Bundesamt für Strahlenschutz

Further development of radiation protection principles by the Federal Office for Radiation Protection

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Content

Preface

The purpose of radiation protection is to protect people and the environment against the harmful effects of ionising and non-ionising radiation. This purpose goes beyond the whole spectrum of technology and measurements. It incorporates technical protection concepts and principles, and observes ethical principles and societal values with regard to the goods that are to be protected, as well as showing which level of protection should be reached or guaranteed, and what precaution and protective measures are to be concretely arranged in order that the protection targets may be reached. As far as this is concerned, the use of radioactive materials, as well as ionising and non-ionising radiation characteristic of the origins of society, must be taken into account as well as environmental radiation impact, especially if they show concrete risk signs. Radiation impact values must be observed and assessed whether they are in isolation or in connection with the impact readings of other dangerous materials.

The technical concepts and principles of radiation protection are the subject of regular assessments and further developments, similar to those from other areas of environment and health protection. As a result, the continually developing knowledge of science and technology must be taken into account as well as the pertinent state of societal discussion of questions of principles adopted in connection with the protection of people and the environment, with consideration for life marked by risk, and the participation of those concerned, as well as the consideration of protective measures. Radiation protection is just one of many relevant aspects in this topic. It is therefore both sensible and necessary to, from time to time, re-establish clearly exactly which principles radiation protection is adopting at any given time, and exactly where the technical and also societal challenges of the future lie.

The principles for further developments in radiation protection outlined here were drawn up by the Federal Office for Radiation Protection (BfS) in close agreement with the Federal Ministry for the Environment (BMU). Under these principles, BfS, as the higher federal authority responsible for radiation protection, for the first time documents comprehensively its own basic positions and perspectives on radiation protection, especially in Germany. The basic principles contain objectives and perspectives for nationwide radiation protection, which are based on a summary of current radiation protection principles. These form the basis of orientation and planned action frameworks, which is suited to helping to establish transparently and comprehensibly the content of the future scope of duties of BfS as regards the continued development of radiation protection, based on the formulation of clear aims. The development of the basic principles is expected to help BfS not only react to future developments in

the field of radiation protection but also actively shape them at an early stage. Its task is also to identify fundamental gaps in knowledge and regulation loopholes and suggesting recommendations as to how these could be eradicated e.g. via legal regulations. It is also a matter of verifying established positions and, if appropriate, modifying them; as well as implementing new positions as and when discoveries would call for them. In this respect, the technical positions, described as follows, get re-assessed within a close forum e.g. as of the new recommendations passed by the International Commission on Radiological Protection (ICRP 103), which were published at the beginning of the year 2008. The deviated positions are referenced as follows.

The existing principles do not (and should not) comment on anything of current legal principles regarding radiation protection. Rather, they establish perspectives and future scopes of actions for radiation protection which are able to make their mark in the field of corrective projects within the interest of radiation protection regulation.

A. Ionising radiation

I. Radiation protection principles

The central technical principle for protection against the harmful effects of ionising radiation, is the convention of a linear dose / effect relationship with no threshold dose (the LNT model), derived from summarising radiation-hygienic assessment of the radiation risk knowledge. It is within this convention that the radiation protection system was established, with the principles of justification, minimisation / optimisation and dose limitation. These principles are elaborated and discussed as follows. These include different applications of ionising radiation and radioactive materials i.e. plannable exposure situations, which are subject to approval (approved activities and tasks) as well as so-called „intervention situations“ (such as accidents and encountered situations) and the special question of the use of ionised radiation and radioactive materials in medicine

A.I.1 Justification

Background

Every use of ionising radiation and radioactive materials in science and technology, as in medicine, requires justification. The central aspect of this justification is the assessment of the benefits of an application and the damages (existing or potential) attached to it. The term „benefits“ recognises such aspects as „chances“ and „advantages“, with „risks“ and „disadvantages“ falling in the category damages. A detailed explanation of the facts can be found at ICRP 103 (The 2007 Recommendations of the International Commission on Radiological Protection, Annals of the ICRP, 2007). A central part of the technical principles of the justification assessment is the radiation protection knowledge for the risks posed by ionising radiation. The non-administration of a dose (wherever this may be applicable), is an important aspect of the justification process and of the justification decision. It is hereby emphasised that each justified usage needs to yield more benefits than harm. The assessment must take into account both kinds of consequences, which can be estimated with all accuracy; and those for which the results can only be judged around considerable uncertainties – which can only be described qualitatively and which are therefore not quantifiable. As far as consideration of the criteria goes: health, societal, social, economical and ecological aspects, and (possibly) radiation-free alternatives are all equally worthy of consideration as well as the interests regarding external and internal security or strategic / social / societal aims.

Examples for a catalogue of criteria can be found in a recommendation by the SSK (Criteria pertinent to the judgement of activities and processes in relation to a justification, Recommendation by the German Commission on Radiological Protection, passed on 16./17.02.2006). The evaluation of benefits and harm factors in individual applications takes place in different ways; as explained in what follows. The process involved in the justification can thus (1) take place within the scope of an individual case observation or (2) result in a decision regarding activity categories; or (3) be a combination of both. The result of the justification can either be that a usage application or a class of usage applications is justified, or – as mandated by a radiation protection directive – individual usage applications or classes of usage applications through a statutory instrument shall be classified as not justified. In the event that significantly new discoveries with regard to the benefits and harm factors are found in conjunction with a particular kind of activity, their justification must be assessed once again.

The justification in connection with the use of ionising radiation and radioactive materials within the scope of plannable activities requires an advance evaluation of the radiation-related risks to the individual, to population groups or to the population as a whole that are to be expected as a result of the activities, and the benefits recognised in such an application for the individual or for society. Within the scope of this assessment processes, there must also be considerations as to whether an objective could also be attained without the application of ionising radiation or radioactive materials. At the time of writing, suitable processes toward quantification, especially in connection with the benefits for the individual or for society, which are suitable as assessment with quantitative statements with regard to the radiation risk, are barely established. As a result, the justification process thus becomes a complex task in many cases.

In the case of activities i.e. in an environment of natural radioactivity, radiation exposure already exists when radiation protection becomes active. Examples of this are for example increased radon exposures in working locations. As far as the general population is concerned, measures in relation to natural radioactivity can be implemented if natural radiation is increased as a result of human action (e.g. in housing which is contaminated with the radon of historical mining relics) or of the introduction of products which contain natural radionuclides, or if new distribution methods for certain products change the exposure situation, as a result of new methods of technical preparation for certain products (e.g. building products, drinking water). In such cases, the justification is related to the question of whether measures to reduce existing radiation exposure rates, or those changed by human behaviour, are justifiable or not. In those cases where the use of the justification principle results in correspon-

ding measures to be taken, these must be dictated according to the appropriate existing principles.

On the other hand, there are also those tasks where the policy for the justification must be shaped according to the principles that apply to activities. This applies e.g. to the use of thoriated electrodes in arc welding, to impact ratings resultant of raw mineral substances with various natural radioactive material content rates, and for activities to which there applies elevated radon or thoron exposures (in mines, water-works or exhibition caves).

In the case of „interventions“ (according to. ICRP 103 this term should be limited to a context of protective measures in connection with the reduction of radiation exposures), it must be proven during the justification process that the required measurements / programmes are of more benefit than harm overall. Within the term „benefits“ in this context are understood not only the lowering of radiation exposures but also all positive aspects which appear, or are expected as a result of the measure or a programme e.g. a restoration programme for mining relics. The evaluation of the damage resulting from a measure incorporates not only all the negative aspects e.g. the radiation exposures, the restrictions and pollution, which are caused by the intervention itself; but also all the costs resulting from the execution of a measure or a programme. Public acceptance plays an important role with the evaluation of the positive aspects as well as the negative ones. After an evaluation of all relevant factors, action values should be bindingly established for restoration programmes, which make it possible to have comparable values that show, in which cases restoration measures are necessary for radiation protection reasons.

In the field of medicine, three different kinds of cases are distinguished:

1. The single-case justification (justifying indication) in connection with the treating doctor: featuring diagnostic and therapeutic principles and the possible radiation-related health risk of the patient at the centre of the consideration.

2. The justification of a particular usage of ionising radiation or radioactive substances for specific procedures within diagnostics or therapy, with observation of the validation ranges and the purpose of corresponding medical guidelines as laid down by the autonomous administration bodies in the field of health and the scientific medical expert communities. The medical guidelines contain systematically developed statements which support the doctors in their decision making and possibly that of other health-related professions, as well as that of patients with respect to an assessed po-

licy in connection with existing health problems. They offer orientation guidelines, and basically do not replace the justifying indication by the treating doctor in each individual case.

3. The justification of precautionary examinations in the scope of early diagnosis programmes, with the use of ionising radiation or radioactive materials, which must evaluate the individual and societal benefits as well as the individual and collective radiation risk that is connected with groups of people overall taken part in early diagnosis programmes.

Both the identification and the evaluation of a "net usage" are not trivial; and, to a certain extent, they can only be measured qualitatively. Alternative processes e.g. without the use of ionising radiation must also be part of the assessment process. Normally, to list reasons and quantification figures in connection with the benefits are not radiation protection tasks; but rather a task that is characterised by the field of sociology as well as by doctors in the field of medicine. It calls for interdisciplinary collaboration. However, this is still not yet generally known, let alone accepted; as shown by the discussion in connection with safety-relevant questions (the compulsory X-ray examinations of people and goods at country borders) or other uses of ionising radiation without medical indication (keyword: „medical-legal exposures“).

Theories

- Justification requires an active process of assessing all courses of action. The reference to low-level exposures alone is not a sufficient reason for justifying a usage application. To the extent that it is not already regulated, the justification of new usages of ionising radiation and radioactive materials must be fundamentally tested at a level of applicable new legal principles. If the justification is for a decision in an individual case only, as it is the case with an indication of a medical doctor, the necessary technical consideration process requires orientational guidance in the form of medical guidelines and comparable recognised standards, which pave the way for actions and decisions to come.

- The justification occurs in many specialist situations, in the scope of societal processes, including protection from radiation. The justification process must be comprehensible and transparent, with the establishment of certain standards. It requires that the active elements and their functions be clearly identifiable, that the assessed ac-

tion options be named, and that details of the relevant damages as well as the relevant benefits information be displayed. It is a foremost requirement that the processes recognised within the benefit-risk assessment, comparable to those attached to the risk assessment, be more strongly definitive from a technical-science perspective. In many cases, this can also mean the application of existing operational, populist and insurance-economical, and sociological methods. The use and transferability of these methods for the purpose of balancing the action options, is to be further developed and transferred.

- Instructions for actions must be created and laid down bindingly in such a way that the implementation of justification processes und the aforementioned principles are enabled and comprehensible.

Explanation

Up to the current day, discussions pertaining to the justification of activities have been ever more dominated by radiation protection risk assessments, with the attempt to replace the justification itself with a reference to the low-level exposures which come with a particular usage case; something that is not permissible on principle. An example of this is how after the events of September 11th discussions of screening and detection methods were brought up amongst persons responsible for security – there were no legal principles attached to their justification. In such a case, one sees that the evidenced individual or societal use of such security devices is obliged to meet safety requirements laid down by the state, but none pertaining to radiation protection. It is primarily a state-sanctioned task to produce legal framework instructions which exist for the purpose of testing the justification.

At the time of writing, as far as the consideration processes within the framework of the justification of activities is concerned, there exists hardly any operational directions for operators, users and those responsible for questions of radiation protection. The establishment of minimal standards for the operational execution of those processes in guidelines is an urgent necessity. To make the consideration process more comprehensible for operators and users, explicit course of actions must be named with a specification of the risks and benefits that go with it. Minimal standards of transparency and comprehensibility (documentation) must be satisfied.

A.I.2 Dose limitation

Background

The adherence alone to relevant dose limitation values for different situations is insufficient for radiation protection. In fact there is always a requirement to justify (c/f A.I.1) and optimise (c/f A.I.3).

Different practices are made use of in radiation protection for dose limitation. Firstly, the dose is restricted by limit values in all cases in which the sources of radiation can be controlled for the purposes of radiation protection and/or the use of ionising radiation and radioactive materials can be planned. Important examples are the limit values for occupational radiation exposure (20 mSv/year) or for exposure of the general population (1 mSv/year). Should control for individuals in a strict sense not be able to be carried out and/or guaranteed (e.g. regarding potential exposure), the limiting of the dose from controllable sources is effected by means of measures or guidelines and/or target or reference values, which are set so that the stated limit value for that individual is adhered to. In contrast to limit values, the measures or guidelines and/or target or reference values do not have any legally binding effect, i.e. regarding the practical implementation of measures for radiation protection, they are accorded a lesser degree of bindingness.

For those exposed occupationally to radiation, adherence to the relevant limit value is checked individually through relevant monitoring measures and is recorded, evaluated and monitored in a central register by the Federal Office for Radiation Protection. The monitoring of limit values for the general population is on the one hand only possible individually through estimation and not, as in the case of occupationally exposed persons, through measurement. On the other hand, individual monitoring based on measure values is also not necessary because of the usually low dose contributions of radiation exposure from activities. The dose calculation is made using estimation procedures, which inevitably imply a range of assumptions and uncertainties. The estimation and/or calculation are arranged by the Radiation Protection Ordinance so that exposure to each individual source is conservatively estimated. Therefore the estimation for exposure from all activities in terms of each individual person of the population can be held as conservative.

For accident situations, intervention guidelines for urgent measures are determined, as well as peak values for the contamination of foodstuffs. The intervention guidelines fulfil two purposes: (1) in the planning phase they are the basis for organisational and content-related

planning and provisions for disaster management. They are geared towards the taking of “imminent danger” urgent measures and thus preventing as far as possible an exceeding of guidelines. (2) In case of emergency the intervention guidelines represent “reference values” for the taking of certain protection measures. Exceeding the guidelines can be justified under certain circumstances if the implementation of a measure itself is connected with the endangering of life and health of exposed or potentially exposed persons.

In encountered situations in which the radiation exposure is attributable to natural sources (e.g. radon in habitable rooms) or in which it represents legacies of earlier human activity (e.g. contaminated sites), measure values serve as justification of cleaning measures and target values for the demarcation of a measures corridor. The aim of measures taken is to achieve the target value and, as far as possible, to go below it. If exposure lies above measure values, cleaning measures are justified and are to be planned and carried out under observance of the optimisation policy so that falling below the target value is most likely to be achieved. Falling below the target does not on the one hand imply that the optimisation process in the sense of radiation protection can be automatically discontinued; on the other hand further costs caused by measures are not inevitably justified. Conversely it also means however that even a provable optimised event above the target value must be accepted from the point of view of radiation protection.

The introduction of diagnostic reference values (DRV) for frequent and/or dose-intensive investigations along the EU Directive 97/43/EURATOM, provides a significant contribution to quality assurance and control as well as a reduction in the exposure of patients through diagnostic radiation uses. In X-ray diagnosis, the DRV represents the upper guideline, which may not be constantly and unjustifiably exceeded. Nuclear medical diagnosis however deals with optimal values, which state the necessary radioactivity amounts that are to be administered for standard procedures on patients in order to guarantee good image quality. In a strict sense they are not valid for individual patients, but relate to the average dose/activity of a group of patients that are exposed using a particular device. Quite significant is the periodic investigation of the radiation exposure of patients where users have adhered to the DRV as well as where appropriate the required error searches on site and the personal advice for the improvement of investigation quality through medical authorities.

Theories

- Regarding controllable sources of radiation and plannable radiation uses, dose limit values represent a significant element of radiation protection.

- Regarding occupationally exposed persons, radiation exposure is to be recorded and evaluated on the basis of individual dose measurements. Radiation exposure from activities and work are to be evaluated equally; should radiation exposure be present simultaneously from activities and work, then the sum of the exposure is to be evaluated. The dose measurements are to be recorded centrally and the adherence to limit values is to be monitored centrally.

- Regarding the population, radiation exposure from activities is to be estimated and/or calculated. A metrological monitoring at individual level is neither possible nor necessary. The monitoring of dose limitation of the population must be based on sufficiently cover-all estimation and calculation procedures. A particular radiation source or radiation use may exhaust only the smallest possible share of the dose value that has been set by the dose limit value. This limitation is also valid for discharge paths.

- With radiation exposure from natural sources or from legacies of former activities, which on the one hand are hardly or not at all controllable, yet on the other hand the exposure path can be influenced by measures, dose limitation is effected through measures and target values. Exposure exceeding the measures values justifies the planning and implementation of measures for dose reduction by adherence to the optimisation policies. The aim of the measure is to fall below the relevant target value. An example of this is the actively followed regulation of the Federal Office for Radiation Protection for dose limitation for radon in habitable rooms (c/f A.III.2).

- In accident situations the dose is limited by guidelines. On the one hand these serve in the planning of measures for disaster management. In an accident situation they represent base values for the taking or ending of protection measures.

- Diagnostic Reference Values are used for the limitation of the dose from diagnostic uses in medicine. Adherence to these is guaranteed through physical-technical procedures as well as through procedures of quality assurance and quality management.

- Dose limitation through dose limit values or through measures and target values must always be supplemented by the use of policies of justification and optimisation in radiation protection.

Explanation

The development in recent decades shows that with the implementation of principles of “dose limitation” and “optimisation”, the exposure of occupationally exposed persons has continually fallen. The reduction of limit values to 20 mSv per year has not led to any recognisable operational difficulties. Monitoring data in the radiation protection register of the Federal Office for Radiation Protection shows far more that already before the corresponding legal determination, the frequency of dose values at the upper end of the dose range (>20 mSv/year) had fallen.

In contrast to dose limitation for occupationally exposed persons, which is basically based on the metrological recording of exposure of that person, this is not possible for the population. As long as there is a cover-all estimation and/or calculation of exposure from individual sources or uses and this only makes up a small share of the dose value that is allowed in total by the dose limitation, the necessity does not arise.

In situations where exposure is actually present if radiation protection is functioning, dose limitation according to the limit value principle is not sensible in practical use. In such situations the principle of dose limitation is most effectively implemented by means of measures values, which are grounds for beginning optimisation procedures, and target values, which define the minimum requirements of the measures. These procedures pertain among others to radon in habitable rooms and to radiologically contaminated sites (c/f A.III.2).

Intervention situations can basically be regarded in the same way as situations with actually present exposure. If in intervention cases the dose nears the value of 100 mSv, in any case the use of wide-reaching protection measures is justified to prevent and/or reduce the exposure. With doses higher than 100 mSv there exists a raised probability for the occurrence of deterministic effects and a significant cancer risk. Exceeding this value can only under extreme circumstances be justified for life-saving or the prevention of accidents of catastrophic extent.

A.I.3 Optimisation

Background

The principle of “optimisation” has considerable significance for practical radiation protection. According to the ICRP recommendation No. 103, “The principle of optimization is defined as

the source-related process to keep the likelihood of incurring exposures (where these are not certain to be received), the number of people exposed, and the magnitude of individual doses as low as reasonably achievable, taking economic and societal factors into account.". This principle is equally anchored in the command of the Radiation Protection Ordinance and the X-ray Ordinance ("... all unnecessary radiation exposure or contamination of humans and the environment is to be avoided" and "... all radiation exposure or contamination of humans and the environment is to be kept as low as possible, even below the limit value, under observance of the state of the art of science and technology and under consideration of all circumstances of the individual case"). With the practical application of the optimisation principle in the framework of planning considerations, strategies are to be used that lead under consideration of circumstances of individual cases to the reduction of exposure of the population and of occupationally exposed persons. Here also, long-term considerations are to be taken, which extend from the planning phase through the operational phase right up to the end of an application or of the operation of a plant. A consequential application of the principle of optimisation also leads to considerations and measures that contribute to a reduction of accident risks and potential exposure.

Guidelines, standards, provisions etc., in which results from generic optimisation considerations are incorporated create a handling and decision corridor for proposers and regulatory authorities for the planning, construction, operation and decommissioning of technical plants and/or the application of ionising radiation and radioactive materials. These pertinent guidelines, standards, provisions etc. are continually further developed in line with the state of the art of science and technology. The prerequisite of approval is then the specific proof of the proposer or operator, whose concrete technical and organisational measures in individual cases are to be implemented in order to accommodate the optimisation policy. Optimisation is not a static procedure. To a greater degree, practically gained experiences are to be continually considered during all phases of planning, through construction and operation to decommissioning for the further development of optimisation requirements. This leads ultimately to the development of a safety and protection culture in an organisation.

In "intervention situations" there is close correlation between justification and optimisation. Whilst in the process of justification it is basically to be proved that intervention measures can result in a net benefit, in the process of optimisation the measures chosen from the possible measures are those that yield the maximum net benefit. This principle to be considered in the case of cleaning programmes is that a weighting of benefits and damages is already undertaken for the determination of a measures value (c/f A.I.1). The optimisation procedure is confined then to choosing from the possible measures that which in individual cases leads

to the long-term falling short of the measures value and a maximum net benefit, and is accepted by the participants.

In the international discussion there is not a consensus that the optimisation process should be limited through the determination in advance of generic values in the sense of performance provisions. Details can be found in the ICRP publication 101 (The Optimisation of Radiological Protection: Broadening the Process; Annals of the ICRP, 2006). The optimisation process ought much more be brought to an end if in the framework of the overall process the optimum has been achieved. There is certainly a consensus in the opinion that with the determination of the optimum, complexities for each further optimisation step must be considered and the costs by very low exposure “measured”, i.e. they must be correspondingly low. It can be helpful here to set a dose or risk target in the optimisation framework, which regulates the magnitude of the optimisation necessity from the point of view of legislators.

A generally useable method for the practical implementation of optimisation cannot be given because of the various factors to be considered in the optimisation process. An exclusive use of quantitative (mathematical) cost-benefit analysis is to be avoided as it would reduce the optimisation process to questions of monetarisation of radiological risks. Should the collective dose be evaluated in the framework of optimisation, it must be carefully checked whether prerequisites are given for this (see A.II.5).

In spite of countless technical problems that are connected like never before with practical implementation, the basic principle of optimisation must take up a central position in practical radiation protection. Only the consequential application of the principle of optimisation leads to the establishment of a safety and protection culture, in which those responsible for and those affected by the concerns of radiation protection strive collaboratively and enduringly for the reduction of radiation exposure. The inclusion of those affected (“stakeholder involvement“) is an important aspect of this safety and protection culture. The process of “stakeholder involvement“ can and must be configured very differently depending on the question and presupposes a high level of social competence by those responsible. Correctly deployed, this form of participation in the preparation of decisions leads to an improvement in the quality of decisions, an increase in the transparency of underlying processes and lastly to a strengthening of trust.

Theories

- Optimisation presupposes an active process of weighing up between management options. Among others the following aspects are to be considered for this: characteristics of affected groups (age, gender, lifestyle habits) and the exposure situation (dose distribution, number of persons exposed, actual or potential exposure), social aspects (individual v. social benefits, non-discrimination within a generation and between generations), effects on the environment and climate, technical and economic aspects and the political and administrative implementability of regulations. Each individual characteristic and aspect can and must be weighted. Optimisation is not to be understood here as a de minimis principle. It is much more about the attainment of the optimum under observation of planned or given parameters. The achievement of low exposure values beneath limit values and guidelines or the falling below a certain relationship of costs and benefits (saved dose) is not on its own proof that the optimum of a certain application has been achieved.

- It is the task of the "operator" and/or of the proposer or approver to take optimisation considerations that are transparently created and documented. It is the task of the authorities to check these considerations and to document in the approval that the optimisation requirements were taken into account. For the implementation of these requirements, management instructions are to be compiled and bindingly carried out. This principle also pertains to areas of applications of ionising radiation and radioactive material in medicine.

- The process of optimisation must through the codifying of minimum standards be comprehensible and transparent. The codifying of such standards in manuals is essential. The manuals must consider the following aspects: scope and application, definition of goal hierarchies, outlining of alternatives, preferences and priorities as well as description of the actual procedure. In the framework of binding regulations, the arrangement of the optimisation process and conditions for the implementation of the process including the type and extent of the inclusion of those affected ("stakeholder involvement") must be determined.

For the appropriate implementation of stakeholder processes, the technical requirement profile of those responsible for radiation protection as well as the organisational structures of radiation protection organisations and authorities must be continuously further developed.

International initiatives in this area, like for example the European ALARA Network, must be supported in their work.

Explanation

Right up to today, discussions on the application of the optimisation principle are again and again replaced by reference to connected low exposure. This is not admissible. The above-mentioned roles of the operator and the authorities are not currently described in the necessary detail. This is required for reasons of transparency and verifiability.

For the weighting process in the framework of optimisation there are currently no management instructions for operators, users and those with posts dealing with questions of radiation protection, which determine the minimum standards for an operational implementation of the basic principles of optimisation and enable the verification of the successful application of the optimisation principle. The minimum standards required here concern the optimisation of underlying procedures, in particular the determination of those participating in the process, their responsibilities, the most important optimisation criteria, the course of the process, the transparency of the procedure and the documentation of results. For each case the type and where necessary scope of stakeholder participation must be decided. Stakeholder participation fundamentally improves the quality of the results. Responsibility for decisions lies however for every case with the relevant authorities.

The training profile of those responsible for radiation protection is currently shaped to a great degree by technical qualifications in the relevant specialities of science and technology and/or medicine. This will also be true in the future. The involvement of stakeholders in decision-making processes presupposes however certain additional abilities, which are not usually subject matter for the occupational training of radiation protection specialists. Offers for further training in social science subjects are rather uncommon. Employees in existing radiation protection organisations and authorities, which have a command of the entire spectrum of competencies, represent rather a minority.

II. Questions

A.II.1 Dose-effect relationship

Background

Our knowledge of the effects and risks of radiation is based on a variety of scientific and medical findings from epidemiological and radiobiological studies, i.e. studies on animals and experimental cells, biophysical modelling, medical investigations and their scientific evaluation. In the evaluation, the evidence (in the English-language meaning of the term „proof of evidence“: that is the proof that the evidence offers) of the data is weighted, giving rise to proof, doubts or hints of a causal correlation between exposure and effect. In the evaluation process the checkpoints of consistency of findings, plausibility and specificity are highly rated. Evidence from findings from humans is weighted more heavily than those from investigations on animals, from cytological studies and from modelling. The highest evidence comes therefore from several independent analytical studies on exposed persons with consistent results, which satisfy the causality criteria (1) consistent chronological interdependence between exposure and effect, (2) strict, consistent correlation between exposure and effect, (3) reliable, definite exposure calculations, (4) evident exposure-effect relationship, (5) freedom from distortions during the collection of data (bias) and other interfering factors (confounding), (6) biological and/or biomedical plausibility of the causal correlation and (7) high statistical confidence in the differences observed between exposed persons and the control group (statistical significance). The quantification of radiation risks is based on summarised, radiation hygienic evaluation in comparable analytical epidemiological studies on groups of persons who were exposed to varying levels of radiation, so that different levels of cancer or leukaemia frequencies subject to dose and/or exposure could be established. An outstanding role is played here by investigations on survivors exposed to radiation from the atom bombs dropped on Hiroshima and Nagasaki. Additionally included here are studies on patients exposed to radiation for medical reasons (e.g. with ankylosing spondylitis, tuberculosis, mastitis, tinea capitis), persons exposed occupationally to radiation (uranium miners, luminous painters, employees in nuclear plants) and on residents of apartments with higher radon charges. Added to this are further studies on chronically exposed groups (workers in nuclear plants, residents in regions of increased environmental contamination from atom bomb production and from atom bomb tests in the former Soviet Union).

For use in radiation protection, the quantification of radiation risk must however be continued by characterising the dose-effect relationship and its gradient and/or curve by extrapolating empirical findings from high to medium exposure levels, as based on the given observation and trial data, down to low dose areas relevant to regulation. Extrapolation is based on the radiation hygienic evaluation of present evidence-weighted findings and constitutes a scientifically established convention for radiation protection. The uncertainties inherent in the extrapolation can be fundamentally reduced through further research efforts but never entirely eliminated. The uncertainties decrease subject to the shortness of the line to be extrapolated. As shown by radon in apartments, for example, the observation area abuts immediately on to the areas relevant to regulation.

Epidemiological studies on survivors of the atom bombs attacks on Hiroshima and Nagasaki, which in duration and number of persons count among the most comprehensive studies, show a linear dose-effect relationship without a threshold dose for all cancer types taken together in the dose area of approx. 3Sv up to the area of small doses, where the lower detection limits lie at approx. 50mSv, subject to the number of persons observed in the study. Relevant to regulation however is the dose area of 20mSv and under for persons exposed occupationally to radiation and from 1mSv and under for the population. This means that the extrapolation range between empirical risk evidence and the estimation area of practical radiation protection amounts to about 1 to 2 magnitudes. The exposure area beneath the stated detection limits is usually for practical and methodical reasons barely accessible for epidemiological risk analysis. The size of the study population necessary for such far-reaching investigations would be extremely large. In comprehensive international research programmes it has been attempted using systems biological methods to better understand and to quantify the radiation risks in dose areas relevant to practical radiation protection.

The dose-effect relationship for leukaemia sufferers is best described over the whole exposure area from 3Sv and under by a linear-quadratic model. In the low dose area, that is less than 100 to 50mSv, the linear part of the linear-quadratic model is definitive for the gradient of the dose-effect curve. Apart from leukaemia, for many other cancer types the number of observed radiation related cancer cases is usually too small for the determination of a cancer-type specific dose-effect relationship. There are exceptions here particularly for lung cancer risks from radon, breast cancer risks for women from photon radiation and thyroid cancer risks for children and young people from incorporation of radioactive iodine. Statistically significant cancer risks were observed, restricted by the size of the study populations, at exposures above about 50mSv effective dose. Individual epidemiological studies indicate that even at exposures beneath 50mSv there are increased radiation risks. In the Oxford-Study,

where among other things cancer risks were investigated in children, who during pregnancy had been exposed to increased radiation exposure from X-rays, a lower detection limit for a statistically significant increased radiation risk of about 10mSv effective dose was described. In the so-called Indoor-Radon Studies, in which lung cancer risks from radon in living areas was investigated, it was shown that a linear exposure-effect relationship is most consistent with the data. With increasing radon concentrations a statistically significant increase in lung cancer risk was detected. Here exposure was considered as the time-weighted mean of radon concentration of inhabited apartments in the last 5 to 35 years. A radon-activity concentration of about 100 Bq/m3 was shown as the lower detection limit of statistical significance for an increased lung cancer risk. This radon concentration in living areas corresponds to a yearly effective dose of about 2mSv and is based on 30 years of exposure at about 60mSv.

At 10mSv of X-rays an individual cell is usually struck by one single physical electron track or by a few electron tracks. One single energy deposit from radiation in a cell can be enough to trigger a cancer, as cellular repair processes are not always quantitatively and qualitatively perfect. Even with smaller doses the minimal exposure incidence is always one singular electron track; only then are relatively fewer individual cells of an organism struck. Since most cancers, according to leading scientific opinion, are usually monoclonal incidents, i.e. originating from one individual damaged cell, the linear dose-effect relationship without threshold dose is the effect model based on radiation hygiene, even at exposures characterised by singular electron tracks in individual cells. Even for doses beneath 10mSv, the linear dose-effect relationship without threshold dose is therefore the convention for the estimation of radiation risk in radiation protection.

On a cellular and systemic level mechanisms are recognised, which considered in isolation make a deviation from the linear dose-effect relationship in low dose-effect areas appear possible. These mechanisms work sometimes in the direction of reducing the effect (i.a. adaptive response, immunological mechanisms), others in the direction of increasing the effect (i.a. bystander effect, genetic instability). Overall no systematic deviation from a linear dose-effect relationship without threshold can currently be founded from these cytological and immunological phenomena.

For hereditary genetic modifications, a linear dose-effect relationship without threshold dose must likewise be supposed because of the same biological mechanisms as for cancers. As no direct observations on humans are available for this, these assumptions are based as far as possible on findings from animal and laboratory experiments.

Theories

- A summarising, radiation hygienic evaluation of the relevant epidemiological studies leads to the conclusion that for all cancer types together and for most individual cancer types the dose-effect relationship in medium doses from 50 to 200mSv is best described by a linear model without threshold dose. Also for doses under 50 to 10mSv, this assumption is radiation hygienically plausible, based on biophysical and general models of the mechanisms of genotoxic and carcinogenic noxas. The assumption for the triggering of stochastic radiation effects (cancer, leukaemia, genetic damage) of a linear dose-effect relationship without threshold dose must be acted upon for use in radiation protection even in the area of smaller doses due to radiation hygienic evaluation. In this sense the linear dose-effect model without threshold dose represents a scientifically founded convention of radiation protection. A linear dose-effect relationship is furthermore also sensible as regards practicability in radiation protection.

- Linear extrapolation realistically estimates radiation risk even at low doses. It is not per se conservative. As seen in the synopsis, a linear estimation of the overall risk from radiation at smaller doses can neither be over nor underestimated. Of course there are individual findings that make an upward or downward deviation from linearity at low doses seem possible, but overall the evidence prevails for a linear correlation between exposure and risk, even at low exposure.

- When looking at individual cancer types, estimated risk values based on linear extrapolation for overall radiation risk can lead to an overestimation of risk for one type of cancer while to an underestimation for another. Also for each individual cancer type, apart from a few exceptions (Osteosarcoma after incorporation of α-radiation, leukaemia from medium to high doses) and allowing for existing uncertainties, linear extrapolation is the best estimation method for low doses. In the presence of resilient, specific data, the specific effect relationship for the cancer type should be acted upon for risk evaluation relating to individual illness cases rather than the generalised dose-effect relationship of radiation protection.

Explanation

On the basis of available evidence, nothing describes the observed radiation effects with greater plausibility than the linear dose-effect relationship without threshold dose. Of course there are clues from individual observations that individual cases of radiation risk can be over

or underestimated through the linear relationship, but in a radiation hygienic synopsis these individual observations do not give significant evidence to justify a fundamental deviation from the radiation hygienic based convention of a linear dose-effect relationship without threshold dose. Connected with this, a sub-linear dose-effect relationship is assumed at the low and protracted exposure usually present at today's regulation relevant radiation exposure, and this ultimately led to the introduction of the DDREF in the ICRP recommendations, This often cited argument will be discussed in the following chapter (for this see Part A.II.2). Central to radiation hygienic evaluation, despite the diverse findings for radiation effects and radiation risks that often obviously contradict one another, is its objective to create a manageable basis for radiation protection, onto which concrete radiation protection standards and measures can be developed. For this the complexity of the empirically described dose-effect relationship and possible effects mechanisms, as well as that of the extrapolation from observations to regulations, must be so far reduced that a generalised description of the dose-effect relationship is possible. This must have been plausibly derived from the overall picture of empirical data and scientific effects models and be formulated in such a way that it does not lead consequently to any significant under or overestimation of radiation risk at small doses. The former would have far-reaching effects on health protection, the latter on economic (i.a. profitability of radiation use) and social (i.a. equality in the workplace) conditions.

Reasons of practicability also support the use of linear estimation in practical radiation protection. With all other models a simple addition of exposure, as required by i.a. occupationally exposed persons or by observance of exposure to natural radiation, is not possible.

A.II.2 Dose and Dose Rate Effectiveness Factor (DDREF)

Background

In the ICRP recommendation no. 60 (1990 Recommendations of the International Commission on Radiological Protection, Annals of the ICRP, 1990) a dose and dose rate effectiveness factor (DDREF) was established for radiation types with low LET amounting to 2. This recommendation of the ICRP has been generally accepted up to now and is part of the scientific basis for the present standard setting in international and national radiation protection. The introduction of a DDREF bisects the gradient of the line, which is represented graphically by the linear dose-effect relationship without threshold dose and estimated from empirical data on groups of persons exposed to radiation. Central estimated values for radiation risks in the area of small doses and low dose rates lie by a factor of 2 under the central estimated values for acute radiation exposure. The DDREF is thus founded scientifically that experi-

mental results from animal testing and a few limited experiences with humans, particularly from medical uses and biophysical model conceptions, made it obvious that cancer induction with low doses and dose rates was relatively lower than with high doses and dose rates. Cellular mechanisms like DNA repairs, programmed cell death and other adaptive reactions have a reducing effect on radiation risk. Radiation effects on later stages of cancer development would also indicate rather lower risk coefficients. A DDREF of 2 is also maintained in the current ICRP recommendation no. 103.

A risk reduction in areas of small doses and dose rates cannot be consistently derived from the available epidemiological observations. The epidemiological studies are usually much more consistent with a linear dose-effect relationship without threshold even in areas of small doses and dose rates, i.e. with a DDREF of 1. A current comparison and evaluation of the results of relevant epidemiological studies with on the one hand acute and on the other hand protracted, chronic exposure victims gives no evidence of the presence of a DDREF. The DDREF of 2 recommended by ICRP may well be consistent with the available data from epidemiology as it does lie within the statistical confidence interval for risk estimation. With the aid of the DDREF derived risk estimates, no central estimation values are constituted, consequently leading to rather an underestimation of radiation risk.

Newer analysis of the data from Hiroshima and Nagasaki actually describes a curvature of the dose-effect relationship for solid tumours in the low dose area. The central estimator for a DDREF, according to these analyses, lies in the area between 1.5 and 2. Here the whole data set up to an exposure of 2Gy was evaluated. As the data set was increasingly narrowed, i.e. the intervals 0 – 2Gy, 0 - 1Gy, 0 – 0.5Gy und 0 – 0.25Gy were considered, the curvature observed in the overall data set increasingly disappeared and the linear term of a linear-quadratic adjustment became increasingly close to the value of the linear adjustment across the overall dose area of 0 – 2Gy. In summary the new analyses gave no evidence of a significant deviation of a DDREF of 1. The Commission of the National Research Council of the USA on Biological Effects of Ionising Radiation (BEIR) recommended in their evaluation of 2005 (BEIR VII) the use of a DREFF of 1.5. From the data from Hiroshima and Nagasaki they estimated a DDREF of 1.3 (95% interval: 0.8 – 2.6), from experimental radiobiological data a DDREF of 1.5 (95% interval: 1.0 – 4.4) and upheld as a combined estimation value a DDREF of 1.5 (95% interval: 1.1 – 2.3).

Newer epidemiological studies on groups of persons having chronic exposure, such as employees in nuclear plants, residents of the Techa river area, which has been contaminated by radioactive waste from atom bomb production in the former USSR, and those of the atom

bomb test sites in Semipalatinsk, show corresponding risk estimators that are higher than the estimated values in the studies on the survivors of the atom bomb attacks in Japan. The results of these studies are in contradiction to the assumption of risk reduction at low doses and dose rates.

Theories

- There is a lack of sufficient evidence from studies on groups of exposed persons for the use of a dose and dose rate effectiveness factor (DDREF).

- The DDREF of 2 for loosely ionising radiation included in the risk estimations and the recommendations of the ICRP, which is the basis for current legal regulation, leads to a corresponding underestimation of radiation risk for loosely ionising radiation in low dose areas and for chronic radiation exposure. It should therefore no longer be used.

Explanation

There is insufficient epidemiological justification for a DDREF of 2. The justification for a DDREF of 2 is based almost exclusively on findings from cell culture and animal tests as well as model conceptions. The confidence interval of risk estimation from epidemiological studies on atom bomb survivors is of the size that comprises a DDREF of 2. The introduction of a DDREF of 2 however fully exploits the confidence interval of the risk to one side for one individual factor and allows no more variance for other influencing factors that could work in the same direction. The exploitation of the entire spatial variance in one direction for one factor is scientifically implausible when it must be justifiably assumed that further factors determine the variance and their direction is not decisively ascertained.

In summary the results from epidemiological studies give no evidence of a significant deviation of the gradient of the linear dose-effect relationship in the area of small doses and low dose rates estimated from the medium exposure areas, and therefore no evidence of a DDREF greater than 1. There is evidence from animal and laboratory experimental investigations, from biophysical model conceptions and from isolated epidemiological studies, mainly after radiation uses in medicine, which hints towards a DDREF greater than 1. But a radiation hygienic evaluation weights the evidence from epidemiological studies higher than that from experimental investigations and model conceptions and leads consequently to the result that a DDREF greater than 1 must be rejected for uses in radiation protection.

A.II.3 Tissue weighting factors

Background

The varying radiation sensitivity of individual organs and tissues for stochastic radiation effects are considered using tissue weighting factors. With help of the tissue weighting factors the effective dose is calculated as a whole body dose from the absorbed dose for individual organs in sum, when different tissues or organs, particularly in cases of partial body exposure and incorporation of radionuclides, are exposed to varying levels of radiation. In the ICRP recommendation no. 103, the tissue weighting factors of ICRP recommendation no. 60 are updated.

With the effective dose it is a matter of an absorbed dose, which is weighted for the radiation type and the radiation sensitivity of the affected organs and tissues. „Effective Dose“ size is an estimated size for the purposes of practical radiation protection and ought therefore only be used in this context. It is valid only for the area beneath the threshold for deterministic radiation effect. The effective dose allows estimation of radiation risk for groups of persons, e.g. those exposed occupationally to radiation, not however for individuals.

The estimation of radiation risk for groups of persons is achieved through the standardisation of the sum of the tissue weighting factors to 1. The values of the tissue weighting factors depend on the current level of knowledge of radiobiology and epidemiology. The values currently established in national radiation protection law were recommended in ICRP no. 60 and were normatively defined in EU directives as well as in the Radiation Protection Ordinance (RPO). If values deviating from ICRP recommendations are used for the estimation of probability of causation and individual radiation risks, this must be explicitly justified. If the dose calculation is carried out with a deviating tissue weighting factor, the result is not a matter of an effective dose in the sense of the normative definition.

For the determination of tissue weighting factors, the ICRP will take into account the following components:

- the attributable leukaemia and cancer mortality risk,
- the weighted probability for attributable non-fatal leukaemia and cancer,

- the weighted probability of serious hereditary effects,

- the relative reduction of life-span from leukaemia and cancer.

Overall the standardisation of tissue weighting factors refers to the nominal risk coefficients for stochastic effects. These are stated by the ICRP for persons exposed occupationally to radiation and for the population. They represent average estimates for the relevant age groups, for all organs and for both sexes. Within the age groups there is an increase by about a factor of 3 of cancer risk for young children compared to adults. Women have about a 30 – 50 % higher radiation-caused cancer risk than men.

Theories

- The ICRP procedures for the determining of tissue weighting factors must be strictly followed.

- Because of the higher radiation sensitivity of women, the radiation protection standards should be adjusted to the radiation risk for women and not to the averaged normative radiation risk for both sexes.

- Because of the particular radiation sensitivity of these female organs – mammary glands, uterus and ovaries – the corresponding tissue weighting factors are to be established so that they correspond to the specific cancer risk of these female organs (a gender-specific tissue weighting factor is to be identified in particular for the mammary glands and not an average for both sexes; uterus and ovaries are subsumed to other organs).

- General tissue weighting factors, as standardised in radiation protection standards, should only find use in radiation protection and for the estimation and recording of radiation exposure for certain tasks. For individual case studies the current best risk estimates are to be consulted.

Explanation

With tissue weighting factors it is a matter of normative determination, for which epidemiological findings and radiobiological knowledge are not only considered, but practicability for radiation protection uses must be guaranteed. This also explains the confinement to the four

values for tissue weighting factors: 0.12, 0.08, 0.04 and 0.01. Because of the higher radiation sensitivity of women overall and the particular radiation sensitivity of female organs, particularly the mammary glands, it is on the one hand necessary to orient radiation protection standards to the higher radiation risk for women overall and not to the average between women and men, and on the other hand to orient the determination and use of tissue weighting factors to the specific cancer risk of the female organs.

Regarded on the basis of absolute radiation risk, the radiation risk for women is determined at around 25% with the breast cancer risk, but without considering the female organs, i.e. mammary glands, uterus and ovaries, it is already around 20% above that of men. The current (RPO 2001) legally stated tissue weighting factor for the thoracic organ of 0.05 no longer conforms to current knowledge of radiation-related breast cancer risk. An adjustment is necessary. The current recommendation no. 103 from the ICRP advises 0.12 as a numerical value, which however still represents an average for both sexes. The use of averaged values for both sexes leads consequently to an underestimation of radiation related breast cancer risk for women and an overestimation of that for men. This is immediately followed by a systematic overestimation or underestimation of the relative risks for all other organs and tissues of women or men. A delimitation of the organ dose for the woman's thoracic organ cannot offset the systematic under or overestimation arising from this averaging. The radiation sensitivity of women overall and in particular that of the mammary glands largely determines the radiation risk for women. Consequently, the averaging itself represents the actual problem of distortion.

General tissue weighting factors, as standardised in radiation protection standards, should only find use in the estimation of radiation risks for population groups and in monitoring tasks for radiation protection (e.g. Radiation Protection Register). The current best estimated values for radiation sensitivity of the organs concerned are to be used for individuals and for particular uses (e.g. mammographic screening in the field of cancer prevention).

A.II.4 Radiation weighting factors (photons, neutrons, protons)

Background

In radiation protection, the calculation of the equivalent dose using radiation weighting factors takes the varyingly intense biological repercussions of different radiation types and quality at an equal energy dose into consideration. The data parameters have been reviewed and defined within the ICRP Recommendation No. 103.

Theories

- As a matter of principle, the concept of radiation weighting factors, as described within the ICRP Recommendation No. 60, is not put into question. According to the ICRP and SSK Recommendations of 2003 and 2004 respectively however, adjustments for protons and neutrons should be undertaken. This necessity was realised within the ICRP Recommendation No. 103.

- General radiation weighting factors, such as those normalised within the radiation protection standards, should only be applied in radiation protection and in the assessment and registration of radiation exposure for certain monitoring tasks.

- In the case of individual risk assessments under precisely defined circumstances, the general radiation weighting factors should not be used. Instead, the energy doses and the respective best estimates be used, namely those based upon the available data concerning biological effectiveness of the relevant radiation type and quality.

- In order to ensure better understanding of the radiation weighting factors and to provide a clear reference base, the reference radiation should be defined explicitly. Given that the assessment of radiation risk relies mainly on the data gathered from survivors of the nuclear bombardment in Japan but also increasingly from groups of persons with chronic radiation exposure and by whom gamma radiation the type of radiation is which defines the actual doses, it is recommended to use gamma radiation as a radiation of reference.

Explanation

The Federal Office for Radiation Protection's expert panel about the RBW in 2003 has basically confirmed the ICRP's procedural method in determining the radiation weighting factors. The SSK, consistent with its 2004 recommendation to the RBW also emulates the ICRP's approach. Within the range of application of the radiation weighting factors, however, the SSK recommends even more precise specifications than the ICRP. Much as in the case of tissue weighting factors, the ICRP and SSK have recommended for radiation weighting factors to be established normatively for the determination of the effective dose. In the case of a deviation from the specified norms, one can no longer speak of an effective dose in the sense of the normative radiation protection standard, but must use a different descriptor for the said dose. As such, the use of different weighting factors should always be mentioned explicitly.

Given the fact that exposure to photonic radiation usually implies a mix of photons of varying energy levels, reasons of practicability continue to dictate the use of a radiation weighting factor of wR = 1 when monitoring the radiation exposure of individuals exposed to radiation at work, and this although variances of a factor of 2 – 3 may occur in between the various quality of photonic radiation.

Experimentally established RBW values with proton radiation point to a value of 2 as being more representative of results than the hitherto value of 5 as per the ICRP Recommendation No. 60. As such, this particular radiation weighting factor has been adapted as per the current ICRP Recommendation No. 103.

As for neutron radiation, radiation weighting factors corresponding to the intensity of the radiation energy are recommended. For this reason, the ICRP Recommendation No. 103 has replaced the previously used tiered function of the dependence of neutron energy and level of radiation weighting factors by a continuous function. The maximum level for a neutron energy of 1 MeV is 20.

For individual risk assessments, much like the procedure with tissue weighting factors, the best estimated value for the radiation weighting factor should be used in each case, based upon the relative biological effectiveness of the relevant radiation quality. In the same way, this is also valid each time for the best estimated value for the individual radiation risk coefficient (differenciated according to age, gender, etc.)

The current system of radiation weighting factors for radiation protection and factors of quality in the field of dose measurement should be maintained. A similar adaptation of quality factors to the changes in radiation weighting factors for protons and neutrons should be implemented.

A.II.5 Collective dose

Background

According to ICRP Recommendations No. 60 and 103, the collective dose is defined as being the product of the arithmetic average of the individual doses multiplied by the amount of exposed subjects. The concept was first introduced in the 70’s in order to limit the uncontrolled increase in dose contribution from long-lived radionuclides in the environment. In the case of certain (recurrent) applications, such as maintenance work in nuclear plants, the

collective dose was and is used to quantify individual aspects of optimisation in work-related and locally-related radiation protection.

It is clear that a summation of minimal dose contributions across a large number of people (such as the world population) and/or over very long periods of time (e.g. generations) leads beyond the limits of the possible application of this concept. Given that the distribution of the intensity of the observed individual doses can often encompass many orders of magnitude, and given that estimation errors and uncertainty depend among other things on the absolute intensity of the dose, a professionally sound application of the collective dose is only reasonable in the case of clearly defined cases. A risk assessment for a part of the population is as such technically wrong and misleading. An evaluation of the collective dose can be, upon strict observance of framework conditions, a professionally sound instrument allowing to ascertain the time changes of radiation exposure (trend analysis) incurred by the use of a specific type of application.

Before using the collective dose concept, the adequacy of the basic and framework conditions must be verified. The collective dose concept can only be used for stochastic radiation risk, for which a linear correlation between dose and effect with no threshold dose but with dependence from the dose effectiveness exists. Such a direct proportionality between dose and radiation risk (linear correlation between dose and effect) is presupposed in the area of low-level doses in the sense of a convention of radiation protection for practical applications (see A.II.1).

A prerequisite for the application of the collective dose is also for the relevant group of individuals to be sufficiently well documented as far as age, gender and distribution of individual doses within the group are concerned. For a group of individuals occupationally exposed to radiation, this may in many cases be taken for granted. Furthermore, the individual doses can be predicted with certain accuracy by observing individuals in similar occupations or as a result of calculations. The collective dose can therefore find application as a valuation standard with the goal of optimising radiation protection.

The current international discussions aim at a further development of the concept of collective dose as per the ICRP Recommendation No. 60. These reflexions partially found entrance into the ICRP Recommendation No. 103.

As far as the choice of protective measures against radiation is concerned, it is not equivalent whether a small number of individuals receives a large dose or a large number of people

receives a small dose. While the respective highest dose may be of interest with regards to the exceeding of threshold values, they hardly contribute to the overall collective dose. In the interest of prioritising individuals over groups of population in radiation protection, it is therefore necessary to assign a greater weight to the distribution of individual doses within a collective as the basis for considerations of radiation protection than to the simple sum of all doses together. As for occupational radiation exposure for which individual data is available, the requirements for the application of the concept of collective dose are at hand. The analysis of the data from the radiation protection register follows this (hardly generally accepted) principle and involves further figures such as age and gender-relevant information.

Theories

- Radiation protection in the area of occupational exposure relies primarily on the consideration of the individual dose. Additionally considering the collective dose may also be meaningful. In doing so, the frequency distribution of the individual doses should be taken as a basis. Further information, such as age, gender and type of occupation, must be taken into account if available.

- As far as radiation protection of population in situations where long-lived radionuclides play a role, the target-aimed solution lies in the assessment and evaluation of the distribution of the individual doses.

- The estimated distribution of individual or collective doses can only offer a basis for making decisions concerning evaluation and optimising of radiation protection if the exposed or potentially exposed population is sufficiently exposed on one hand and if the distribution of the exposures can be described in sufficient detail. In the case of a strong non-homogenous distribution, the estimation of the collective dose is not meaningful from a professional stand point. In order to achieve a good describability of a potentially exposed population group, especially in the case of non-homogenous exposures, it may be helpful to proceed with spacial and/or temporal samples. In such a case, it should be noted that no single area of exposure of relevant increase in risk from this sampling can be excluded from the assessment and evaluation. This is only warranted when the sampling criteria lie significantly below existing risk or dose thresholds. The establishment of sampling criteria relies on the basis of the practical feasibility of the estimation of the collective dose. The do not represent a definition in the sense of a de minimis risk. Such special and temporal sampling is to be mentioned, documented and justified.

Explanation

In the field of occupational radiation exposure, for which mostly centrally documented parameters describing exposed groups and individual dose data are available, not only are assessments and evaluations of individual doses to be included into considerations of practical radiation protection, but their distribution should also be taken into account. A differentiated treatment of various parameters influencing dose distribution allows answering specific questions with regards to dose limitation as well as the optimising of radiation protection measures. Focussing on the assessment and evaluation of the collective dose condenses the individually available information pertaining to occupational radiation exposure into a value which can still be informative in the sense of a general trend of exposure development, given that it has lost important information concerning the optimising of exposures. For this reason, the exposure distribution and the exposure parameters influencing it should obtain clear priority over the collective dose.

For the assessment of radiation-related risks which the general population may be exposed to, the concept of collective dose can only serve as a coarse instrument for the comparison of various routes of exposure. Due to frequently considerable uncertainty, it is recommended against the use of point estimators. In fact, under consideration of these uncertainties, estimate ranges are rather used. This is especially valid for exposure lying within a dose range in which the direct epidemiological evidence is either negligible or simply inexistent. For a sufficiently large population group, the age distribution may be taken for the distribution within the respective total population accordingly. The size of the groups concerned can be estimated. For an evaluation of the exposure through environmental contamination caused by long-lived radionuclides and from measure meant to diminish these exposures, statements should be issued concerning the longer term. Information about population development are however only available for relatively short terms of a few decades. Projections as to the size of the population group to be observed for longer periods of time are afflicted with significant uncertainties. Changes in ageing, which are not less related to medical advances, lifestyle and nutritional habits, cannot be predicted with any useful accuracy or in the very least, only with great uncertainty. Within a group of population, the individual doses may be strongly inhomogeneous and be distributed across vast ranges. In the case of a significant inhomogeneity of the dose distribution, the greater part of an estimated collective dose would be comprised of large number of individuals with a very small individual dose. An additional problem lies in the fact that individual doses cannot be measured but must be calculated with the help of models. The unavoidable uncertainty of models increases even more when estimating collective doses. All these factors point to the use of collective dose for groups of po-

pulation as being generally linked to great uncertainty and as such of little informational quality. Collective dose aimed at radiation protection can hardly be used, if at all, and could potentially only be used to assess exposure trends. In order to enable the involvement of the population in risk assessment and evaluation as well as in the assessment of measures in radiation protection, the consideration of exposure distribution within the relevant population groups along with an assessment and evaluation of the individual parameters are necessary, as they would substantially influence the exposure distribution. Only such a differentiated approach allows for the identification of sensitive factors of influence and their verification with regards to the reduction of exposure by means of radiation protection measures. Should the collective dose be used as a planning tool, then it is to be assessed in a timely manner. In such a case, distance from conservative calculation processes when determining individual doses in approval procedures should be maintained.

A.II.6 Procedure determining population exposure

Background

Article 45 of the EU basic standards requires the assessment of doses emanating from radioactive emissions from technical and medical nuclear facilities received by the population or, as the case may be, groups or individuals of reference to be carried out as realistically as possible. This means that the assessment is based on the observed individuals' actual exposure.

However, within the framework of approval procedures, (prospective) dose assessments are to be carried out using conservative models, theses and parameters which systematically exaggerate the actual exposure, as per the AVV of paragraph 47 of the Radiation Protection Ordinance.

The same conservative models and assumptions are then also used in order to calculate the population's yearly radiation exposure (retrospective dose assessment) caused by radionuclide emanations in water and air, albeit modified by an elaborate consideration of the atmospheric propagation on the basis of site-specific measurements and of the actual emanations instead of the maximum allowed emanations since the commissioning of a nuclear facility.

The calculation of the pre-pollution caused by radioactive emissions (especially I-131) emanating from medical nuclear facilities are also subject to the AVV of paragraph 47 of the Ra-

diation Protection Ordinance, whereas realistic or experimental planning data is used in calculating the emission of radioactive material.

Theories

- The hitherto common procedure for exposure calculation in Germany which uses conservative radioecological models should be maintained to ends of planning, approval procedures as well as other prospective assessments.

- Planning constitutes an exception in which the effects are determined according to risk-oriented evaluation procedures. These should allow a realistic calculation of exposure as expected in plausible future exposure situations and marginal conditions as well as the resulting risks.

- A realistic dose calculation is to be sought for the assessment of exposure to radioactive materials which are already present in the environment as well as to emissions caused by approved occupations. This concerns tasks as well as work.

- In the face of potential outlay, a retrospective calculation should exclude a realistic dose calculation, even though conservative assessments demonstrate a negligible chance of exposure.

Explanation

A conservative calculation of exposures using the tools provided by the AVV of paragraph 47 of the Radiation Protection Ordinance or similar is then necessary when planning aspects are the central focus of attention. This arises from the fact that each and every administrative decision must be based on a comprehensive exposure prognosis which takes into account the possible future changes of individual contamination channels.

The situation presents itself under a different light in the case of risk-oriented evaluation procedures, such as those suggested by the Federal Office for Radiation Protection in the procedure for the search of repositories, but also within the discussions surrounding the analysis of long-term consequences of permanent radioactive waste repositories, given that a conservative approach, due to its mostly unclear over-exaggeration of the exposures and the resulting risks, virtually renders any comparative risk-oriented evaluation impossible. In this case, the calculation procedures using the actual expected exposures are necessary. Plausible

future exposure situations and marginal conditions are prognosticated on the basis of current circumstances and knowledge and with consideration of future developments.

When calculating the model parameters, a median-oriented approach is warranted by reasons of principles and feasibility. The median can often be estimated reliably, even on the basis of limited data. Dose conversion factors and risk evaluators from the ICRP are, for example, median-oriented. Medium-scale risks are often the only ones known and are furthermore insensitive to extreme individual scenarios or behaviours.

An exposure calculation according to the guidelines of article 45 of the EU basic standards is required to be as realistic as possible when evaluating existing emissions, so as not to come to any wrong administrative decisions, such as the ones concerning the necessity to cleanse contaminated sites (for which realistic models are used in Germany) or when calculating the exposure arising from active facilities.

A realistic dose calculation is not of any practical use if only negligibly low exposures (such as those not exceeding the approval threshold) can occur, especially when this is the result of a conservative assessment. In such cases, the considerable financial effort necessary to calculate a realistic risk exposure would not only be difficult to justify but also erroneously send out the signal that a risk assessment in such an area of exposure would require an exposure calculation to be as precise as possible.

III. Special application areas

A.III.1 Clearance

Background

With the increasing decommissioning and dismantling of nuclear power plants over the next few decades, questions on the clearance of large quantities of slightly radioactive material will move to the fore. To answer these, numerous framework guidelines, manuals for authorisation, regulatory statutes and models for the determination of doses must be compiled. For this it is necessary to know the expected streams of materials.

Currently the questions of clearance are being discussed both nationally and internationally. Key aspects here are the determination of numerical values for clearance in the framework of the Revision of Basic Safety Standards of the IAEA and the EU Basic Standards for radiation protection, which are entirely based on radio-ecological exposure model simulations.

In the Federal Republic of Germany clearance is approved when an effective dose in the area of 10 µSv in a calendar year and a collective dose of 1 person-Sv is adhered to for individuals of the population. The limitation of the collective dose can however be exceeded if in reasonable individual cases this is justified by optimisation considerations.

Theories

- For the derivation of clearance values, conservative, cover-all exposure models must be consulted following the current procedure for the limitation of individual doses. The modelling should be based on conditions (quantities etc.) expected in Germany in the future. If the collective dose is consulted as an additional evaluation criterion, this should be defined with realistic median-based modelling approaches and parameters.

- It must be ruled out that in practice, through the accumulation of high quantities of clearance materials on few disposal sites, higher exposure occurs than accepted.

- The limit value for the effective dose for individuals of the population should not be chosen ‘in the area of’ 10 µSv but should be fixed at 10 µSv/a (limit value).

- An international harmonisation is to be aimed for. This should not however be so purchased that the conservative methods for derivation or the clear separation between the dose values for clearance (10µSv/a) and for exposure from activities for individuals of the population (1mSv/a) be abandoned.

Explanation

As the derivation of clearance values and clearance limits and their designations in the Radiation Protection Ordinance represent classic planning instruments, which should replace the burdensome authorisation process for each individual case (and in this respect represent a simplified authorisation process), the derivation should be based on a conservative exposure model in order to guarantee adherence to the dose value of 10 µSv for the highest exposed population groups. For the limitation of the collective dose as a planning instrument, it should however be avoided that calculated values of this size are determined for the most part by the summing of (unknown) conservatism factors, therefore possessing no significance. The most exact consideration possible of the quantities, volumes, etc. forecasted as a result of the decommissioning and dismantling of nuclear plants in Germany in the next few decades is needed to render it unnecessary either to correct clearance values determined on the basis of generic models or to accept a possible exceeding of the dose value of 10 µSv/a with their retention.

Currently only a few conventional disposal sites are ready to accept clearance materials (for example construction waste). This leads to the fact that these disposal sites are used intensively for the dumping of clearance materials. If this trend continues it can be assumed that significantly higher quantities of clearances materials will be stored at these disposal sites than is accepted in the currently implemented model calculations for the derivation of clearance values. In order to prevent such a development with the consequence of an exceeding of the maximum (individual or collective) dose values, either the models must be correspondingly adapted - consequences would be consistently significantly lower clearance values - or a central register for example of disposed quantities and activity concentrations would have to result from clearance decisions in order to be able to limit accumulations at individual disposal sites.

Increasingly, international approaches are envisaged in which the generally recognised insignificance threshold of 10 µSv/a is mixed with the population limit value of 1 mSv/a. This is whether the 10 µSv/a is viewed as an accumulation point of a distribution that ranges to 1 mSv/a, or whether an additional dose of 1 mSv/a is assumed in model calculations for the

derivation of clearance values/clearance limits, if the underlying modelling scenarios and parameters are estimated conservatively. An adoption of these approaches, which can also be found in the Safety Guides of the IAEA, would lead on the one hand to the restrictive values of the Radiation Protection Ordinance having to be adapted. On the other hand, an amalgamation of the dose value for the determination of an irrelevance threshold and the limit value for the population would be the consequence that may considerably hamper the risk communication of both values.

A.III.2 Limiting exposure to radon in buildings

Background

In Germany the average radon concentration in buildings amounts to around 50 Bq/m3 ambient air, where the values in individual buildings can fluctuate by several degrees as a result of differing geological characteristics in the underlying ground, the building construction type and the ventilation situation. The overall evidence from indoor studies carried out to date on lung cancer risk caused by radon shows that the data is best described by a linear exposure-effect relationship without threshold value. Since even low radon concentrations lead to a small increase in lung cancer risk and the majority of the population is affected by this, a not insignificant portion (estimated at between 5% and 6%) of lung cancer illnesses annually in Germany are caused by radon - here only the influence of smoking is significantly higher. According to current knowledge, radon in buildings therefore represents the highest environmental radiological risk.

Not least through the extensive scientific work that has been carried out in the last two decades by the Federal Office for Radiation Protection and under the framework of the UFOPLAN can the significant geological and constructional factors of influence on radon concentration in houses be clarified.

Theories

- Today's detailed knowledge of health risks from radon and relevant influencing factors require and allow technically better founded legal regulation than has been possible in the framework of non-binding guidelines.

- As a concentration above which cleaning measures are required, and as a target for the reduction of raised concentrations a value of 100 Bq/m3 ambient air (corresponding to an annual dose of approx. 2 mSv) should be aimed for.

- Simultaneously with the reduction of raised concentrations in affected individual buildings, a reduction of the average value of radon concentrations of all buildings should be aimed for in areas where raised radon concentrations must be reckoned with. Additionally in these areas, measures should be made compulsory that are graded according to radon concentration for the reduction of excessive radon from the foundations of living areas.

Explanation

Analyses of the epidemiological indoor studies carried out in Europe and worldwide on lung cancer risk caused by radon show consistently that the data can be best compared to a linear dose-effect relationship without threshold value. The epidemiological studies show a statistically significant increase in lung cancer risk with increasing radon concentration. An average radon concentration over 30 years of about 100 Bq/m3 was found to be the lower detection limit of statistical significance. A value of 100 Bq/m3 (measure and target value) is therefore to be set for the reduction of raised radon concentrations.

It can be shown that a reduction of the average value of radon concentration in all buildings effects a more effective reduction of the expected number of radon-caused lung cancer illnesses than the solitary reduction of individual, significantly raised values. This is essentially because in the former case a significantly higher number of apartments (and therefore inhabitants with a raised individual risk) are included. Alongside the classic approach of capping peak values, equivalent measures should be attempted for the general reduction of radon concentrations in new-builds and in housing stock in areas with raised radon concentrations. The time periods accepted for the implementation of cleaning measures in the housing stock should be graded in accordance with the level of radon concentration (and therefore the lung cancer risk of the inhabitants).

With reasonable financial outlay, tested constructional methods are available that allow the implementation of both objectives of such a reduction strategy.

A.III.3 Limiting exposure to radionuclides in drinking water

Background

With the conclusion of the investigations of the Federal Office for Radiation Protection on radiation exposure to radionuclides in drinking water, there exists in 2008 for the first time a representative overview for the Federal Republic of Germany as a whole. Because of the representativeness for the overall area of the Federal Republic and the inclusion for the first time of all dose-relevant radionuclides in the simultaneous partial improvement of detection limits, this study sets a new standard for the assessment of radiation exposure to natural radionuclides from the consumption of drinking water.

An important result of this study is the basic confirmation of the available findings of natural radioactivity in drinking water and the radiation exposure resulting from this1. The newly specified average value for radiation exposure is around 0.009 mSv per year for adults and around 0.05 mSv per year for infants. This confirms that drinking water in Germany only slightly contributes to the overall average annual radiation exposure from natural sources of 2.1 mSv. On consideration of the spread, it is clear that for adults in individual cases and in particular for infants, higher radiation exposure was also determined that exceeded dose guidelines.

Radiation exposure from drinking water is subject in Germany to the scope of the regulations of the Drinking Water Ordinance. In the most recent amendment of this in 2001, the provisions of the EU Drinking Water Directive of 1998 were largely adopted, which in turn are based on the recommendations from the same year on drinking water quality from the World Health Organisation WHO. In the meantime the recommendation of the WHO from 2006 is available in a revised form.

In agreement with the recommendations of the WHO, the EU Drinking Water Directive prescribes the health-related assessment of drinking water on the basis of a total indicative dose of 0.1 mSv/a. Currently however there are no binding regulations regarding which age groups, which standard consumption levels and which radionuclides are to be considered in the dose calculation.

[1]. A summary of this can be found in the annual reports *Environmental Radioactivity and radiation contamination* from the Federal Ministry for Environment, Nature Conservation and Nuclear Safety

In agreement with the recommendations of the WHO, the adult age group is exclusively considered in the EU Drinking Water Directive, for which a drinking water consumption of 730l per year is assumed. This represents a standard consumption level that makes a very high estimate of the consumption of the population and only disregards extreme consumption levels.

The WHO recommends the consideration of all radionuclides that contribute to ingestion dose, including the radon decay products Pb-210 and Po-210. Radon is considered separately by the WHO as on the one hand it contributes to the ingestion dose and to the inhalation dose, and on the other hand the dose contribution can be significantly reduced at manageable cost by relatively simple ventilation measures.

According to EU guidelines however, radon and its (long-lived) decay products Pb-210 und Po-210 are not to be considered for dose calculation.

Besides ingestion, radon in drinking water can by gas release lead to radiation contamination through inhalation. More details about this can be found in Chapter A.III.2 on radon in habitable rooms.

The as yet open question on the determination of radiation exposure from radionuclides in drinking water makes it urgently necessary to find appropriate definitions. On the one hand these must allow for the general objectives of the Drinking Water Directive. It is particularly worth mentioning here that water for human use can be harmlessly used for a whole lifetime, i.e. the precautionary principle must be considered (see Chapter D.II), and a high level of health protection must be guaranteed. On the other hand, the established principles of radiation protection must accommodate the requirement that each susceptible age group is considered and all dose-relevant radionuclides are observed that contribute to the overall dose.

Theories

- As radiation exposure through drinking water only constitutes a part of the radiation exposure of the general population, it is necessary to allocate to drinking water a maximum permissible proportion in general for the population as the dose value deemed permissible (“constraint“). Here the provisions of the WHO, the EU Drinking Water Directive and the German Drinking Water Ordinance are to be followed, which stipulate for this a maximum of 1/10 of the dose value for the population of 1 mSv/a.

- Today's detailed knowledge of health risks from radiation demand that in the assessment of radiation exposure to natural radionuclides in drinking water, all radionuclides that contribute substantially to the ingestion dose are to be considered in the determination of the overall dose. This includes Ra-226, Ra-228, the uranium isotopes, Pb-210, Po-210 and Rn-222.

- Alongside the aforementioned comparison group of adults and the concentrations of radionuclides derived by the WHO and the EU Drinking Water Directive for this group of persons and their consumption rates, a protection concept for the assessment of health risks from radionuclides in drinking water ought also to take into account the age group of infants and young children, who are recognised to be particularly sensitive to radiation.

- According to the Bottled Water Regulations, the guideline of 0.1 mSv/a should be adhered to for infants.

- In this way, the basic requirements of the Drinking Water Directive are fulfilled and a high level of health protection is guaranteed.

- In the longer term uniform values for consumption rates should be defined that take as a basis the dose calculation according to the Radiation Protection Ordinance and the Drinking Water Ordinance.

Explanation

Particularly high quality standards are placed on drinking water following general rules of hygiene. The establishment of limits and requirements is implemented according to the current levels of scientific knowledge and technical development. According to the reasoning of the current amendment of the Drinking Water Ordinance, the total indicative dose for drinking water is so established that only technically unavoidable contamination is tolerated. The aim of the Drinking Water Ordinance is to provide the consumer with water that can be used without compunction for the various purposes of human use. The water must for this purpose be 'pure', i.e. free from unnecessary and undesirable contamination.

The WHO recommends the consideration of all radionuclides that contribute to the ingestion dose, including the radon secondary products Pb-210 and Po-210; only radon is considered separately. According to EU guidelines however, radon and its (long-lived) decay products

Pb-210 und Po-210 are not to be considered for dose calculation. There is no technical reason for such an approach. The Federal Office for Radiation Protection deems it prudent to include in the dose calculation all radionuclides relevant to the ingestion dose, so also Rn-222, Pb-210 and Po-210.

In the current recommendation of the ICRP No. 103 from 2007, the ICRP realises in 'existing' situations and here in scenarios with long-lasting raised radiation exposure that the dose guideline should be smaller than 1 mSv/a and that a value of no more than around 0.3 mSv/a would be appropriate. The dose guideline of 1 mSv/a or less also relates to overall exposure from various sources. Besides drinking water, the influx of natural radioactive substances with other foodstuffs is also to be considered. A national average of around 0.3 mSv/a is recognised for this.2. Because of the complex national and international flow of trade, the determination of regionally differentiated or individually characterised values is not practicably affordable. For such situations, radiation protection provides the opportunity of establishing guidelines 3 for exposure to individual sources. In this way it should be ensured that the protection targets (here: 1 mSv/a) are observed even in the case of the combined effect of different sources of radiation on the same person.

The differences in the consumption rates used in the various policies reflect different, historically evolved protection philosophies and conventions, as well as in places different consumption habits and levels of knowledge. Basically it is essential to establish standardised consumption rates that dose calculation is based on. The determination of radiation contamination from natural sources is made from the most realistically possible radiation protection estimates. This is sensible, as the radioactivity coming from natural sources is not well-targeted but ubiquitous, and the expenditure connected with a reduction of the resulting exposure should lead to a reduction in actually occurring exposure, not overwhelmingly to a reduction a priori of overestimated exposure.

Significant geographical areas are affected by concentrations of natural radionuclides in drinking water that can lead to the exceeding of dose guidelines. This is because of the high content of natural radionuclides in the rock and sediment that can also appear in untreated water. In these cases it should be checked whether the untreated water is suitable for use or whether it is necessary and feasible to treat the water to reduce the radionuclide concentrations. Besides the costs of water treatment, the problem of radioactive waste also requires

[2] Of this more than 50% is accounted for by the radioactive isotope potassium, which is essential to metabolism.
[3] The technical term often used here is the English word 'constraint'

discussion here. If different sources are available, the required water quality can be alternatively achieved through blending. Further aspects include the expected consequences for water management and the provision structures and safety.

A.III.4 Medical Radiation Exposure

Background

The radiation exposure of the population in Germany through X-ray diagnosis or nuclear medical investigations is relatively high at around 1.8 mSv or 0.13 mSv per head and year compared to other Health Care Level I countries. This is attributed primarily to the prevalence of such examinations.

In order to optimise the radiation protection of the patient, the duties and rights of doctoral and dental posts were broadened and diagnostic reference values (DRV) were introduced within the framework of the amendment to the Radiation Protection Ordinance and the X-ray Ordinance. The aim of these measures is to improve the quality of examinations and to reduce in the mid-term the dose per examination. These measures alone will be insufficient to achieve a long-lasting basic change to the current situation.

Theories

- Future efforts for the reduction of radiation exposure to the population - and particular population groups such as children - through radiation diagnostic measures must start with the justifying indication. For various reasons these are currently not so restrictively managed as is desirable under both radiation hygienic and health-economic points of view. So, by the estimation of the President of the German X-ray Society (Deutsches Ärzteblatt, 1999), about half of all X-ray examinations could be dispensed with. This may disproportionately concern the performance of sub-section radiologists, which is mostly linked with a lower dose. The dose reduction potential must therefore be estimated significantly lower in practice.

- In order to avoid a further increase in the radiation exposure of the population through radiological and nuclear medical diagnosis, new technologies are to be radiation hygienically evaluated at an early stage by the Federal Office for Radiation Protection.

- The comprehensive introduction of early-recognition measures by means of radiological methods requires a radiation hygienic assessment on the basis of risk-benefit analyses and the detailed establishment of structural minimum requirements of early-recognition programmes within the framework of accreditation according to Art. 25, Para. 1 of the X-ray Ordinance.

Explanation

Alongside the already implemented measures for quality assurance and quality management, a reduction in the number of examinations is the most effective possibility for reducing the radiation exposure of patients. While the focus of radiation hygienic measures to date predominantly concerns the physical-technical arena and the implementation of examinations, in the future the diagnosis is to be considered more closely. As the justifying indication results from a weighing-up of benefits and risks, knowledge of radiation risk is of decisive importance. Unfortunately, the risk estimation underlying radiation exposure from individual examination types is insufficiently known to many radiologists/sub-section radiologists and most referring doctors. The compilation of an indications catalogue, including the expected patient doses as required by the patient protection guidelines 97/43/Euratom, could bring about an improvement here. The primary aim of this approach is to help doctors in hospitals and in general practice to choose the most appropriate imaging technique for the given situation. A further practicable approach to a solution on a national level is to incorporate recommendations for radiological performance in a so-called Disease-Management-Programme – under consideration of the already existing medical guidelines from the side of the autonomous healthcare bodies and relevant scientific medical associations.

The introduction of innovative radiological and nuclear medical technology into the medical routine will also open up in the future new diagnostic and therapeutic options. This development makes it necessary to continuously adapt the regulations for the acquisition and updating of technical knowledge of radiation protection in each area (current example: teleradiology). Furthermore, the radiation exposure of patients and of staff using new technology is to be evaluated. It is particularly to be avoided that an unjustifiable rise in the radiation exposure of the population is brought about through unconsidered use of new technology and the use of unperfected protocols. For this reason it is crucial, already in the early evaluation of new diagnostic technologies, to carry out accompanying radiation hygienic studies in order to comprehend the examination practices and the radiation exposure resulting from them. Dose-optimised examination protocols can be compiled and realised based on the collected data.

Current health strategies tend ever more strongly towards early recognition measures. For this the imaging techniques of radiological diagnosis come into special significance. While interest to date has concentrated on conventional X-ray images, e.g. X-ray mammography, the trend in some Health Care Level I countries shows that dose intensive techniques, e.g. X-ray computer tomography, are increasingly being used. The background is that modern CT systems allow a spatial, high-resolution representation of large examination areas within a few seconds. So the entire abdomen or thorax region can be comprehended in breath-taking technology without motion artefacts. This new technology can be used for early-detection examinations, e.g. in the large intestine area (virtual colonoscopy for the early detection of intestinal tumours) and/or in the heart area (calcium scoring, early detection of arteriosclerotic plaque). This development requires the interdepartmental preparation of concepts for the licensing of radiological examination technologies as techniques for early recognition according to Art. 25, Para. 1 of the X-ray Ordinance on the basis of established risk-benefit analyses. In this context alternative imaging techniques without the application of ionising radiation are also particularly to be considered.

B. Non-ionising radiation

Non-ionising radiation (NIR) means the part of the electromagnetic spectrum, where respective particle energy is below 12.4 eV. This threshold equates to a wave length of 100 nm. This lies within the range of ultraviolet radiation. The range of non-ionising radiation is divided in static fields and - depending on the frequency - in low-frequency electric and magnetic fields (up to 100 kHz) and high-frequency electromagnetic fields ((>100 kHz – 300 GHz) respectively, as well as in optical radiation, which also includes ultraviolet radiation (UV). Ultrasound is per definition also classified as non-ionising radiation. Technical applications that use non-ionising radiation or where this radiation arises as a by-product have become completely part of our daily life, our private as well as our work environment and in medicine. Thus all areas of application of electrical energy with low-frequency, electric and magnetic fields are interconnected. All wireless information transmission and communication methods use high-frequency electromagnetic fields or optical radiation. Moreover, optical radiation is used for lighting purposes as well as for material processing. Ultraviolet radiation plays an important role in the field of medicine, in industry and is often used for cosmetic purposes such as sun tanning.

So far only acute harmful health effects, which occur above certain thresholds, have been proven as a consequence of a non-ionising radiation exposure. The range of ultraviolet radiation with its skin cancer trigger effect is an exception, although even here radiation protection considerations concern largely acute effects. Limit value recommendations, which take into account safety factors, are issued based on these thresholds of effects. The currently applicable limit values for stationary low-frequency and high-frequency installations are laid down in the 26th Ordinance on Implementation of the Federal Emission Protection Law (Ordinance on electromagnetic fields 26. BImSchV), Continuously carried out assessments of the scientific level of knowledge show on the one hand that no harmful health effects have been proven to date when thresholds are adhered to. On the other hand, there are some hints of possible biological effects with unspecified health relevance in connection with intensities of medium- and high-frequency fields beneath the applicable threshold. Thus, national as well as international organisations such as the German Commission on Radiological Protection, the ICNIRP und WHO recommend further research to investigate possible biological effects and so to be able to better assess their health relevance.

The NIR area of responsibilities also includes possible health risks caused by the application of ultrasound. Health relevant temperature increases and mechanical, in particular cavitating

effects in tissue cannot be ruled out in the use of new, powerful procedures. Further research need exists with regards to the threshold values of mechanical effects and derived indices (mechanical and thermal index). Similar gaps of knowledge also pertain within the area of infrasound.

Radiation protection principles have not been developed to the same extent in the area of non-ionising radiation as they have been in the area of ionising radiation. Up to today it was of prime importance to ensure that known health relevant limit values were remained below. The principles presented here are for the future discussion on the further development of general radiation protections principles (limit values, justification, optimisation, precaution etc.) in the area of non-ionising radiation. It must be taken into account that in accordance with the current scientific level of knowledge, all proven health effects of low-frequency and high-frequency electromagnetic fields are connected to the acute exposure above certain intensity thresholds. A link necessary for observations between the exposure length with the dose only exists within the area of optical radiation. Even here a dose concept only exists in a rudimentary form. In this light, aspects of precaution and minimisation, which so far have been discussed rather controversially on a national as well as an international level, might acquire a different content and meaning than in the area of ionising radiation.

B.I Explanation

Background

Although no dose-effect relationships are known so far, the discussion about the significance of principles of justification and precaution within non-ionising radiation are based on the plausible assumption that a reduction of exposure also leads to a reduction of a possible risk. So far, only acute effects are known, which are only proven above certain thresholds of exposure. The effect mechanisms for these effects are also established. Ultraviolet radiation is an exception, as here stochastic effects are known as well. There can be no scientific doubt that ultraviolet radiation is one of the chief causes of skin cancer. The main problem is uncontrollable sun exposure. However, at the time of writing no exact damage mechanisms are known and no methods for a dose assessment in the population are available. Attempts to quantify risk coefficients for the UV-radiation range have so far proved unsuccessful. Acute effects are the basis of exposure restrictions. Beyond this, only a qualitative assessment of health risks is possible.

Radiation protection recommendations in the field of non-ionising radiation are mainly based on the restriction of exposure beneath values, which are significantly below effect thresholds. These known thresholds for acute effects are also implemented in the area of UV-radiation. No justification concepts have to date been discussed in the area of non-ionising radiation.

As opposed to ionising radiation, the man-made non-ionising radiation is a result of the increasing technologising of all areas of life. Most new developments are based on international norms and the distribution of products is subject to international law.

When considering the technical application of non-ionising radiation, societal acceptance of new technologies is just as important as the scientific risk assessment. The public pays attention to the high-frequency electromagnetic fields of information and communication technologies as well as to the low-frequency fields of electricity supply and this has in the past led to comprehensive, intensive societal discussions. One reason for this discussion process has been the subjectively as uncontrollable perceived immersion of our daily life with new technologies and their application. Central points of discussion throughout society have been the perception of health risks through electromagnetic fields. A comprehensive risk assessment which takes into account the opinions and interests of various stakeholders, must consider society's risk perception on top of carrying out a mere scientific risk estimate. This means that on the one hand the risk perception must be captured and taken serious and on the other hand the scientific risk estimate must be communicated as well as possible to the public.

Theories

- When justifying exposure a distinction must be made between the scientific risk estimate and societal questions.

- Radiation protection is limited to the risk estimate and its communication.

- The question of justification should be mainly asked during the process of developing new technologies (see B.II).

Explanation

The question of a risk estimate necessary in this context is currently primarily based on the knowledge of acute effects and of exposure-effect relationships with thresholds. That means that there are no scientifically proven risks beneath certain thresholds. But there are also

scientific indications of biological effects beneath this threshold for acute effects, whose health relevance can currently not yet be conclusively evaluated. Thus, no sound quantitative risk assessment can be carried out in large parts of the non-ionising radiation range. Even a qualitative assessment is difficult due to a lack of possible effect models. If and what contribution radiation protection can make to the question of justification must be answered by society.

B.II New Technologies

Background

Recent decades have been shaped by a rapid technologising of all areas of daily life. It is foreseeable that this development will continue in the future. A variety of new technical applications generate non-ionising radiation, some of them even in areas relevant to limit values (See also examples in B.III). Here, above all the modern wireless communication technologies and also the development of new higher-performance light sources are to be mentioned.

A radiation protection evaluation of new technologies is up to now usually only possible after their introduction onto the market, as the data required is in many cases not made available in advance to radiation protection. Changes to technical details, which could lead to improved radiation protection, are mostly no longer realisable under these circumstances. An example from the past is the cordless telephone after the DECT Standard. The permanent emission of high-frequency fields through the control channel is not required for applications in domestic use. A current example is infrared heating chambers, which were developed as an alternative to conventional saunas without the participation of radiation protection and to a large extent without specialist knowledge of the possible health effects. They are currently being heavily marketed.

Principally the open questions about new technologies can be divided into two categories:

1. Frequency ranges, in which effects mechanisms are recognised with threshold character. Here there is concern justified to some extent that through the sum of the continually rising number of sources, the limit values will be increasingly exhausted. It is not to be ruled out that local interaction leads to exposure that is precarious in the view of radiation protection.

2. Newly developed niches of the electromagnetic spectrum such as Tera-Herz (THz) radiation. Up to now there have only been few and pricey THz sources on the market. In the future however a variety of practical applications could arise, from medical diagnosis to communication systems. Possible effects are currently extrapolated from knowledge of adjacent microwave and infrared areas, but cannot however be explained without argument. Up to now there has been a lack not only of research projects on effects research but also of measurement and calculation techniques for the defining of exposure.

Theories

- Only through the early participation of those involved in radiation protection in the development of new technologies can the specifications of a precautionary radiation protection (see also D.II) be implemented for field-emitting sources. An exposure minimisation through technical optimisation of all field sources is required. A corresponding inter-ministerial consultation particularly with the Federal Ministry for Education and Research is to be sought.

- Basic research on radiation protection must take place before the introduction onto the market of new devices, where gaps in knowledge exist (e.g. the THz area) or where these are assumed to be scientifically founded.

Explanation

Possible health risks in the application of new technologies can only be recognised early on if radiation protection has participated already in the development phase. This should be in the interests of all participants. In the future, the credibility of radiation protection also depends on the extent to which it is in a position to influence proactively new technological developments.

B.III Limit value setting

Background

In Germany there is currently a lack of general legal basis for the protection of the population from non-ionising radiation. The regulations existing for individual frequency areas, such as the Federal Control of Pollution Act, cannot close these gaps. They regulate only individual sources, such as radio and television transmitters with a transmission power over 10W EIRP

or low voltage plant or 162/3 Hz and 50 Hz, which are operated at voltages greater than 1000 V. The criteria for product safety present in the framework of European norms do not always meet the requirements which are set out in the radiation protection regulations. So for example according to these norms, individual devices can cause pollution in their surroundings that fully exhausts the limit value recommendations.

The area of optical radiation is completely unaddressed by current radiation protection law. There are only technical norms here.

With the exception of the telecommunications area, beyond the BEMFV (German: ordinance on method of proof regarding the limitation of electromagnetic fields) and the 26th Federal Emission Protection Law and from certain low-frequency plant beyond the 26th Federal Emission Protection Law, there are no specific legal regulations for the protection of the general population from exposure to non-ionising radiation. The existing norms alone cannot sufficiently prevent uncontrolled exposure of the population to NIR sources. Examples of this are solaria, infrared saunas, anti-theft systems and non-medical use of ultrasound on the human body.

The existing recommendations of the European Council for the protection of the population from electromagnetic fields can in individual cases be consulted, but are not legally binding and do not cover the area of optical radiation.

The international situation is similar. No country can be identified that has a comprehensive legal radiation protection regulation for non-ionising radiation. In many European countries there are, as in Germany, provisions for individual frequency areas. Mentioned here above all are radio transmitters and electricity stations. In individual countries furthermore, there are legal regulations for certain optical sources, such as for example solaria.

A worldwide comparison by the WHO shows that many countries orientate their mostly delegated regulations (e.g. norms) to the recommendations of the ICNIRP. Alongside this in some countries of the former Eastern Bloc, e.g. in Russia, there are considerably lower “limit values”, whose legal bindingness is however unclear. They have however in recent years been significantly raised with the introduction of new technologies. In the USA the regulatory provisions existing for example for radio applications are oriented to the recommendations of the IEEE (Institute of Electrical and Electronics Engineers), an American standards organisation. Regarding the SAR values for mobile telephones, these values are more conservative by around a factor of 2 than the European recommendations. The WHO is currently endea-

vouring to achieve a harmonisation of all international recommendations for radiation protection.

The area of protection in the workplace is comparatively well regulated. Nationally, countless accident prevention provisions and corporate occupational provisions exist. In the European framework, workplace protection guidelines for the whole area of non-ionising radiation are compiled.

Theories

- The protection of the population in the area of non-ionising radiation can only be ensured by legally biding regulations.

- Basic regulations should arise through the determination of limit values and be internationally harmonised.

Explanation

The recommendations that are voluntary find insufficient regard and are in part insufficiently implemented by European norms. An effective protection of the population is therefore only to be guaranteed by legally binding regulations.

The credibility of limit values can only be facilitated when they are internationally comparable. Considerable differences lead automatically to a loss of trust regarding the relevant institutions.

C. The Protection of Nature and the Environment

The development of protection concepts for flora, fauna and environmental media

Background

Before a backdrop of international developments for the long-term protection of the biosphere stemming from the declaration of Rio in 1992 with its concepts of sustainability and conservation of biodiversity, it has in recent years been increasingly postulated that radiation protection concepts must equally demonstrate protection of the environment as well as the protection of humans. In Germany this has up to now for example become part of the requirements set by the Environmental Impact Assessments (EIA).

At present in the framework of international research projects, relevant protection targets are being developed and suitable concepts for the guaranteeing of such protection targets are being compiled. The discussion has begun in the IAEA and the ICRP regarding the involvement of protection of the environment in radiation protection regulations but this has not yet been finalised.

In the area of non-ionising radiation, the sun is a natural source of ultraviolet radiation, which leads to a significant degree of exposure for the environment. The possible damage to the living environment, above all in the context of changes in the atmosphere caused by man, has long been recognised. The protection of the environment in this context cannot be supplied by radiation protection alone. The question of the air quality of the atmosphere takes the foreground here.

Increasingly it is also large-scale plant causing pollution in the living environment area, which can lead to negative effects there. Examples are high-performance HF transmitters for the investigation of the atmosphere or offshore wind farms and related submarine cabling.

The question of the effects of electromagnetic emissions on the living environment has not only nationally but also internationally been sorely neglected until now. The attempt at a systematic compilation of the knowledge gained to date has only once been undertaken in an international seminar in October 1999 run by the Federal Office for Radiation Protection in collaboration with the WHO and the ICNIRP. The scientific foundations for a resilient assessment of possible damages to flora and fauna have not yet been systematically compiled.

Theories

- International activities for the formulation of suitable protection targets and the compilation of scientific concepts for compliance with these are to be substantially shaped by Germany.

- A harmonisation of protection targets and relevant detection concepts for other pollutants are to be kept in mind.

- Protection targets and procedures are to be determined on the basis of a society-wide discussion.

- In order to arrange not too expensive procedures for comparably low emissions, the complexity of the procedures should be oriented towards expected emissions and pollution - an approach that from the German side should be increasingly brought into international discussions. In the same way, internationally propagated approaches should only be undertaken if they satisfy these proportionality criteria.

- In the future, increased attention should be devoted to the protection of the environment from non-ionising radiation. Through targeted research it is to be clarified under which conditions damage to the environment from non-ionising radiation is possible and which protection measures are effective. In the framework of Environmental Impact Assessments, the possible consequences of pollution from electromagnetic fields should be tested.

- Damage to flora and fauna caused by UV is partially known. Through changes in the atmosphere caused by man, this aspect is increasingly growing in significance.

Explanation

Even when many things indicate that the emission and pollution regulations of the German Radiation Protection Ordinance which focus on the protection of humans also guarantee the protection of the environment, individual regulations are also required to be able to determine and document conformance to these protection targets.

A harmonisation is required of protection targets and concepts with existing practices for other pollutants, which for example are considered in the framework of the Environmental Impact Assessments in Germany. This is in order that comparable approaches can be deve-

loped for the environmental assessment of different potentially toxic substance classes. In ecotoxicology, scientific testing procedures have long been developed for this, which should be analysed and evaluated for their suitability to detect the protection of the environment from radioactive substances. On the one hand this is in order to be able to exclude different practices, which are not based on the specific qualities of particular substances but possibly on totally different protection targets for different classes of potentially environmentally toxic substances. On the other hand this is in order to profit from the long years of experience of ecotoxicology. Extensive experience is drawn on here from the Federal Environment Agency and the Federal Agency for Nature Conservation.

A broad social discussion about protection targets aimed for in Germany and the procedures for their implementation is to be sought, as in recent years a consensus has increasingly developed in international radiation protection bodies to consider social debate regarding new recommendations more than has been usual to date (“stakeholder involvement“).

D. Regarding further questions of pure radiation protection

D.I Risk-based assessment procedures

Background

The estimation of radiation effects and risks and the radiation protection regulations derived from these are based on scientific knowledge of radiation effects, the assessment of radiation risks but moreover on reflections on their social acceptability. Discussions about this were carried out in international and national bodies primarily staffed by scientists, such as the ICRP, UNSCEAR, Euratom Article 31 Group and the German Commission on Radiological Protection, and their recommendations contributed to radiation protection. These recommendations, particularly those of the ICRP, have in the past been implemented almost unchanged as binding international and national radiation protection regulations. Comparable developments can be seen for non-ionising radiation, but also for other physical, chemical and biological pollutants.

Characteristic for these practices is (1) an estimation based on scientific knowledge of exposure and effects and what they depend on, (2) a discussion on the acceptability of risks in scientific bodies and, stemming from this, (3) the development of regulation policies and procedures, which have specialised application only for a particular pollutant. The regulatory practice shows increasingly that protection from individual pollutants is much less the focus of observations than the protection of human health from contamination from a variety of individual pollutants from different environmental media, i.e. water, soil, air and in the broader sense foodstuffs. Shortcomings of the practices, as they have evolved over the course of time in the estimation, assessment and regulatory practice for individual pollutants, are (a) the non-comparability of risk contributions to human health inherent in the regulations of individual pollutants, (b) the strong dependence of standards set in the regulations on knowledge at that time of the effects of pollutants and thus the need for regular adaptation to changing knowledge, (c) the lack of standardised practices for the assessment of health and environmental risks from various pollutants in one environmental media, and (d) the widely lacking possibilities for social participation in discussions on the acceptability of risks and the regulatory policies and practices following from this.

From the characterisation of procedures and the identification of shortcomings the need arises (1) to develop an assessment reference that enables a comparison of different health

risks from environmental pollutants, allows an assessment of complex exposure situations and demonstrates the highest possible consistency, (2) to assign to science the task of best possible exposure and effect estimation and the modelling of the exposure-effect relationship in the risk assessment procedure, and (3) to open up social and political dialogue on the assessment of risks and also the determination of protection resources and protection targets.

Exposure in the environment and in the world of work that is relevant to regulation today is characterised as a rule by exposure to known individual pollutants at a relatively low level. As a consequence of this, regulation of individual pollutants is increasingly less relevant than contamination from all pollution taken together, including radioactive material from water, soil and air. On the other hand we are today confronted with a broad introduction of new contaminants without the possibility of adequate estimation and assessment of the risks before such introduction (e.g. new technologies in the NIR sector). With changes in estimation and assessment questions about individual pollutants with a known spectrum of effects through to complex exposure with often many individual materials contributing in a small way to exposure and/or the introduction of exposure to newly assessed adverse effects, the development and introduction of a consistent assessment reference becomes ever more necessary.

Theories

- The scientific process for the estimation of radiation risks requires comprehensive consistency even regarding other environment pollutants for a distinct and comprehensible procedure with a high level of transparency and an environmental medium (i.a. water, soil, air) as well as regulation contexts (i.a. occupationally exposed persons, population, drinking water, foodstuff). A pluralistic participation of subject specialists is necessary for complex or scientifically controversial topics and is to be anchored in procedures. With socially controversial topics, participation from individual representatives of affected and organised social groups should be enabled right from the risk assessment phase in particular cases.

- Normal specification, which should not and cannot be carried out exclusively by scientists, must be determined at the start of the risk assessment in a legitimised procedure. To this belong i.a. the questions of (tolerable, unthinkable, etc.) risk levels, the determination of adversity of documented effects on humans and the interpretation of precautions. Reasonable participation of those affected and social groups is to be enabled. This participation is offered objectively, constitutionally and democratical-

ly, as the definition of protection target and protection level and the determination of conventions for risk assessment are designated by social and political goals.

- A risk-based assessment procedure determines the social framework for the risk assessment and defines the assessment framework that can then be filled out at different specialist levels. A risk-based assessment procedure is established on the determination of the risk that society is prepared to accept as a consequence of its own actions and to ask of non-participating third parties. This determination requires social discourse and should take place in a democratically legitimate procedure. In this sense, a risk-based assessment is largely independent of current scientific knowledge, i.e. changes in this knowledge may well involve a change in the exposure-effect relationship but not necessarily that of the acceptable characterised risk level as it is defined in social discussion and political discourse. A comparable risk assessment is enabled through the risk-based assessment of individual pollutants and their collectivity, among others in environmental media and certain exposure circumstances, such as for example the work place or the meeting of safety criteria for the disposal of radioactive waste.

- The justification of acceptable risk levels caused by additional exposure from human activities in the presence of natural contamination, i.e. natural radiation contamination, is to be tested with a view to its plausibility. In ethical discussion, this problem among others is described as naturalistic fallacy, i.e. the incorrect deduction of normative conclusions from scientific facts. Additional man-made radiation exposure cannot be justified by the presence of natural radiation contamination. The amount of additional man-made radiation exposure can be compared however with natural radiation contamination.

- A risk level to be aimed for and/or to keep below has been established in international discussion as between 1 in 1,000,000 and 1 in 10,000 per lifetime for serious illness caused by genotoxic pollutants that have been released into environmental media by human activity. In general this means that the overwhelming part of the exposed and/or potentially exposed population is to be protected at a level of 1 in 1,000,000. Should this risk target not be achievable for all individuals, a deviation to a risk level of 1 in 10,000 is permissible for the highest exposed person and/or person groups, if lower risks cannot be achieved on the basis of the optimisation principle.

Explanation

The current position discussed above reflects in significant parts the recommendations of the Risk Commission (ad hoc commission for the reorganising of procedures and structures for risk assessment and standard setting in health-related environmental protection in the Federal Republic of Germany) and recommendations of international organisations such as the World Health Organisation for water and air quality, which affect the aforementioned positions. Furthermore the European Union has made the risk-based strategy i.a. the basis of its Drinking Water Directive (c/f A III.3). The Federal Office for Radiation Protection was significantly involved in the work of the risk commission implemented by the Ministry for Health and the Ministry for the Environment.

The estimation of radiation risks also affects the evidence-based summarised technical assessment of scientific data, which demonstrate a hazard, give clues or justify doubts. The summarised radiation hygienic assessment is established on the technical estimation of risks but also takes into account the perceptions of those risks in society. The perception in turn is characterised by factors like controllability, identifiability of cause, responsibility and so on. From this it is clear that the assessment of risks is subject to many influencing factors and does not rely solely on scientific facts. Risk assessment should therefore not conclusively be carried out by scientific bodies, but rather a broad social discussion should be opened. In this all participants must be clear that the basis of risk assessment and related measures is always the scientific estimation of health risks.

From this understanding it is necessary that the parameters of the risk assessment are clarified in a social discussion before the estimation and assessment of risks. The parameters of risk assessment include:

1. The determination of property for protection and protection targets.

   The question to be clarified is who or what is to be protected by a measure. Is the general public or the individual to be protected? What is the aim of the measure? Should absolute protection be guaranteed, should a danger be contained or, in the sense of precaution, be treated? The determination of property for protection and protection targets are described by the qualitative parameters of the risk assessment.

2. The determination of protection levels.

The protection level aimed for answers the question as to what is viewed as adequately safe. In this context the questions of the security of the risk declaration and basic acceptability are to be answered, i.e. whether in the sense of danger containment and/or precaution, unfavourable or realistic assumptions should be worked with. In the context of danger containment, proof of safety is often necessary in which unfavourable, overestimated and quickly implemented procedures can be worked with. In areas of precaution, i.e. in exposure areas where there is no threat of acute hazard, questions of optimisation/minimisation and/or avoidance of exposure come to the fore. For these questions, the most realistic estimation possible of the risk is necessary. Optimisation and/or minimisation procedures on the basis of overestimated assumptions often lead to false technical and economic decisions.

Determinations of risk level and of the necessary security of estimation results may be established by scientific facts, but are ultimately to be understood as a social convention and realised correspondingly. Statements are also needed here as to what is understood to be a negligible, unthinkable, acceptable or tolerable risk.

The argument that certain low radiation exposures are acceptable because they are so low and only constitute a fraction of natural radiation contamination is based on the known naturalistic fallacy from ethical discussion that the normative conclusion (“acceptable”) is derived from scientific facts. Normative conclusions should be founded ethically on normative and social values and should not be deduced from scientific facts or natural data. Natural risks are often difficult to reduce. Drawing the conclusion from this idea that additional risks of the same or smaller levels coming from human activities are therefore to be accepted, is ethically and logically unfounded and therefore in the sense of radiation protection not to be justified. That natural contamination plays a role in risk comparison should not however be contested. It is much more that a comparison of exposure levels for radiation protection decisions can be made more transparent and comprehensible.

Through present radiation protection, i.e. under observation of protection principles of justification, limit setting and optimisation for activities, the values obtained for radiation exposure for the population lie in the region of a few microsieverts per year. Excluded from this is radiation exposure from medicine, which is basically individually justified, in contrast to exposure of the population from other activities, whose justification results from a social justification. For example, with regard to an approved value of 10 µSv per year, a lifetime risk of a little more than 1 in 100,000 can be ascribed to the current risk coefficient for cancer mortality from the ICRP 103 of around 5 per Sv and an accepted lifetime of 70 years at the stated ap-

proved value. The permitted guideline for overall dose from natural radionuclides in drinking water of 100 µSv per year corresponds therefore to a risk value of a little more than 1 in 10,000. The vast majority of the population have exposure below the stated reference and limit values. So the radiation protection practised today is not oriented towards the exhaustion of reference and limit values but, particularly through optimisation requirements, it realises radiation contamination well below the reference and limit values. Therefore it can be noted for this that actually a protection level can be achieved for the population that is comparable to other regulation areas like water, soil and air.

D.II Precaution

Background

The responsible exposure to risks for environment and health caused by human activity quite generally requires that the principle of precaution must take its place as an autonomous measure, besides the containment of concrete dangers through the adoption of prohibition and protection measures. In the area of low exposure, as omnipresent in the lives of us all, great uncertainties exist beyond the actual risks. In the area of ionising radiation, the uncertainties require that risks to health must be estimated through extrapolation from exposure areas. The convention founded radiation hygienically of a linear dose-effect relationship without threshold dose up to very small dose values justifies the necessity of using the precaution principle (see also A.I.3, Optimisation) in the area of ionising radiation. In spite of all research efforts, it can be expected that existing uncertainties may well be reduced but it will never be possible to completely eliminate them. In the area of non-ionising radiation, a damage occurrence concept characterised by an effect threshold applies, although this is from basic considerations of damage effects. But also here there are hints of biological effects beneath this threshold, whose health relevance can currently not yet be conclusively evaluated.

Although the energies of non-ionising, high and low frequency electromagnetic fields are too low to contribute directly to cancer induction, mechanisms for cancer promotion are however discussed in scientific discussion. For this reason precaution is also indicated here, in particular regarding youths and young adults for whom particular radiation sensitivity cannot as yet be ruled out.

In the area of UV, precaution is particularly important especially for infants and young people, as at these ages a substantial share of the overall risk of contracting skin cancer is accumulated.

Theories

- Precaution represents a second important principle besides danger containment in the handling of risks, which serves for the maintaining of health and should therefore be anchored in the relevant legal regulations as a radiation protection principle.

- A precaution programme should be published and implemented for children and young people dealing with the risks of UV radiation, raising awareness of the risks of UV and giving guidance for the responsible handling of those risks during unchecked sunbathing. For this reason the Federal Office for Radiation Protection has adopted a solarium ban for under 18s.

Explanation

The necessity for precaution in the area of ionising radiation that is recognised generally in health politics has to date not yet entered the consciousness of the population for non-ionising radiation. A change is necessary in the regulations for protection against the dangers of non-ionising radiation, which are anyway out-of-date.

In spite of the observed increase in skin cancer illnesses in Germany and the corresponding recommendations from science, there is a lack like never before of regulatory initiatives that tackle this problem that has no simple solution.