of all cancer types after lung cancer (SSK in Vorbereitung). Other combinations of models of adaptation, risk projection or detriment calculation yield values that can span a broad spectrum from insignificantly low to broad dominance of skin cancer risk. This shows that the modelling of skin cancer incidence is much more sensitive to the selection of model parameters than other cancers. This fact can also have far-reaching impacts on the detriment concept currently in use (cf. Section 4.1.2).

Conclusion: For almost all organs, the risk coefficient differs from the detriment, which mainly includes lethality, by no more than a factor of 2. In contrast, skin cancer not only has by far the highest incidence risk coefficient of all organs (higher than all others summed) but also, due to the assumed very low lethality of the prevalent basal cell carcinoma, a very low detriment. This leads to a difference between detriment and risk coefficient that is more than 100 times the difference for other organs. More recent analyses of the LSS cohorts indicate that skin cancer is not radiation induced below around 0.5 Gy, i.e. that the skin would be excluded from the list of organs with organ weighting factors.

3.1.4 Cardiovascular diseases

For many years, stochastic radiation effects were the main focus of radiological protection. On the basis of the LNT model (cf. Section 4.1.1), it is generally assumed for these that there is no dose below which radiation effects can be completely ruled out. Large parts of the overall radiological protection system are based on this premise. For some years, however, more and more attention has been given to studies on radiation-induced cardiovascular diseases that cannot be easily classified in the traditional categories of stochastic and deterministic effect; it is also difficult to determine the nature of the dose-response relationships for these diseases. Importantly, it remains unresolved whether an LNT model is an appropriate convention to sufficiently address radiological protection concerns. It is accordingly also unclear to what extent these diseases should be integrated in the existing radiological protection system or whether the system must be expanded to include radiation-induced cardiovascular diseases.

ICRP engaged with this problem in Publication 118 (ICRP 2012a). The SSK has also commented on the issue multiple times (SSK 2012, SSK 2018).

In cell cultures or animal experiments, a number of cellular and molecular changes can be triggered by radiation within hours, days or weeks. Whether, however, these changes are causal for the emergence of the effect chains that lead to increased cardiovascular risk in humans within years to decades is difficult to prove in the experimental setting, not least because biological experiments in general are difficult to transfer to humans. Generally, in this area there is a lack of relevant animal models, applied exposure scenarios and completed experiments (SSK 2018).

Due to the long time period between the initiating event, i.e. a radiation exposure, and the clinically relevant endpoint (e.g. heart attack), it is difficult to assess the pathogenic relevance of specific cellular components, tissue reactions or even individual molecules. It is generally not possible to derive a linear dose-response relationship from the multitude of individual cases. There are cases of high doses with specific effects that have not been observed with medium

doses, and other effects with medium doses that were not observed with high doses. Low doses seem to have mostly anti-inflammatory effects, and high doses have inflammatory effects. Currently, however, neither key target cells nor basic causal mechanisms of the cardiovascular impacts of radiation have been conclusively established.

Recent radiobiological studies increasingly show that the effects of radiation following exposures to a dose of several hundred millisievert differ not only in terms of their extent, but also, and in particular, in the type of effects seen following high exposures. This suggests not only that the response mechanisms are different in the high and low-dose range, but also that dose-response relationships overall exhibit a more non-linear trajectory (SSK 2018).

There are many epidemiological studies of cardiovascular diseases in radiation-exposed populations. However, most studies do not, or only partially include, major risk factors such as smoking, hyperlipidaemia, hypertonia, diabetes mellitus, obesity and physical inactivity. While it can be assumed that subtypes of cardiovascular diseases exhibit different dose-response relationships, robust study results are generally only available for larger groups of cardiovascular diseases such as cerebrovascular disease or ischaemic heart disease.

In most of the epidemiological studies, the data are analysed using an LNT model without any special justification and the slope coefficient, i.e. the excess relative risk per dose, ERR/D, is provided as the main result. The Life Span Study (LSS) of the atomic bomb survivors of Hiroshima and Nagasaki is one of the most important information sources for estimating the risk of cardiovascular diseases following exposure to medium doses of radiation. An analysis of the mortality data showed statistically significant associations between the weighted colon dose and rheumatic heart disease, hypertensive heart disease and heart failure (Shimizu et al. 2010). No association was found, however, for ischaemic heart diseases. Differences and changes in the background mortality rates of specific types of cardiovascular diseases need to be taken into account when comparing these results with other studies. For instance, the mortality rate due to cardiovascular diseases in Japan increased significantly in the 1990s (Ozasa et al. 2014).

In some epidemiological studies, the results were best described by a linear dose-response relationship, while in others they could be described equally well by functions with far lower risk values at low doses (particularly purely quadratic functions and linear functions with a threshold level higher than several hundred mGy). Overall, the SSK sees no possibility to make statements regarding the form of the dose-response relationship at low doses (SSK 2018). In the view of the SSK (SSK 2018), there is also no clear picture here of the possible dependence of risk on dose rate or dose fractionation.

To compare the risks for cancer and cardiovascular diseases, an SSK publication (SSK 2018) carried out estimates for the LSS as well as estimates for Western populations. In the LSS, mortality in atomic bomb survivors was analysed from 1950 to 2003 using the LNT model. Shimizu et al. (Shimizu et al. 2010) found an ERR per dose of 0.11 (95% CI: 0.05 - 0.17) Gy^{-1} for cardiovascular diseases and estimated that 210 of the 19,054 deaths from cardiovascular disease were associated with radiation exposure. Ozasa et al. (Ozasa et al. 2012) found an ERR per dose of 0.47 (95% CI: 0.38 - 0.56) Gy^{-1} for solid cancers and estimated that 527 of the 10,929 deaths due to cancer were associated with radiation exposure. Taking into account the indications of non-linearity of the dose-response relationship for cardiovascular diseases, the ERR per dose in the range of some hundred mGy for cardiovascular diseases is almost one order of magnitude below that of cancer, and the absolute risk is less by around a factor of 3.

ICRP has estimated that the excess lifetime risk for cardiovascular and cerebrovascular diseases is approximately 1% following radiation exposure at a dose of 500 mGy (ICRP 2012a). BEIR VII estimated that the excess lifetime risk for cancer is also approximately 1% following

radiation exposure with a dose of 100 mGy (BEIR 2006). The corresponding lifetime risk per dose for cancer is therefore higher than the ICRP estimate for cardiovascular diseases by a factor of around 2 to 3. This is consistent with the above-mentioned estimate for the LSS.

Cardiovascular diseases are covered in the current ICRP definition of detriment. Major uncertainties remain with regard to establishing a potential excess risk for cardiovascular diseases in the low-dose range. However, for establishing a limit on the occupational lifetime dose, cardiovascular diseases play a less important role because excess mortality due to cardiovascular diseases in the range of a few hundred millisievert is around 2 to 3 times lower than the excess mortality due to cancer. It can be assumed that cardiovascular diseases are of lesser importance than cancer when setting occupational exposure limits (SSK 2018).

Conclusion: For many years, stochastic radiation effects were the main focus of radiological protection. For some years, however, more and more attention has been given to studies on radiation-induced cardiovascular diseases that cannot be easily classified in the traditional categories of stochastic and deterministic effect; it is also difficult to determine the nature of the dose-response relationships for these diseases. Importantly, it remains unresolved whether an LNT model is an appropriate convention to sufficiently address radiological protection concerns. It is accordingly also unclear to what extent these diseases should be integrated in the existing radiological protection system or whether the system must be expanded to include radiation-induced cardiovascular diseases.

3.1.5 Benign tumours

Benign (non-cancerous) tumours are characterised by a well-differentiated, homogeneous and tissue-typical structure, slow growth and distinct borders to the surrounding tissue. They do not exhibit invasive growth into neighbouring tissue and do not develop satellite growths (metastases). Benign tumours show no or only low-grade cellular changes and have low mitotic activity. However, some benign tumours can be early stages of malignant (cancerous) tumours (e.g. colorectal adenoma). Classification as benign or malignant is, for this reason among others, not always a simple matter.

It has been shown many times that ionising radiation can induce malignant tumours (cancer). The data basis on the induction of benign tumours by ionising radiation is much more uncertain. This is for a number of reasons:

- In general, statistics on incidence are not complete.
- Because benign tumours are very seldom the cause of death, figures for them cannot be derived from death certificates.
- In the context of radiation research, there is a lack of pressure to conduct systematic studies because benign tumours impair quality of life much less than cancerous tumours or not at all.

The mechanisms that give rise to benign and malignant tumours are comparable (Marino-Enriquez und Fletcher 2014). Genetic and epigenetic changes as well as the creation of a tumour-promoting environment play a role. It can therefore be generally assumed that benign tumours can be induced by radiation exposure and belong in the category of stochastic effects commonly used in radiological protection.

Epidemiological studies on the relationship between ionising radiation and benign brain tumours support a significant positive relationship for meningiomas (Braganza et al. 2012). Estimating associations for other benign brain tumours (schwannoma, pituitary adenoma, acoustic neuroma) is not possible due to a lack of studies.

Thyroid nodules are common and generally benign (Dean und Gharib 2008). Epidemiological studies show that radiation exposure in childhood increases the risk of benign thyroid nodules (Imaizumi et al. 2015). This is true, however, only for long periods after exposure, not for short periods (< 10 years). The excess risk is particularly marked for large nodules (> 10 mm). This suggests that the excess relative risk per thyroid dose for thyroid nodules averaged over longer periods is comparable with the risk for thyroid cancer (Jacob et al. 2014). There are not enough studies of exposure in adulthood to draw conclusions on increases in the incidence of thyroid nodules.

Isolated results from animal experiments and epidemiological studies have been published on other benign tumour types, in particular for the following localisations: pituitary gland, salivary glands, breast, colon, kidneys, liver, ovaries, uterus, bones and cartilage, skin.

Conclusion: To date, there is only little empirical evidence available regarding ionising radiation as a cause of benign tumours. Some benign tumours severely restrict quality of life and may even have life-threatening consequences. This is particularly true for benign intracranial tumours. Radiation-related benign tumours should therefore generally be taken into account in radiological protection when assessing the health risks of radiation exposures. Benign tumours are not currently covered in the ICRP recommendations. This should be changed in future. Benign tumours should either be incorporated in the detriment or their exclusion should be justified.

3.1.6 Cataracts

At the beginning of the 2000s, it was found that significantly lower radiation doses than originally believed can lead to cataracts (opacity of the lens of the eye) (Chodick et al. 2008, Minamoto et al. 2004, SSK 2009b, Worgul et al. 2007). There has since been intense discussion of whether cataract is a deterministic or stochastic effect or whether it can even be classified as either within this radiological protection concept. Until about the end of the 20th century, experts were certain that cataract was a deterministic effect with clear threshold doses. It was assumed that the threshold dose after acute radiation exposure was about 2 Gy and between about 5 Gy and 7 Gy after chronic exposure over many years (ICRP 1991b). For this reason, the dose limit for occupational radiation exposure was relatively high, at 150 mSv per calendar year. In 2011, ICRP changed the limit to 20 mSv per year in its “Statement on Tissue Reactions” in light of the results of numerous studies (ICRP 2012a).

The following items are relevant for characterising deterministic effects or tissue reactions:

- Cell death processes: high sensitivity of the lens epithelial cells to cell death would indicate a deterministic effect. However, there is no supporting evidence for this (Hamada 2017, Harocopos et al. 1998).
- Presence of a threshold dose: it is currently unclear whether a threshold dose exists for cataracts. Some epidemiological studies show that the lower confidence limit of excess relative risk includes zero, meaning that the lack of a threshold dose cannot be excluded as a possibility (Nakashima et al. 2006, Neriishi et al. 2007). There is some evidence that cases of early-onset cataracts within ten years after radiation exposure exhibit a threshold dose, but late-onset cases do not (Hamada et al. 2020). ICRP Publication 118 (ICRP 2012a) still assumes a threshold dose (more precisely, a nominal threshold dose, i.e. the dose that causes a tissue reaction in 1% of exposed persons) and determines a dose of 0.5 Gy for cataract.
- Severity of disease depends on dose: it is difficult to determine whether the severity of a cataract is dose dependent. To date, it is unclear whether an opacity of the lens always

develops into a full blown cataract or whether it can remain a slight or moderate opacity of the lens (Ainsbury et al. 2021, Neriishi et al. 2007). If all opacity, once induced, resulted in a complete opacity of the lens, the deterministic effect criteria "severity of disease" would not apply.

- Dose rate effects: previously, it was assumed that the dose rate, the distribution of the dose over time (either acute or chronic exposure) plays a large role in cataract risk (ICRP 2012a). However, this could not be confirmed by more recent studies (Chodick et al. 2008). This deterministic effect criteria therefore does not apply.

The exact mechanism that causes cataracts following radiation exposure is still unknown (Ainsbury et al. 2016), but emerging evidence points to major similarities to the processes encountered with stochastic effects (Hamada et al. 2014, Hamada 2017, Hamada et al. 2020, Jacob et al. 2012):

- slow or faulty repair
- abnormal differentiation
- excessive proliferation
- telomere effects
- ageing processes
- morphological changes of the lens crystallins
- inflammatory processes

The question remains whether the drastic lowering of the dose limit from 150 mSv per calendar year to 20 mSv is justified. It has resulted in the lens of the eye being better protected than tissue where tumours can form (Hamada et al. 2014). Another factor to consider in this context is the fact that operative lens replacement is now a routine procedure now and consequently the impacts of radiation-induced cataracts on individual lives have been reduced considerably.

Conclusion: Current knowledge on the development of radiation-induced cataract are not sufficient for a clear decision on whether cataract is a stochastic or deterministic effect or neither. The current scientific findings do at least imply that it is unlikely that cataract can be considered a "classic" deterministic effect. The level of the dose limit should be discussed again in light of the fact that the limit for the lens of the eye at 20 mSv per calendar year means it is better protected than tissues where tumours can form.

3.1.7 Environmental protection

In Germany, the "environment" refers to the whole system of people, the natural environment and landscape, cultural goods, other real assets as well as the interrelationships between these objects of protection. The ecosystem comprises natural goods, water, soil, air, the climate, plants and animals as well as their interrelationships. The SSK regards humans, animals, plants and other living organisms as well as water, soil and air as objects of protection to be considered in radiological protection, based on the potential impacts of ionising radiation (SSK 2016c). With respect to non-human species, the protection objectives lie in preventing or reducing the frequency of harmful radiation effects to a level where radiation only has negligible effects on the conservation of biological diversity and the preservation of species. Beyond the protection of non-human species, radiological protection also needs to include the protection of environmental media and real assets as well as issues of sustainability.

For the assessment of radiation exposure of non-human species, ICRP has defined 12 reference animals and plants (RAPs) as representatives of organism groups (ICRP 2008b) and

recommended dose rates called derived consideration reference levels (DCRLs) for these (ICRP 2014d). These levels are to be understood as total dose rate values (sum of anthropogenic and natural doses). For assessment of the protection of non-human species, the SSK views it as sufficient to limit the focus to the 12 RAPs as these cover a broad swath of different species and because the existing uncertainties make further differentiation seem inappropriate. The assessment can be confined to the 75 radionuclides set out in (ICRP 2008b), particularly because radiation exposure would be drastically overestimated for very short-lived radionuclides for non-human species using the dose conversion factors of (ICRP 2009a). As described in Section 2.2.6, ICRP has now made a tool available, the software package BiotaDC, which can be used to define other organisms based on their mass and shape and makes it possible to calculate doses for all radionuclides in ICRP Publication 107. Based on current knowledge, the SSK views this as a step that makes radiological protection more complicated without providing added and appropriate protection.

The SSK views the protection of RAPs, including the preservation of species and conservation of biodiversity, as secured if the radiation exposure of all relevant RAPs remains under the upper levels of the respective DCRL bands. Because the upper levels of the DCRL bands are not exceeded in planned exposure situations under the applicable German radiological protection rules, assessments of radiation exposure of non-human species can be refrained from for these exposure situations. In the case of existing exposure situations, RAPs are to be appropriately incorporated into the optimisation process in the event that anthropogenic changes cause exposures above the upper levels of the DCRL bands. In emergency exposure situations, the radiological protection of humans must always be paramount. To the extent water, soil or plants have been contaminated in emergencies, measures to remove such contamination should only be considered if they directly serve to protect humans. The protection of non-human species should, however, be included in late phases of emergency exposure situations while evaluating other courses of action.

Nuclide-specific contamination of soils, limnic and marine waters can be assessed based on the ICRP data sets to facilitate the implementation of the recommendations for the protection of non-human species. If these contamination levels are not exceeded, none of the upper levels of the DCRL bands will be exceeded. The SSK has determined these levels for the 75 radionuclides of (ICRP 2008b) and tabulated them (SSK 2016c). They can be applied to mixed radionuclides using the molecular formula. This creates a workable tool that can be used in environmental assessments to determine whether there is a possibility of deleterious effects for non-human species.

With regard to protection of environmental media, the SSK is of the opinion that radioactive contamination of the water and soil by radionuclides in planned exposure situations should be regarded as negligible with respect to the protection of non-human species as well as ecosystems if the lower limits of the DCRL bands are not exceeded. To the extent the protection of non-human species and ecosystems is to be assessed separately from the protection of humans in existing or emergency exposure situations, the upper levels of the DCRL bands must be applied as a benchmark. It is unnecessary to introduce limits for the assessment of radioactive contamination of the air according to ecotoxicology criteria.

The radioactive contamination of real goods can impair their utility and subsequently cause considerable disadvantages for the respective owner. This type of contamination should be considered when planning measures for emergency exposure situations. Furthermore, contamination within the economic cycle should, on the basis of a broader analysis of the radioactivity in environmental assessments, be identified directly at its place of origin to avoid uncontrolled release into the material flows of the economy. Appropriate provisions should be defined for handling, decontamination, reuse or disposal, which can be used, if needed, for real

assets with elevated radionuclide concentration as the result of existing or emergency exposure situations.

The principle of sustainability should be integrated in order to ensure sustainable development with respect to protecting the environment within the domain of radiation protection. In addition to the protection of human health, the protection of non-human species as well as the stability over time of sufficiently negligible contamination of environmental media are objectives to be attained. The principle of sustainability thus goes beyond the precautionary principle. The latter nevertheless also strongly supports sustainability and is a tool for both risk prevention and resource conservation that must be applied when making decisions with major environmental implications.

Regional or local trends of radioactive environmental contamination, which can result in radiologically relevant contamination if suitable measures are not taken, should be evaluated under the aspect of prevention and any undesired development should be counteracted. The generally limited duration of planned discharges must be taken into account during such an assessment. The trend in the concentration of long-lived radionuclides in environmental media should be monitored to prevent long-term changes in large-scale to global concentrations of radionuclides that could foreseeably become radiologically relevant. There are many existing long-term monitoring programmes. Their findings should be evaluated specifically with regard to this issue. The licensing of installations which are subject to monitoring under radiological protection law and which discharge radionuclides into environmental media should always include e review of whether, through the implementation of measures to reduce emissions, a reduction of the discharges in the sense of the ALARA principle can be achieved with reasonable efforts and expenditure.

Conclusion: For assessment of the protection of non-human species, the SSK considers it sufficient to confine the scope to the 12 RAPs and 75 radionuclides of ICRP Publication 108. Based on current knowledge, no additional and appropriate protection would be afforded by observations exceeding this scope. For environmental assessments, it is useful to stipulate radionuclide-specific contamination of soils, limnic and marine waters that are presumed to have no deleterious effects for all 12 RAPs. With regard to the various exposure situations, the SSK has provided practical recommendations for the protection of non-human species. Given that protection of the environment should encompass all environmental media and the principle of sustainability, the SSK has made recommendations for implementing this appropriately (SSK 2016c).

3.1.8 Gender-specific radiosensitivity

In its recommendations on gender-specific radiosensitivity, “Sex Specific Differences in Radiation Sensitivity”, the SSK assesses the epidemiological, clinical and biological data on this topic (SSK 2009a). The SSK finds that, while relevant studies provide indications of possible gender-specific differences in radiosensitivity (endpoints: mortality and cancer), clear evidence is lacking. After analysing the various studies, the SSK cannot share the certainty expressed in some statements from other national and international institutions regarding a generally higher radiation sensitivity in women. After careful analysis, the SSK concludes that it is not necessary at present for radiological protection to consider possible gender-specific differences in radiosensitivity. However, the SSK points out that further research is needed in order provide conclusive evidence of gender-specific differences in the radiation-induced incidence of tumours in specific organs and in the radiation sensitivity of entire organisms, and to understand them on the basis of molecular, cellular and tissue reactions to irradiation.

Few studies on this subject have been published in the years since the SSK’s statement. Narendran et al. 2019 conclude in their review that the “available data suggest that long-term

radiosensitivity in women is higher than that in men". They cite, for instance, a study of the effects of the Chernobyl reactor accident that finds indications of a 2.5-times higher incidence of thyroid tumours in women in comparison to men in contaminated areas. However, that study lacks dosimetric information (Yablokov et al. 2009). A study of cancer induced by plutonium incorporation by workers at the Mayak facility shows significantly higher excess relative risks for women in comparison to men: two times higher for lung cancer, ten times higher for liver cancer and four times higher for bone cancer (Hunter et al. 2013). A more recent study by the same group finds, however, that there is no higher excess relative risk for all of the other cancer types in aggregate (Sokolnikov et al. 2015). The current analysis of data from Hiroshima and Nagasaki (Brenner et al. 2022) also indicates gender-specific differences, as did earlier analyses. Excess relative risk per 1 Gy for all solid tumours together was 0.60 and 0.64 for mortality and incidence in women, but 0.28 for both endpoints in men. Although clarification is still needed with regard to the form of the dose-effect relationship for various tumours (cf. Section 4.1.1), these results suggest that there are indeed gender-specific differences with regard to radiation-induced carcinogenicity. It is, however, questionable whether these should impact radiological protection practices. There is, for example, no plausibility for a gender-specific impact on detriment. If gender-specific risks for specific carcinomas are reported, their share in the detriment is either very low (e.g. thyroid) or the estimate of the gender-specific difference is associated with considerable statistical, epidemiological and sometimes also diagnostic uncertainty. The factor of 2 in excess relative risk in the LSS study does not seem to translate into a similar factor in detriment. For reasons of practicability and in light of insufficient scientific evidence, overall, gender-specific radiological protection remains unwarranted.

It seems that differences with regard to stochastic effects cannot generally be transferred to tissue reactions. It would appear that the SSK finding of 2009 (SSK 2009a) that there is no evidence of more severe side effects of appropriate radiotherapy in either women or men continues to hold true (Foray und Bourguignon 2019).

Conclusion: The SSK finds that, while relevant studies provide indications of possible gender-specific differences in radiosensitivity, clear evidence is lacking. Currently, the SSK sees no basis for incorporating possible gender-specific differences in radiosensitivity in the system of radiological protection. However, the SSK does recognise the need for further research to provide conclusive evidence of gender-specific differences in the radiation-induced incidence of tumours in specific organs and in the radiation sensitivity of entire organisms, and to understand them on the basis of molecular, cellular and tissue reactions to irradiation.

3.2 Issues of practical implementation

In addition to fundamental aspects of radiological protection strategies, issues of practical implementation play an important role, not least with regard to the goals of clarity and transparency, which are required so that radiological protection and its principles can be supported and communicated by practitioners. The principles of justification, optimisation and dose limitation are the main pillars of radiological protection. This section provides a brief overview of the SSK recommendations on dose limits

- for occupational exposures;
- for the public; and
- with regard to organ dose limits.

The directly related recommendations and statements are referenced where necessary.

3.2.1 Limits for occupationally exposed persons

In the last two decades, the SSK has produced recommendations on the area of limits for occupationally exposed persons, in particular on justification of activities, calculation of doses, introduction of dose constraints and justification of the limits for occupationally exposed persons. These SSK recommendations assume, as does ICRP Publication 103 (ICRP 2007a), that protection of human health and the environment from the adverse impacts of ionising radiation should continue to be based on the foundational principles of justification, limitation and optimisation.

The recommendation "Introduction of dose constraints to protect against occupational radiation exposure when transposing Directive 2013/59/ Euratom into German radiological protection law" of December 2014 (SSK 2014c) is of foundational importance for occupationally exposed persons. This recommendation refers to the implementation of the basic radiological protection standards of 2013 (Euratom 2014) and specifies dose constraints for occupationally exposed persons below the existing dose limits. It handles issues such as: in how far the existing regulations on dose constraints and optimisation instruments are compatible with the requirements laid down in Directive 2013/59/Euratom in the field of nuclear technology; whether and potentially under what conditions an improvement in occupational radiological protection can be expected from the introduction of dose constraints in line with this directive; and whether and in which areas outside of nuclear technology an improvement in occupational radiological protection can be achieved with the introduction of dose constraints or other optimisation instruments used in nuclear installations. For the area of nuclear power plants and installations for nuclear supply in particular, the recommendation finds that the existing regulations and optimisation instruments in radiological occupational health in this area are in line with the requirements laid down in Directive 2013/59/Euratom and that no additional dose constraints are necessary in radiological occupational health beyond the existing on-site dose constraints. The recommendation covers conditioning installations, interim storage of radioactive waste, research institutes, radionuclide laboratories, medicine, accelerators, industrial radiography, the NORM industry, transports of radioactive materials and flight personnel, providing different recommendations for each area. In most cases, the SSK concludes that the introduction of dose constraints would not be an appropriate optimisation instrument for radiological protection; instead, the focus should primarily be on identifying the reasons for any marked differences in exposures. This recommendation is thus directly linked to Section 5.9 of ICRP Publication 103 (ICRP 2007a) and examines the form it takes in the German regulatory system and in practical radiological protection activities in Germany.

The SSK recommendation "Basic principles for determining dose limits for occupationally exposed persons" of September 2018 (SSK 2018) is also fundamentally important. The starting assumption is the finding, which is consistent with that of ICRP Publication 103 (ICRP 2007a), that the limits were derived with the aim of preventing detrimental deterministic effects and limiting the probability of inducing stochastic effects to a level deemed tolerable. The detailed recommendations of the SSK in this document are tailored for the protection strategies and standards for

- workplaces with ionising radiation and carcinogenic substances, for which a more thorough alignment is recommended;
- limiting the lifetime occupational dose, which, in Germany, is an effective dose of 400 mSv. In principle, it is recommended to maintain this, with, however, continuing discussion about the level of the dose limit;
- limiting the annual dose, which has been unchanged for more than 20 years at 20 mSv per year; maintaining this is recommended; and

– identifying areas requiring action, which especially includes efforts to reduce existing uncertainties in quantifying the risks of ionising radiation and to increase transparency of the estimation and decision-making processes to improve understanding of the risk management measures taken.

In this way, this SSK recommendation (SSK 2018) builds on ICRP Publication 103 (ICRP 2007a) and interprets it for the specific situation in Germany (e.g. with regard to the occupational lifetime dose, which is an extension of the ICRP concept); however, it does not deviate from the principles of ICRP.

The SSK recommendation "Risk of Cancer attributed to exposures during several years close to the dose limit for the professional life according to § 56 StrlSchV" of April 2007 (SSK 2007) also has a direct link to these topics. The recommendation examines the issue of cancer risk for individuals who receive doses in the range of the lifetime occupational dose of 400 mSv within a relatively short period in order to evaluate the limit for lifetime occupational dose according to section 56 StrlSchV (2001). The studies on cancer risk that were evaluated lead to the conclusion that, after lengthier periods of exposure with a total dose in the range of the lifetime occupational dose limit, there are indications of an increased cancer risk and no indications that the risk coefficient would be lower than for acute exposures as in atomic bomb survivors. In the view of the SSK (SSK 2014a), although the results do not rule out the DDREF value of 2 as recommended by ICRP, they do likely indicate that, under certain limiting conditions, no DDREF should be used for low dose-rate exposure. On this basis, the SSK maintains its decision not to recommend retaining a reduction factor for cancer risk after exposure with low-dose rates (cf. Section 3.1.1). This recommendation thus contradicts the findings in ICRP Publication 103, where ICRP expresses its view: "that the adoption of the LNT model combined with a judged value of a dose and dose rate effectiveness factor (DDREF) provides a prudent basis for the practical purposes of radiological protection, i.e., the management of risks from low-dose radiation exposure," and that ICRP "finds no compelling reason to change its 1990 recommendations of a DDREF of 2".

In the directly related recommendation "Dose- and dose-rate effectiveness factor (DDREF)" of February 2014 (SSK 2014a), the SSK re-examines the DDREF on the basis of a survey of the current state of scientific knowledge, following more recent publications from UNSCEAR and WHO that did not use the factor. Radiobiological and radiation epidemiological studies were analysed and additional criteria relevant to radiological protection were consulted to assess the DDREF. In the summary assessment, the SSK states that the evaluated studies could not provide a basis for a uniform understanding of the DDREF. Based on these findings, the SSK no longer considers there is no longer sufficient justification for the DDREF used in radiological protection and recommends discontinuing its use. The SSK also suggests international coordination on this issue. This reaffirms the already-mentioned position of the SSK (SSK 2014a) with regard to the DDREF (cf. Section 3.1.1), which deviates from ICRP Publication 103 (ICRP 2007a).

The recommendation "Basis for calculations determining body dose equivalents for external radiation exposures" of December 2016 (SSK 2016b) pertains to calculating body doses, including for occupationally exposed persons. In this publication, the SSK presents the method for dose calculation for photon radiation, neutron radiation, electron radiation and mixed radiation fields as well as contamination of the skin surface. This particular publication is a third edition, which takes into account changes in radiological base data and in the legal framework for radiological protection since the previous edition. This update includes, in particular, the ICRP-recommended drastic reduction of the limit value for the equivalent dose for the eye lens and the changed radiation and tissue weighting factors. This SSK publication

builds on the framework set out in ICRP Publication 103 (ICRP 2007a) and the further ICRP recommendations based on it.

The basic principle of justification in all areas of radiological protection (activities, practices, medical procedures and applications as well as interventions) is explored in the recommendation "Justification: Criteria for the evaluation of practices and procedures" of February 2006 (SSK 2006b). The general position of the SSK that the establishment of a binding procedure for justification is required is fully in agreement with ICRP Publication 103 (ICRP 2007a). Benefits and risks of the actions to be justified and their radiation-free alternatives need to be examined in line with the current knowledge and technology, giving due consideration to radiation exposure and the associated risk, environmental impacts and economic and social factors. Conversely, planned human actions that result in the radiation exposure of humans and the environment and are classified as not justified are prohibited under German law.

Another notable SSK recommendation in this context is "Organisational requirements for operational radiological protection to be successful" of February 2020 (SSK 2020b). In this recommendation, the SSK focuses on which circumstances require the introduction of a formalised management system to achieve comprehensive, effective and efficient radiological protection in an organisation; which requirements are appropriate for this type of system; and which rules and requirements are conducive to ensuring the good cooperation of multiple radiation protection officers in fulfilling a responsibility or linked responsibilities. Related topics are mentioned in ICRP Publication 103 (ICRP 2007a), particularly in Section 5.5 and in detail in Section 6.6. The SSK recommendation sets out provisions for successfully implementing radiological protection and complying with limits for occupationally exposed persons that are in line with ICRP Publication 103.

Conclusion: Further efforts should be made to standardise the terms and concepts used to derive dose limits and to stipulate methods for estimating and evaluating health risks in a range of different workplaces.

In the opinion of the SSK, the justification behind the current 100 mSv effective dose limit over a period of five years should be reviewed. Although the scientific evidence required to evaluate radiation-related health risks at such doses remains unchanged, society's view of the associated risks is certainly subject to change over time, thus increasing the need for such review. An open discussion should be fostered that takes social and scientific aspects into account with the aim of arriving at a consensus regarding the occupational exposure risks deemed tolerable for society.

The current radiological protection system provides no lifetime occupational dose limit. The SSK proposes considering whether the introduction of a dose limit for the occupational lifetime could be an appropriate complement to existing annual dose limits and five-year dose limits.

3.2.2 Limits for the general population

A working group of the SSK is developing a statement on "Basic principles of determining radiation exposure limits for the general public" to evaluate the current limits on public exposure of 1 mSv per year as a result of planned activities. This statement first compiles information on doses the public receives due to planned radiation exposure from anthropogenic sources in Germany. The effective doses calculated are around at least two orders of magnitude below the limit of 1 mSv per year, and additionally, the calculation method overestimates actual exposures. The statement also presents the current scientific research with regard to cancer incidence risks attributable to an effective dose. There is sufficient evidence enabling the estimate of cancer risks due to X-rays and gamma radiation exposures with an annual dose of

3 mSv over a period of multiple decades, which allows for the extrapolation of claims regarding a longer-term exposure with an annual dose at the level of the dose limit. However, because this kind of estimate is subject to considerable uncertainty, which cannot reliably be determined at this point in time,the SSK concludes that a lower dose limit would not provide an additional protective effect for the public. In this statement, the SSK reaffirms the current ICRP dose limit.

There are two SSK recommendations that are directly related to this topic and focus on the methods for calculating radiation exposure, the recommendation "Determining Radiation Exposure" of September 2013 (SSK 2013) and the recommendation "Implementation of the dose limit for members of the public for the sum of exposures from all authorised practices" of February 2015 (SSK 2015b). Both recommendations cover requirements for the degree of reality in determining radiation exposure on the basis of radioecological modelling systems; the 2015 recommendation includes the concrete design of individual calculation steps and model assumptions and was used for preparing AVV activities (BMU 2020). Both recommendations are therefore consistent with ICRP Publication 103 (ICRP 2007a) and implement the requirements of ICRP Publication 101a (Representative Person, ICRP 2006).

In the context of dose limits for the public, other notable recommendations include "Operational intervention levels for measures to protect the population against incidents involving releases of radionuclides" of October 2019 (SSK 2019), which focused in particular on the development of operational intervention levels (OILs) triggering the intervention levels for early measures in emergencies and radiological criteria and operational intervention levels for (gradually) halting measures in emergency and existing exposure situations. The various derived reference levels for short and longer periods and for triggering various protective measures conform with the recommendations of Section 6.2 of ICRP Publication 103 (ICRP 2007a).

Conclusion: The SSK suggests asking ICRP to more clearly formulate the reasoning for the selection of the value of 1 mSv per year as the transition between the lowest and medium bands of the dose constraints and reference levels (Table 5 in ICRP Publication 103) and for the selection of the dose constraint for the public in its revision of the basic recommendations. In particular, potential benefits or potential disadvantages of lowering the level should be considered, taking into account all aspects of radiological protection and the associated costs (including adapting the regulations for occupationally exposed persons).

3.2.3 Organ dose limits

"Equivalent dose limits for occupational radiation exposure" of December 2020 (SSK 2020a) is a current and important SSK publication on applying organ dose limits. It advises against an equivalent dose limit beyond the organ dose limits provided in Directive 2013/59/Euratom (Basic Safety Standards, Euratom 2014) as already transposed in the German Radiation Protection Act. The basis for this recommendation is the finding that there is no evidence for the potential occurrence of radiation-induced diseases outside of cancer, benign tumours or heritable genetic diseases in other organs at the maximum equivalent dose that occurs in these organs when complying with limits on the effective dose and the equivalent dose in the eye lens, skin and extremities. In this recommendation, the SSK examines the dosimetry concept of ICRP Publication 103 (ICRP 2007a) for concrete application in the context of German radiological protection law. The principles developed in this SSK recommendation are also the basis for forgoing provisions for organ doses in calculating the radiological impacts of discharges in normal operation, as described in the general administrative provision on activities (*AVV Tätigkeiten*, BMU 2020).

There are specific recommendations for the eye lens and skin, "Monitoring the Eye Lens Dose" of July 2015 (SSK 2015a) and "Dose limits for occupational skin exposure to ionising radiation" of October 2011 (SSK 2011). The first recommendation focuses primarily on

verification with measurements and on the appropriateness of various dose measurement parameters for measuring the equivalent dose for the eye lens, rather than the organ dose limit for the eye lens. The second recommendation finds that a change in the existing organ dose limit for the skin together with limiting the effective dose does not seem to be indicated and, in this regard therefore, is in line with the recommendation "Equivalent dose limits for occupational radiation exposure" as well as the recommendations of ICRP Publication 103 (ICRP 2007a).

Conclusion: The current regulatory framework with regard to guidance on organ dose limits conforms with ICRP Publication 103 (ICRP 2007a). Because there appears to be no need in Germany to change the current status, there are no suggestions here for ICRP with regard to revising the basic recommendations.

3.2.4 Operational Intervention Levels (OILs)

ICRP Publication 103 (ICRP 2007a) proposes establishing a reference level from 20 mSv to 100 MsV residual effective dose in the first year in an emergency exposure situation. For the user, however, there are no indications provided on which level is proportionate and justified depending on the scale and severity of the protective measures under consideration. This can lead to the use of inappropriate reference levels and also to the justification of serious interventions in the lives of members of the general public. In the view of the SSK (SSK 2019), this is the case, for example, with the relocation measures following Fukushima, where the authorities settled on a reference level of 20 mSv residual effective dose, meaning the lowest level in the recommended range. In its protective measures for handling the radiological impacts, Japan appears to have primarily chosen restrictive operational intervention levels, probably with the expectation that this would be more likely to engender public confidence. Further examples of this include the tightened maximum permitted values in food and Japan's waste criteria for decontamination measures. Although this conforms with the very common approach in radiological protection of making conservative assumptions across the board, the necessary proportionality and justification of protective measures in radiological emergencies can be brought into question.

A quotation from the SSK recommendation "Operational intervention levels for measures to protect the population against incidents involving releases of radionuclides" (SSK 2019) provides further explanation:

> "An overarching reference level for the residual dose per year applies to an emergency exposure situation and following recategorisation as an existing exposure situation. As stipulated in ICRP 103, the initial reference level for emergency exposure situations needs to be established in the band from 20 mSv to 100 mSv effective dose in the first year. Because protective measures can also include very serious interventions such as relocation, the SSK has set a residual effective dose in the first year at the upper reference level of 100 mSv, in accordance with the Basic Radiological Principles (SSK 2014b). This level was also used in Section 95 of the Radiation Protection Act (StrlSchG 2017), However, this level may be reduced during the course of an emergency for optimisation purposes. The responsible authority must set a reference level of up to 20 mSv residual dose per year for existing exposure situations, although the aim is to reduce it to around 1 mSv a^{-1} effective dose over time."

Additionally, on the topic of relocation, another quotation from Section 5.6 of the SSK recommendation "Operational intervention levels for measures to protect the population against incidents involving releases of radionuclides" (SSK 2019) is relevant:

> "Considerations on ordering 'relocation'

‘Relocation’ has a much greater impact than ‘evacuation’. ‘Relocation’ is used to describe the transfer of residents from one area to another during a post-accident phase, and only serves to prevent external irradiation from the ground and inhalation of resuspended radioactive substances. It has a far more invasive and prolonged effect on the private, social and business life of residents, which is why decisions are based on both radiological and non-radiological aspects. Only the radiological aspects are covered in this recommendation.

An informed decision regarding ‘relocation’ can only be taken once the radiological situation has been ascertained on the basis of the level and spatial distribution of contamination by dry or wet (rain) deposited radionuclides and their exposure-critical characteristics such as half-life, emitted (e.g. penetrating) radiation, behaviour in the biosphere, etc. Here, public exposure largely attributable to prolonged external radiation from gamma-emitting radionuclides. In areas evacuated at an earlier stage, this short-term measure may ultimately lead to ‘relocation’. Once the prevailing radiological situation has been assessed, there is no immediate urgency to make an informed decision on relocation or measures to be taken promptly or even as a precaution, e.g. evacuation, as relocation is designed to limit the external doses accumulated from gamma radiation over prolonged periods.

The primary radiological benchmark for this protective measure, which encroaches heavily on those affected, is the residual effective dose projected for representative persons in the first year. This recommendation does not provide an operational intervention level for ‘relocation’ because the decision to employ this severe measure relies heavily on a number of influencing factors which only become apparent once the incident occurs, e.g. characteristics relating to the affected area, development of the local dose rate over time as a function of the main radionuclides present in the contamination, possible decontamination measures and behavioural recommendations, public responses or sociopsychological aspects influencing the feasibility of the measure.

Instead, this recommendation describes key factors and considerations for ‘relocation’ in terms of radiological emergency response.

The reference level of 100 mSv residual dose in the first year is the suitable benchmark as a radiological criterion for ‘relocation’ for the first year after a contamination occurs. Reference levels for subsequent years are not predetermined. When making a decision about ‘relocation’, the projected effective dose via all exposure pathways in the first year is assessed and compared to the reference level. The ingestion pathway does not need to be taken into account as it can be assumed that there are sufficient uncontaminated or only slightly contaminated foodstuffs available. Residual dose assessments in the first year should be as realistic as possible and include the impact that implemented protective measures and typical public behaviours would have on the assessments. The setting of a dose as representative as possible of the population’s location and duration of stay is key to this area. Modelling for exposure of individuals is largely influenced by the assumption relating to the average amount of time representative persons spend outdoors in the contaminated area.”

3.2.4.1 Operational intervention levels (OILs)

Operational intervention levels are easily accessible parameters for decision-making about appropriate measures.

Operational intervention levels (OILs) are necessary for these decisions on protective measures in emergency situations and existing exposure situations. This term is not used in the ICRP publications.

In the SSK recommendation "Operational intervention levels for measures to protect the population against incidents involving releases of radionuclides" (SSK 2019), the approach to determining operational intervention levels is described for a number of protective measures.

3.2.4.2 Establishing operational intervention levels (OILs) for protective measures

On this point, it is important to choose a dose constraint such that the protective measure can provide proportionate and justified radiological protection. It is key to clearly differentiate between intervention levels and dose limits. ICRP Publication 103 (ICRP 2007a) distinguishes very clearly between limits in planned activities and intervention levels for radiological incidents leading to an emergency and existing exposure situation.

The SSK recommendation on operational intervention levels (SSK 2019) uses the term "dose constraint" deliberately to illustrate that this is a constraint and not a limit.

3.2.4.3 Modelling the exposure pathway

The decisive factor here is that the assumptions and parameters used to model the relevant exposure pathway are as realistic as possible. This presents problems for some radiological protection professionals insofar as they are accustomed to preferring conservative assumptions in analyses of planned exposures. Additionally, it is much easier to use and justify conservative assumptions and parameters. Making realistic assumptions and setting realistic parameters, in contrast, requires greater effort and expertise.

Conclusion: Operational intervention levels are easily accessible parameters for decision-making about appropriate measures. Operational intervention levels (OILs) are necessary for decisions on protective measures in emergency situations and existing exposure situations. This term is not used in the ICRP publications. it is important to choose a dose constraint such that the protective measure can provide proportionate and justified radiological protection. This requires use of realistic assumptions and parameters when modelling the exposure pathway.

4 Additional topic areas identified by the SSK for further treatment

4.1 Fundamental issues

Despite acknowledgement of the unquestionable successes in recent years, broader radiological protection circles are thinking about improving and adapting radiological protection to current developments, and in certain areas deficiencies have been noted. These relate to technical aspects of regulatory frameworks, implementation and communication and its results relating to the perception of radioactivity, radiation and their impact, as well as, in particular, societal acceptance of radiological protection measures.

The SSK takes these critical discussions seriously and sees the following points as relevant for the future development of radiological protection:

– The radiological protection system has become more and more complex over the course of time. The possibility of simplifying key issues should be reviewed.

– Quantities and units in radiological protection and the distinction between protection quantities and operational quantities must be explained clearly.

– The system of limits, intervention levels and reference levels and the organisation of these levels must be clearly described and well justified in the various exposure situations.

- In particular, the role of dose constraints must be presented in a credible way to avoid misunderstandings.
- Clarity needs to be created around what should be considered tolerable or acceptable without additional optimisation in line with the ALARA principle in the different exposure situations.
- Guides should be developed on how the principles of radiological protection can be communicated in a way that is both scientifically correct and generally comprehensible (e.g. the different dose-risk models – in particular the LNT model – particularly in light of the major uncertainties).
- The purpose, possibilities and above all limits of epidemiological studies in evaluating the risks of low doses of radiation should be highlighted.
- Unjustified conservativeness should be avoided.
- ICRP should avoid making recommendations before a broad scientific consensus has had time to emerge (some problematic past examples: radon, cataract, environmental protection).
- The risks of incorporation relative to those of external exposure must be explained clearly.
- The lessons from the Fukushima Daiichi accident, summarised comprehensively by UNSCEAR and the SSK, should be incorporated in future recommendations.

4.1.1 The LNT model

Many decisions in radiological protection depend on the estimation of the stochastic risk associated with a particular dose, in particular the risk of cancer incidence or cancer mortality. For medium and high effective doses, e.g. above 50 mSv to 100 mSv, fairly robust data are available from long-term studies of the atomic bomb survivors of Hiroshima and Nagasaki and other epidemiological studies (e.g. Ozasa et al. 2012, Grant et al. 2017). In radiological protection, however, the general focus is on low doses on the order of a few millisieverts,where there is much less certain data on their potential effect. Making certain assumptions for stochastic risk in this dose range, chiefly regarding whether it is possible to extrapolate findings from high to low doses, therefore cannot be avoided. The predominant underlying model is that of linear dose dependency without a threshold dose, i.e. it is assumed that the cancer risk increases proportionally with the dose, and that no dose can be associated with zero risk (linear non-threshold model – LNT).

ICRP already recommended assuming this type of dose dependency more than 50 years ago in Publication 9 (ICRP 1966): "…as the existence of a threshold dose is unknown, it has been assumed that even the smallest doses involve a proportionately small risk of induction of malignancies." Since then, the assumption has not changed, even though the arguments used to support it have not always been the same. In Publication 103 (ICRP 2007a), ICRP writes: "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." The approach here is less about the scientific evidence for extrapolating cancer risk from high to low doses; rather, it is a pragmatic assumption that, firstly, does have a certain plausibility and, secondly, reflects the ethical principle of prudence in the sense of care or caution (good sense, moderation) (ICRP 2018b).

The SSK has continuously supported this use of the LNT model and taken it as a basis for its own deliberations. Thus, for example, the recommendation "Basic principles of determining

dose limits for occupationally exposed persons" (SSK 2018) discusses a number of more recent studies that not only update risk assessments for the atomic bomb survivors but also perform similar analysis on data from other cohorts. These cohorts included over 20,000 workers in the Russian Mayak nuclear power plant (Hunter et al. 2013, Sokolnikov et al. 2015), almost 60,000 workers in the French nuclear industry (Metz-Flamant et al. 2013), over 300,000 workers in the French, British and American nuclear industries (Leuraud et al. 2015) and 30,000 people residing near the Techa River in Russia, who were subject to chronic radiation exposure due to radioactivity in the drinking water (Schonfeld et al. 2013, Davis et al. 2015). While the Mayak study finds somewhat lower excess relative risk than the study of Hiroshima and Nagasaki, the results of these other studies generally support the assessment to date. This is noteworthy, not least due to the fact that the cohorts were not subject to acute radiation like in Hiroshima and Nagasaki, but to sporadic exposure with low partial doses or chronic exposure over many years. The results must therefore also be discussed in relation to the currently assumed dose and dose rate effectiveness factor (cf. Section 3.1.1). With regard to the assumption of linear non-threshold dose dependency, it is of course significant that none of the more recent studies indicates deviations from linearity. However, a threshold dose in the range from below 50 mSv to 100 mSv cannot be ruled out due to the relatively large statistical uncertainties.

The syntheses and meta-analyses published in the last five years have not yet been discussed by the SSK (cf. overview in Rühm et al. 2022). For example, the US National Council on Radiation Protection and Measurements (NCRP) came to the conclusion: "The most recent epidemiologic studies show that the assumption of a dose-threshold model is not [just] a prudent pragmatic choice for radiation protection purposes. The consistency of the better-designed and larger studies with dose-response functions that are essentially linear or LQ, argues for some risk at low doses." (Shore et al. 2018) A monograph published by the US National Cancer Institute made a similar argument: "…new epidemiological studies directly support excess cancer risks from low-dose ionizing radiation. Furthermore, the magnitude of the cancer risks from these low-dose radiation exposures was statistically compatible with the radiation dose-related cancer risks of the atomic bomb survivors" (Hauptmann et al. 2020). The conclusions of some studies on dose dependency for specific cancer entities were less clear cut. While there was no evidence of deviations from linearity, the summary study of different groups of cancer indicated differences if lung, breast, uterus, CNS and prostate cancer were analysed separately. For example, detailed analyses of the newest data from Hiroshima and Nagasaki suggested that dose dependency in exposed men may be better fit by a linear-quadratic model, while there was no evidence of deviation from linearity for women who were exposed (Grant et al. 2017). For men, however, the quadratic components of the model fit mostly disappeared when CNS, esophageal, bone, thyroid and (non-melanocytic) skin cancer were excluded. For women, the fit was stronger if breast, stomach and thyroid cancer were excluded. The authors concluded: "analysis based on all solid cancer as a single outcome is not the optimal method" (Cologne et al. 2019). For skin cancer (Sugiyama et al. 2014), a linear dose-response relationship with a threshold dose of 0.63 delivered the best fit (cf. Section 3.1.3).

ICRP will certainly want to follow up on all of these indications of deviations from strict linearity in its discussions of epidemiological evidence. ICRP will also have to deal with the basic issue of the plausibility of the LNT model in the low-dose range. Although the critical study by the French Academy of Sciences, which was strongly in favour of assuming a threshold dose (Tubiana et al. 2005), was available to ICRP during its discussions to prepare its most recent general recommendations and did receive attention (ICRP 2007a), it was not discussed in detail and its supporters have repeatedly reiterated its arguments (Calabrese 2021, Scott 2021). The report of the High Level Expert Group (European Commission 2009), which led to the establishment of various European networks for radiological research and has since then been instrumental in setting the research priorities of EURATOM, reflected the view that

more recent findings on the mechanisms of radiation effects have thus far not gained much of a foothold in the scientific foundations of radiological protection. The relevant biological issues include: adaptive response, the bystander effect, genomic instability, tissue effects, hormesis (cf. overview in Averbeck et al. 2018). However, it must be pointed out that these effects, should they have significance for the cancer risk of low doses, in no way all support a threshold dose, but rather in some cases suggest supralinearity.

Conclusion: The SSK does not currently see any proof that findings on biological effects suggesting a non-linear dose-response relationship would contradict the use of the LNT model for radiological protection purposes. However, the SSK recommends a thorough review of the underlying argumentation. It must nevertheless be reiterated that using a linear dose-response relationship as a basis for risk estimates in radiological protection does not imply linearity of the fundamental biological effect mechanisms. In this regard, the LNT model is first and foremost an instrument of radiological protection, not necessarily a description of an effect mechanism.

4.1.2 Detriment

The purpose of the ICRP detriment concept is to enable a quantitative comparison of stochastic radiation damage for the various organs. To do so, organ-specific nominal risk coefficients are weighted using a function intended to express the amount of damage or, respectively, the severity of a disease. This function incorporates a variety of variables that do not depend on radiation parameters, but on characteristics of the disease itself.

The concept of detriment as described in ICRP Publication 103 (ICRP 2007a) neither reflects a pure mortality risk model nor a pure incidence risk model. Instead, ICRP defines a weighted probability of harm (detriment) for each type of cancer and heritable effects, which takes into account both the likelihood of cancer increased by radiation exposure and certain "non-radiation" parameters such as the lethality of a cancer type, the loss of life expectancy, and the reduction of quality of life. For example, with equal probability of occurrence, a thyroid cancer with a good prognosis is rated and weighted less than lung cancer with poor prognosis and high lethality. The damage-weighted risk per dose is referred to as "detriment" (unit Sv^{-1}).

The parameters that are involved in the determination of the risk coefficient, such as the model of the linear no-threshold dose–response relationship (LNT, cf. Section 4.1.1) or the dose and dose-rate effectiveness factor (DDREF, cf. Section 3.1.1) are the subject of lasting debates in the radiological protection community and are in some aspects controversial. The ICRP definition of the detriment, particularly the measure of damage, in contrast, is surprisingly little discussed and hardly questioned. This is even more remarkable because both the method of including the radiation damage and the choice of values for the "damage parameters" (lethality, loss of life expectancy, and reduction of quality of life, see below) can be done very differently. (Breckow 2020). Both the selection of parameter values and their relationship in the ICRP detriment model involves only some limited objective components, meaning that these already include a certain assessment of the relevance or significance of damage. The ICRP detriment model represents one possible, but not the only possible measure of a damage-weighted risk. Not least for this reason, the SSK recommendation on DDREF calls for "in the case of adjusting the DDREF […] in parallel all of the other parameters pertaining to the detriment (should) be adapted to the latest scientific findings" (SSK 2014a).

In ICRP Publication 60 from 1990 (ICRP 1991b), ICRP had already developed a similar model based on mortality data to describe a weighted probability of damage. In ICRP Publication 103 (ICRP 2007a), this model has been refined and is now essentially based on incidence data, expressed by the nominal risk coefficient R_I with respect to a cancer type or organ. The sum of all organ-specific detriments is the "total" detriment, which is given in ICRP Publication 103

for the whole population as 5.7% per Sv. This includes the detriment for hereditary damage with 0.1% per Sv, which, therefore, plays a minor role compared to that for cancers.

The detriment for each organ or each type of cancer comes from the product of the nominal risk coefficient R_I and the severity of the damage.

The "minimum quality of life" q_{min} is a decisive parameter in the damage function. The larger q_{min}, the more restrictive a (non-fatal) cancer is considered and the stronger the assessment of the associated reduction of quality of life. A larger q_{min} means greater damage and, thus, a greater detriment with the same incidence probability. In addition, a larger q_{min} means a less pronounced dependency on lethality (Cléro et al. 2019, Breckow 2020). Surprisingly, ICRP makes little use of the possibility to reproduce this variability which, in principle, is incorporated in the detriment model: almost all organs are assigned the same value for q_{min}.

With the important exception of skin cancer (cf. Section 3.1.3), the minimum quality of life variable, q_{min}, and the relative loss of life expectancy have only a small impact on the amount of damage, whereas the lethality factor has a very strong effect. This is in good agreement with sensitivity analyses by Zhang et al. (Zhang et al. 2020), who investigated the influence of various parameters on the detriment calculation.

The ICRP detriment is a useful tool for defining a measure of damage which considers, in addition to lethality, non-fatal contributions as well. It offers the possibility to compare different cancers or organs in terms of their contribution to the total risk. The degree of damage represented in the detriment model by a weighting function does not depend on any radiation parameters. It is subject to a temporal trend that reflects the improved prognosis through advances in cancer diagnosis and therapy (Breckow 2020). However, this also means that the detriment, i.e., the "radiation risk" may decrease over time, even if the nominal risk coefficient remains unchanged. This circumstance is not without problems for acceptance and may raise questions as to whether this type of definition of detriment adequately represents radiation risk.

The damage function includes several parameters that are intended to represent the severity of a cancer. However, other values or even other parameters could be conceivable, such as the severity of cancer therapy and its side effects, which could be incorporated into a model as well. However, completely different models would also be feasible. Not only a "refinement" of the model, but on the contrary also a coarser model could fulfil the intended purpose of the detriment concept. A suitable model that aims in this direction could, for example, be an approach that only considers the mortality alone and no other parameters.

The ICRP detriment model serves, among others, the purpose of laying the foundation for the concept of the effective dose by determining the tissue weighting factors w_T. The w_T values for the different organs roughly represent the ratio of the organ-specific detriment to the total detriment. However, these ratios, as well as other characteristics of the effective dose, would not necessarily have to change if another, perhaps simpler model, was chosen.

Both the effective dose and the underlying concept of detriment are for radiological protection purposes only and are not suitable to carry out risk estimates for individuals or special populations (e.g. SSK 2003). It is true that dose limits are based on risk assessments. However, both in radiological protection and other areas of environmental and occupational protection, the risks that are considered as and are consequently linked to dose limits are not determined on the basis of a detriment but as a rule by considering mortalitiy data. This process is described in detail in an SSK recommendation on the justification of dose limits (SSK 2018). Various damage-weighted risk variables are known in environmental and occupational protection, such as the concept of DALY (Disability Adjusted Life Years) of the World Bank and the WHO (described, e.g., in SSK 2018). The ICRP concept of detriment, however, is applied nowhere

outside of radiological protection. Thus, at least for this reason, with this concept, no comparability with carcinogenic substances from other areas can be achieved.

Conclusion: The concept of detriment certainly is of some elegance and does seem to help reflect the contributions of the different organs to radiation-induced risk. However, this subtlety comes at the expense of transparency and comprehensibility of risk assessments in radiological protection. The question is whether fine-tuning like this is really needed for the purposes of radiological protection or whether a simpler but more transparent model would be equally suitable.

4.1.3 Introduction of a traffic light model for communicating radiological protection

The 1977 ICRP Publication 26 formulated a comprehensive concept of radiological protection (ICRP 1977a). It distinguished between stochastic and non-stochastic effects and proposed extending radiological protection to workers and the general public.

The publication recommended not only dose limits but also the general radiological protection principles justification and optimisation. Optimisation was specified further as the ALARA principle (keeping doses as low as reasonably achievable, economic and social factors being taken into account). ICRP Publication 26 also gave a general rationale for the dose limits:

“The aim of radiation protection should be to prevent detrimental non-stochastic effects and to limit the probability of stochastic effects to levels deemed to be acceptable.”

The situation for stochastic effects is far more complicated than that for non-stochastic effects, for which there is a threshold dose. Radiological protection assumes that there are no threshold doses for stochastic risks (such as malignant tumours, leukaemia, hereditary diseases). Hence the higher the radiation dose, the greater the number of persons affected, although the severity of the disease is not dependent on the level of the radiation dose. This raises the question of what is considered an “acceptable” dose. The approach taken in Publication 26 compares the radiation-induced stochastic risk of occupationally exposed persons with the risks in other occupations regarded as “safe”: “comparing this risk with that for other occupations recognised as having high standards of safety”. Using this approach in combination with some other assumptions, ICRP concluded that the risk associated with an equivalent dose of 50 mSv per year was “acceptable.” This concept was aligned with the approach taken in other professions and explained in detail in ICRP Publications 27 (ICRP 1977b) and 45 (ICRP 1985). It should be noted here that the term "acceptable" as used in these early ICRP publications corresponds to the term "tolerable" in ICRP Publication 60, which is also used in this meaning in the following.

However, ICRP Publication 60 (ICRP 1991b) did not continue with this comparative approach. Instead, it sought to define the terms “unacceptable” “tolerable” and “acceptable”. “Unacceptable” means a risk is not acceptable under normal operations, although it might have to be accepted after accidents or disasters. “Tolerable” refers to situations that are not welcome but can be tolerated, while “acceptable” means risks that can be accepted once protection has been optimised. ICRP Publication 60 drew the boundary between unacceptable and tolerable at an annual occupational probability of death by exposure of 1 in 1,000. This was justified as follows (ICRP 1991b, Annex C, C14):

“A report of a Study Group of the British Royal Society (1983) concluded that imposing a continuing annual occupational probability of death of 1 in 100 would be unacceptable, while they found the situation less clear with regard to an annual probability of death of 1 in 1000. They felt that the latter probability level could “hardly be called totally unacceptable provided the individual at risk knew of the situation, judged he had some commensurable benefit as a result, and understood that everything reasonable had already been done to reduce the risk.”

However, the annual probability of death is only one of the attributes which are appropriate to take into account. In the following, a number of other aspects will be considered."

Taking into account these considerations, more recent epidemiological data on the cancer risk in Hiroshima and Nagasaki, and a multiplicative model for risk assessment, an annual limit for occupational exposure was set at 20 mSv, i.e. 100 mSv in a five-year period, with no more than 50 mSv of exposure in a single year. This issue is not revisited by the current recommendations set out in ICRP Publication 103 **(**ICRP 2007a**)**, which maintain the existing limits.

Experience shows that in many cases dose limits, constraints and reference levels are not clearly differentiated, and their meaning is often misunderstood. With that in mind, the terms are explained here again in line with the ICRP Publication 103 glossary and the German Radiation Protection Act (StrlSchG 2017):

- A dose limit is the value of the effective dose or the equivalent dose to individuals from planned exposure situations that shall not be exceeded.
- A dose constraint is a prospective and source-related restriction on the individual dose from a source. The dose constraint provides a basic level of protection for the most highly exposed individuals from a source, and serves as an upper bound on the dose in optimisation of protection from that source. For occupational exposures, the dose constraint is a value of individual dose used to limit the range of options considered in the process of optimisation. For public exposure, the dose constraint is an upper bound on the annual doses that members of the public should receive from the planned operation of any controlled source.
- A reference level represents the level of dose or risk in emergency or existing controllable exposure situations above which it is judged to be inappropriate to plan to allow exposures to occur, and below which optimisation of protection should be implemented. The chosen value for a reference level will depend upon the prevailing circumstances of the exposure under consideration. While ICRP Publication 103 recommends specific values for dose limits and reference levels, it does not explain the grounds for selecting these values.

Laying down limits, constraints and reference levels should include clear definitions of "tolerable" and "acceptable" in relation to the radiation doses and risks. At present, however, ICRP basic recommendations do not always sufficiently distinguish between use of the terms "tolerable" and "acceptable*"*.

What is acceptable and what is tolerable depends on the respective situation, specific circumstances and social factors. Not everything that is desirable or appropriate is feasible, and not everything that is feasible is desirable or appropriate. What might be tolerated or accepted in an emergency may be neither tolerable nor acceptable in existing or planned exposure situations.

A traffic light model can be used to communicate the system of dose limits, constraints and reference levels (cf. Sections 3.2.1 and 3.2.2).

- The upper reference level for existing and emergency exposure situations constitutes the boundary between tolerable (amber) and no longer tolerable (red). In the tolerable range, protection must be optimised. In emergency exposure situations in the no-longer-tolerable range, action is necessary and virtually always justified.
- The lower reference level for existing and emergency exposure situations constitutes the boundary between acceptable (green) and tolerable (amber). Optimisation is necessary in the tolerable range. If the lower reference level is not reached in an emergency exposure situation, the situation should be treated as an existing exposure situation.

- In planned exposure situations, a dose limit is the dividing line between tolerable and no longer tolerable. The limit must not be exceeded. Below the limit, optimisation is required.
- In planned exposure situations, a de minimis level is a dose level below which additional doses from a source would be excluded or exempted from legal regulations. These doses are acceptable. However, whether or not a de minimis level generally marks the boundary between acceptable and tolerable is disputed.
- A dose constraint (as defined in German law) implies that anything below this level is acceptable in both existing and emergency exposure situations. In such cases, further optimisation of protection is no longer necessary.
- A dose constraint according to ICRP Publication 103 lies in the tolerable range in planned exposure situations. Below the constraint, optimisation is required. For existing and emergency exposure situations there are (according to ICRP Publication 103) no constraints, only reference levels (see above).

It must be pointed out that to date, limits set in radiological protection only clearly defined the boundary between tolerable and no longer tolerable. There is no generally valid definition of acceptability of radiation exposure that can be applied to all fields, even though indications can be derived from applicable rules and standards and the literature. For planned exposure situations there is only the ALARA principle. This does not include any general lower limit for exposures below the tolerance threshold. The goal is always “what is reasonably achievable” (ICRP 2007a). This could be the basis for deriving an acceptance threshold.

As an intuitive, easy-to-understand model, a traffic light system with tolerance and acceptance thresholds has potential as a communication method in radiological protection.

The tolerance risk would correspond to the dose limit in planned exposures and to the upper reference level in existing and emergency exposure situations. Any exceedance of the level would be deemed no longer tolerable. Optimisation should be undertaken in the amber range (below the dose limit in planned exposure situations, or between the respective reference levels in existing or emergency situations). This would follow the ALARA principle, social and economic factors being taken into account. There should be a discussion on whether a general acceptable risk can also be determined for planned exposures. This would mean that, in all three exposure situations, no further optimisation would be necessary below the acceptable risk.

How the traffic light system is used and presented would have to be tailored to the specific exposure situation.

Conclusion: Although the general concept of radiological protection has proven implementable and practicable, it is, at least in part, difficult to communicate. This applies in particular to the definitions of tolerable and acceptable risk, and the importance of constraints and reference levels as optimisation tools. A traffic light model, based on systems now commonly used in areas of environmental protection, occupational health and safety and food safety, could help improve communication in this area.

4.1.4 Practicable, realistic, individualised approach for the radiological protection system

The system of radiological protection set out in ICRP Publications 26 (ICRP 1977a) and 103 (ICRP 2007a) is certainly practicable. The SSK therefore advocates that, in principle, changes should only be made if they significantly improve radiological protection.

In the opinion of the SSK, new recommendations put forward for the revised ICRP Publication 103 need to be critically reviewed in terms of their practicability and impacts in practice. In

particular, it would be highly desirable to simplify the system, so that it can be communicated to the public more effectively. Unfortunately, all efforts in this direction have led to even more complicated and varied parameters.

The importance of justification must be stressed. Not only activities must be justified, but protective measures, too, as they can have both desirable and undesirable consequences. As part of justification, prospective dose calculations and risk assessments are generally carried out. In this context, the SSK recommends also considering total risks and total doses, proceeding as practically and realistically as possible.

ICRP Publication 103 lays down that any decision that alters the radiation exposure situation must do more good than harm. This principle, which is important in practice too (e.g. deaths due to evacuations after Fukushima), is also easy to communicate to the lay public and can help avert demands for unjustified radiological protection measures.

Recommendations that can be applied in practice and a realistic approach in dose and risk calculation also facilitate communication with the public and occupationally exposed persons. This underscores the need for the system of radiological protection to be as simple as possible. Excessively conservative risk and dose estimates can lead to counter-productive radiological protection measures which cause more harm than good. In general, realistic dose and risk estimates are essential for good radiological protection (SSK 2013).

The SSK views individual assessment of radiological risk as an important and beneficial means of optimising protection in the use of radiation for medical therapy and diagnosis. However, the disadvantages of using this approach in the general system of radiological protection should be weighed very carefully. This is especially the case if ICRP is considering changing radiological protection from a dose-based to an individualised, risk-based concept. Such approaches are only feasible for excess exposure situations in which all possible disadvantages (such as individual radiological risk in the insurance sector or in professional training) are ruled out.

Conclusion: Realistic dose and risk estimates are essential for good radiological protection. For that reason, conservativeness in dose calculations should be avoided as far as possible in favour of realistic figures for dose and risk. The radiological protection system should be simplified. In particular, individualising general radiological protection could complicate the system further and create disadvantages for the persons affected.

4.1.5 Uncertainties in radiological protection

All areas of radiological protection must factor in uncertainties and variability. This relates to measuring the activity of radiation sources and radionuclides in the environment, dosimetry, epidemiological risk assessment and, not least, the models used. Neither conformity with requirements nor verifiability of physical or chemical effects can be assessed unless uncertainties are considered. As regards the metrological and epistemological aspects, the SSK refers here to an internationally recognised methodology of the JCGM Guides, which should also be used in the revision of ICRP Publication 103.

Uncertainties and variability should be dealt with using an internationally accepted method such as that set out in the JCGM Guides (JCGM 2008a, 2008b, 2012a, 2012b, 2020).[2]

The Joint Committee for Guides in Metrology (JCGM) is a cooperation of Bureau International des Poids et Mesures (BIPM), the International Electrotechnical Commission (IEC), the

[2] https://www.bipm.org/en/committees/jc/jcgm/publications

International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), the International Laboratory Accreditation Cooperation (ILAC), the International Organization for Standardization (ISO), the International Union of Pure and Applied Chemistry (IUPAC), the International Union of Pure and Applied Physics (IUPAP) and the International Organization of Legal Metrology (OIML).

The JCGM Guides (JCGM 2008a, 2008b, 2012b) follow the terminology laid down in the International Vocabulary of Metrology (VIM) (JCGM 2012a). This defines uncertainty, also referred to as standard uncertainty, as a parameter that characterises the dispersion of the (true) values of a measurand, based on the information used.

A general aspect of uncertainties should be considered independently of the quantity in question. The Guide to the Expression of Uncertainty in Measurement (GUM) (JCGM 2008a) identifies two kinds of uncertainty, referred to as Type A and Type B uncertainties. UNSCEAR refers to them as aleatory and epistemic uncertainties. This distinction does not relate to the different qualities of the uncertainties, but to the way in which the uncertainties are calculated. Type A uncertainties are calculated from repeated observations or counting measures, while Type B uncertainties are attributable to other sources. Type B uncertainties cannot be handled using frequentist statistics, but need the Bayesian interpretation of probability. In many cases, Type B uncertainties are predominant in the overall uncertainty.

Uncertainties and variability are described through probability density functions (PDFs). Both PDFs depend on the information available. The PDFs fully describe the uncertainty in terms of the unknown and undetectable true values of the quantities that must be assigned based on estimates. Only probability statements can be made about the true values, based on the information on input variables in an evaluation.

Every measurement, analysis and evaluation aims to obtain an estimate of the true value of a quantity. The information on the unknown and undetectable true value of the quantity is fully described in a (posterior) PDF. The PDFs are Bayesian probabilities.

In a Bayesian approach (Weise und Wöger 1993) PDFs can be derived using Bayes' theorem or the principle of maximum information entropy (Jaynes 1982). GUM Supplement 1 (JCGM 2008b) gives detailed instructions on how to establish the PDFs using the available information.

However, the GUM Supplement does not determine whether the quality and reliability of the available information is sufficient for an assessment. See e.g. (Barthel und Thierfeldt 2015).

The shared PDF of the input variables describes the incomplete knowledge of the quantity considered and, where relevant, the probability density of the quantity in a population. Uncertainties and variabilities can be described with the same method and in many cases are difficult to differentiate. The posterior PDF of the quantities considered can be derived from the shared PDF of the input variables based on a model of the evaluation using the Markov formular and application of the Monte Carlo methods (ISO 2019b).

The PDFs can be presented entirely in graph form or using suitable points from the distributions, such as mean values, medians and specified quantiles. The best estimate of a quantity is the expected value of the posterior PDF and its assigned standard uncertainty, the root of the variance of the PDF. The term coverage interval is applied to an interval containing the true value of a measurand with a stated probability. The coverage interval is distinct from the confidence interval, which only permits statements on the results of future measurement.

Characteristic values of the distributions such as decision thresholds, detection limits and limits of coverage intervals can be calculated according to ISO 11929 (all parts) (ISO 2019a, 2019b, 2019c, ISO 2020). The standards series ISO 11929 is also recommended in various standards for measuring environmental radioactivity, but is not limited to that field.

Conformity with requirements can also be addressed using standard measurement uncertainties and coverage intervals limits according to ISO 11929 (SSK 2016a). Decision thresholds and detection limits in accordance with ISO 11929 can be used to assess individual measurements and review the suitability of measuring methods for a measurement purpose.

Today, the issue of uncertainties must also be considered in the overall context of digitalisation. The Task Group on the Digital SI of the International Committee for Weights and Measures (CIPM) states that the greatest challenge in further developing the metric system lies in developing and establishing a globally uniform, clear and safe data exchange format for use in IoT networks, based on the international system of units (SI) . It is necessary to fully digitalise the system to facilitate efficient processes in industry, quality infrastructure and its organisations, and in modern research and development worldwide.

That is why new data analysis tools must be considered with a view to digitalisation, namely artificial intelligence methods. There are currently no metrology tools available for determining uncertainties using AI. Besides the methodology per se, assessment methods must be developed for explainability and robustness. An independent evaluation or certification of algorithms can only be undertaken based on reference data, which must not be part of the training data. See also Section 4.2.4.

In general, statements by ICRP should also consider associated uncertainties and variabilities of all associated quantities, based on the available information according to the JCGM Guides. This also includes considering whether the available information is sufficient to allow a robust statement. This is not the case, for example, for the recommendations on radon, leading to the unfortunate situation that ICRP recommendations on radon dosimetry are no longer consistent with those of UNSCEAR.

In this context it should be noted that the radon problem, as well as risk estimates in general, have to contend with model uncertainties. There is a JCGM recommendation on this problem as well (JCGM 2020). The ICRP should take this approach too.

In many cases, determining dose limits or reference levels is based on what is detectable, for instance when a risk deviates significantly from the background risk. The question of detectability should be answered in line with the statements in ISO 11929 (ISO 2019a, 2019b, 2019c, ISO 2020).

However, detectability of a risk does not mean that this risk is relevant for radiological protection or for establishing dose limits and reference levels. Detectability is a scientific question to which a clear answer can be given. The question of the relevance of the observation, on the other hand, cannot be answered definitively, but only in the form of an evaluation.

Conclusion: As a rule, statements by ICRP should also take into account the uncertainties and variabilities of all associated quantities on the basis of the available information according to the JCGM Guides. This includes assessing whether the available information is sufficient to make a robust statement. The question of detectability of increased risk, e.g. when a risk significantly deviates from the background risk, should be answered in line with the statements in ISO 11929. Assessing the relevance of a risk goes beyond the scope of that question.

4.1.6 Ethical aspects

In the almost 100 years since its inception, ICRP has rarely addressed ethical values explicitly in its recommendations. Science, technology and experience were generally considered the only sources from which relevant information and ideas could and should be obtained. The first ICRP publications which expressly addressed ethical values related to radiological protection of non-human species (ICRP Publication 91, ICRP 2003) and the disposal of radioactive waste (ICRP Publication 122, ICRP 2013a). It was another few years before there was an ICRP

publication dedicated solely to ethical aspects, specifically the ethical foundations of the system of radiological protection (ICRP Publication 138, ICRP 2018b). Today, ethical issues are a recurring theme for ICRP, addressed, for example, in the drafts currently being discussed "Ethics in Radiological Protection for Medical Diagnosis and Treatment" (TG 109) and "Radiological Protection in Veterinary Practice" (TG 110). The position paper recently published by the members of the outgoing Commission (Clement et al. 2021), which outlines the priority areas of the next general recommendations updating ICRP Publication 103 (ICRP 2007a), brings ethical aspects to the fore. The paper suggests that the review of the system of radiological protection "should identify areas where explicit incorporation of the ethical basis alongside the scientific basis would be beneficial."

Although to date no SSK publications have focussed primarily on ethical questions, developments in this area are constantly addressed in the SSK discussions. The SSK expressly supports the efforts of ICRP to improve the integration of scientific and technological aspects on the one hand and social science and ethical considerations on the other. The SSK sees a need for discussion in particular on the values that various ICRP documents describe as fundamental. ICRP Publication 138, Ethical Foundations of the System of Radiological Protection, highlights four core values (beneficence/non-maleficence, prudence, justice, dignity) and three procedural values (transparency, accountability, inclusivity). However, these appear somewhat disconnected from the six areas highlighted in ICRP Publication 91 as particularly relevant for environmental issues (sustainable development, conservation, preservation, maintenance of biodiversity, environmental justice, human dignity). While the draft publications on ethical issues relating to medicine and veterinary medicine refer to these concepts, they do not consider them to be adequate and supplement them with others.

Conclusion: ICRP should endeavour to maintain clarity and coherence in the system of radiological protection. To this end, the relationship between the ethical values in specialised areas (e.g. medicine, environmental protection) and those of the basic recommendations set out in ICRP Publication 138 (beneficence/non-maleficence, prudence, justice, dignity, transparency, accountability, inclusivity) should be discussed and explained.

4.1.7 Culture of radiological protection

In the field of occupational safety, we speak today of an accepted concept of safety culture. Many hold the opinion that the culture of radiological protection should be part of the general safety culture. See (Michel 2009, IRPA 2014). It therefore makes sense to bear the concept of safety culture in mind when considering a definition of radiological protection culture. The term safety culture is used to describe how occupational safety is achieved. It covers "the attitudes, beliefs, perceptions, and values that employees share in relation to safety"(Cox und Cox 1991).

Efforts to establish a safety culture were galvanised by the accident at Chernobyl, which drew attention to this issue and made the safety repercussions of bad management and human factors glaringly obvious (Flin et al. 2000, IAEA 1986). The term safety culture was first coined in the Summary Report on the Post-Accident Review Meeting on the Chernobyl Accident (IAEA 1986). It was introduced as a means of explaining how a lack of knowledge and deficient understanding of risk and safety in an organisation and its employees ultimately contributed to the disaster.

Various definitions of the term safety culture have since been given. While the culture of radiological protection can be seen as an element of general industrial safety culture, it goes beyond that in cases where the presence of radioactivity and radiation in medicine, research and daily life justify the need for radiological protection. Radiological protection culture must offer a consistent system in all areas of application.

The UK Health and Safety Commission has put forward the following definitions of a safety culture: “The safety culture of an organisation is the product of individual and group values, attitudes, perceptions, competencies and patterns of behaviour that determine the commitment to, and the style and proficiency of, an organisation’s health and safety management” (HSE 1993).

Building on that definition, the professional radiological protection association Fachverband für Strahlenschutz and the International Radiation Protection Association (IRPA) highlighted the importance of a culture of radiological protection (Michel 2009, IRPA 2014). The following definition of radiological protection culture can be taken as a basis: “The term “radiological protection culture” describes how radiological protection in the work place, medicine and daily life is legally regulated, administered, implemented, maintained and perceived. Radiological protection culture reflects the attitudes, beliefs, perceptions, goals and values that employees, experts, regulatory authorities and society as a whole share with regard to radiological protection.”

Conclusion: The ICRP should actively support strengthening radiological protection culture as set out in the principles formulated by IRPA and the Fachverband für Strahlenschutz.

4.2 Specific issues

4.2.1 Operational quantities ICRU 95 (ICRP and ICRU)

In its Report 95 Operational Quantities for External Radiation Exposure (ICRU 2020), the International Commission on Radiation Units and Measurements (ICRU) recommended new operational, measurable quantities for radiological protection. The document was drawn up by the ICRU and published jointly with ICRP from 2017 to 2020, following public consultation.

Operational quantities for radiation measurements supplement the protection parameters (especially effective dose) which, by nature, cannot be measured. Operational quantities are used for prospective and retrospective assessment of radiation fields through measurement or calculation. Instruments such as area monitors and personal dosimeters are designed for measuring operational quantities and routinely calibrated with reference fields for this purpose.

The ICRU presented its recommendations on the new quantities to the Consultative Committee for Units (CCU) of the Bureau International des Poids et Mesures (BIMP). It is important to bear in mind that radiological protection is not a priority topic in metrology. Consequently, there was only limited interest and expertise on the part of the CCU and CCRI (Consultative Committee for Ionizing Radiation) in radiological protection units and quantities. That being the case, no intervention was to be expected from the CCU – rightly so, given the current distribution of tasks. Nevertheless, it must be asked whether this process represented an efficient use of resources. Implementing the ICRU proposal will involve very high costs, making it especially important to ask whether introducing new quantities actually improves radiological protection. In light of this, the ICRU and ICRP should explore the potential for improving their processes for the future. To achieve that, the ICRU and ICRP would have to significantly raise their level of competence in metrological issues. Only this can ensure that radiological protection has the same opportunities to develop as other fields and that its interests are successfully represented.

The decision on whether or not to introduce the operational quantities is a national one. The process developed such momentum that some countries began implementing the new quantities after the report was published, so that now – especially since ICRP approved the report – pressure is growing on other countries to do the same.

4.2.2 Problems in the introduction of new quantities

ICRU Report 95 states that existing dosimeters can be easily recalibrated to the new operational quantities, but in fact this is not the case for nearly all area monitors and personal dosimeters in use – especially whole body dosimeters. In low-energy fields, dosimetry systems with only one detector (single-element detectors) will not meet the angular dependence requirement and can therefore no longer be used in future. Apart from a few exceptions, therefore, new dosimeters would have to be developed and type-tested to implement the new operational quantities.

The aim of the proposed new quantities was to ensure a particularly accurate estimate of the protection parameter (e.g. effective dose), not to make the measurement as easy as possible. Considering that dosimetry still usually requires relatively low but conservative accuracy of measurements (factor 2), it is highly debatable whether practical radiological protection gains anything from the new operational quantities.

Optimising radiological protection is generally achieved through comparative before and after measurements which are virtually independent of the reference quantity.

Moreover, in most cases the values determined by dosimetry lie in a much different range to the dose limits. More precise calculations are only made if the values obtained approach the limits. The values obtained through dosimetry only represent one of many input variables, such as direction of the radiation, location of the dosimeter on the body. Even if the new operational quantities did ensure a better estimate, the improvement in accuracy is likely to be rather small in terms of the system of radiological protection overall.

The proposed new quantities allow the dose levels for x-ray diagnostics to be reduced by up to a factor of 2 in the case of unchanged exposure conditions. Consequently, communication will need to be stepped up to counter the assumption that the main intent behind the change of operational quantities is to allow lower radiation exposure values to be recorded in national dose registers.

A working group convened by EURADOS drew up a report entitled Evaluation of the Impact of the New ICRU Operational Quantities and Recommendations for their Practical Application (EURADOS 2022). This report came to some basic conclusions regarding

- the need to redesign dosimeters and measuring instruments
- the apparent dose reductions
- calibration and type-testing
- the impacts for space and aircrew dosimetry
- benefits and costs

that would result from the introduction of the new operational quantities, which are reproduced below:

> Many types of passive dosimeters and some instruments will need a certain amount of redesign and in some cases – typically single-element dosimeters – this redesign would be radical and costly.
>
> - For some types of device, it will be possible to simply change the calibration, e.g. the calibration factor of an instrument or the effective calibration energy for a dosimeter.
> - For other types, it may be possible to retro-fit modifications, e.g. adding different filtration, to obtain an acceptable response.

- The existing over-response of some dosimeter types – including those using "conventional" lithium fluoride LiF (Mg, Ti) – will be exacerbated in the lower photon energy range.
- For multi-filter dosimeters it should be possible to apply or adapt algorithms to achieve an acceptable response. More work is needed to confirm this. Probable measurement uncertainties also need to be evaluated.
- Otherwise, a redesign of dosimeters will be necessary in order to regain satisfactorily flat response characteristics across the required energy and angle ranges.
- Extremity dosimeters will only be able to provide good estimates of the new quantities if the kerma-approximation conversion coefficients are used.
- Given that some of the necessary changes will be radical, EURADOS doubts that the modifications are "reasonably straightforward" as asserted by the ICRU and ICRP.

Introducing the new operational quantities will lead to an apparent reduction in collective whole body doses arising from diagnostic/interventional procedures.

- However, the reduction is only apparent – the actual doses, as represented by the protection quantities, will not change. This should not lead to any easing of radiation protection measures.
- By contrast, eye lens doses will not change. It will therefore become much more difficult to control eye lens doses by controlling whole body doses.

Adopting the new operational quantities will significantly decrease (by a factor of 2 or more) measured whole body doses arising from diagnostic/interventional procedures, not only in the medical sector but also in veterinary and dental practice. The reduced doses arise because the conversion coefficients in the energy range used in x-ray diagnostic and interventional procedures are lower for the individual equivalent dose H_p than for $H_p(10)$. The reduction is to be welcomed, because the new operational quantities give a better estimate of the protection quantities than the old ones do over this range. However, care must be taken in the interpretation of these lower doses. In particular, it must be understood that there is no actual change in the "true" doses received by individuals, and consequently no justification for relaxing radiological protection measures.

Eye lens dose will not change significantly. Except at high photon energies, conversion coefficients for eye lenses are similar to those for $H_p(3)$. This means that any current practices in which eye lens dose is controlled by means of whole body monitoring will probably no longer work.

The complication with beta reference radiations is that they are not mono-directional and cannot be easily measured. However, a complete set of coefficients for the new quantities for use with calibration sources has already been calculated (Behrens 2021) and is available for inclusion in the next revision of ISO 6980.

For neutrons, the only modification required is implementing new fluence to dose quantity conversion coefficients. For monoenergetic neutrons the conversion coefficients can, after interpolation if necessary, be taken directly from ICRU 95, while coefficients for commonly used radionuclide sources are presented in the EURADOS report.

ICRP does not recommend using the new operational quantities for space dosimetry. Instead it proposes calculating the effective equivalent dose using conversion coefficients of particle fluence to mean absorbed doses in organs or tissues, and mean quality factors for protons, charged pions, alpha particles and heavy ions ($2 < Z \leq 28$) for females and

males using the reference Voxel phantom (ICRP 2009d). While the new operational quantities do enable dose calculation up to higher radiation energies, this does not change ICRP's position.

The new quantities should bring benefits that will improve radiological protection by enabling a better estimation of the effective dose. This applies primarily to radiations in the diagnostic/interventional photon energy range and for higher-energy radiations such as those generated in particle accelerators.

The new quantities provide a better risk estimate than the current quantities set out in ICRU Publication 47 (ICRU 1992). This was one of the primary intentions behind the new quantities, which are designed to be closer surrogates for the protection quantities and therefore better estimators of risk.

Switching to absorbed dose D for tissue reactions brings some advantages, such as in differentiating between tissue reactions and the stochastic effects associated with the individual equivalent dose H_p. ICRP is still examining whether it is correct to treat the formation of eye lens cataracts as a tissue reaction (Section 3.1.6). It is therefore too soon to fully endorse changing to the new operational quantities.

For medical diagnostic/interventional applications using x-rays, the use of the new operational quantities will reduce the current overestimation of effective dose. Education is needed to ensure that stakeholders appreciate that, while measured doses will fall, the effective doses – which most closely represent detriment – will stay the same.

The impacts of the new operational quantities on space and aircrew dosimetry will be minimal. In other high-energy fields such as those around particle accelerators and proton therapy units, the new quantities should allow consistent assessment of worker doses and more efficient use of radiological protection resources.

The full implementation of the new quantities will require additional resources.

Moreover, it is likely that countries will introduce the new operational quantities at different rates. This is not surprising as it reflects the history of the current operational quantities. In the present case, countries with limited radiological protection resources may be particularly concerned about the costs. In light of these considerations, full adoption of the new quantities might not be achieved until the late 2030s. During such a lengthy transition period, there would inevitably be a loss of harmonisation, with different countries using different quantities.

In the view of the SSK, introducing the new operational quantities would put radiological protection at risk of losing the current globally uniform quantities that are indispensable for a common understanding and data exchange.

For this reason, in spite of the efforts to ensure transparency and participation, the process between the ICRU and ICRP must be viewed critically.

At present, it is not clear whether the benefits of introducing the new operational quantities will outweigh the disadvantages. Further work on this issue is recommended.

Conclusion: As introducing new operational quantities has far-reaching consequences and the development of new measuring systems and procedures requires time and investments, the SSK recommends that ICRP seek dialogue with the ICRU to reconsider the introduction of the new operational quantities in the light of the EURADOS findings. An exchange with CCRI and IAEA on this topic is also recommended.

4.2.3 Relative biological effectiveness and radiation weighting factor

Energy deposition in tissues and organs varies according to radiation type. It can be characterised using the linear energy transfer (LET), which indicates the density of the energy transferred to the secondary electrons per unit path length when a particular radiation penetrates a medium. The LET of X-rays, gamma rays and electron rays of similar energies is around 0.2 keV μm^{-1} (sparsely ionising radiation), while for neutrons, accelerated ions and alpha particles values of 10 keV μm^{-1} to 100 keV μm^{-1} or more are found (densely ionising radiation).

Due to different energy deposition patterns, sparsely and densely ionising radiations do not have the same relative biological effectiveness (RBE). This quantity is defined as the ratio of the absorbed dose D_{ref} of a reference radiation (usually 200 kV x-ray radiation) that causes a specific biological effect to the dose D_{test} of the radiation being studied that is needed to give an identical effect to the same biological object under the same conditions. RBE values can vary widely for different biological endpoints or different effect levels. For this reason, RBE is also dependent on the dose.

In radiological protection, different types of radiation are characterised using the organ equivalent dose $H_T = w_R D_T$. This is obtained by multiplying the absorbed dose D in the organ T by a radiation weighting factor w_R. This factor reflects typical and relevant RBE values for stochastic effects. In contrast to the RBE, the radiation weighting factor is not dependent on dose. To some extent, the radiation weighting factor is based on experimental data, but ultimately it is a normatively specified value intended to make it easier for the system of radiological protection to deal with different forms of radiation. With this in mind, there must be regular discussion of which RBEs should be considered "typical and relevant" and which radiation weighting factors ensure adequate protection from the radiation types under discussion. Consequently, ICRP has revised some of its recommendations for the radiation weighting factors several times over the past decades.

ICRP Publication 26 (ICRP 1977a), for example, gave a weighting factor of 10 for neutrons. It was later recognised, however, that the relative biological effectiveness for cancer induction is heavily dependent on the neutron energy. To reflect this, ICRP Publication 60 (ICRP 1991b) gave five different values between 5 and 20 for five different energy ranges. This was further refined in ICRP Publication 103 (ICRP 2007a), which then offered a continuous dependency of the factor (three continuous functions for three dose ranges) alongside the graded dependency of the factor. The highest factor nevertheless remained 20, at a neutron energy of 1 MeV.

For estimating neutron risk, the difference in the neutron components of the Hiroshima and Nagasaki atomic bombs plays an important role. Based on the slight supralinearity of the ERR for colon doses of 200 mGy to 400 mGy that had been observed in Nagasaki but not to the same extent in Hiroshima, Sasaki et al. (Sasaki et al. 2016) concluded that the relative biological effectiveness of neutrons is dose dependent. According to their calculations, the RBE for neutron doses of between 10 mGy and 100 mGy should be in the 10-30 range, but rise to around 85 for lower doses. As more data from the Life Span Study becomes available, this will be the subject of further analyses and discussions.

With regard to the RBE of protons, ICRP lowered its recommended radiation weighting factor from 10 in Publication 26, to 5 in Publication 60 and 2 in Publication 103. This is based less on new radiobiological findings than on the fact that protons used in radiobiological experiments prior to 1977 demonstrated relatively low energies and hence a high linear energy transfer (LET). In subsequent years, however, studies focussed on higher-energy protons of 100 MeV to 200 MeV, as used in radiotherapy since around 2000. The LET of the latter is so low that it can barely be described as densely ionising radiation. Despite this shift in interest to higher

energies, ICRP should consider also indicating various energy-related radiation weighting factors for protons (and heavier ions), as is already the case for neutrons.

For alpha particles, the same radiation weighting factor of 20 has applied since ICRP Publication 26. There does not appear to be any experimental or epidemiological data that would suggest this recommendation needs revising. This point should nevertheless be investigated much more thoroughly, as the weighting factor for alpha radiation is instrumental in the dosimetry of radon exposure, and discrepancies remain between the dosimetric and the epidemiological approaches to radon dose conversion (cf. Section 0).

Relative biological effectiveness plays a role not only in the estimation of stochastic risks (thus also serving as a basis for determining radiation weighting factors), but in the estimation of tissue reactions (or deterministic effects) as well. When tumours are treated with neutrons, protons and heavy ions, the surrounding tissue is also always exposed. The equivalent dose is not always suitable for calculating the resulting risks, because, as described above, radiation weighting factors reflect a weighting related to stochastic risks. The RBEs for effects of this type are often many times higher than those for tissue reactions. For example, an RBE range of 2 to 6 was found for reproductive cell death, apoptosis and cell cycle disturbance by neutrons with 14 MeV (maximum energy) (Slabbert et al. 2000, Oya et al. 2008, Zölzer und Streffer 2008). For a higher neutron energy of 66 MeV (maximum energy), the RBE for reproductive cell death was in the 2 to 3 range (Slabbert et al. 2000). At 14 MeV, although not at 66 MeV, the RBE was dependent on the sensitivity to gamma radiation, and therefore probably the repair capacity, of the irradiated cells.

Slightly lower RBEs of 1.2 to 2.2 were reported for the cellular effects of proton therapy (Sorensen et al. 2021). For the spread-out Bragg peak (SOPB) an RBE value of 1.1 to 1.3 is generally assumed, possibly increasing to 2.1 shortly before the dose decline behind the tumour (Durante 2014). There is also discussion of the possible need for more detailed determinations of the LET in front of, in and behind the tumour. This would allow a more accurate estimate of the RBE for tissue reactions (Kalholm et al. 2021).

A relatively broad variability of the RBE was ascertained for the effect of densely ionising radiation on the reproductive system and foetal development. The values were generally in the range of 2 to 7, although in individual cases values were higher by an order of magnitude, especially for incorporated radionuclides (Wang und Yasuda 2020).

Increasing attention is also being given to the question of how far the molecular, cellular and tissue-related processes triggered by densely ionising radiation differ from those caused by sparsely ionising radiation (Durante 2014, Durante und Flanz 2019, Permata et al. 2021, Walenta und Mueller-Klieser 2016).

Conclusion: The SSK sees a range of indications from RBE studies that prompt a review of the radiation weighting factors. For alpha radiation in particular, which is instrumental in the dosimetry of radon exposure, it is not clear whether its current value of 20 appropriately reflects its role in risk.

4.2.4 Digitalisation, AI

International and national strategies to implement the digital transformation will have impacts on radiological protection.

It is important that the radiological protection community monitors the international coordination process constructively and states its own needs and interests. For that reason, the SSK recommends that the ICRU and ICRP look into the possibility of jointly signing the Joint Statement of Intent on the digital transformation in the international scientific and quality

infrastructure[3] (BIPM et al. 2022) and take an active part in shaping and developing the transformation.

The BIPM, the International Organisation of Legal Metrology (OIML), the International Measurement Confederation (IMEKO), the International Science Council (ISC) and its data committee (CODATA) signed the Joint Statement on 30 March 2022. It provides a platform for the signatory organisations to come together to indicate their support, in a way appropriate to their particular organisation, to the development, implementation, and promotion of the SI Digital Framework as part of a wider digital transformation of the international scientific and quality infrastructure. Other international organisations are expected to sign the joint statement in future. The joint statement is part of an ongoing initiative by the International Committee for Weights and Measure (CIPM) and its Task Group on the Digital SI (CIPM-TG-DSI) to develop and establish a world-wide uniform and secure data exchange format based on the International System of Units (SI).

In addition to international developments, developments at national level also impact radiological protection. The digital transformation especially affects legal metrology (Measures and Verification Act, and Measures and Verification Ordinance; the latter is also relevant for the area "digitalisation of the energy transition") (MessEG 2013, MessEV 2014, Thiel und Leffler 2013).

The MessEG and MessEV are particularly important for the quality control of measurement data. Metrological surveys of other exposure types (beta or neutron radiation, radon exposure) do not meet these very high quality standards. This makes using addition methods to determine a total dose problematic, as the data do not have the same basis or quality. This can hinder acceptance and presents a bureaucratic obstacle within the area of application of the MessEG.

Conclusion: A review should be undertaken into how far quality control procedures in radiological protection can be aligned to assess different exposure types and whether this can be incorporated into the digital transformation.

4.2.5 Citizen science in radiological protection

Citizen science is a scientific approach which gives members of the public – "citizen scientists" – an active role in the research process. These citizen scientists are not full-time specialists in the particular field such as radiation research. Those involved in citizen science projects are unpaid volunteers. Activities include collecting exposure data such as the gamma local dose rate in residential areas (Bonn et al. 2016). Such citizen science projects are generally launched, led and evaluated by scientific institutions. The citizen scientists contribute data they have collected. As a rule these projects take a top-down approach (Bonney et al. 2009). Other citizen science projects are launched by civil society organisations, only involving people working in scientific institutions after a certain point (Bonn et al. 2016). These initiatives, referred to as grassroots citizen science, follow a bottom-up approach (Van Oudheusden und Abe 2021).

4.2.5.1 Examples of citizen science in radiological protection

Citizen science projects can make a valuable contribution to radiological protection, both in data collection and in communication with the public. Technological advances could strengthen the role of citizen scientists in radiological protection, especially as regards data acquisition.

[3] https://www.bipm.org/documents/20126/42177518/Joint-Statement-Digital-Transformation.pdf/c2a4d4c5-3b93-39a6-4378-676406ac2845?t=1648563803442

However, mobile apps for radiological protection and monitoring are still very new, having essentially been developed in the wake of the Fukushima accident (Liutsko et al. 2018).

One example of bringing exposure measurement, monitoring and communication into the public domain is the grassroots citizen science project Safecast (Brown et al. 2016, Van Oudheusden und Abe 2021). Safecast was launched in response to the Fukushima disaster of March 2011 and is an international volunteer driven non-profit organisation. Its goal is to compile useful, accessible and granular environmental data. All Safecast data is published under a CC0 licence and may be used free-of-charge. Even a short time after the disaster in Fukushima, individuals and small groups of citizens began measuring radiation levels, borrowing or buying measuring devices in order to gather their own data on the radiation caused by radioactive contamination. These efforts were a reaction to the critical public need for more reliable and usable data that government bodies, nuclear power plant operators and emergency services had failed to provide following the disaster. They had even intentionally disseminated misleading information in order to maintain the illusion of safety (Morita et al. 2013). The Safecast citizen science project quickly grew and extended its geographical range (Safecast 2022). Its goal in Japan is monitoring and facilitating an open exchange of information on environmental radioactivity and other harmful substances. The Safecast group developed a participative, open-source solution for mapping radiation in the form of local dose rate monitoring networks. The data collected in the course of this project has proved useful for experts and political decision-makers and for communicating with the public (Brown et al. 2016). The opportunity for members of the public to monitor their own homes and surroundings following the disaster, thus making themselves independent of the government, is seen as one of the main results of the Safecast project. The authors of a Safecast-related publication reported that taking their own measurements gave members of the public a stronger sense of agency and guidance in their decision-making (Brown et al. 2016), for example on whether to remain in their homes. People's perception of acceptable radiological risk varies widely and depends on their knowledge, occupational background and present situation. The Safecast project avoided declaring what should be seen as safe. Instead, the aim was to give the citizens involved the tools and resources to help them to understand the complexities of radiation measurements and make their own decisions. Nevertheless, the authors conclude that while Safecast helped to quickly fill crucial gaps regarding the exposure situation and gave the public the means to make informed decisions such as whether to stay in their homes, ultimately the onus is on the government to provide and communicate such information (Brown et al. 2016).

4.2.5.2 Positive effects and limitations of citizen science

In principle, citizen science and its associated research projects can have a range of positive effects for the citizen scientists themselves, for people working in scientific institutions and ultimately for society as a whole (Kenens et al. 2020, Kenens 2020). Citizen science allows members of the public to play their part in adding to scientific knowledge, something that can benefit scientific understanding. In addition, citizen science offers the opportunity to introduce innovative ideas to the scientific community. This can generally lead to greater acceptance and understanding of scientific problems and how to tackle them. Not least, depending on the research question, helping to build knowledge can improve the environment and society and promote individual happiness (Bürger schaffen wissen – Die Citizen Science Plattform, Wissenschaft im Dialog 2023). For professionals in scientific institutions, involving citizen scientists offers a means of collecting comprehensive data sets over large areas and time periods. It inspires and generates research questions from the public. It can also strengthen social acceptance of research findings. The benefit to society is in helping to shape transparent research and better transfer research results to practice through the early inclusion of civil actors. Thus, citizen science helps strengthen civil society and administration (Bürger schaffen

wissen – Die Citizen Science Plattform, Wissenschaft im Dialog 2023). Involving citizen scientists in ongoing interdisciplinary research projects alongside experts in dosimetry, social sciences and emergency preparedness, and alongside authorities, can enhance understanding and trust between the different actors in the field of radiological protection and emergency preparedness. Moreover, citizen science projects can strengthen communication of radiological protection issues to the public. This could be achieved, for example, by radiological protection experts building contacts to schools and other educational institutions, especially where this leads to new participants for citizen science projects in radiological protection (Van Oudheusden et al. 2019). These participants might then act as multipliers for the topic in their immediate social circle.

At present, however, there is a lack of regulatory guidelines – a Good Practice Citizen Science in Radiation Protection – to provide a framework with qualitative minimum standards for conducting such studies, in particular as regards exposure measurements but also in relation to the interaction between institutions and the citizen scientists. Successful citizen science projects in the field of radiological protection could subsequently be used for the targeted communication of results "from the public to the public". The European Radiation Dosimetry Group (EURADOS) already incorporated citizen science in its Strategic Research Agenda (SRA), which sets out the future research needs in the field of dosimetry in the context of radiation research in Europe. EURADOS finds that, in the case of a nuclear incident, a fast, efficient and reliable estimate of doses for affected persons is a basic prerequisite for further decision-making by the competent authorities. The dose estimate is made more difficult by the fact that several exposure scenarios may exist simultaneously. For example, internal exposure from incorporated radionuclides and external exposure from different sources. Monitoring the dose rate measurement using different methods (manual, stationary, by car, by air) is generally the first step in assessing doses for population groups and determining critically exposed subgroups. Given the availability of affordable dose rate measurement devices, citizen scientists can play an important role in this context. However, in its SRA, EURADOS notes that this would require the development of standard and validated protocols. The SRA also underlines the need to develop and assess accessible, user-friendly, accurate and reliable measuring instruments with clear instructions for use, which enable citizen scientists to take their own radiation measurements. In February 2019, a workshop entitled Learning from Citizen Science after Fukushima – Probing the Role and Potential of Citizen Science in Nuclear Science and Technology Governance in Japan and Belgium was held in Brussels for radiological protection researchers, members of security authorities, civil society representatives and political decision-makers. The workshop identified the challenges facing citizen science in the field of radiological protection following an emergency situation and made recommendations (Van Oudheusden et al. 2019). Another limitation highlighted at the workshop was the current lack of a uniform regulatory framework for managing grassroots citizen science projects. The workshop found recurring questions in this context to be "how can we work together with citizen scientists?" and "how can we support them?" (Van Oudheusden et al. 2019). It also stressed the importance of considering context factors in cooperation between professionals in scientific institutions and citizen scientists. This means, for example, considering political and legal frameworks in the field of nuclear safety. In Japan, Safecast initiated radiation monitoring by members of the public directly after a life-changing calamitous event, triggered by a critical public need for safety that many believed was not being met by the official bodies or the government (NAIIC 2012). In Europe, such an event has not occurred (even if the accident at Chernobyl in 1986 is a part of the collective memory and led to citizen driven initiatives on radiation monitoring). This could explain why public interest in this topic is less marked in Europe than in Japan (Van Oudheusden et al. 2019). Another challenge for citizen science projects are time and financing constraints, questions of responsibility and what is expected

from a project. Moreover, participants in the workshop noted the need for a more symmetric relationship between scientific institutional professionals and citizen scientists. Citizen scientists should not just be seen as "suppliers" of exposure data, but should be assigned an active role in the scientific design of citizen science projects (Van Oudheusden et al. 2019), in line with the co-design method (Slattery et al. 2020).

Conclusion: There is currently no ICRP recommendation on implementing citizen science projects in radiological protection, for example in the context of a disaster like Fukushima. Should an ICRP review conclude that such projects would be beneficial, the SSK recommends developing and putting in place "Good Practice Citizen Science in Radiation Protection" regulatory guidelines.

4.2.6 Radiological protection issues in the application of new medical procedures

Alongside natural radiation exposure, people also experience exposure from civilisation sources. Almost all this human-induced exposure is the result of medical applications. For Germany, the average annual effective dose from this source is currently 1.7 mSv per capita (BMUV 2022).

Continuous developments, for instance in device technologies, radiopharmaceuticals and information technology regularly lead to new procedures and applications in the clinical routine. New technologies and applications connected to the use of ionising radiation should represent an improvement on established procedures for both patients and operators, as far as possible also in terms of radiation exposure. The application of new technologies and methods in medicine can generally lead to higher exposures for patients. This can be acceptable if the higher exposure is justified, for example because of the information obtained or a better prognosis. It is not acceptable, on the other hand, if improper application, ill-considered use without adequate indication, lack of quality assurance or technical problems during the use of new technologies lead to elevated exposures or a reduction in diagnostic or therapeutic benefit.

Errors in application often arise from a combination of technical malfunction and operational difficulties. In particular, it must be borne in mind that there is less knowledge of possible problems and sources of error for new procedures than for established ones. For that reason, in clinical use it is essential to ensure that operators are carefully instructed in new technologies and given appropriate training, with the goal of achieving the highest possible level of safety for both operators and patients. In addition, there must be a critical evaluation of potential new risks arising from new procedures. Ideally, systematic, planned studies on radiation exposure should be carried out during initial clinical tests and hence long before the broad introduction of new procedures into the daily clinical routine. The aim of such studies is to determine the dose and optimise the investigation and treatment protocols, in order to ensure that medical radiation exposure is kept as low as reasonably achievable.

The approach described above is set out in Directive 2013/59/EURATOM (Euratom 2014) and is already anchored in German radiological protection law. Under Article 55 (2)(a) of the Euratom directive, new types of practices must be justified. Core requirements of Euratom in this respect are carrying out a critical risk-benefit assessment and ensuring adequate quality, taking into account the basic principles of radiological protection (justification, dose limitation and optimisation). In Germany one obligation is to ensure that, in uses for the purpose of medical research, exposure is estimated for each person included in the research project (section 138 (5) Radiation Protection Ordinance).

Beyond fundamental questions of medical radiological protection, the basis for any decision on introducing a new technology in medicine should be a health technology assessment (HTA) (WHO 2011). A possible approach can be found in (WHO 2021), giving due consideration to

the specific characteristics of the use of ionising radiation. Internationally accepted criteria would be helpful for evaluating the benefit and risk of the use of ionising radiation in new technologies or procedures.

The example of PET-CT (positron emission tomography in combination with computed tomography) illustrates what may need to be considered in a risk-benefit-analysis of the use of new equipment technologies and the definition of quality standards. This imaging procedure has been clinical routine since the beginning of the 2000s. PET-CT captures different metabolic functions using radioactively labelled pharmaceuticals (radiotracers) and identifies anatomical characteristics of the investigated body regions using x-rays.

This procedure improves the PET scan through CT-supported absorption correction. Depending on the indication of the examination, the low-dose CT that in many cases is adequate for anatomical orientation, may need to be replaced with a more dose-intensive diagnostic CT scan. Moreover, the combination of PET and CT significantly improves the possibility of diagnosing different diseases through the fusion of physiological and morphological data, allowing an anatomical classification. This brings considerable added value, for instance for tumour therapy, as tumours and metastases can be clearly distinguished from other structures. Procedures available in the past could not do this with the same degree of certainty.

The justification for the use of PET-CT must pay careful attention to good application practices, as the procedure requires expertise in nuclear medicine and radiology (IAEA 2008) and, in the case of PET-CT supported radiotherapy, in radiooncology too. It is imperative that staff receive comprehensive training. Benefit and risk must be assessed not only for CT and PET separately, but also for their combined use. This assessment must consider both the resulting exposure for the patient and the type and severity of the disease. Quality assurance has to cover not only each individual device modality but also the combination.

Conclusion: A risk-benefit assessment that takes account of the basic principles of justification of the radiological risk, dose reduction and dose optimisation is indispensable for patient safety. In this context, ICRP should discuss drawing up uniform and standardised criteria for the risk-benefit assessment.

5 Expert statement

Sections 2 to 4 have identified a range of topics suitable for inclusion in a future review of the ICRP basic recommendations. However, in these sections the issues are simply listed and described; they are not put in order of importance, and their potential impacts on radiological protection are not considered.

In the following expert statement, the SSK ranks these topic areas to create an order of priority for discussion. This prioritisation relates to the relevance of the topic for the goal of revising and updating ICRP Publication 103, and as such is a recommendation by the SSK to ICRP. However, it also presents the SSK's opinion of the need for research and consultation at national level, and in this sense is directed at the Federal Environment Ministry in fulfilment of the advisory mandate referred to in Section 1.

While the adoption of the basic recommendations in ICRP Publication 103 represented an extremely important milestone in the development of radiological protection, it was in no way the end of discussions regarding fundamental aspects of radiological protection and its conceptual structure. Among the topics which were and are more or less permanent – and at times very controversial – subjects of discussion among international experts, both before and after the adoption of ICRP Publication 103, is the basic assumption that the dose-effect

relationship may be approximated by a linear no-threshold (LBT) model. The LNT model is one of the most, if not the most important assumption in radiological protection and serves as a foundation for a large part of the overall system. This principle of LNT is closely linked to other assumptions, models and parameters which are incorporated into radiological protection, above all the concepts of dose and dose-rate effectiveness factor (DDREF), detriment and the radiation and tissue weighting factor.

Overriding these concepts are always considerations concerning in particular the practicability, transparency, individualisation, resilience and acceptance of radiological protection structures. An appropriate balance must be established between conservatism and realism, continuity and the need to adapt to new findings or requirements, and between many other conflicting goals.

Equally, radiological protection should pay more attention to the consideration of uncertainties and their sources.

The SSK also believes the topics listed merit a high priority. In this context, the SSK finds as follows:

- LNT (cf. Section 4.1.1): The SSK does not currently see any proof that findings on biological effects suggesting a non-linear dose-response relationship would contradict the use of the LNT model for radiological protection purposes. However, the SSK recommends a thorough review of the underlying argumentation. It must nevertheless be reiterated that using a linear dose-response relationship as a basis for risk estimates in radiological protection does not imply linearity of the fundamental biological effect mechanisms. In this regard, the LNT model is first and foremost an instrument of radiological protection but not necessarily a description of an effect mechanism.
- DDREF (cf. Section 3.1.1): The SSK recommends adjusting the DDREF in line with current findings and, if appropriate, abolishing it. Due to its importance for risk evaluation and impact on radiological protection, the SSK further recommends that any general adjustment of the DDREF should also include adapting other parameters pertaining to detriment (i.e. to radiation-related damage) to current findings.
- Detriment (cf. Section 4.1.2): The SSK considers the detriment concept to be suitable for damage weighting. In its current form, it is generally capable of taking the organs' different contributions to risk into appropriate account. However, the underlying rationale of the process is very unclear, with almost no explanation given for how the range of parameters used were selected. This subtlety comes at the expense of transparency and comprehensibility of risk assessments in radiological protection. In future, there should be an examination into whether the choice of parameters and their values are appropriate for calculating the detriment, and whether fine-tuning like this is really needed for the purposes of radiological protection or whether a simpler but more transparent model would be equally suitable. In the opinion of the SSK, ICRP should seek to compare this approach with damage weighting concepts from other fields of environmental protection or occupational health, and, where appropriate, adopt or adapt individual elements of them.
- Weighting factors (cf. Sections 3.1.3, 3.1.8, 4.2.2): The SSK sees a number of indications in RBE studies that suggest the need to review radiation weighting factors. In particular, it is not clear if the risk contribution of alpha radiation is adequately reflected in the current value of 20.

  The tissue weighting factors are essentially derived from the ratio of the organ-specific detriment to total risk. The SSK considers it would be appropriate to review these in the light of more recent studies. The detriment for skin cancer plays a particularly important role. For almost all organs, the risk coefficient differs from the detriment, which is mainly

based on lethality, by no more than a factor of 2. By contrast, skin cancer not only has by-far the highest incidence risk coefficients of all organs (higher than all others summed) but also, due to the assumed very low lethality of the prevalent basal cell carcinoma, a very low detriment and hence a low tissue weighting factor. More recent analyses of the LSS cohorts indicate that skin cancer is not radiation induced below around 0.5 Gy, i.e. that skin would be omitted from the list of organs with tissue weighting factors.

The SSK finds that relevant studies have provided indications of possible gender-specific differences in radiosensitivity, but that clear proof is lacking. Currently, the SSK sees no basis for incorporating possible gender-specific differences in radiosensitivity in radiological protection measures. The SSK does see a need for further research in order to provide conclusive evidence and an understanding of possible gender-specific differences in the radiation-induced incidence of tumours in individual organs and in the radiation sensitivity of entire organisms based on molecular, cellular and tissue reactions to irradiation.

– Practicability, realism (cf. Sections 3.1.8, 4.1.4): All new recommendations in a revised version of ICRP Publication 103 should be subject to critical scrutiny in terms of their practicability and impacts in practice. This includes stressing the importance of justification. Not only activities must be justified, but also the associated protective measures, as protective measures can have both desired and undesired consequences.

  In the necessary prospective dose calculations and risk estimates, the SSK also always recommends considering total risk and total doses, proceeding as realistically as possible. Conservativeness in dose calculations should be avoided as far as possible and realistic figures given for doses and risks. The radiological protection system should be simplified. In particular, individualising general radiological protection could complicate the system further and create disadvantages for patients. The general principle should be to only make a change to the system if this represents a significant improvement in radiological protection.

– Uncertainties in radiological protection (cf. Section 4.1.5): As a rule, statements by ICRP should also take into account the uncertainties and variabilities of all associated quantities on the basis of the available information according to the JCGM Guides. This includes assessing whether the available information is sufficient to make a robust statement. The question of detectability of increased risk, e.g. when a risk significantly deviates from the background risk, should be answered in line with the statements in ISO 11929. Assessing the relevance of a risk goes beyond the scope of that question.

– Cardiovascluar diseases (cf. Section 3.1.4): For many years, stochastic radiological effects were the main focus of radiological protection. For some years, however, more and more attention has been given to studies on radiation-induced cardiovascular diseases that cannot be easily classified in the traditional categories of stochastic and deterministic effect; it is also difficult to determine the nature of the dose-response relationships for these diseases. Importantly, it remains unresolved whether an LNT model is an appropriate convention to sufficiently address radiological protection concerns. It is accordingly also unclear to what extent these diseases should be integrated in the existing radiological protection system or whether the system must be expanded to include radiation-induced cardiovascular diseases.

Alongside the above topic areas on fundamental issues of radiological protection, the SSK also considers radon, which is particularly relevant for radiological protection, to be another high-priority topic. In particular, converting a radon activity concentration into a dose, i.e. calculating the radon dose coefficient, is a problem that still has not been solved satisfactorily. In this context, the SSK finds as follows:

- Radon (cf. Sections 2.2.4, 0): A reassessment of all available findings on dose calculation, including new analysis of the Wismut data and the PUMA (Pooled Uranium Miners Analysis) study should result in a consensus-worthy and workable ICRP recommendation with regard to radon dose coefficients. Beyond this, the goal for the future should generally be recommendations on radon protection based on activity concentrations or exposure values rather than dose values, so that dose conversions can be largely avoided.

Besides the high-priority topics, the SSK sees a number of individual issues that need to be considered in a future revision of the ICRP basic recommendations. These are, in no order of precedence:

- Operational quantities (cf. Section 4.2.1): As introducing new operational quantities has far-reaching consequences and the development of new measuring systems and procedures requires time and investments, the SSK recommends that ICRP seek dialogue with the ICRU to reconsider the introduction of the new operational quantities in the light of the EURADOS findings. An exchange with CCRI and the IAEA on this topic is also recommended.
- Radiological protection issues in new medical procedures (cf. Section 4.2.5): A risk-benefit assessment that takes account of the basic principles of justification of the radiological risk, dose reduction and dose optimisation is indispensable for patient safety. In this context, ICRP should discuss drawing up uniform and standardised criteria for the risk-benefit assessment.
- Digitalisation, AI (cf. Section 4.2.3): In the opinion of the SSK, a review should be undertaken into how far quality control procedures in radiological protection can be aligned to assess different exposure types and whether this can be incorporated into the digital transformation.
- Citizen science in radiological protection (cf. Section 4.2.5): There is currently no ICRP recommendation on implementing citizen science projects in radiological protection, for example in the context of a disaster like Fukushima. Should an ICRP review conclude that such projects would be beneficial, the SSK recommends developing and putting in place "Good Practice Citizen Science in Radiation Protection" regulatory guidelines.
- Ethical aspects (cf. Section 4.1.6): ICRP should endeavour to maintain clarity and coherence in the system of radiological protection. To this end, the relationship between the ethical values in specialised areas (e.g. medicine, environmental protection) and those of the basic recommendations in ICRP Publication 138 (beneficence/non-maleficence, prudence, justice, dignity, transparency, accountability, inclusivity) should be discussed and explained.

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Annex
Ongoing ICRP Task Groups (as at 30 November 2022)

TG 36	Radiation Dose to Patients in Diagnostic Nuclear Medicine
TG 91	Radiation Risk Inference at Low-dose and Low-dose Rate Exposure for Radiological Protection Purposes (cf. Section 4.1.1 The LNT-Model)
TG 96	Computational Phantoms and Radiation Transport
TG 97	Application of the Commission's Recommendations for Surface and Near Surface Disposal of Solid Radioactive Waste
TG 98	Application of the Commission's Recommendations to Exposures Resulting from Contaminated Sites from Past Industrial, Military and Nuclear Activities
TG 99	Reference Animal and Plant (RAP) (cf. Section 3.1.7 Environmental protection)
TG 102	Detriment Calculation Methodology (cf. Section 4.1.2 Detriment)
TG 103	Mesh-type Reference Computational Phantoms (MRCP)
TG 105	Considering the Environment when Applying the System of Radiological Protection (cf. Section 3.1.7 Environmental protection)
TG 106	Application of the Commission's Recommendations to Activities involving Mobile High Activity Sources
TG 108	Optimisation of Radiological Protection in Digital Radiography, Fluoroscopy, and CT in Medical Imaging
TG 109	Ethics in Radiological Protection for Medical Diagnosis and Treatment (cf. Section 4.1.6 Ethical aspects)
TG 110	Radiological Protection in Veterinary Practice
TG 111	Factors Governing the Individual Response of Humans to Ionising Radiation
TG 112	Emergency Dosimetry (cf. Section 3.2.4 Operational Intervention Levels (OILs))
TG 113	Reference Organ and Effective Dose Coefficients for Common Diagnostic X-ray Imaging Examinations
TG 114	Reasonableness and Tolerability in the System of Radiological Protection (cf. Section 3.2 Introduction of a traffic light model for communicating radiological protection)
TG 115	Risk and Dose Assessment for Radiological Protection of Astronauts
TG 116	Radiological Protection Aspects of Imaging in Radiotherapy
TG 117	Radiological Protection in PET and PET/CT
TG 118	Relative Biological Effectiveness (RBE), Quality Factor (Q), and Radiation Weighting Factor (wR) (cf. Section 4.2.3 Relative biological effectiveness and radiation weighting factor)
TG 119	Effects of Ionising Radiation on Diseases of the Circulatory System and their Consideration in the System of Radiological Protection (cf. Section 3.1.4 Cardiovascular diseases)
TG 120	Radiological Protection for Radiation Emergencies and Malicious Events (cf. Section 3.2.4 Operational Intervention Levels (OILs))

TG 121 Effects of Ionising Radiation Exposure in Offspring and Next Generations

TG 122 Update of Detriment Calculation for Cancer (cf. Section 4.1.2 Detriment)

TG 123 Classification of Harmful Radiation-induced Effects on Human Health for Radiological Protection Purposes

TG 124 Application of the Principle of Justification (cf. Section 4.1.6 Ethical aspects)

TG 125 Ecosystem Services in Environmental Radiological Protection (cf. Section 3.1.7 Environmental protection)

TG 126 Radiological Protection in Human Biomedical Research

TG 127 Exposure Situations and Categories of Exposure