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Protecting Consumers against the Risks of Ionising and Non-ionising Radiation

Summary of the Closed Meeting 2018

Adopted at the 295th meeting of the German Commission on Radiological Protection on 13 July 2018

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Schutz der Verbraucher vor Risiken der ionisierenden und nichtionisierenden Strahlung

Zusammenfassung der Klausurtagung 2018 der SSK

Preface

Since 1981, the German Commission on Radiological Protection (SSK) has held closed meetings almost on an annual basis, or it has organised annual conferences that are open to a broader number of participants. These gatherings are used to discuss fundamental scientific topics along with the latest developments in radiation protection. The 2018 closed meeting was held on 15 and 16 March 2018 at the *Juliusspital* hospital in Würzburg, Germany, with a focus on protecting consumers against the risks of ionising and non-ionising radiation.

Members of the programme committee were:

- Dipl.-Phys. Markus Figel, *Helmholtz Zentrum München* (German Research Centre for Environmental Health in Munich)
- Dipl.-Ing. Markus Fischer, *Berufsgenossenschaft Energie Textil Elektro Medienerzeugnisse* (German Social Accident Insurance Institution for the energy, textile, electrical and media products sectors), Cologne
- Dipl.-Ing. Günter Ott, *Bundesanstalt für Arbeitsschutz und Arbeitsmedizin* (Federal Institute of Occupational Safety and Health), Dortmund
- Dr. Stefan Thierfeldt, Brenk Systemplanung GmbH, Aachen
- Dr. Wolfgang Weiss, *Bundesamt für Strahlenschutz* (German Federal Office for Radiation Protection), Neuherberg (retired).

Bonn, September 2018

Dr. Stefan Thierfeldt
Chair of the programme committee

Prof. Dr. Joachim Breckow
Chair of the German Commission on Radiological Protection

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1 Introduction

The German Commission on Radiological Protection's closed meeting held in Würzburg, Germany, in March 2018 covered the topic of 'Protecting consumers against the risks of ionising and non-ionising radiation' with the aim of investigating consumer protection in terms of radiation protection, and of looking at the differences and overlaps regarding the legislation and provisions in place for these two fields. This topic was chosen due to the frequent introduction of new applications in the field of non-ionising radiation which require new legislation.

The following topics were covered during the closed meeting: new legislation for ionising and non-ionising radiation, legislation for naturally occurring radioactive material (NORM), consumer protection in the wake of incidents and accidents, and consumer protection against optical radiation and electromagnetic fields. The closed meeting was rounded off with a podium discussion. The full agenda of the closed meeting is provided in the annex.

2 General points

The first set of presentations focussed on the fundamentals of consumer protection in terms of ionising and non-ionising radiation. Two presentations provided an overview and context of the two fields, while two subsequent talks presented the structural legislative framework for each field.

In her introductory presentation, Ms S. Mobbs (Eden Nuclear and Environment Ltd, UK) talked about the derivation of exemption values based on the European Commission recommendation 'Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) Below which Reporting is not Required in the European Directive' (Radiation Protection 65) from 1993 (adopted into German law in Appendix III, Table 1, columns 2 and 3 of the 2001 version of the German Radiation Protection Ordinance – *StrlSchV*) which forms the statutory framework for any and all handling of ionising radiation during practices. These values are also provided in the latest basic safety standards on radiation protection introduced by the EU (Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation). They are based on radiological models that assume the use of low quantities (several Mg) of substances, and link the activity of such substances to an effective individual dose of 10 µSv/a in realistic exposure scenarios and 1 mSv/a in exceptional cases. The exemption values provided by the European Commission have now been in use for almost 20 years and are likely to remain in place over the next 15 years until subsequent basic safety standards of radiation protection will be introduced. This gives rise to the question of sustained validity in terms of the derivation of these values (radiological scenarios, assumptions about underlying individual scenarios). A detailed review carried out in Great Britain on behalf of the responsible authorities shows that the modelling used to arrive at the exemption values can continue to remain in place due to its conservativity, also given the change in consumer habits, the increase in recycling rather than disposing of materials, and due to a number of other developments. These results can be carried over to other industrialised European countries. As a consequence, there is no reason why the exemption values from 1993 should not continue to be applied in the current basic safety standards on radiation protection standards and future national legislation.

E. van Deventer (World Health Organisation, WHO) talked about international standards for consumer products in the area of non-ionising radiation. In her presentation, Ms van Deventer talked about non-ionising radiation in the form of electromagnetic radiation ranging from

0 GHz to 300 GHz, as well as visible and UV light. Corresponding provisions already exist for sound, in particular infrasound and ultrasound. There are many ways in which people can be exposed to non-ionising radiation, thus making it extremely important in terms of consumer protection. Consumer products are defined as products which consumers may own directly or which consumers may indirectly use or operate. Examples of such consumer products which may lead to substantial public exposure were provided and cover every frequency range, starting with extremely low frequency (ELF) fields and on to intermediate high-frequency fields, microwaves, Wi-Fi, mobile radio frequencies, the Internet of Things (IoT) through to laser pointers, laser scanners and sunbeds. Certain consequences of exposure to products involving such frequencies can be observed and measured directly, e. g. currents induced in the human body, local temperature increases, and sunburn. Other indirect consequences such as childhood leukaemia, brain tumours or skin cancer, however, cannot be as clearly associated with exposure to non-ionising radiation as is the case with ionising radiation. For this reason, the provisions put in place to protect the population against non-ionising radiation are completely different to those for ionising radiation. The WHO is currently working on such a framework, particularly for areas that are highly relevant in terms of protecting the population. To this end, the WHO is working closely with the International Labour Organisation (ILO) as many of the provisions will also affect health and safety practices in the workplace.

M. Petzoldt and B. Keller (both Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU) presented the general structural legislative framework put in place in Germany to protect against ionising and non-ionising radiation.

Mr Petzoldt's presentation provided an overview of the current changes to radiation protection legislation and its comprehensive revision by the BMU. He started by looking at the structural changes, including the key role that the German Radiation Protection Act (StrlSchG) will play when it replaces the Atomic Energy Act (AtG) as the main standard. In addition to the introduction of the Radiation Protection Act (StrlSchG), there will still be a Radiation Protection Ordinance (StrlSchV), which will be much more comprehensive in scope and cover various areas such as protection against damage due to ionising radiation and X-rays, emergency protection, protection of the population against exposure to radiation, and more extensive consumer protection legislation. Additional ordinances will also be introduced alongside the StrlSchV. Only a few basic changes have occurred when it comes to protection against ionising radiation. One such example is that exposure due to all practices requiring a licence pursuant to the StrlSchG and the Federal Mining Act (BBergG) is now handled in the same way with a combined dose limit of 1 mSv/a for the general public, while organ dose limits will only be retained for a small number of organs, and the dose limit for the eye lens has been reduced to 15 mSv/a.

After this, Ms Keller's presentation showed that non-ionising radiation legislation is quite different to that in place for ionising radiation. The provisions put in place to protect against non-ionising radiation are based on the Treaty on the Functioning of the European Union (TFEU), while ionising radiation provisions are based on a fundamental European agreement, the Treaty establishing the European Atomic Energy Community (Euratom). The EU's regulatory competence extends much further for non-ionising radiation, which is why product safety requirements are largely standardised throughout EU Member States by way of European ordinances and directives. While the safety standards are specified in concrete terms in harmonized standards on product safety and also integrate occupational health and safety and population protection, regulations at European level must also serve to dismantle trade barriers in the EU and to place products on the market. An effect that can be directly measured on a biological level always forms the basis for non-ionising radiation protection provisions. In order to enshrine protection in legislation, a basic limit value and a safety factor must be stipulated to

account for such effects. In Germany, the Federal Immission Protection Act (BImSchG) forms the basis for protecting the population against electromagnetic field immissions. The 26th Ordinance Implementing the Federal Immission Control Act (BImSchV) was then enacted on the basis of this, while the Act to protect against Non-ionising Radiation used on Humans (NiSG) governs protection against the effects of non-ionising radiation and ultrasound on humans. Additional provisions for health and safety at workplaces are also in place.

These four presentations outlined the roots underlying current provisions for ionising and non-ionising radiation on a domestic and international level, along with the differences that exist between the two fields in terms of their respective legal landscape. Provisions to protect against ionising radiation are based on a well-established dose-response relationship, while provisions pertaining to non-ionising radiation focus on avoiding biological effects beyond the respective thresholds. When it comes to consumer protection, provisions for non-ionising radiation are based on international regulations that are interdependent to a much higher degree than those for ionising radiation.

3 New legislation

K. Engelbrecht-Greve and A. Pütz (both Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU) provided an overview of the new provisions laid down in the Act to protect against the Damaging Effect of Ionising Radiation (Radiation Protection Act – StrlSchG) and the Act to protect against Non-ionising Radiation used on Humans (NiSG).

Ms Engelbrecht-Greve focussed on the justification of practices involving consumer goods and type-approved devices. As one of the three principles of radiation protection, the principle of justification is of particular importance in legislation to protect against the damaging effect of ionising radiation. As an extension of the previous law and by implementing Directive 2013/59/Euratom, the principle of justification is also anchored in the German Radiation Protection Act. One change to the previous law and an addition to the general principle of justification is the formalised method where the Federal Office for Radiation Protection (BfS) verifies the justification of practices, which, in exceptional cases, serves to support and ease the responsible authorities' duty to do so. Here, the German Radiation Protection Act differentiates between a general process to assess the justification of a practice and a special process to verify the justification of a new practice in connection with consumer goods and type-approved devices.

Ms Pütz pointed out that many areas are not yet governed when it comes to non-ionising radiation, and then showed how legislation based on the Act to Protect against Non-ionising Radiation used on Humans (NiSG) should stipulate requirements in terms of the expertise needed by people who use non-ionising radiation sources on humans.

The medical world has been using non-ionising radiation successfully for diagnostic and therapeutic purposes for many years now. However, non-ionising radiation sources such as lasers, high-energy flashlights and ultrasound are now being increasingly used for cosmetic and other non-medical purposes, e. g. for permanent hair removal, to smooth out wrinkles, to remove tattoos, and to destroy fat tissue. Demand for cosmetic treatments is huge, meaning that a number of manufacturers now offer their – often very inexpensive – products on the German and other European markets.

Nowadays, almost anyone can use non-ionising radiation sources for cosmetic and other non-medical purposes without requiring any special qualification to do so. There are currently no legal requirements pertaining to the safe and correct use of non-ionising radiation sources

provided the device is not classified as being a medical product or subject to health and safety regulations. However, such devices pose health risks if not used correctly, as they may lead to severe side effects such as burns, scarring, permanent pigment changes, cell damage and inner bleeding.

4 NORM (Naturally Occurring Radioactive Material)

Four presentations were given on NORM to provide a legislative overview for naturally occurring radioactive material, including its implementation and use in the two areas relevant to consumer protection – construction products and waste disposal.

R. Barthel provided an introductory overview of the 'Regulations and scenarios for NORM residues after 15 years of practical experience' together with their implementation. The provisions laid down in Part 3 of the 2001 version of the German Radiation Protection Ordinance (StrlSchV) represent the first time that a comprehensive and systematic set of rules have been put in place in Germany to protect the population against naturally occurring radioactive material. These provisions are based on the requirements of Council Directive 96/29/Euratom of 13 May 1996 (EU basic safety standards on radiation protection), which includes the first-ever international legal framework of its kind on NORM. As already covered in the general points presentations, it is important to know about the history behind the development of these rules so as to be able to understand and apply them correctly. The fields of work for which significant exposures may occur due to naturally occurring radiation sources, the residue groups requiring surveillance, and the stipulation of surveillance limits in accordance with Appendixes XI and XII of the 2001 version of the German Radiation Protection Ordinance (StrlSchV) were all based on comprehensive studies performed in the late 1990s. Should any of the circumstances or material flows change significantly, the fields of work and groups of residues, and possibly also the surveillance limits, would need to be updated. R. Barthel's presentation covered the positive experience to date in terms of implementing existing provisions, but also included the regular use of the fallback provision in Section 102 of the 2001 version of the StrlSchV (Surveillance of other materials) that enables the competent authority to take protective measures for materials that are not residues in terms of Appendix XII, Part A of the 2001 version of the StrlSchV. In such cases, individual assessments were carried out in line with the requirements of Section 98 of the 2001 version of the StrlSchV and were generally instigated by the waste producer. The experience gleaned from these assessments provided the bases for future NORM provisions already implemented in Annexes 1 and 3 of the German Radiation Protection Act (StrlSchG).

B. Hoffmann from the Federal Office for Radiation Protection (BfS) gave a talk on the European standardisation within the scope of the Construction Products Regulation (CPR). This presentation covered the origins of the provisions laid down in Sections 133 to 135 of the German Radiation Protection Act (StrlSchG) with regard to the amount of activity in construction products. There is a long history surrounding the initiatives to limit radionuclide content in construction products whose gamma radiation and, to a lesser extent, radon exhalation lead to sustained public exposure. Principles applied throughout the EU to limit the activity were published by the European Commission in 1999 in the form of 'Radiological Protection Principles concerning the Natural Radioactivity of Building Materials (Radiation Protection 112)'. This recommendation contains what is known as an index formula to limit Ra-226, Th-232 and K-40 activity concentrations in building materials. These requirements have been legally enacted in the EU Construction Products Regulation (CPR, EU/305/2011), which supersedes the Construction Products Directive (CPD, Council Directive 89/106/EEC). The CPR requires buildings to be erected in such a way that residents need not have any

concerns about being exposed to dangerous radiation levels. This specific requirement was enacted in the form of Council Directive 2013/59/Euratom. Within this context, CEN Technical Committee TC351 (Construction products: Assessment of release of dangerous substances) formed a working group tasked solely with investigating radioactivity in construction products. On the one hand, this work resulted in a preliminary test standard for the gamma-spectrometric determination of the nuclide content of radium, thorium and potassium in construction products, and on the other hand, a technical report was prepared describing a possible procedure for determining the population dose from the measured specific activities. The technical report 'Dose assessment of emitted gamma radiation' (CEN/TR 17113) was published in 2017. The national standardisation institutes are currently voting on the draft testing standard (CEN/TS 17216) to harmonise the dose models used.

D. Rosen (Federal Association of the German Brick and Tile Industry) then talked about 'Implementing the basic requirement set out in the BauPVO' with a view to the 'Emission of dangerous radiation'. This presentation covered the perspectives of manufacturers as well as building material distributors. Manufacturers are required to comply with two different legal fields: the provisions of Council Directive 2013/59/Euratom implemented in Germany in the form of the Radiation Protection Act (StrlSchG), and an additional declaration of radiation emitted by building materials in connection with the Construction Products Regulation (CPR). This presentation focussed on the manufacturer's assessment and labelling requirements when distributing construction products in accordance with the Construction Products Regulation (CPR). Providing Ra-226, Th-232 and K-40 concentration levels for building materials represents a problem for users because they lack the knowledge and expertise required to determine whether a product can be used safely or whether it represents a hazard. In addition, modern building materials contain a large proportion of air in order to achieve a high degree of insulation, meaning that the activity of a certain radionuclide must always be related to the correct effective density. The presentation therefore proposed a tiered approach involving two different index formulae, whereby falling below the index value 1 in the unmodified formula means trade is permitted without any restrictions, exceeding the index value 1 requires a separate valuation with a formula modified in terms of density (also resulting in permission for trade if falling below the index value 1 in the modified formula), and exceeding the index value 1 for both formulae requires a suitable restriction of the application of the construction product. The German Institute of Building Technology (DIBt) is currently using the above approach to assess each type of building material. The presentation also included the co-applicability of German and European legislation and regulations. There is currently no European classification system in place. Road-building materials form an exception to the considerations put forward because the exposure scenarios provided cannot be applied.

P. Asenbaum's (District government Arnsberg) presentation rounded off the NORM topic by looking at 'Consumer protection in disposal of NORM waste'. This talk started with a look at German waste law within a European context. Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives (Waste Framework Directive), for example, stipulates a number of major requirements, including a five-level waste hierarchy. Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste (Landfill Directive) provides a European requirement in terms of landfill waste disposal. Among others, these directives are implemented in Germany by way of the Waste Management Act (KrWG), including the various accompanying waste law regulations such as the landfill ordinance. Any waste containing naturally occurring radioactive material is subject to waste law as well as requirements set out in radiation protection law, currently Part 3 of the 2001 version of the German Radiation Protection Ordinance (StrlSchV). This means that such NORM waste must be disposed of subject to exemption from radiation protection law, subject to approval by the authorities, and in compliance with landfill disposal law. The accompanying

exemption and order procedure involves a site-specific radiological assessment of the waste, along with an accompanying assessment of the disposal installation, i. e. landfill site. The waste generator and the disposal authorities then liaise with one another and agree on the disposal path to be complied with. The presentation also included examples of how to implement these requirements, and used landfills in the Rhenish liginite mining region as an example. Since 2009, there are no longer any landfills that do not comply with EU law. Due to the sophisticated base and surface sealing layers used at modern landfills, which are subject to extensive internal and external monitoring, class I, II or III landfills are technically suited to disposal of NORM waste, as substantiated by the existing radiological assessments. Disposal of such waste does not require hazardous waste disposal sites. This approach ensures the requisite consumer protection and protection of workers.

5 Consumer protection following incidents and accidents

In 2009, a number of steel objects were found in Europe, including in Germany, which emitted increased levels of gamma radiation. Some of these objects were then confiscated. The apparent reason for this was a highly radioactive Co-60 source present in scrap steel in the Far East that was either accidentally or negligently melted down. The Federal Office for Radiation Protection (BfS) used this as an opportunity to investigate possible entry routes for contaminated steel objects and to assess safeguarding German scrap yards and ironworks by installing radiation portal monitors (RPMs) at the entrances to such sites. The BfS also conducted a preparatory study involving computer simulations to investigate the minimum detectable activity, e. g. of Co-60 and Cs-137 in loads of scrap.

R. Merk (Federal Office for Radiation Protection – BfS) presented the results of a BfS departmental research project involving ‘Radioactive objects in scrap’ which was handled by Brenk Systemplanung GmbH. The project comprised research, surveys (e. g. among scrap yards and melting shops), computer simulations and experiments involving real radioactive sources in real waste containers. The preparatory computer simulations performed by the Federal Office for Radiation Protection (BfS) were investigated further on an expert level during the departmental research project. The results of both approaches line up well with one another, particularly given the complexity of the issue and the underlying simulation geometry (modelling hundreds of irregular items of scrap and the gamma radiation penetrating, scattered or absorbed by them). The minimum detectable activity determined during the course of the theoretical study by way of simulation was confirmed during the experiment involving a real scrap container. This also rendered it possible to provide a series of conceivable recommendations.

The following three presentations looked at protecting consumers in radiological emergency situations.

F. Gering (Federal Office for Radiation Protection – BfS) provided an overview of measures to be performed following major accidents. Before, during and after a major accident involving a significant release of radioactive substances into the environment, a number of very different measures are available to avoid or reduce the negative effects of the accident on humans and the environment. In general, the number of applicable measures increases with increasing time since the accident, while the effectiveness of the measures decreases. On an international level, there is a certain degree of consensus regarding the key measures to be taken, particularly during the early phase of an accident, which is also backed up by clear recommendations from the IAEA. However, especially when planning the transition phase (days, weeks or even months after an accident), there is no standard approach available on an international level. The reactor

accident in Fukushima was used as an example for presenting potential protective measures aimed at developing existing standards for planning and implementing protective measures, and for highlighting potential deficits or deviations.

F. Meinerzhagen (*Gesellschaft für Anlagen- und Reaktorsicherheit*, GRS) gave a presentation prepared by W. Rother, H. Kracht and T. Schlummer (all Federal Ministry for the Environment, Nature Conservation and Nuclear Safety – BMU) on emergency plans and emergency protection ordinances. Council Directive 2013/59/Euratom was transposed into German law by way of the German Radiation Protection Act (StrlSchG), which led to a series of updates for the emergency management system in place at federal and *Land* level. To date, emergency preparedness requirements primarily consisted of recommendations largely based on emergencies at nuclear facilities. The new legislation imposed by the StrlSchG now requires the development of emergency plans covering the entire spectrum of emergency situations. It also lays down requirements for early protective measures within the context of disaster control along with large parts of the mid-term and long-term emergency management yet to be passed as a general administrative provision. To this end, reference scenarios were determined as a planning basis, and risk analyses for the individual reference scenarios were used to prepare optimised protection strategies that include high-priority measures as well as other measures relevant to the given reference scenario designed to protect the population and emergency services. Where present and agreed upon, constraints and other radiological criteria are included in the emergency plans and serve as the basis for deciding on the measures to be taken. Certain dose or contamination levels can be stipulated in advance, also by way of decree, as binding limits for future emergencies or in the event of an incident.

In an emergency, the responsible federal/state department or law enforcement authorities will decide on the measures to be performed and then carry out said measures. General plans and stipulations regarding responsibilities form part of the general federal emergency plan. Certain federal authorities also provide special emergency plans for certain fields. In the future, all federal plans are to be specified in more detail by way of corresponding state emergency plans.

On a federal level, the Federal Radiological Situation Centre is a new organisational unit tasked with coordinating and assessing an emergency situation.

F. Lange reported on the development of Operation Intervention Levels (OILs) for protective measures to be implemented in a radiological emergency. Emergency protection measures are to be planned for incidents involving a release of radioactive substances into the surroundings. Here, protective strategies are to be developed and optimised in advance using risk analyses and postulated scenarios. Radiological emergency preparedness and response is designed to reduce human exposure to radiation in order to

- avoid major deterministic effects and
- minimise stochastic effects based on the principle of proportionality.

In terms of emergency exposure situations, proportionality means that protective measures to reduce stochastic effects should be justified. The negative consequences of a planned measure, including its economic and social impact, must be weighed against the dose incurred without performing the measure.

Decisions regarding the protective measures to be taken following a release require swift measurements to ascertain the prevailing radiological situation, primarily the local dose rate or surface contamination measurements. The decision on the protective measures to be taken is based on Operational Intervention Levels (OILs), which are criteria stipulated in advance to determine when emergency response is required to protect the population and emergency workers based on contamination measurements taken at the site of the accident.

As part of emergency planning, BMU tasked the SSK with developing OILs for the radiological incidents listed in the catalogue of scenarios. Here, decisions have to be taken in terms of the dose reference level to be used as a basis for performing a measure in case of an incident. The dose reference level needs to be justified and proportionate to the Basic Radiological Principles. In addition, exposure models need to be used or developed and corresponding parameters supplied so as to provide as realistic a relationship as possible between the OIL measurand and human exposure.

Finally, H. v. Philipsborn and J. Putzger gave a presentation on ‘Measuring devices for the population – How consumers can protect themselves’.

6 Protection against optical radiation

This set of presentations covered the biological effects of light on humans along with the risk potential associated with temporary blinding and the challenges of using optical radiation safely in consumer products.

M. Honnacker (Bavarian State Ministry for the Environment and Consumer Protection) presented the challenges and experience as a result of monitoring consumer products that use optical radiation. The “new approach” and its further development into a “new legislative framework” formed the basis for extremely liberal access for products to the European domestic market. This gives economic players easy access to the market for their products, but it also means they bear the burden of ensuring legal compliance and safety. Many of these products are sold as consumer products to users who have not received specific training on how to handle dangerous products. The use of optical radiation in consumer products is a source of risk that is often underestimated. The federal and state authorities responsible for market supervision represent the safety net in this situation, and they adopt the German state’s role as guarantor for the safety of its citizens and for fair, equal market access conditions for everyone involved.

In his presentation, H.-D. Reidenbach (Technical University of Cologne) talked about the health risk associated with temporary blinding, e. g. by a laser pointer. He also reported on findings from current research into the functional dependency of the visual impairment period on the exposure situation (beam density, length of exposure and wavelength) which was determined experimentally in test person experiments. Due to its associated subsequent visual phenomena, blinding has a major impact on temporal impairment of visual functions such as acuity and colour vision. Findings from the latest research can be used to derive quantitative estimates for distance-related visual impairments. Among other things, this enables a better assessment of the risk potential associated with blinding. In addition, Mr Reidenbach’s talk showed that visible laser radiation from products classified harmless in terms of potential eye damage constitutes a major risk of blinding, meaning that it can be considered a new radiation protection quality.

M. Münch (*Charité Universitätsmedizin Berlin*) talked about ‘Light and darkness – How they influence human physiology and psychology’. During her presentation, Ms Münch provided a brief overview of the latest developments in terms of the biological effects of light with a particular focus on the sustained, chronic impact of daylight and artificial light and any associated risks.

As a *zeitgeber*, light plays a key role when it comes to chronobiology because it passes on general information about the Earth's 24-hour light/dark cycle to the body’s endogenous (internal) clocks and synchronises the body with said cycle. Over the last few decades it has been shown that these seemingly trivial relationships have a major long-lasting impact on the extremely complex human system of physical and mental functions. The quality and quantity

of light (electromagnetic radiation in the visible spectrum), and the times/time of day at which exposure to light take place, both affect these functions in different ways in terms of duration and effectiveness.

All of the photoreceptors in the human retina are involved in processing signals from inbound photons and are responsible for so-called 'non-visual' light effects in various neuronal networks, such as wakefulness, the circadian rhythm, mood, and cognitive ability. Until recently it was thought that these effects of light were largely sent via the photopigment melanopsin and were limited to non-visual functions. However, recent findings show that retinal ganglion cells are intrinsically sensitive to light and also play a part in the visual process, e. g. in perceiving brightness and contrast. This provides new opportunities and horizons in terms of research and real-life practice.

7 Electromagnetic fields – Limits of application and protection

This set of presentations covered the benefits and risks of using electromagnetic fields (EMFs) in medical and non-medical applications, and when developing wireless communication equipment.

M. Moser presented the benefits and risks of using EMFs, particularly when used on humans for non-medical purposes. Nowadays, medical applications use the full EMF spectrum for diagnostics, treatment and therapy. The effect of EMFs is based on two fundamental mechanisms of action: muscle and nerve cell irritation, and energy coupling, i. e. warming of the body. In order to achieve the intended effect, strong EMFs are often used which are above the applicable limits and sometimes exceed thresholds for injury to health. The administering physician is responsible for weighing up the risks against the benefit of such an application and for ensuring the application is used in an optimal manner. Over the last few years, the number of non-medical EMF applications for humans has increased significantly, particularly in terms of the cosmetics and spa industries where medical products are being used for non-medical purposes, known as off-label applications. Such applications can be performed by non-professionals and private persons, and in theory even by children.

A. Antal (University of Göttingen) presented the non-invasive neuromodulation technique in the form of transcranial Direct Current Stimulation (tDCS). This technique provides scientists and doctors with an opportunity to gain basic insights into brain functions, in turn enabling them to treat a series of neurological and psychiatric illnesses. The different regulatory pathways in place for devices in the U. S. and in Europe have led to varying global availability of tDCS. As a result of this, the use of tDCS, including off-label applications, has grown rapidly without there being any clear understanding of the safety and effectiveness of the technique. In addition, there are many over-the-counter (OTC) devices and do-it-yourself (DIY) device instructions available, which gives cause for major concern. The ethical implications associated with the involuntary use of tDCS to manipulate a person's behaviour or to achieve compliance with socially accepted norms are also a regular subject of debate.

In his presentation, P. Unger (Deutsche Telekom Technik GmbH) described 'The present and future of wireless communication'. He covered the major developments in terms of mobile networks and their influence on immissions from electromagnetic fields. Wireless communication has developed rapidly since the introduction of GSM, the first-ever digital cellular technology. The arrival of the smartphone saw the use of mobile data services become ubiquitous beyond the realms of voice communication with more and more people using a smartphone as their primary device for accessing the Internet. Devices, vehicles and machines are also increasingly becoming interconnected to provide more intelligent and thus more

efficient processes. New and more efficient mobile communication concepts are required due to the variety of applications and increasing number of connected devices. The standards for the 2nd, 3rd and 4th generation technologies (GSM, UMTS and LTE respectively) are still being improved, but the 5G mobile standard is just around the corner and set for release in 2020. Care must be also taken to protect humans from EMFs when introducing new mobile technologies, and the development of new solutions is constantly flanked by questions related to radiation protection in order to be able to monitor and evaluate the effects of the immissions in detail.

8 Podium discussion

The podium discussion revolved around the question 'How is the population protected against ionising and non-ionising radiation?' This was the final item on the agenda and designed as a brief summary of the broad range of content covered during the two-day meeting. A. Böttger, J. Breckow, M. Fischer, J. Kopp, G. Ott, S. Thierfeldt and W. Weiss took part in the podium discussion.

Mr Weiss kicked off the discussion by summarising the multitude of content covered during the closed meeting on 'Protecting consumers against the risks of ionising and non-ionising radiation'. The discussion then moved on to take stock of the status quo regarding each topic, the legislation and regulations in place, and the problems currently being faced as well as possible solutions to current deficits.

Mr Böttger then reviewed the development of ionising radiation regulations. The IAEA and the European Commission are currently preparing requirements for Member States based on the UNSCEAR assessment and the ICRP's basic radiation protection recommendation. In contrast to the IAEA's Basic Safety Standards, the EU's basic radiation protection standards are to be transposed into domestic law with advisory groups such as the SSK called upon as and when deemed necessary. What is new here is that the IAEA's Basic Safety Standards also provide provisions for non-ionising radiation.

Mr Thierfeldt and Mr Kopp then gave a summary and interpretation of the topics related to ionising radiation that were covered during the first day of the meeting. Mr Thierfeldt explained that the presentations given during the first day showed that ionising radiation has a consistent, long-lasting system consisting of primary parameters (limiting public exposure, trivial dose levels, etc.) and derived, measurable parameters (exemption values and clearance levels, etc.) that are associated with primary limits and constraints through various scenarios. This system has been in place for around 30 years (although some of the primary limits have been around for longer) and, thanks to it being anchored in the EU's basic safety standards for radiation protection, will remain in place for around another 15 years. A similar picture can be seen in the special field of NORM, although the primary and derived parameters involve different scenarios to the practices described in Part 2 of the 2001 version of the German Radiation Protection Ordinance (StrlSchV). Due to the long-standing application of these standards, their bases and scope of validity often tend to be forgotten, in turn giving rise to the need for an update, as was provided in the presentations. The provisions added especially to the new version of the StrlSchV will have a major impact on material management due to Germany dismantling its nuclear power plants, in turn meaning that they require particular consideration. In addition, initial approaches for new versions of regulations for mass-related exemption values showed that the values provided in Appendix III, Table 1, column 3 of the 2001 version of the StrlSchV cannot be simply replaced by the new low exemption values which can be applied to any amount (Annex VII, Table A, Part 1 of Council Directive 2013/59/Euratom), meaning that considerations should perhaps be made with regard to retaining those values.

Mr Kopp talked about the emergency protection regulations which the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) needs to coordinate with the many administrative and institutional levels involved. Scenarios for emergency protection planning have to be developed on the basis of abstract event sequences because they are rarely based on actual, current experience. However, certain questions can be investigated by way of experiments and model calculations, such as the situation covered in the presentations where a radiation source was discovered in scrap metal. One challenge posed by the new German Radiation Protection Act (StrlSchG) is the requirement to include consumers in emergency protection measures, e. g. special provisions in transport regulations enforced in the wake of nuclear accidents which could lead to contamination of consumer goods, in turn requiring said goods to be rejected at the border. Here, care must also be taken to include provisions for people who have not been exposed but are concerned about the situation at hand. This is why it is important to provide the population with clear and understandable information. It is also important to point out that reference levels cannot represent limits in emergency situations because the concept of limits cannot be applied to situations that cannot be planned for. This is particularly difficult to convey due to the public's general unwillingness to accept the risks associated with ionising radiation. In view of the already significant scope of the emergency plans, it is not advised to try and devise emergency plans for every eventuality of a radiological emergency because experience shows that it is not possible to predict every eventuality that may occur during an incident.

The following discussion involving all of the meeting's participants focussed on the following points:

- Reference levels and constraints permit a flexible approach in terms of radiation protection and provide a framework for optimising existing situations. Provisions currently under development also need to focus on the time after the foreseeable dismantling of German nuclear power plants as this will give rise to radiation protection tasks for the medical, industrial and research sectors.
- To date, public dissemination of plans for emergency protection measures and their content has had little effect. A clear indicator of this major information deficit is the fact that the distribution of iodine tablets is the only emergency protection measure the population is really aware of.

Mr Ott and Mr Fischer then provided a summary and interpretation of the topics related to non-ionising radiation that were covered during the second day of the meeting. Mr Ott explained that a legal framework has been created over the last 10 years to protect the population from optical radiation, including the Act to protect against Non-ionising Radiation used on Humans (NiSG), the Ultraviolet Protection Ordinance (UVSV), and provisions to protect against EMFs during treatments and therapies on humans. There is, however, a major imbalance in terms of the commercial and private regulations currently in place, meaning that there are still a number of challenges when it comes to product and application safety as well as market supervision. This is highlighted by the fact that the power of lasers available on the market continues to increase while prices are decreasing. There are currently no laser accident statistics available. Extrapolations based on individual cases indicate that there may be around 800 cases per year, but it would be better to have a standardised means of statistical collection in place.

Mr Fischer then provided a summary on electromagnetic fields. The presentations described a number of medical and non-medical applications. Particularly with medical applications, a prerequisite for an effective device fit for purpose is that it emits electric, magnetic or electromagnetic fields which exceed the permissible levels put in place to protect humans and exclude any detrimental health effects. This becomes a clear problem if medical equipment is

used by unqualified persons for purposes other than those originally intended (off-label use). There is also a need for regulation in terms of brain stimulation (neuroenhancement), although it is currently unclear how this field will develop and to what extent regulation will be required. When it comes to mobile communications and the rollout of the 5G network, there is still the issue of personal risk perception as people tend not to consider their mobile phone a risk, yet they certainly think that transmitter masts pose a problem.

The ensuing discussion involving all of the meeting participants yielded interesting comments on the reduction of exposure by introducing small cells, i. e. low-powered cellular radio access nodes with a shorter range that enable mobile phones to require less transmission power than is the case with conventional cellular radio access nodes (macrocells).

Mr Breckow, Chair of the German Commission on Radiological Protection (SSK), provided the closing remarks on the subjects covered during the two-day meeting. Ionising radiation protection is based on well-established and proven concepts which make up a closed system that has been developed over many decades and does not require any major updates despite the latest radiation protection legislation. Parts of this system are complex and need to be investigated in more detail, but the system is built upon such solid foundations that substantial radiation protection can be guaranteed. In contrast, the concepts available to protect against non-ionising radiation are far from developed and require further investigation. While it may seem tempting to simply adopt the system in place for ionising radiation, this would only be partially possible and upholding the principles of justification and optimisation would prove particularly difficult to carry over. Major problems are to be expected in terms of protecting consumers against non-ionising radiation due to the often altogether different quality of the many non-ionising radiation applications available and given the fact that neither the current situation is sufficiently regulated, nor is it possible to foresee every future development. This is compounded by the fact that public opinion of entire fields of technology and individual applications may change in the future. Where possible, experience gleaned from the field of ionising radiation should be taken into account.

Mr Greipl then thanked all of the attendees on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) for their contributions. In hindsight, it may have made sense to arrive at a clear definition of the term ‘consumer’ and to provide a distinction from health protection. These aspects were highlighted by the fact that consumer protection against ionising radiation is governed in terms of health protection, while consumer protection against non-ionising radiation focuses much more on the consumer as such, not in the least due to the many more fields of application and effects on humans which can be triggered as a result of non-ionising radiation. Radiation protection pertaining to mobile networks and compliance with limits will continue to play a role in the future. The current German government’s coalition agreement includes safeguards to protect against electromagnetic fields due to the onset of digitalisation, including in particular the upcoming rollout of the 5G mobile standard.

Legal framework

26. BImSchV	The 26th Ordinance Implementing the Federal Immission Control Act, 16 December 1996, Federal Law Gazette I 1996, 1966, redrafted in its amendment dated 14 August 2013, I 3266
BauPVO	Regulation (EU) No 305/2011 of the European Parliament and of the Council of 9 March 2011 laying down harmonised conditions for the marketing of construction products and repealing Council Directive 89/106/EEC. Official Journal L 088, 4 April 2011, p. 5–43
BBergG	Federal Mining Act (BBergG), 13 August 1980, Federal Law Gazette I 1980, 1310, last revised by Article 2(4), 20 July 2017, I, 2808
BImSchG	German law on protection against harmful environmental effects from air pollutants, noise, shocks or vibration, or similar phenomena (Federal Immission Protection Act - BImSchG), 15 March 1974 Federal Law Gazette I 1974, 721 (1193), last revised by Article 3, 18 July 2017, Federal Law Gazette I, p. 2771
CEN/TR 17113	Construction products - Assessment of release of dangerous substances - Radiation from construction products - Dose assessment of emitted gamma radiation; German version CEN/TR 17113:2017
CEN/TS 17216	Construction products - Assessment of release of dangerous substances - Determination of the activity concentrations of radium-226, thorium-232 and potassium-40 using gamma-ray spectrometry. Project, planned document number DIN CEN/TS 17216
NiSG	Act to protect against non-ionising radiation used on humans (NiSG), 29 July 2009, Federal Law Gazette I, p. 2433 (no. 49); last amended by Article 5, 8 April 2013, Federal Law Gazette I, p. 734
Council Directive 1999/31/EC	Council Directive 1999/31/EC of 26 April 1999 on the landfill of waste, Official Journal L 182, 16 July 1999, p. 0001 – 0019
Directive 2008/98/EC	Directive 2008/98/EC of the European Parliament and of the Council of 19 November 2008 on waste and repealing certain Directives, Official Journal L 312/3, 22 November 2008
Council Directive 2013/59/Euratom	Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom. Official Journal of the European Union, L 13/1, 17 January 2014
Council Directive 96/29/Euratom	Council Directive 96/29/Euratom of 13 May 1996 laying down basic safety standards for the protection of the health of workers and the general public against the dangers arising from ionising radiation. Official Journal of the European Communities L159/1, 29 June 1996

RP 112	Radiological Protection Principles concerning the Natural Radioactivity of Building Materials (Radiation Protection 112), European Commission 1999
RP 65	Principles and Methods for Establishing Concentrations and Quantities (Exemption Values) Below which Reporting is not Required in the European Directive (Radiation Protection 65), European Commission 1993
StrlSchG	Act to protect against the damaging effect of ionising radiation (Radiation Protection Act - StrlSchG). Article 1 of the Act to reform the law on protection against the damaging effect of ionising radiation dated 27 June 2017 (Federal Law Gazette I, p. 1966)
StrlSchV	Ordinance on protection against damage and injuries caused by ionising radiation (Radiation Protection Ordinance), 20 July 2001 (Federal Law Gazette I, p. 1714; 2002 I, p. 1459), last amended in accordance with Article 10 by Article 6 of the Act, 27 January 2017 (Federal Law Gazette I, pp. 114, 1222)
UVSV	Ordinance on protection against the damaging effects of artificial ultraviolet radiation (Ultraviolet Protection Ordinance), 20 July 2011, Federal Law Gazette I, p. 1412

Closed meeting agenda

Protecting consumers against the risks of ionising and non-ionising radiation 2018 closed meeting held by the SSK on 15 and 16 March 2018 at the *Juliusspital in Würzburg, Germany*		
Thursday, 15 March 2018		
	C. Greipl, J. Breckow	**Welcome**
General points *Chair: S. Thierfeldt*		
1	***S. Mobbs,*** ***E. van Deventer***	***S. Mobbs:*** **Derivation of exemption values – defining the scope of radiation protection regulations** ***E. van Deventer:*** **International standards for consumer protection against non-ionising radiation**
2	***M. Petzoldt,*** ***B. Keller***	**General structural legislative framework in Germany to protect against IR and NIR**
	Discussion	
New legislation *Chair: J. Breckow*		
3	***K. Engelbrecht-Greve***	**Radiation Protection Act and Ordinances: Justification of practices involving consumer goods and devices whose type has been approved**
4	***A. Pütz***	**New legislation based on the Act on the protection against non-ionising radiation used in humans (NiSG)**
	Discussion	

NORM *Chair: S. Thierfeldt*		
5	***R. Barthel***	**Regulations and scenarios for NORM residues after 15 years of real-life experience**
6	***B. Hoffmann, D. Rosen***	**Special regulations for building materials:** **Part 1:European standardisation within the scope of the Construction Products Regulation (CPR)** **Part 2:Implementing the basic requirement set out in the BauPVO: Emission of dangerous radiation**
7	***P. Asenbaum***	**Consumer protection when disposing of NORM waste**
	Discussion	
Consumer protection following radiation accidents and incidents *Chair: J. Kopp*		
8	***R. Merk***	**Radioactive objects in scrap – theory, experiment, real-life experience**
9	***F. Gering***	**Overview of measures following major accidents (e. g. Fukushima)**
10	***F. Meinerzhagen***	**General and special emergency planning and emergency protection ordinances**
11	***F. Lange***	**Operation Intervention Levels (OILs) for protective measures in a radiological emergency**
12	***H. v. Philipsborn, J. Putzger***	**Measuring devices for the population – how consumers can protect themselves**
	Discussion	

Friday, 16 March 2018		
Protection against optical radiation *Chair: G. Ott*		
13	***M. Honnacker***	**Challenges associated with the safe use of optical radiation in consumer products**
14	***H.-D. Reidenbach***	**Blinding - The indirect effect of optical radiation**
15	***M. Münch***	**Light and darkness – How they influence human physiology and psychology**
	Discussion	
Electromagnetic fields – limits of application and protection *Chair: M. Fischer*		
16	***M. Moser***	**Use of EMF on humans – benefits vs. risks**
17	***A. Antal***	**Neuroenhancement and direct current stimulation therapy: Is electricity the solution for everything?**
18	***P. Unger***	**The present and future of wireless communication**
	Discussion	
	Podium discussion: **'How is the population protected against ionising and non-ionising radiation?'** ***(W. Weiss, S. Thierfeldt, J. Breckow, J. Kopp, G. Ott, M. Fischer, A. Böttger)***	
	Closing address *(C. Greipl)*	