

**Ordinance on Protection against the Harmful Effects of Ionising Radiation –
Radiation Protection Ordinance
(*Verordnung zum Schutz vor der schädlichen Wirkung ionisierender Strahlung –
Strahlenschutzverordnung – StrlSchV*)¹**

¹ Es handelt sich um eine nicht amtliche Übersetzung, die reinen Informationszwecken dient.

Table of contents

Part 1

Definitions

Section 1	Definitions
-----------	-------------

Part 2

Radiation protection in planned exposure situations

Chapter 1

Justification of types of practice

Section 2	Unjustified types of practice
Section 3	Procedure for assessing the justification of types of practice in accordance with section 7 of the Radiation Protection Act
Section 4	Procedure for verifying the justification of types of activity in accordance with section 38 of the Radiation Protection Act

Chapter 2

Prior verification of radioactive substances or ionising radiation

Section 1

Exemptions from licensing and notification requirements of an activity; exemptions from licensing requirements

Section 5	Handling not requiring a licence
Section 6	Possession of nuclear fuel not requiring a licence
Section 7	Operation of installations for the generation of ionising radiation not requiring a licence or notification
Section 8	Operation of stray radiation emitters not requiring a licence
Section 9	Non-notifiable verification, testing, maintenance and repair of X-ray equipment or stray radiation emitters
Section 10	Exemption from the obligation to provide financial provision
Section 11	Exemption levels

Division 2

Cross-border transportation of radioactive substances

Section 12	Cross-border transportation requiring a licence
Section 13	Notifiable cross-border transportation
Section 14	Exceptions; other provisions regarding cross-border transportation
Section 15	Conditions for the issuance of a licence for cross-border transportation

Division 3

Type approval

Section 16	Technical requirements for type approval of a device that contains other radioactive substances
Section 17	Technical requirements for type approval of installations for the generation of ionising radiation

Section 18	Technical requirements for type approval of X-ray emitters
Section 19	Technical requirements for type approval of basic-protection devices
Section 20	Technical requirements for type approval of high-protection devices
Section 21	Technical requirements for type approval of full-protection devices
Section 22	Technical requirements for type approval of X-ray equipment for training purposes
Section 23	Technical requirements for type approval of stray radiation emitters
Section 24	Obligations incumbent on the holder of a type approval
Section 25	Obligations incumbent on the owner of a type-approved device
Section 26	Publication

Division 4

Residues

Section 27	Determination of residues requiring monitoring
Section 28	Establishment of exposures caused by residues
Section 29	Release of residues requiring monitoring from the monitoring obligation for recovery or disposal in accordance with the Circular Economy Act (<i>Kreislaufwirtschaftsgesetz</i>)
Section 30	Release of residues requiring monitoring from the monitoring obligation for recovery as a construction product

Chapter 3

Clearance

Section 31	Clearance of radioactive substances; dose criterion
Section 32	Application for clearance
Section 33	Issue of clearance
Section 34	Mixing ban
Section 35	Unrestricted clearance
Section 36	Specific clearance
Section 37	Clearance in individual cases
Section 38	Ex officio clearance
Section 39	Agreement in the case of specific clearance for disposal
Section 40	Method of recovery and disposal under the law on waste
Section 41	Determination of the procedure
Section 42	Obligations incumbent on the holder of a clearance

Chapter 4

Operational organisation of radiation protection

Section 43	Obligations incumbent on the radiation protection supervisor
Section 44	Obligations during use by other radiation protection executives
Section 45	Radiation protection order
Section 46	Provision of the Radiation Protection Act and of the Radiation Protection

Ordinance

Chapter 5

Specialist and general knowledge

- Section 47 Requisite specialist knowledge in radiation protection
- Section 48 Updating the specialist knowledge
- Section 49 Requisite general knowledge in radiation protection in connection with use on people and animals in veterinary medicine
- Section 50 Revocation of recognition of the requisite specialist knowledge or requisite general knowledge
- Section 51 Recognition of courses

Chapter 6

Requirements pertaining to the performance of practices

Division 1

Physical radiation protection surveillance; controlled areas

- Section 52 Establishment of radiation protection areas
- Section 53 Demarcation, marking and securing of radiation protection areas
- Section 54 Preparation of firefighting
- Section 55 Access to radiation protection areas
- Section 56 Metrological control in radiation protection areas
- Section 57 Contamination and decontamination
- Section 58 Leaving and evacuation of radiation protection areas
- Section 59 Establishment of radiation protection areas in the case of practices with naturally-occurring radioactive substances
- Section 60 X-ray rooms
- Section 61 Irradiation rooms
- Section 62 Rooms for the operation of stray radiation emitters
- Section 63 Training
- Section 64 Obligation to establish the body dose; monitored persons
- Section 65 Procedure in establishment of the body dose
- Section 66 Measurement of the personal dose
- Section 67 Establishment of the body dose of air crew
- Section 68 Employment with a radiation passport
- Section 69 Protection of pregnant and breastfeeding women
- Section 70 Protection when handling unsealed radioactive substances; employment restrictions

Division 2

Special provisions for the protection of occupationally-exposed persons

- Section 71 Categories of occupationally-exposed persons

Section 72	Dose constraints for activities
Section 73	Dose limitation for exceeding limits
Section 74	Specially-authorised exposures
Section 75	Other protective measures
Section 76	Special rules for the protection of space crew

Division 3

Medical surveillance of occupationally-exposed persons

Section 77	Medical surveillance of occupationally-exposed persons
Section 78	Medical surveillance subsequent to ending of activity
Section 79	Medical certificate
Section 80	Official decision
Section 81	Special medical surveillance

Division 4

Special rules on radiation protection in schools and relating to apprenticeship and training relationships

Section 82	Radiation protection in schools and relating to apprenticeship and training relationships
------------	---

Division 5

Security of radiation sources

Sub-division 1

Highly-radioactive sources

Section 83	Limits for highly active radiation sources
Section 84	Register of highly active radiation sources

Sub-division 2

Safety and security of radiation sources

Section 85	Accounting and notification
Section 86	Record-keeping and notification of clearance
Section 87	Safekeeping and storage of radioactive substances
Section 88	Maintenance and testing
Section 89	Leakage test
Section 90	Radiation measurement equipment
Section 91	Marking obligation
Section 92	Special marking obligations
Section 93	Removal of markings
Section 94	Relinquishment of radioactive substances
Section 95	Take-back of highly active radiation sources
Section 96	Surrender of stray radiation emitters

Section 97 Storage and availability of documents

Section 98 Instruction in practices with radioactive sources

Division 6

Protection of the public and of the environment

Section 99 Limitation of the discharge of radioactive substances

Section 100 Establishment of the expected exposure of members of the public

Section 101 Establishment of the exposure received by members of the public

Section 102 Permissible discharges of radioactive substances

Section 103 Emissions and immissions monitoring

Section 104 Limiting exposure due to hazardous incidents

Division 7

Incidents

Section 105 Preparatory measures for the prevention, detection and limitation of the effects of an incident during use on humans

Section 106 Preparatory measures for emergencies or hazardous incidents

Section 107 Measures in the event of an emergency or hazardous incident

Section 108 Reporting a significant incident

Section 109 Investigation, recording and retention

Section 110 Tasks of the competent supervisory authorities

Section 111 Tasks incumbent on the central body

Section 112 Reporting and recording of incidents in accordance with other legal provisions

Section 113 Exception

Division 8

Use of ionising radiation or radioactive substances on humans

Sub-division 1

Technical requirements

Section 114 Requirements for equipment in use on humans

Section 115 Quality assurance before start-up; acceptance test

Section 116 Constancy assessment

Section 117 Records

Section 118 Stock inventory

Sub-division 2

Requirements in connection with use on humans

Section 119 Justifying indication

Section 120 Protection of special groups

Section 121 Measures during use

Section 122 Restriction of exposure

Section 123 Requirements in connection with the operation of X-ray equipment for teleradiology

Section 124	Information obligations
Section 125	Diagnostic reference levels, population dose
Section 126	Risk analysis before radiation treatments
Section 127	Storage, passing on and transmission of records, X-ray images, digital image data and other examination data
Section 128	Designation of medical and dental bodies for quality assurance
Section 129	Notification of the commencement and discontinuation of a practice with a medical or dental body
Section 130	Quality assurance measures by medical and dental bodies
Section 131	Medical physics expert
Section 132	Tasks of medical physics experts

Division 9

Special requirements for the use of radioactive substances or ionising radiation for medical research

Section 133	The principle of consent after information and questioning
Section 134	Consent of the person involved in the research project
Section 135	Information and questioning
Section 136	Use on persons who are incapable of giving consent and on minors
Section 137	Other prohibitions and restrictions on use
Section 138	Special protection obligations
Section 139	Quality assurance
Section 140	Record-keeping obligations; further rules on records
Section 141	Reporting obligations
Section 142	Final report
Section 143	Official protection order

Division 10

Use of ionising radiation or radioactive substances on animals in veterinary medicine

Section 144	Use-related requirements
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Division 11

Authorised persons

Section 145	Authorised persons relating to use on humans
Section 146	Entitled persons in veterinary medicine
Section 147	Entitled persons outside the use on humans or in veterinary medicine

Chapter 7

Manufacturers' information obligations

Section 148	Information obligations of the manufacturer of devices
-------------	--

Chapter 8

Supervisory programme

Section 149	Supervisory programme
-------------	-----------------------

Part 3

Radiation protection in emergency exposure situations

- Section 150 Dosimetry for emergency workers
- Section 151 Special medical surveillance of emergency workers
- Section 152 Support from and consultation with authorities, aid organisations and emergency workers in an emergency

Part 4

Radiation protection in existing exposure situations

Chapter 1

Protection against radon

Division 1

Common provisions for recreation rooms and workplaces

- Section 153 Determination of areas in accordance with section 121 subsection (1), first sentence, of the Radiation Protection Act
- Section 154 Measures for the protection of new buildings from radon in areas in accordance with section 121, subsection 1, first sentence, of the Radiation Protection Act

Division 2

Radon at workplaces in internal areas

- Section 155 Measurement of radon 222 activity concentrations, recognised body
- Section 156 Workplace-related estimation of exposure
- Section 157 Determination of exposure and body dose
- Section 158 Further requirements for occupational radiation protection

Chapter 2

Protection from radioactivity in construction products

- Section 159 Determination of the specific activity

Chapter 3

Radioactively-contaminated sites

- Section 160 Determination of public exposure
- Section 161 Test levels for radioactively-contaminated sites and for the decommissioning and remediation of uranium ore mining equipment and facilities
- Section 162 Emissions and immissions monitoring for the decommissioning and remediation of uranium ore mining equipment and facilities
- Section 163 Principles for the optimisation of remediation measures
- Section 164 Contents of remediation plans
- Section 165 Protection of workers at radioactively-contaminated sites

Chapter 4

Other existing exposure situations

- Section 166 Protection of workers in other existing exposure situations

Part 5

Cross-exposure situation provisions

Chapter 1

Loss, finding and acquisition; contaminated metal

Section 167	Loss
Section 168	Finding and acquisition
Section 169	Contaminated metal
Section 170	Information of the competent Federal Ministry

Chapter 2

Dose and measured values

Section 171	Dose and measured values
-------------	--------------------------

Chapter 3

Common provisions for occupational exposure

Section 172	Measuring bodies
Section 173	Radiation protection register
Section 174	Radiation passport
Section 175	Authorised doctors
Section 176	Obligations to tolerate

Chapter 4

Appointment of authorised experts

Section 177	Appointment of authorised experts
Section 178	Extension of the appointment
Section 179	Verification of reliability
Section 180	Independence
Section 181	Expert qualifications
Section 182	Criteria for tests
Section 183	Obligations incumbent on authorised experts appointed by the authority

Part 6

Final provisions

Chapter 1

Regulatory offences

Section 184	Regulatory offences
-------------	---------------------

Chapter 2

Transitional provisions

Section 185	Type approval (sections 16 to 26)
-------------	-----------------------------------

Section 186	Residue (section 29)
Section 187	Clearance (sections 31 to 42)
Section 188	Operational organisation of radiation protection (sections 44 and 45)
Section 189	Requisite specialist and general knowledge in radiation protection (sections 47, 48 and 51)
Section 190	Transitional provisions in connection with radiation protection areas (sections 52 to 62)
Section 191	Dose constraints for practices (section 72)
Section 192	Register of highly active radiation sources (section 84)
Section 193	Determination of the exposure expected and received for members of the public (sections 99, 100, 101 and Annex 11)
Section 194	Restriction of exposure due to hazardous incidents (section 104)
Section 195	Equipment for use on humans (section 114)
Section 196	Medical and dental bodies (section 128)
Section 197	Dose and measured values (section 171 and Annex 18)
Section 198	Radiation passport (section 174)
Section 199	Authorised doctors (section 175)
Section 200	Officially-appointed authorised experts (section 181)

- Annex 1 List of non-justified types of practice
- Annex 2 Required documents for assessing the justification of types of practice
- Annex 3 Practices not requiring a licence
- Annex 4 Exemption levels, clearance levels for different clearance types, levels of high-activity radioactive sources, limits for surface contamination, list of radionuclides and daughter nuclides considered in the calculations
- Annex 5 Monitoring limits as well as methods of recovery and disposal for the determination of the monitoring requirement of residues
- Annex 6 Principles for the determination of exposures from residues
- Annex 7 Preconditions for release from monitoring in the case of joint landfilling of residues requiring monitoring with other residues and waste
- Annex 8 Determinations for clearance
- Annex 9 List of data on highly active radiation sources (HASS) which are recorded in the register of highly active radiation sources (HASS Register)
- Annex 10 Radiation symbol
- Annex 11 Assumptions in the calculation of exposure
- Annex 12 Central offices of the Federation for emissions and immissions monitoring
- Annex 13 Public information in preparation for an emergency
- Annex 14 Criteria for the significance of an incident involving medical exposure and exposure of the person examined in the case of a non-medical use
- Annex 15 Criteria for the significance of an incident in a planned exposure situation
- Annex 16 Criteria to determine the type and extent of the risk associated with a practice
- Annex 17 Activity index and values not to be exceeded in accordance with section 135 subsection (1), third sentence, of the Radiation Protection Act
- Annex 18 Dose and measured values
- Annex 19 Tests for obtaining and retaining the requisite expert qualifications for practising an activity as an officially-appointed authorised expert in accordance with section 172 subsection (1) of the Radiation Protection Act

Part 1

Definitions

Section 1

Definitions

(1) Discharge: release of liquid, aerosol-bound or gaseous radioactive substances by intended pathways.

(2) Equivalent dose: product of absorbed dose detected in the soft tissues as specified by the International Commission on Radiation Units and Measurements (ICRU) and ICRU quality factor Q in accordance with Annex 18 Part D, which allows for the influences exerted by the type and energy of radiation. If several radiation types and energies are present, the total equivalent dose shall be the sum of their calculated individual contributions.

(3) Operating site: land on which nuclear installations are located, and to which the radiation protection executive may limit access, or with regard to which the radiation protection executive may limit the maximum period of time that persons may spend there.

(4) Diagnostic reference levels:

1. dose limits when using ionising radiation on humans, or
2. recommended activity values when using radioactive substances on humans,

for typical examinations, related to standard phantoms or patient groups, for individual device categories.

(5) Dose constraint: an effective dose or equivalent dose that serves as the upper limit for the exposure to be considered in the planning and optimisation of protection measures for persons in planned exposure situations.

(6) Energy dose: energy deposited in matter, an organ or tissue by ionising radiation, divided by the mass of the irradiated matter, organ or tissue.

(7) Healthy person as defined in the research project: a person on whom a radioactive substance or ionising radiation has been used or is to be used for the purpose of medical research, and who does not suffer from or is not suspected of suffering from the illness which is being researched in the research project.

(8) Intervention: use of X-ray imaging techniques to facilitate the introduction and guidance of devices and substances in the body for medical purposes.

(9) Maximum operating conditions: the combination of technical adjustment parameters that lead to the highest mean ambient dose rate under normal operating conditions of X-ray emitters in accordance with section 18 subsection (1) no. 1, X-ray equipment in accordance with sections 19 to 22, and stray radiation emitters in accordance with section 23, and of X-ray emitters in accordance with section 18 subsection (1) no. 2 and subsection (2); these shall include the voltage for accelerating electrons, the X-ray tube current, and any other parameters such as activation time or electrode gap.

(10) Surface contamination: contamination of a surface with radioactive substances, including the non-fixed and fixed activity that has penetrated via the surface. The unit of the measured value of the surface contamination shall be the activity for surface areas in becquerels per square centimetre.

(11) Surface contamination, non-fixed: contamination of a surface with radioactive substances with regard to which it cannot be ruled out that the radioactive substances will be further dispersed.

(12) Ambient dose: equivalent dose, measured with the measured values in

accordance with Appendix 18 Part A at a specific location.

(13) Ambient dose rate: ambient dose generated within a specific interval of time, divided by the length of the interval.

(14) Personal dose: equivalent dose measured with the measured values stated in Annex 18 Part A on a part of the body surface that is representative of the exposure.

(15) Inspector: a natural person who independently carries out expert activities in an expert organisation.

(16) Authorised expert:

1. a natural person who independently conducts expert activities (individual authorised expert), or
2. a legal person or unregistered association of persons without legal capacity who perform expert activities (expert organisation).

(17) Specific activity: the ratio of the activity of a radionuclide to the mass of the material in which the radionuclide is distributed. In solid radioactive substances, the reference mass to determine the specific activity equals the mass of the body or object which is inseparable from the radioactivity when used as intended. For gaseous radioactive substances, the reference mass equals the mass of the gas or the mix of gases.

(18) Hazardous incident: succession of events in the case of the occurrence of which the operation of the nuclear installation, of the installation for the generation of ionising radiation, or the practice, may not be continued for safety reasons and for which the nuclear installation or the installation for the generation of ionising radiation is to be designed, or for which protection arrangements are to be provided in the practice as a precaution.

(19) Person accompanying animals: a person capable of giving consent who has reached the age of 18, and who voluntarily accompanies or cares for an animal outside of the scope of his or her professional activity.

(20) Surveillance, medical: a medical examination, health assessment and advice given to an occupationally-exposed person by an authorised doctor.

(21) Transportation:

1. import into the territorial scope of this Ordinance from a country which is not a Member State of the European Union,
2. export from the territorial scope of this Ordinance to a country which is not a Member State of the European Union, or
3. cross-border goods transportation from a Member State of the European Union into the territorial scope of this Ordinance, or to a Member State of the European Union from the territorial scope of this Ordinance.

(22) Incident: an event in a planned exposure situation that led to, could have led to or could lead to an unanticipated exposure, including the occurrence of a hazardous incident or emergency. No incident shall be deemed to have occurred if the event is not relevant in terms of radiation protection.

(23) Person authorised to carry out medical research: the holder of a licence in accordance with section 31 of the Radiation Protection Act (*Strahlenschutzgesetz*), or the person who, subsequent to his or her notification in accordance with section 33 subsection (3), first sentence, of the Radiation Protection Act, may begin the notified use.

Part 2

Radiation protection in planned exposure situations

Chapter 1

Justification of types of practice

Section 2

Unjustified types of practice

Practices which are to be attributed to the unjustified types of practice designated in Annex 1 may not be carried out.

Section 3

Procedure for assessing the justification of types of practice in accordance with section 7 of the Radiation Protection Act

(1) In addition to the respective licensing or notification documents, the documents to be passed on in accordance with section 7 subsection (1), first sentence, of the Radiation Protection Act shall include the documents in accordance with Annex 2 Part A, as well as an explanation of the doubts raised by the authority competent for the licensing or notification procedure.

(2) If a highest *Land* authority competent for radiation protection forwards the documents that were passed on to it to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, such authority shall give its written opinion on any doubts raised by the authority responsible for the licensing or notification procedure, and shall transmit its opinion together with the documents without undue delay.

(3) The deadline period for an examination in accordance with section 7 subsection (2), first sentence, of the Radiation Protection Act shall commence when the Federal Office for Radiation Protection determines that the documents are complete. The Federal Office for Radiation Protection shall inform the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, and the authority competent for the licensing or notification procedure, or the highest *Land* authority in cases falling under subsection (2), when the examination is commenced.

(4) The Federal Office for Radiation Protection may also subsequently request documents needed for the examination after it determines that the documents are complete.

(5) The Federal Office for Radiation Protection shall submit the report to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety without undue delay on completion of the examination, and shall publish the report in the Federal Gazette (*Bundesanzeiger*). The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety shall inform the authority competent for the licensing or notification procedure, or the highest *Land* authority in cases falling under subsection (2), of the outcome of the examination.

Section 4

Procedure for verifying the justification of types of activity in accordance with section 38 of the Radiation Protection Act

(1) The authority competent for issuing a licence in accordance with section 40 or section 42 of the Radiation Protection Act, or a type approval in accordance with

section 45 of the Radiation Protection Act, shall submit the following to the Federal Office for Radiation Protection together with the application to be passed on in accordance with section 41 subsection (5), first sentence, section 43 subsection (2), first sentence, or section 46 subsection (3), first sentence, of the Radiation Protection Act:

1. a description of why the intended use, intended storage or intended operation constitutes a new type of practice, and
2. the documents needed to verify the justification of the type of practice, in particular the documents listed in Annex 2.

The Federal Office for Radiation Protection may subsequently request the documents needed for the verification; the deadline in accordance with section 38 subsection (1), first sentence, of the Radiation Protection Act shall remain unaffected thereby.

(2) The Federal Office for Radiation Protection shall inform the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, the authority competent for issuing the licence in accordance with section 40 or section 42 of the Radiation Protection Act, or the type approval in accordance with section 45 subsection (1) no. 1 or 3 to 6 of the Radiation Protection Act, as well as the highest *Land* authorities competent for radiation protection, of the commencement of a verification.

(3) When verifying the justification of the type of practice, the Federal Office for Radiation Protection shall in particular evaluate whether

1. the effectiveness and suitability of the consumer product, installation, equipment, X-ray equipment or stray radiation emitter justify the intended use, storage or operation,
2. the design is suitable to ensure that exposure during normal use and the likelihood and consequences of misuse or accidental exposure are as low as possible.

(4) The Federal Office for Radiation Protection shall publish its opinion concerning the justification of the type of practice in the Federal Gazette without undue delay after its completion.

(5) The Federal Office for Radiation Protection shall pass the opinion without undue delay

1. to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety,
2. to the authority responsible for the suspended licensing or approval procedure, and
3. in the case of an application in accordance with section 40 or section 42 of the Radiation Protection Act, to the competent points of contact of the other Member States in accordance with Article 76 para. 2, first sentence, of Directive 2013/59 Euratom.

The authorities competent for granting a licence in accordance with section 40 or section 42 of the Radiation Protection Act, or type approval in accordance with section 45 subsection (1) no. 1 or 3 to 6 of the Radiation Protection Act, shall pass information to the Federal Office for Radiation Protection regarding licences granted for consumer products and type approvals. The Federal Office for Radiation Protection shall publish a list with the significant information regarding the subject matter of these licences or type approvals.

Chapter 2

Prior verification of radioactive substances or ionising radiation

Division 1

Exemptions from licensing and notification requirements of an activity; exemptions from licensing requirements

Section 5

Handling not requiring a licence

(1) A licence in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act shall not be required in the cases stated in Annex 3 Parts A and B. The radioactive substances associated with the practices in accordance with Annex 3 Part A or Part B nos. 3 to 9 shall not be taken into consideration when verifying the prerequisites in accordance with Annex 3 Part B no. 1 or 2.

(2) In the case of handling that is licensed in accordance with section 12 subsection (1) no. 3 or subsection (2) of the Radiation Protection Act, handling not requiring a licence in accordance with subsection (1) for the radioactive substances listed in the licence, including under the exemption levels in accordance with Annex 4 Table 1 columns 2 and 3, shall not be permissible. This shall not apply if, in an individual establishment or independent branch establishment, non-commercial operators handle radioactive substances at the place of activity of the holder of the licence, in several buildings or parts thereof, installations or facilities that are spatially separated, and it is adequately safeguarded that the radioactive substances from the individual buildings, parts of buildings, installations or facilities cannot interact.

Section 6

Possession of nuclear fuel not requiring a licence

(1) The provisions of section 5 subsections (2) to (4) of the Atomic Energy Act (*Atomgesetz*) shall not apply to a person who is

1. permitted to handle nuclear fuel
 - a) without a licence in accordance with section 5 subsection (1) in conjunction with Annex 3 Part B no. 1 or 2, or
 - b) based on a licence in accordance with section 12 subsection (1) no. 3 or section 12 subsection (2) of the Radiation Protection Act,
- or is
2. permitted to carry nuclear fuel
 - a) without a licence on the basis of section 28 of the Radiation Protection Act, or
 - b) based on a licence on the basis of section 27 subsection (1) of the Radiation Protection Act.

(2) The removal of nuclear fuel from government custody in accordance with section 5 subsection (6) of the Atomic Energy Act, or from storage licensed in accordance with section 6 of the Atomic Energy Act, or in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act, shall also be permissible if the recipient is authorised to possess the nuclear fuels in accordance with subsection (1), or if these nuclear fuels are intended to be transported for export.

Section 7

Operation of installations for the generation of ionising radiation not requiring a licence or notification

Anyone who operates an installation for the generation of ionising radiation of the type specified in Annex 3 Part C shall not require a licence in accordance with section 12 subsection (1) no. 1 of the Radiation Protection Act, nor shall they be required to notify in accordance with section 17 subsection (1) of the Radiation Protection Act.

Section 8

Operation of stray radiation emitters not requiring a licence

The cases designated in Annex 3 Part D shall not require a licence in accordance with section 12 subsection (1) no. 5 of the Radiation Protection Act.

Section 9

Non-notifiable verification, testing, maintenance and repair of X-ray equipment or stray radiation emitters

The following persons shall not be required to effect a notification in accordance with section 22 subsection (1) of the Radiation Protection Act:

1. anyone who professionally verifies, tests, maintains or repairs stray radiation emitters in accordance with Annex 3 Part D no. 3,
2. anyone who, without switching on X-rays, carries out activities in accordance with section 22 subsection (1) of the Radiation Protection Act on application devices, ancillary equipment and accessories, the necessary software and equipment to analyse medical findings that do not require radiation protection measures.

Section 10

Exemption from the obligation to provide financial provision

(1) No financial provision in accordance with section 13 subsection (2) of the Radiation Protection Act shall be required for the issuance of a handling licence in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act and in accordance with section 6 subsection (2) no. 3 and section 9 subsection (2) no. 4 of the Atomic Energy Act if

1. the total activity of the radioactive substances which are handled at the individual establishment or independent branch establishment, in the case of non-commercial operators at the place where the applicant operates, does not exceed 10^6 times the exemption levels in accordance with Annex 4 Table 1 column 2, and in the case of enriched uranium where the mass of uranium 235 does not exceed 350 grams, and
2. it is adequately safeguarded that the other radioactive substances from the individual buildings, parts of buildings, installations or facilities cannot interact.

(2) Furthermore, no financial provision in accordance with section 13 subsection (2) of the Radiation Protection Act shall be required for granting a handling licence in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act if the individual establishment or independent branch establishment, in the case of non-commercial operators at the place where the applicant operates, is handling other radioactive substances in several buildings or parts thereof, installations or facilities that are spatially separated, and if

1. the activity of the other radioactive substances in the individual buildings or parts thereof, installations or facilities, does not exceed 10^6 times the exemption levels in accordance with Annex 4 Table 1 column 2, and
2. it is adequately safeguarded that the other radioactive substances from the individual buildings, parts of buildings, facilities or installations cannot interact.

(3) In application of subsection (1) or (2), the proportion of unsealed radioactive substances may not exceed 10^5 times the exemption levels in accordance with Annex 4 Table 1 column 2.

- (4) Subsections (1) and (2) shall not apply to highly active radiation sources.

Section 11

Exemption levels

Radionuclides for which exemption levels exist, and the applicable exemption levels relevant in accordance with the Radiation Protection Act, shall be derived from Annex 4 Table 1 columns 1 to 3.

Division 2

Cross-border transportation of radioactive substances

Section 12

Cross-border transportation requiring a licence

(1) Anyone who brings highly active radiation sources into the territorial scope of this Ordinance on a non-temporary basis for their own use in the context of authorised handling from a country which is not a Member State of the European Union shall require a licence if

1. its activity is or exceeds in each case ten times the value for highly active radiation sources in accordance with Annex 4 Table 1 column 4,
2. it, as well as its protective containers or storage containers, are not marked in accordance with section 92 subsection (1), first sentence, no. 1 and section 92 subsection (1), second sentence, subsection (5), or
3. no documents in accordance with section 94 subsection (3) are attached thereto.

(2) Anyone who brings the following radioactive substances into the territorial scope of this Ordinance on a non-temporary basis for their own use in the context of authorised handling from a country which is not a Member State of the European Union shall require a licence:

1. highly active radiation sources
 - a) the activity of which is or exceeds ten times the value for highly active radiation sources in accordance with Annex 4 Table 1 column 4,
 - b) which, in addition to their protective or storage containers, have no markings in accordance with section 92 subsection (1), first sentence, no. 1 and section 92 subsection (1), second sentence, or
 - c) to which no documents in accordance with section 84 subsection (3) are attached,
- or
2. other radioactive substances in accordance with section 3 subsection (1) of the Radiation Protection Act or nuclear fuels in accordance with section 3 subsection (3) of the Radiation Protection Act the activity of which per despatched unit is or exceeds 10^8 times the exemption levels in accordance with Annex 4 Table 1 column 2.

(3) No licence in accordance with subsection (1) shall be required insofar as a licence exists in accordance with section 3 subsection (1) of the Atomic Energy Act which, in accordance with section 10a subsection (1) of the Atomic Energy Act, covers transportation in accordance with subsection (1). No licence in accordance with subsection (2) shall be required insofar as a licence exists in accordance with section 3 subsection (1) of the Atomic Energy Act, which in accordance with section 10a subsection (1) of the Atomic Energy Act covers transportation in accordance with subsection (2).

Section 13

Notifiable cross-border transportation

(1) Anyone who transports other radioactive substances in accordance with section 3 subsection (1) of the Radiation Protection Act, or nuclear fuel in accordance with

section 3 subsection (3) of the Radiation Protection Act,

1. from a country that is not a Member State of the European Union into the territorial scope of this Ordinance, or
2. from the territorial scope of this Ordinance into a country that is not a Member State of the European Union,

and who does not require a licence in accordance with section 12 subsection (1) or (2), shall register the transportation by electronic means with the authority competent in accordance with section 188 subsection (1), second sentence, of the Radiation Protection Act. Proof of the registration in accordance with the first sentence with the authority competent for monitoring in accordance with section 188 subsection (1), second sentence, of the Radiation Protection Act, or with the body nominated thereby, shall be provided on customs clearance. The print-out of the electronically-generated form specified by the competent authority in accordance with section 188 subsection (1), second sentence, of the Radiation Protection Act shall be used for the registration.

(2) Anyone who transports nuclear fuel in accordance with section 3 subsection (1) of the Radiation Protection Act in the form of

1. up to 1 kg of uranium which is enriched to 10 % or more, but less than 20 %, with uranium 235, or
2. less than 10 kg of uranium which is enriched to less than 10 % with uranium 235,

from a country that is not a Member State of the European Union into the territorial scope of this Ordinance, shall register the transportation in accordance with subsection (1), in derogation from section 3 subsection (1) of the Atomic Energy Act.

(3) In the case of transportation into the territorial scope of this Ordinance requiring registration in accordance with subsection (1), first sentence, or subsection (2), the transporting party shall take precautions in order to ensure that the radioactive substances to be transported are only relinquished subsequent to transportation to persons who hold a licence in accordance with section 12 subsection (1) No. 1 or 3, in each case also in conjunction with subsection (2), of the Radiation Protection Act, or with section 6 subsection (1), section 7 subsection (1), first sentence, or subsection (3), first sentence, or section 9 subsection (1) of the Atomic Energy Act.

Section 14

Exceptions; other provisions regarding cross-border transportation

(1) No licence in accordance with section 3 subsection (1) of the Atomic Energy Act, or with section 12 of this Ordinance, shall be required, and no registration need be effected in accordance with section 13 of this Ordinance, by anyone who

1. transports one of the substances or devices in accordance with Annex 3 Part E,
2. transports other radioactive substances designated in section 3 subsection (1) of the Radiation Protection Act, or nuclear fuel in accordance with section 3 subsection (3) of the Radiation Protection Act, subject to customs supervision through the territorial scope of this Ordinance,
3. temporarily transports substances within the meaning of no. 2 into the territorial scope of this Ordinance for their own use within the framework of licensed handling, insofar as these are not highly active radiation sources, or
4. transports consumer products in accordance with section 42 of the Radiation Protection Act.

(2) Sections 12 and 13 of this Ordinance shall not apply to transportation by the Federal Armed Forces (*Bundeswehr*).

- (3) Other provisions on transportation shall remain unaffected thereby.

Section 15

Conditions for the issuance of a licence for cross-border transportation

(1) A licence for cross-border transportation in accordance with section 12 subsection (1) shall be granted if

1. there are no facts giving rise to reservations regarding the reliability of the applicant, the latter's legal representative or, in the case of legal persons or associations of persons without legal capacity, the party entitled by law, articles or memorandum of association to effect representation or to manage the business, and
2. the applicant has taken precautions to ensure that, subsequent to transportation, the radioactive substances are initially only relinquished to persons who hold the requisite authorisation for handling.

The licence in accordance with the first sentence may only be granted for highly active radiation sources if it is guaranteed that

1. they and their protective or storage container are marked in accordance with section 92 subsection (1), first sentence, no. 1 and section 92 subsection (1), second sentence, and
2. the written documents in accordance with section 94 subsection (3) are enclosed.

(2) The licence in accordance with section 12 subsection (2) shall be granted if

1. there are no facts giving rise to reservations regarding the reliability of the applicant, the latter's legal representative or, in the case of legal persons or associations of persons without legal capacity, the party entitled by law, articles or memorandum of association to effect representation or to manage the business, and
2. it is guaranteed that the radioactive substances to be transported will not be used in a way that endangers the internal or external security of the Federal Republic of Germany or the fulfilment of its international obligations in the area of nuclear energy and radiation protection.

Subsection (1), second sentence, shall apply mutatis mutandis.

Division 3

Type approval

Section 16

Technical requirements for type approval of a device that contains other radioactive substances

(1) The type of a device that contains other radioactive substances in accordance with section 3 subsection (1) of the Radiation Protection Act may only be approved in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act if it is guaranteed that

1. it only contains other radioactive substances in accordance with section 3 subsection (1) of the Radiation Protection Act that
 - a) are sealed, and
 - b) are covered so as to prevent contact,
2. the ambient dose rate at a distance of 0.1 metres from the accessible surface of the device does not exceed 1 mSv per hour under normal conditions,
3. the device is designed in such a way that the safe enclosure of the radioactive substances is ensured during the intended operation and, apart from the quality controls carried out by the manufacturer in accordance with section 24 subsection (2) and any leakage tests to be performed in accordance with section 25 subsection (4), no further leakage tests are required on the radioactive substances inserted into the device, and
4. the activity of the radioactive substances contained in the device does not exceed ten times the exemption levels in accordance with Annex 4 Table 1 column 2.

(2) In individual cases, the authority competent for licensing the type may permit deviations from the conditions in accordance with subsection (1) no. 1(a) or no. 3 or 4, insofar as the annual expected effective dose for a member of the public caused by the device does not exceed 10 µSv.

Section 17

Technical requirements for type approval of installations for the generation of ionising radiation

The type of an installation for the generation of ionising radiation which is not intended for use on humans may only be approved in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act if it is safeguarded that the ambient dose rate during an hour of normal operating conditions at a distance of 0.1 metres from the accessible surface of the device does not exceed 1 µSv.

Section 18

Technical requirements for type approval of X-ray emitters

(1) The type of an X-ray emitter that is intended for use neither on humans nor on animals, and where the subject of examination is not enclosed by the protective housing, may only be approved in accordance with section 45 subsection (1) no. 2 of the Radiation Protection Act if it is safeguarded that

1. in the case of an X-ray emitter for X-ray fine structure examinations, the ambient dose rate with closed radiation emission windows and the maximum

operating conditions stated by the manufacturer or transporting party does not exceed 3 μSv at a distance of 1 m from the focal spot, or

2. in the case of an X-ray emitter that does not fall under no. 1 for which the ambient dose rate averaged over an appropriate time, depending on the use, and with closed radiation emission windows and the maximum operating conditions stated by the manufacturer or transporting party, does not exceed the following limits at a distance of 1 m from the focal spot:
 - a) 2.5 mSv per hour at rated voltages of up to 200 kilovolts,
 - b) 10 mSv per hour at rated voltages of over 200 kilovolts, and 2.5 mSv per hour after dropping to an X-ray voltage of 200 kilovolts.

(2) The type of an X-ray emitter that is intended for the use of X-rays on animals may only be permitted in accordance with section 45 subsection (1), no. 2 of the Radiation Protection Act if it is safeguarded that the ambient dose rate averaged over an appropriate time, depending on the use, for use with closed radiation emission windows and the maximum operating conditions specified by the manufacturer or transporting party,

1. does not exceed 1 μSv at a distance of 1 m from the focal spot, and
2. does not exceed 100 μSv per hour at a distance of 0.1 m from the accessible surface of the device, excepting the area of the surface where the radiation emission window is located, insofar as the X-ray tube assembly is suited for hand-held operation.

Section 19

Technical requirements for type approval of basic-protection devices

The type of X-ray equipment that is not intended for use on either humans or animals may only be approved as a basic-protection device in accordance with section 45 subsection (1) no. 3 of the Radiation Protection Act if it is ensured that

1. the protective housing outside the X-ray tube or the X-ray emitter also encloses the object to be treated or examined in such a way that openings are present exclusively for inserting and removing the object,
2. the ambient dose rate does not exceed 10 μSv per hour at a distance of 0.1 m from the accessible surface of the protective housing and at a distance of 0.1 m from the openings at maximum operating conditions stated by the manufacturer or transporting party, and
3. the X-ray tube or X-ray emitter can only be operated when the protective housing is completely closed; this shall not apply to
 - a) openings in the protective housing in accordance with no. 1 if the insertion and removal of the object to be treated or examined is effected exclusively with a sample changer or conveying device, and the dimensions of the openings are adjusted for this purpose, or
 - b) examination methods that require the continuous operation of the X-ray emitter if the ambient dose rate inside the opened protective housing does not exceed 10 μSv per hour.

Section 20

Technical requirements for type approval of high-protection devices

The type of X-ray equipment that is not intended for use on humans or on animals may only be permitted as a high-protection device in accordance with section 45 subsection (1) no. 4 of the Radiation Protection Act if it is safeguarded that

1. the protective housing outside the X-ray tube or the X-ray emitter also fully encloses the object to be treated or examined,
2. the ambient dose rate does not exceed 10 μSv per hour at a distance of 0.1 m from the accessible surface of the protective housing – with the exception of internal areas in accordance with no. 3(a) – at the maximum operating conditions stated by the manufacturer or transporting party,
3. the X-ray tube or X-ray emitter can only be operated when the protective housing is completely closed; this shall not apply to
 - a) protective housings that can only be reached into when the ambient dose rate in the accessible part of the interior does not exceed 250 μSv per hour at the maximum operating conditions specified by the manufacturer or transporting party, or
 - b) examination methods that require the continuous operation of the X-ray emitter if the ambient dose rate inside the opened protective housing does not exceed 10 μSv per hour.

Section 21

Technical requirements for type approval of full-protection devices

The type of X-ray equipment that is not intended for use on humans or on animals can only be permitted as a full-protection device in accordance with section 45 subsection (1) no. 5 of the Radiation Protection Act

1. if it is safeguarded that
 - a) the protective housing outside the X-ray tube or the X-ray emitter also fully encloses the object to be treated or investigated,
 - b) the ambient dose rate does not exceed 3 μSv per hour at a distance of 0.1 m from the accessible surface of the protective housing at the maximum operating conditions stated by the manufacturer or transporting party, and
2. if two independent safety devices safeguard that
 - a) the X-ray tube or X-ray emitter can only be operated when the protective housing is completely closed, or
 - b) with examination procedures that require the continuous operation of the X-ray emitter, the protective housing can only be opened during the operation of the X-ray emitter if the radiation emission window is closed and the ambient dose rate inside the protective housing does not exceed 3 μSv per hour.

Section 22

Technical requirements for type approval of X-ray equipment for training purposes

The type of X-ray equipment that is not intended for use on humans or on animals shall only be permitted as X-ray equipment for training purposes in accordance with section 45 subsection (1) no. 6 of the Radiation Protection Act if it is safeguarded that

1. the conditions of section 21 are complied with, and

2. the maximum operating conditions specified by the manufacturer or transporting party cannot be exceeded.

Section 23

Technical requirements for type approval of stray radiation emitters

The type of a stray radiation emitter shall only be permitted in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act if it is safeguarded that

1. the ambient dose rate does not exceed 1 µSv per hour at a distance of 0.1 m from the accessible surface of the stray radiation emitter at the maximum operating conditions stated by the manufacturer or transporting party, and
2. the stray radiation emitter can only be operated based on technical measures if the safety devices serving radiation protection are present and effective.

Section 24

Obligations incumbent on the holder of a type approval

The holder of a type approval shall

1. operate a quality assurance system,
2. carry out quality control prior to the relinquishment of the completed type-approved device in order to ensure that the type-approved device manufactured corresponds to the properties relevant to radiation protection of the type approval,
3. have the quality control in accordance with no. 2 supervised by an authorised expert to be designated by the authorising authority,
4. prior to the relinquishment of the manufactured type-approved device,
 - a) affix the type approval marking and other information to be determined by the authority competent for authorising the type, and
 - b) in the case of a type-approved device in accordance with section 45 subsection (1) no. 1 first or second alternative of the Radiation Protection Act, these are to be marked in accordance with section 91 subsection (1), and
 - c) in the case of a type-approved device in accordance with section 45 subsection (1) no. 1 first alternative of the Radiation Protection Act to additionally mark the device in such a way that the radionuclides contained and their activity at the time of their manufacture are visible insofar as this is possible in line with the size and characteristics of the equipment,
5. provide the acquirer of a type-approved device with the following documents, together with the device:
 - a) a copy of the approval certificate,
 - b) proof of the outcome of the quality control in accordance with no. 2, specifying the date of the control,
 - c) an operating manual in German indicating the measures for radiation protection, and
6. safeguard that a type-approved device in accordance with section 45 subsection (1) no. 1 first alternative of the Radiation Protection Act can be taken back by him or her after the end of use.

Section 25

Obligations incumbent on the owner of a type-approved device

(1) The owner of a type-approved device shall keep the following documents ready with the equipment:

1. a copy of the approval certificate,
2. the operating manual, and
3. in the case of a device that contains other radioactive substances in accordance with section 45 subsection (1) no. 1 first alternative of the Radiation Protection Act, the results of the leakage test in accordance with subsection (4), first sentence.

Section 24 no. 5 shall apply mutatis mutandis in the case of the relinquishment of the type-approved device.

(2) No modifications may be made to the type-approved device that affect properties relevant to radiation protection.

(3) Anyone who operates or uses a type-approved device shall adjust the operation without undue delay in cases of a type approval in accordance with section 45 subsection (1) nos. 2 to 6 of the Radiation Protection Act or, in cases of a type approval in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act, shall decommission the device without undue delay and implement protective measures to prevent radiation damage, if

1. the withdrawal or revocation of the type approval or a declaration that a type-approved device may no longer be operated has been communicated, or
2. the type-approved device no longer corresponds to the properties stated in the approval certificate.

(4) The owner of a type-approved device that contains other radioactive substances in accordance with section 45 subsection (1) first alternative of the Radiation Protection Act shall have it tested for integrity and leak tightness every ten years by an authorised expert appointed in accordance with section 172 subsection (1) no. 4 of the Radiation Protection Act. The deadline for the test in accordance with the first sentence shall be the quality control date stated in the approval certificate in accordance with section 24 no. 5 (b). The authority competent for approval of the type may adopt rules in the approval certificate deviating from the first and second sentences for the leakage test.

(5) The owner of a type-approved device that contains other radioactive substances in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act shall return the device to the holder of the licence after the end of use without undue delay, insofar as he or she does not provide it to a third party for further use. If this is not possible, he or she shall surrender it at a *Länder*-level collection centre or in a place designated by the competent authority.

Section 26

Publication

The authority competent for the approval of the type shall publish in the Federal Gazette the significant elements of the type approval, its amendments, withdrawal, revocation, the extension of the approval period, and the declaration that type-approved device may no longer be operated.

Division 4

Residues

Section 27

Determination of residues requiring monitoring

The monitoring limits determined in Annex 5, and the methods of recovery and disposal, shall apply to the determination of residues requiring monitoring in accordance with section 61 subsection (2), first sentence, of the Radiation Protection Act.

Section 28

Establishment of exposure caused by residues

Exposures caused by residues shall be assessed in accordance with the principles determined in Annex 6.

Section 29

Release of residues requiring monitoring from the monitoring obligation for recovery or disposal in accordance with the Circular Economy Act (Kreislaufwirtschaftsgesetz)

(1) In the event of intended recovery or disposal of residue requiring monitoring in accordance with the Circular Economy Act, the applicant shall submit the following documents to the authority competent for release from monitoring:

1. a declaration on the part of the applicant regarding the fate of the future waste,
2. a declaration of acceptance by the processing or disposing party, and
3. proof that a copy of the declaration of acceptance by the recoverer or disposer has been transferred to the authority competent for the recovery or disposal installation in accordance with the Circular Economy Act.

(2) The authority competent for the recovery or disposal installation in accordance with the Circular Economy Act may require that the authority competent for release from monitoring create consent to the requirements for the methods of recovery or disposal within a period of 30 calendar days after receipt of the copy of the declaration of acceptance on the part of the recoverer or disposer. Subsection (3) shall remain unaffected thereby.

(3) In the event of intended recovery or disposal of future waste in order to safeguard the dose criterion in accordance with section 62 subsection (3), first sentence, of the Radiation Protection Act, the authority competent for the release from monitoring shall reach an agreement with the authority competent for release from monitoring in the area of responsibility of which the future waste will be recycled or disposed of, within a period of 30 calendar days after receipt of the proof in accordance with subsection (1) no. 3. Consent may not be granted if the dose criterion cannot be complied with. Consent shall be deemed to have been granted if it is not refused within 30 calendar days of receipt of the request.

(4) In the decision on the release of residues from the monitoring obligation for the purpose of storage together with other residues and waste, the competent authority may assume under the conditions in accordance with Annex 7 that an effective dose exposure to which members of the public are exposed not exceeding 1 mSv per calendar year will not be exceeded without further measures.

(5) The provisions contained in the Circular Economy Act, and in the ordinances

on record-keeping of the proper disposal of waste issued on the basis of that Act, shall remain unaffected thereby.

Section 30

Release of residues requiring monitoring from the monitoring obligation for recovery as a construction product

(1) The applicant shall submit the following documents to the authority competent for release from monitoring in the case of intended recovery of residues requiring monitoring as construction products:

1. a declaration on the part of the applicant concerning the fate of the residues,
2. a declaration of acceptance on the part of the manufacturer of the construction product intended to contain the residues, and
3. a confirmation on the part of the manufacturer of the construction product intended to contain the residues that the exposure to gamma radiation expected to be emitted from the construction product does not exceed the reference level in accordance with section 133 of the Radiation Protection Act.

(2) The authority competent for release from monitoring shall review when taking the decision on the release of residues requiring monitoring for recovery in a construction product that the dose criterion in accordance with section 62 subsection (3), first sentence, of the Radiation Protection Act is not exceeded.

(3) The provisions contained in the Circular Economy Act, and in the ordinances issued on the basis of that Act, shall remain unaffected thereby.

Chapter 3

Clearance

Section 31

Clearance of radioactive substances; dose criterion

(1) The following may only be used, recovered, disposed of, possessed or transferred to a third party as non-radioactive substances after issuance of clearance:

1. radioactive substances originating from activities in accordance with section 4 subsection (1), first sentence, no. 1 in conjunction with section 5 subsection (39) no. 1 or 2, or from activities in accordance with section 4 subsection (1), first sentence, nos. 3 to 7 of the Radiation Protection Act, and
2. movable articles, buildings, rooms or parts thereof and components, floor areas, installations or parts thereof (articles), which originated from, were contaminated by or were activated by activities specified in accordance with section 4 subsection (1), first sentence, no. 1 in conjunction with section 5 subsection (39) no. 1 or 2, or from activities in accordance with section 4 subsection (1) nos. 3 to 7 of the Radiation Protection Act.

Substances and articles shall in particular require clearance that originated from controlled areas in which

1. unsealed radioactive substances are or have been handled,
2. unsealed radioactive substances are or have been present, or
3. there was a possibility of activation.

(2) The dose criterion for clearance shall be that only an effective dose in the range of 10 μ Sv per calendar may occur to members of the public caused by the substances and articles to be cleared.

(3) Clearance shall not replace authorisation in accordance with section 7 subsection (3) of the Atomic Energy Act.

(4) Section 58 subsection (2) and sections 99 to 102 shall remain unaffected thereby.

(5) The competent authority is to grant exemptions from subsection (1), second sentence, if it is proven by means of suitable evidence-preserving measurements that there is no contamination or activation. The first sentence shall not apply to practices in accordance with section 4 subsection (1), first sentence, no. 4 of the Radiation Protection Act. The procedure followed in order to prove that there is no contamination or activation shall be described in a company document and by providing information relating to the type and scope of the practice.

Section 32

Application for clearance

(1) Clearance may be requested by the holder of

1. a licence in accordance with sections 6, 7 or 9 of the Atomic Energy Act,
2. a plan approval decision or licence in accordance with section 9b of the Atomic Energy Act, or
3. a licence in accordance with section 12 subsection (1) Nos. 1 to 3 of the Radiation Protection Act.

(2) Unrestricted clearance shall not require any determinations on the future use,

recovery, disposal or possession of the substances and articles to be cleared, or on their passing on to third parties.

(3) In the case of specific clearance, the future use, recovery, disposal or possession of the substances and articles to be cleared, or their passing on to third parties, shall be restricted

1. on the basis of the material properties of the substances and articles to be cleared, or
2. on the basis of requirements as to the future use, recovery, disposal or possession of the substances and articles to be cleared, or their passing on to third parties.

(4) One-off clearance shall only constitute unrestricted clearance if all possible future uses, usages, recoveries, disposals or possession of the substances and articles to be cleared, or their passing on to third parties, have been taken into consideration for each individual case in the record-keeping regarding compliance with the dose criterion for clearance. In derogation from the first sentence, unrestricted clearance shall be considered for an aqueous solution in individual cases if, in addition to the dose criterion for clearance, the radiological parameters for tritium and radon 222 in accordance with Annex 3a of the Drinking Water Ordinance (*Trinkwasserverordnung*) in the version of the Notice of 10 March 2016 (Federal Law Gazette [BGBl.] Part I p. 459) in the respectively applicable version, are complied with.

Section 33

Issuing clearance

(1) The competent authority shall issue clearance if the dose criterion for the clearance is complied with.

(2) Clearance shall be issued in writing in a clearance notice.

(3) The competent authority may issue clearance under the suspensive condition that it confirm the proof of agreement with the content of the clearance notice by the radiation protection executive who is the holder of the clearance.

(4) Section 17 subsection (1), second to fourth sentences, of the Atomic Energy Act on content-related restrictions, obligations imposed and time limits, shall apply *mutatis mutandis* in the respectively applicable version. Furthermore, clearance may be granted subject to a condition, a reservation of revocation or a reservation of the subsequent inclusion, amendment or extension of a condition.

Section 34

Mixing ban

Anyone who can apply for clearance, and the radiation protection executive who is the holder of the clearance, may not deliberately bring about, cause or facilitate the conditions on which the granting of clearance is contingent, or compliance with the content of the clearance notice, by mixing or diluting.

Section 35

Unrestricted clearance

The competent authority may assume that the dose criterion for clearance is complied with if the applicant proves that, for unrestricted clearance,

1. the clearance levels in accordance with Annex 4 Table 1 column 3 are complied with,
2. the determinations in accordance with Annex 8 Part A no. 1 and Part B are

complied with, and

3. in cases in which there is a solid surface on which the contamination can be measured, the surface contamination levels in accordance with Annex 4 Table 1 column 5 are complied with.

Section 36

Specific clearance

(1) The competent authority may assume that the dose criterion for clearance is complied with if the applicant proves that, for specific clearance,

1. of rubble from the demolition of buildings with an expected mass exceeding 1,000 Megagram (Mg) per calendar year
 - a) the clearance levels in accordance with Annex 4 Table 1 column 6 are complied with, and
 - b) the determinations contained in Annex 8 Part A no. 1 and Part F are complied with,
2. of floor areas
 - a) the clearance levels in accordance with Annex 4 Table 1 column 7 are complied with, and
 - b) the determinations contained in Annex 8, Part A no. 1 and Part E are complied with,
3. of solid substances to be disposed of on landfills
 - a) the determinations contained in Annex 8 Part A no. 1 and Part C are complied with,
 - b) in cases in which there is a solid surface on which the contamination can be measured, the surface contamination levels in accordance with Annex 4 Table 1 column 5 are complied with, and
 - c) with an expected mass
 - aa) of up to 100 Mg per calendar year, the clearance levels in accordance with Annex 4 Table 1 column 8 are complied with, or
 - bb) of more than 100 Mg and up to 1,000 Mg per calendar year, the clearance levels in accordance with Annex 4 Table 1 column 10 are complied with,
4. of substances to be disposed of in an incineration facility
 - a) the determinations in Annex 8 Part A no. 1 and Part C are complied with, and
 - b) in cases in which there is a solid surface on which the contamination can be measured, the surface contamination levels in accordance with Annex 4 Table 1 column 5 are complied with, and
 - c) with an expected mass
 - aa) of up to 100 Mg per calendar year, the clearance levels in accordance with Annex 4 Table 1 column 9 are complied with, or
 - bb) of more than 100 Mg and up to 1,000 Mg per calendar year, the clearance levels in accordance with Annex 4 Table 1 column 11 are complied with,
5. of buildings, rooms and parts thereof, as well as components for reuse and further use
 - a) the clearance levels in accordance with Annex 4 Table 1 column 12 are

- complied with, and
- b) the determinations in accordance with Annex 8 Part A no. 1 and Part D are complied with,
- 6. of buildings, rooms, parts of rooms and components intended for demolition
 - a) the clearance levels in accordance with Annex 4 Table 1 column 13 are complied with, and
 - b) the determinations in accordance with Annex 8 Part A no. 1 and Part D are complied with,
- 7. of scrap metal for recycling
 - a) the clearance levels in accordance with Annex 4 Table 1 column 14 are complied with,
 - b) the determinations in accordance with Annex 8 Part A no. 1 and Part G are complied with, and
 - c) in cases in which there is a solid surface on which the contamination can be measured, the surface contamination levels in accordance with Annex 4 Table 1 column 5 are complied with.

(2) In the case of specific clearance for disposal and specific clearance of scrap metal for recycling, the competent authority may also not have received any indications that the dose criterion for clearance has not been complied with at the site of the waste disposal facility.

(3) In the case of specific clearance for disposal and specific clearance of scrap metal for recycling, the competent authority may waive provision of proof that the surface contamination levels in accordance with Annex 4 Table 1 column 5 are complied with if it can be ruled out that persons can be contaminated by the substances to be cleared.

Section 37

Clearance in individual cases

(1) The applicant may also provide evidence in individual cases that the dose criterion for the clearance is complied with. This shall apply insofar as

- 1. the conditions and determinations required for specific clearance are not complied with in the individual case,
- 2. no clearance levels have been determined for individual radionuclides,
- 3. liquid substances are involved other than those in accordance with Annex 8 Part B, or
- 4. the competent authority has received indications that the dose criterion for clearance has not been complied with at the location of the waste disposal facility, having consulted the clearance levels in accordance with Annex 4 Table 1 column 8, 9, 10, 11 or 14.

The first sentence shall also apply insofar as clearance for use in mining takes place in accordance with section 1 subsection (1) of the Ordinance on Underground Waste Stowage (*Versatzverordnung*) of 24 July 2002 (Federal Law Gazette Part I p. 2933), most recently amended by Article 5 para. 25 of the Act of 24 February 2012 (Federal Law Gazette Part I p. 212), in the respectively applicable version.

(2) The determinations in Annex 8, Part A no. 2 shall be taken into consideration in the record-keeping.

Section 38

Ex-officio clearance

Clearance may also be issued *ex officio* if there is no licence-holder.

Section 39

Agreement in the case of specific clearance for disposal

(1) In the case of intended clearance for the disposal of masses of more than 10 Mg per calendar year, the competent authority shall reach an agreement with the highest *Land* authority responsible for the implementation of this Ordinance in the area of competence of which the masses to be cleared are to be disposed of.

(2) Consent shall be deemed to be granted if it is not refused within 30 calendar days after the time of receipt of the request by the authority competent for the intended clearance. If it cannot be ruled out based on an estimate that the dose criterion for clearance at the location of the waste disposal facility will not be complied with in the case of the intended clearance, the highest *Land* authority responsible for compliance with this Ordinance in whose area of competence the masses to be cleared are to be disposed of shall refuse to give its agreement.

Section 40

Method of recovery and disposal under the law on waste

(1) In the case of specific clearance for disposal, of specific clearance for scrap metal for recycling, and of specific clearance in an individual case, the authority competent for the clearance may not have any reservations as to the permissibility under the law on waste of the envisaged method of recovery or disposal, and as to whether it will be complied with.

(2) Prior to issuance of clearance, the applicant shall submit to the authority competent for clearance a declaration on the fate of the future waste and a declaration of acceptance on the part of the operator of the recovery or disposal installation, or a different agreement between the applicant and the operator of the recovery or disposal installation. At the same time, the applicant shall forward a copy of the declaration of acceptance, or of the agreement, to the authority competent for the recovery or disposal installation in accordance with the Circular Economy Act, and shall prove such to the authority competent for clearance.

(3) The authority competent for the recovery and disposal installation in accordance with the Circular Economy Act may demand agreement with regard to the requirements for the method of recovery or disposal from the authority responsible for clearance within a period of 30 calendar days after receipt of the copy.

(4) The provisions contained in the Circular Economy Act and in the ordinances on the proper disposal of waste issued on the basis of this Act shall remain unaffected thereby.

Section 41

Determination of the procedure

(1) The competent authority may determine the procedure in a licence in accordance with section 6, 7 or 9 of the Atomic Energy Act, in a plan approval decision or licence in accordance with section 9b of the Atomic Energy Act, in a licence in accordance with section 12 subsection (1) nos. 1 to 3 of the Radiation Protection Act, or in a special notice

1. on compliance with the requirements and determinations on evidence for
 - a) unrestricted clearance,
 - b) specific clearance, or
 - c) clearance in individual cases, and
2. on determining conformity with the content of the clearance notice.

(2) At the request of the party who may request clearance, the competent authority may determine whether specific conditions are already complied with for granting clearance.

(3) The determination on compliance with specific conditions may be included

1. in a licence in accordance with sections 6, 7 or 9 of the Atomic Energy Act,
2. in a plan approval decision or licence in accordance with section 9b of the Atomic Energy Act,
3. in a licence in accordance with section 12 subsection (1) nos. 1 to 3 of the Radiation Protection Act, or
4. in a separate notice.

The determination shall be used as the basis for the clearance procedure.

Section 42

Obligations incumbent on the holder of a clearance

(1) The radiation protection executive who is the holder of the clearance shall determine the agreement beforehand with the content of the clearance notice for each mass or partial mass to be used, recycled, disposed of, possessed or passed on to third parties on the basis of clearance as a non-radioactive substance.

(2) Measurements of the specific activity (clearance measurements) that are required to determine agreement with the content of the clearance notice, and the results of which are to be documented by the radiation protection executive who is the holder of clearance.

(3) The radiation protection executive who is the holder of the clearance shall inform the competent authority without undue delay if one of the conditions for granting the clearance is no longer complied with.

Chapter 4

Operational organisation of radiation protection

Section 43

Obligations incumbent on the radiation protection supervisor

(1) The radiation protection supervisor shall ensure compliance with the obligations assigned to the radiation protection executive by the present Ordinance, insofar as the corresponding tasks and powers in accordance with section 70 subsection (2) of the Radiation Protection Act were transferred to him or her. Section 70 subsection (1), second sentence, of the Radiation Protection Act shall remain unaffected thereby.

(2) The obligations contained in the following provisions may not be transferred to the radiation protection supervisor: section 44 subsection (2), section 45 subsection (1), first sentence, and subsections (3) and (4), section 54, section 79 subsection (5), section 98, first sentence, no. 4, also in conjunction with the second sentence, section 99 subsection (3), section 104 subsection (1), first sentence, subsection (3), first sentence, and subsection (4), section 106 subsections (2) to (4), section 117, subsections (1), and (2) and section 138 subsection (1).

Section 44

Obligations during use by other radiation protection executives

(1) A radiation protection executive who is the holder of a licence in accordance with section 12 subsection (1) no. 1, 3, 4 or 5 of the Radiation Protection Act, or who has lodged a notice in accordance with section 17 subsection (1), first sentence, or section 19 subsection (1) of the Radiation Protection Act, shall ensure that the competent authority is informed without undue delay as soon as another person uses the installation for the generation of ionising radiation, the radioactive substances, the X-ray equipment or the stray radiation emitter on his or her own responsibility. The obligation incumbent on the other person to apply for a licence as a radiation protection executive in accordance with section 12 subsection (1) no. 1, 3, 4 or 5 of the Radiation Protection Act, or to make a notification in accordance with section 17 or 19 subsection (1) of the Radiation Protection Act, shall remain unaffected thereby.

(2) The radiation protection supervisor and the other person shall, by contract, clearly define their obligations and the obligations of their respective radiation protection supervisors, medical physics experts and other persons acting under their responsibility. The contract shall be submitted to the competent authority on request.

Section 45

Radiation protection order

(1) The radiation protection executive shall ensure that a radiation protection order is issued. The radiation protection order may be a component of other necessary operating instructions, in particular in accordance with laws on occupational health and safety, immission control, dangerous goods or hazardous substances.

(2) The radiation protection order shall list the protection measures to be observed in the establishment. Such measures may include, in particular

1. the creation of a plan for the organisation of radiation protection, where necessary providing that one or more radiation protection supervisors or persons with the necessary specialist knowledge in radiation protection shall be constantly present or immediately reachable,
2. the arrangement of the operating procedure relevant for radiation protection,

3. the measurements and measures specified for establishing the body dose in accordance with the exposure conditions,
4. the arrangements for determining dose reference levels for the exposure of employees and other persons,
5. keeping an operating book in which the relevant operations for radiation protection are to be entered,
6. arrangements for the prevention, investigation and notification of incidents,
7. the regular function testing and maintenance of irradiation facilities, installations for the generation of ionising radiation, X-ray equipment, stray radiation emitters, equipment and devices that are relevant to radiation protection, as well as record-keeping on the function tests and maintenance,
8. the arrangements for protection against disruptive actions or other interventions by third parties, against the loss of radioactive substances, or against the unauthorised start-up of an irradiation device, of an installation for the generation of ionising radiation, of X-ray equipment or of a stray radiation emitter, in compliance with the regulations on handling classified information, and
9. the creation of a plan for regular alarm drills, as well as for deployment in emergencies and hazardous incidents, where necessary with rules for fire protection and preparatory measures for emergencies and hazardous incidents.

(3) The radiation protection order shall be updated without undue delay in the event of significant changes.

(4) The issuance of a radiation protection order shall only be necessary in the event of the notifiable operation of X-ray equipment and of the operation of stray radiation emitters, as well as of a notification in accordance with section 56 or 59 of the Radiation Protection Act, if the competent authority obliges the radiation protection executive to do so.

Section 46

Provision of the Radiation Protection Act and of the Radiation Protection Ordinance

The radiation protection executive shall ensure that the Radiation Protection Act and this Ordinance are constantly kept available for inspection in establishments or independent branch establishments, or at the place of activity in the case of non-commercial operators, if at least one person is regularly occupied or works under the supervision of another person.

Chapter 5

Specialist and general knowledge

Section 47

Requisite specialist knowledge in radiation protection

(1) The acquisition of the requisite specialist knowledge in radiation protection shall be verified and certified by the competent authority. The following documents shall be submitted to the competent authority for this purpose as a rule:

1. proof of the appropriate training for each area of application,
2. proof of practical experience, and
3. proof of successful attendance at recognised courses.

Attendance at the course may not have taken place a total of more than five years previously.

(2) Proof of practical experience shall be provided by submitting written confirmation by the person in whose area of responsibility or under whose supervision the practical experience was acquired. The proof is to include the following information in particular:

1. personal information,
2. a list of the practices with an indication of the periods of employment in the respective area of application, and
3. the name of the facility in which the practices were carried out.

The duration, type and scope of the practical experience to be acquired shall depend on the training and on the respective area of application. The practical experience may only be acquired at a facility which, due to its technical and human resources, is capable of imparting the necessary practical skills.

(3) The requisite specialist knowledge in radiation protection shall be imparted in the courses for acquiring the knowledge required for the respective area of application. The following in particular is to be imparted in addition to the legal foundations, depending on the respective area of application:

1. scientific and technical foundations,
2. applied radiation protection, and
3. general and use-specific radiation protection measures.

The courses are to include practical exercises in radiation protection. Successful attendance at a recognised course may be assumed if the final examination on the contents of the course has been successfully passed.

(4) The competent authority may fully or partially recognise a qualification in radiation protection acquired abroad as requisite specialist knowledge in radiation protection if such qualification is comparable to the specialist knowledge in radiation protection required for the respective area of application. In order to establish comparability, evidence of qualifications acquired abroad and proof of relevant professional experience, as well as other qualifications, shall be submitted to the competent authority, insofar as these are required in order to establish comparability.

(5) The requisite specialist knowledge in radiation protection shall be obtained by passing the final examination of a state or state-recognised vocational training course if the competent authority has previously determined that the requisite specialist knowledge in radiation protection for the respective area of application is imparted in this training course. The authority that is competent in accordance with the respective training and examination regulations or licensing regulations for the examination system shall issue the certificate of the requisite specialist knowledge in radiation protection.

(6) For medical-technical radiology assistants, proof of the requisite specialist knowledge shall be deemed to have been provided with the permit in accordance with section 1 subsection (1) no. 2 of the Act on Technical Assistants in Medicine (*MTA-Gesetz*) for the reserved practices in accordance with section 9 subsection (1) no. 2 of the Act on Technical Assistants in Medicine.

Section 48

Updating the specialist knowledge

(1) The requisite specialist knowledge in radiation protection shall be updated at least every five years by successfully attending a course recognised by the competent authority, or other further training recognised as appropriate by the competent authority. Proof of the updating of the requisite specialist knowledge shall be submitted to the competent authority on request.

(2) In derogation from subsection (1), the requisite specialist knowledge in radiation protection may be updated in another appropriate way in individual cases. The updating shall be appropriate for ensuring a state of knowledge that corresponds to the imparting of knowledge in a course or other further training in accordance with subsection (1), first sentence. The update shall be proven to the competent authority. The latter shall decide on the recognition of the update.

Section 49

Requisite general knowledge in radiation protection in connection with use on people and animals in veterinary medicine

(1) The following persons shall as a rule obtain the requisite general knowledge in radiation protection in accordance with section 74 subsection (2), second sentence, of the Radiation Protection Act:

1. doctors or dentists in accordance with section 145 subsection (1) no. 2,
2. doctors who are present at the location of the technical implementation of teleradiology in accordance with section 14 subsection (2), first sentence, no. 3 of the Radiation Protection Act,
3. persons with other successfully-completed medical training in accordance with section 145 subsection (2), no. 5,
4. veterinary surgeons in accordance with section 146 subsection (1) no. 2,
5. persons in accordance with section 146 subsection (2) no. 5.

(2) Section 47 subsections (1) to (5) shall apply *mutatis mutandis*. At the request of a course organiser, the competent authority may permit the certificate of successful completion of a recognised course to replace proof of acquisition of the requisite knowledge.

(3) Section 48 shall apply *mutatis mutandis* to the updating of the requisite knowledge in radiation protection.

Section 50

Revocation of recognition of the requisite specialist knowledge or requisite general knowledge

(1) The competent authority may withdraw recognition of the requisite specialist knowledge or requisite general knowledge in radiation protection, or may impose conditions on its continued application, if the proof of the further training measures is not or submitted or is not submitted in full, or if a review in accordance with

subsection (2) reveals that the requisite specialist knowledge or requisite general knowledge in radiation protection is absent, or is not available to the necessary extent.

(2) If justified doubts exist as to the requisite specialist knowledge or requisite general knowledge in radiation protection, the competent authority may arrange for a review of the specialist knowledge or requisite general knowledge.

Section 51

Recognition of courses

Courses in accordance with section 47 subsection (3), section 48 subsection (1), first sentence, section 49 subsection (2), first sentence, in conjunction with section 47 subsection (3), and section 49 subsection (3), in conjunction with section 48 subsection (1), first sentence, shall be recognised by the authority competent for the course venue if

1. the course content is appropriate for communicating the necessary skills and knowledge in radiation protection in accordance with section 47 subsection (3),
2. the qualification of the training personnel, the teaching materials used and the facilities at the course venue ensure that knowledge can be imparted properly, and
3. a performance check takes place.

Chapter 6

Requirements pertaining to the performance of practices

Division 1

Physical radiation protection surveillance; radiation protection areas

Section 52

Establishment of radiation protection areas

(1) The radiation protection executive shall ensure that radiation protection areas in accordance with subsection (2), first sentence, are established in case of the following practices if the exposure of persons may exceed one of the limits for members of the public in accordance with section 80 subsections (1) and (2) of the Radiation Protection Act:

1. practices requiring a licence in accordance with section 12 subsection (1) of the Radiation Protection Act,
2. practices requiring a licence in accordance with section 6, 7, 9 or 9b of the Atomic Energy Act, or a plan approval decision in accordance with section 9b of the Atomic Energy Act, or
3. notifiable practices in accordance with section 17 or 19 of the Radiation Protection Act.

Radiation protection areas shall also be established in case of such practices if it can be expected that the non-fixed, area-specific activity of surfaces within an area exceeds the values contained in Annex 4 Table 1 column 5.

(2) Radiation protection areas shall be established as

1. a supervised area if persons in operating areas that are not part of the controlled area can receive an effective dose of more than 1 mSv per calendar year or an equivalent dose of more than 50 mSv for hands, forearms, feet or ankles, or a local skin dose of more than 50 mSv,
2. a controlled area if persons can receive an effective dose of more than 6 mSv per calendar year or an equivalent dose of more than 15 mSv for the ocular lens or 150 mSv for hands, forearms, feet or ankles, or a local skin dose of more than 150 mSv, and
3. an exclusion area if the ambient dose rate in an area can be higher than 3 mSv in one hour; an exclusion area shall be deemed to constitute part of the controlled area.

A time spent exposed of 40 hours per week and 50 weeks per calendar year shall be authoritative when determining the boundary of controlled areas or supervised areas, unless there is other well-founded information on the time spent exposed. The competent authority may determine that other areas are to be treated as radiation protection areas if this is necessary for the protection of persons or of the general public. The first sentence, no. 3, shall not apply to the operation of X-ray equipment for the purpose of the examination of humans and of the examination of animals in veterinary medicine.

(3) Areas in which only X-ray equipment or stray radiation emitters are operated shall only be deemed to be radiation protection areas during activation time. The competent authority may permit areas to be defined as controlled areas or exclusion areas during the operation of installations for the generation of ionising radiation or irradiation facilities only during the activation time of these installations or devices if persons or the general public are not endangered thereby.

Section 53

Demarcation, marking and securing of radiation protection areas

(1) The radiation protection executive shall ensure that controlled areas are demarcated and marked in accordance with section 52 subsection (2), first sentence, no. 2 and, in addition to the marking in accordance with section 91 subsection (1), are marked visibly and permanently with the additional words "Controlled Area". The competent authority may permit exceptions to the first sentence if persons or the general public are not endangered thereby.

(2) In the case of controlled areas in which exclusively X-ray equipment or stray radiation emitters requiring a licence are operated, the radiation protection executive shall ensure that these areas are marked at least with the words "No entry – X-rays" during the activation time and operational readiness. Permanent marking in accordance with section 91 subsection (1) and subsection (1), first sentence, shall not be necessary.

(3) The radiation protection executive shall ensure that exclusion areas in accordance with section 52 subsection (2), first sentence, no. 3 are demarcated and marked visibly and permanently at least with the additional words "Exclusion area – X-rays", in addition to the marking in accordance with section 91 subsection (1). He or she shall ensure that the exclusion areas are secured in such a way that persons, including with individual body parts, cannot enter uncontrolled. The competent authority may allow exceptions to the first and second sentences if persons or the general public are not endangered thereby.

(4) In derogation from subsection (3), exclusion areas that have been established within part of an X-ray or irradiation room do not have to be separately marked or demarcated if only persons on whom ionising radiation will be used, or carers or comforters, are able to stay in the X-ray or irradiation room during the activation time of the X-ray equipment, the installation for the generation of ionising radiation or the irradiation device.

(5) In the case of the mobile handling of radioactive substances and mobile operation of installations for the generation of ionising radiation, X-ray equipment, stray radiation emitters or irradiation facilities, the radiation protection executive shall ensure that a controlled area that is to be established is demarcated and marked in such a way that uninvolved persons cannot enter it unintentionally. Demarcation shall not be required if it can be ruled out that uninvolved persons can unintentionally enter the supervised area. No additional demarcation or marking of exclusion areas inside the controlled area shall be required.

Section 54

Preparation of firefighting

(1) The radiation protection executive shall ensure that the necessary firefighting preparation measures are planned with the authorities competent in accordance with *Land* law. It shall be determined in particular at which locations the fire brigade or, in underground operations, the underground fire services

1. can act in the event of an emergency without special protection from the risks of radioactive substances (risk group I),
2. can only act when using special equipment (risk group II), and
3. can only act when using special equipment and with the assistance of a person who possesses the requisite specialist knowledge to assess the danger of ionising radiation during operation arising in this area, as well as the necessary protection measures (risk group III).

The radiation protection executive shall ensure that the respective areas concerned are clearly visible at the entrance and permanently marked with signs indicating "risk group I", "risk group II" or "risk group III".

(2) Subsection (1) shall not apply in the case of the exclusive operation of X-ray equipment or stray radiation emitters.

Section 55

Access to radiation protection areas

- (1) The radiation protection executive shall ensure that access
1. to a supervised area shall only be permitted to persons if
 - a) they are performing a task for operational purposes in this area,
 - b) it is necessary for them to be in this area in order to use ionising radiation or radioactive substances on themselves or as a carer, comforter or person accompanying animals,
 - c) they are trainees or students and need to spend time in this area in order to achieve their training goal, or
 - d) they are visitors,
 2. to a controlled area shall only be permitted to persons if
 - a) they need to act in order to carry out or maintain the operational processes intended to be carried out in this area,
 - b) it is necessary for them to be in this area in order to use ionising radiation or radioactive substances on themselves or as a carer, comforter or person accompanying animals, and a person entitled to practice medical, dental or veterinary practice who has the requisite specialist knowledge in radiation protection has agreed, or
 - c) this is necessary for trainees or students in order to achieve their training goals,
 3. to an exclusion area shall only be permitted to persons if
 - a) they must act in order to implement the operational processes provided for in this area, or for compelling reasons, and they are under the supervision of a radiation protection supervisor or of a person designated by him or her who has the requisite specialist knowledge in radiation protection, or
 - b) it is necessary for them to be in this area in order to use ionising radiation or radioactive substances on themselves or as a carer or comforter, and a person authorised to practice medicine or dentistry who has the requisite specialist knowledge in radiation protection has agreed in writing.

The competent authority may also permit other persons to have access to radiation protection areas if adequate protection of such persons is ensured. Access rights on the basis of other legal provisions shall remain unaffected thereby.

- (2) A pregnant woman may only be permitted to access
1. an exclusion area in derogation from subsection (1), first sentence, no. 3, if it is necessary for her to be there for her own examination or treatment,
 2. a controlled area in derogation from subsection (1), first sentence, no. 2 (a) and (c) if the radiation protection executive, or the radiation protection supervisor if he or she has the requisite specialist knowledge in radiation protection,

- a) permits her to access such area, and
 - b) uses appropriate monitoring measures in order to ensure that the special dose level in accordance with section 78 subsection (4), second sentence, of the Radiation Protection Act is complied with and that this is documented,
3. a controlled area in derogation from subsection (1), first sentence, no. 2(b) as a carer or comforter if compelling reasons make this necessary.

A permit granting pregnant women access to controlled areas in accordance with the first sentence no. 2 or 3 shall be documented. The records shall be retained for five years from the time of access.

(3) In derogation from subsection (1), first sentence, no. 2(b), a breastfeeding woman as a person accompanying animals may not be permitted access to controlled areas in which unsealed radioactive substances are handled.

Section 56

Metrological control in radiation protection areas

(1) The radiation protection executive shall ensure that the following limits are measured in radiation protection areas, individually or in combination, to the extent required in order to establish the exposure:

- 1. the ambient dose or the ambient dose rate,
- 2. the concentration of radioactive substances in the air, or
- 3. the contamination of the workplace.

(2) The radiation protection executive shall ensure that the time and results of the measurements are recorded without undue delay. The records shall be retained for at least five years after the most recent measurement, or after the end of the practice, and shall be provided to the competent authority on request. The radiation protection executive shall ensure that, on completion of the practice, the records are deposited with a body stipulated by the competent authority.

(3) The radiation protection executive shall ensure that the display of devices monitoring the ambient dose or ambient dose rate in exclusion areas is also visible outside these areas.

Section 57

Contamination and decontamination

(1) In the event that unsealed radioactive substances are present in radiation protection areas, and to the extent necessary for the protection of the persons or property located there, the radiation protection executive shall ensure that it is determined whether any contaminations are caused by these substances.

(2) The radiation protection executive shall ensure that measures are taken without undue delay in order to prevent the spread of radioactive substances or their incorporation into the body, if

- 1. it is determined on traffic areas, at workplaces or on clothing in controlled areas that the non-fixed surface contamination exceeds 100 times the values of Annex 4 Table 1 column 5,
- 2. it is determined on traffic areas, on the operating site or on clothing in supervised areas that the non-fixed surface contamination exceeds ten times the limit of Annex 4 Table 1 column 5, or
- 3. outside a radiation protection area on the site, the surface contamination of

floors, buildings and moveable articles, in particular clothing, exceeds the values of Annex 4 Table 1 column 5.

The first sentence shall not apply to articles that are conveyed as dangerous goods in accordance with section 2 of the Transport of Dangerous Goods Act (*Gefahrgutbeförderungsgesetz*), or relinquished in accordance with section 94.

(3) If the values for surface contamination in accordance with subsection (2), first sentence, no. 3 are exceeded, the radiation protection supervisor shall ensure that the results of the measurements and estimations are recorded without undue delay. The radiation protection supervisor shall ensure that these records are retained for a period of at least ten years and are submitted to the competent authority on request.

(4) If the values for surface contamination designated in subsection (2), first sentence, no. 1 or 2, cannot be complied with in the long term, the radiation protection supervisor shall ensure that persons employed in such work areas are protected by special measures.

(5) Subsections (1) to (3) shall not apply to persons who spend time in a radiation protection area for the use of ionising radiation or radioactive substances on themselves or as a carer or comforter.

Section 58

Leaving and evacuation of radiation protection areas

(1) The radiation protection executive shall ensure that persons who leave a controlled area in which radioactive substances are present are checked for contamination. If any contamination is found, the radiation supervisor shall ensure that measures are taken without undue delay that are appropriate for preventing further exposure and the spread of radioactive substances. If unsealed radioactive substances could be present in a supervised area, the competent authority may determine that an assessment is also to be conducted when leaving the supervised area. If a contamination is found in accordance with the second or third sentence, the obligations to record, retain and communicate in accordance with section 167 subsections (1), (2) and (3), first sentence, and subsection (4), of the Radiation Protection Act shall apply *mutatis mutandis*.

(2) If movable articles, particularly tools, measuring devices, measuring equipment, other devices, parts of installations or clothing are evacuated from a controlled area for the purpose of handling, use or other usages with the goal of reuse or repair outside a radiation protection area, the radiation protection executive shall ensure that they are inspected as to whether they have become activated or contaminated. The radiation protection executive shall ensure that articles cannot be removed from the controlled area if

1. the limits in accordance with Annex 4 Table 1 column 3 will be exceeded if they are activated, or
2. the limits in accordance with Annex 4 Table 1 column 3 or 5 will be exceeded if they are contaminated.

If contamination or activation in a supervised area is not ruled out, the competent authority may determine that the first and second sentences are also to apply to supervised areas. The first and second sentences shall not apply to articles that are conveyed as dangerous goods in accordance with section 2 of the Transport of Dangerous Goods Act, or are relinquished in accordance with section 94. The assessment in accordance with the first and second sentences shall not be required for controlled areas in which there are no radioactive substances and in which no activation can take place. Section 31 shall not apply.

(3) Subsections (1) and (2) shall not apply to persons who spend time in a

radiation protection area for the use of ionising radiation or radioactive substances on themselves or as a carer or comforter.

Section 59

Establishment of radiation protection areas in the case of practices with naturally-occurring radioactive substances

In the case of a practice notified in accordance with section 56 or 59 of the Radiation Protection Act, the competent authority may order radiation protection areas to be established in accordance with section 52 on the basis of the exposure conditions. In this case, sections 53 and 55 to 58 shall only apply insofar as the competent authority orders the measures specified therein.

Section 60

X-ray rooms

(1) The radiation protection executive shall ensure that X-ray equipment is only operated in an X-ray room.

(2) X-ray rooms must be completely enclosed, and must be designated in the licence in accordance with section 12 subsection (1) no. 4 of the Radiation Protection Act, in the certificate in accordance with section 19 subsection (3), first sentence, no. 1 of the Radiation Protection Act, or be referred to as an X-ray room in the decision in accordance with section 19 subsection (3), second sentence, of the Radiation Protection Act.

(3) The radiation protection executive shall ensure that workplaces, traffic routes or changing rooms are only situated in the controlled area of X-ray equipment which is operated in an X-ray room if it is ensured that no people are there during activation time. This shall not apply to workplaces which may not be located outside the controlled area for reasons of the proper use of the X-rays.

(4) Subsection (1) shall not apply

1. to X-ray equipment to be operated in an irradiation room in accordance with section 61,
2. to X-ray equipment with regard to which the licence permits operation outside of an X-ray and irradiation room,
3. to basic-, high- and full-protection devices in addition to X-ray equipment for training purposes, and
4. in the exceptional cases in accordance with section 19 subsection (2) no. 5 of the Radiation Protection Act in which the condition or size of the person or animal to be examined imperatively requires operation outside of an X-ray room in an individual case.

Section 61

Irradiation rooms

(1) The radiation protection executive shall ensure that the following devices are only operated in completely-enclosed rooms that meet the requirements of subsection (3) (irradiation rooms) in use on humans or animals in veterinary medicine:

1. X-ray equipment for treatment,
2. installations for the generation of ionising radiation, and
3. irradiation facilities

- (a) that contain highly active radiation sources, or
- (b) with regard to which the total activity of the radioactive substances exceeds the value of Annex 4 Table 1 column 4.

(2) Irradiation rooms must

1. be completely enclosed,
2. be of such a size that the necessary tasks can be carried out without hindrance,
3. have appropriate facilities available for monitoring the person on whom the ionising radiation will be used, and
4. be of such a size that, with installations for the generation of ionising radiation and irradiation facilities in accordance with subsection (1) no. 3,
 - a) the operational equipment which discharges the radiation is located in an adjacent room outside the controlled area, and
 - b) at least one emergency stop button is located in the radiation room which can be used to turn off the installation, close the emitter of the irradiation device or retract the radioactive material into the shielding.

Section 62

Rooms for the operation of stray radiation emitters

The competent authority may determine for stray radiation emitters requiring a licence for the protection of persons or of the public that they may only be operated in completely enclosed rooms.

Section 63

Training

(1) The radiation protection executive shall ensure that the following persons are given training

1. persons who work on practices requiring notification or a licence,
2. persons who are granted access to a controlled area in accordance with section 55 subsection (1), first sentence, no. 2 (a) or (c).

Training shall be carried out for the first time prior to the commencement of a practice or before first access to a controlled area. The training shall subsequently be repeated at least once per year. The first sentence, no. 1, shall not apply to persons who are active in the construction of installations for the generation of ionising radiation.

(2) In particular, the training shall include information on

1. working methods,
2. potential dangers,
3. safety and protection measures to be applied,
4. the content of the Radiation Protection Act relating to their work or presence, the licence or notification, the radiation protection training, and
5. the processing and use of personal data for the purpose of monitoring dose levels and complying with radiation protection principles.

This training may be part of other requisite training courses, in particular in accordance with provisions on occupational health and safety, immission control, dangerous goods or hazardous substances.

(3) The training shall be conducted in a form and language that is understandable for the trainees. The training shall be conducted orally. The competent authority may permit the training to take place by means of e-learning or audio-visual media if a

performance review is conducted and the opportunity for follow-up questions is ensured.

(4) The radiation protection executive shall ensure that persons other than those designated in subsection (1) who are permitted access to controlled areas are given prior training on potential dangers and their avoidance. This shall not apply to persons on whom ionising radiation or radioactive substances are used.

(5) The radiation protection executive shall ensure that the training includes the indication that pregnancy should be notified as soon as possible in view of the risks of exposure to the unborn child, and that where unsealed radioactive substances are present, contamination can lead to the internal exposure of an unborn or breastfeeding child.

(6) The radiation protection executive shall ensure that the content and timing of the training are recorded without undue delay. The record shall be signed by the person receiving training. The radiation protection executive shall ensure that the records are retained for five years after the training in cases falling under subsection (1), and one year in cases falling under subsection (4), and are provided to the competent authority on request.

Section 64

Obligation to establish the body dose; monitored persons

(1) The radiation protection executive shall ensure that the body dose of persons spending time in a radiation protection area is determined in accordance with the provisions of section 65 subsection (1). If it is anticipated that, for a stay in a supervised area for all or for individual persons, an effective dose of 1 mSv, a equivalent dose exceeding 15 mSv for the ocular lens, and 50 mSv for local skin, will not be reached per calendar year, the establishment of the body dose may be waived for these persons. The second sentence shall not apply if the competent authority demands the establishment. The second sentence shall apply mutatis mutandis to a stay in the controlled area if the competent authority has consented thereto. The radiation protection executive shall endeavour to ensure that the results of the establishment are available at the latest six months after a stay in the radiation protection area.

(2) Subsection (1) shall apply mutatis mutandis to persons who may receive an effective dose of more than 1 mSv, an equivalent dose exceeding 15 mSv for the ocular lens, or local skin dose of more than 50 mSv per calendar year when carrying out a practice that is not connected with the stay in a radiation protection area. Subsection (1) shall apply mutatis mutandis to deployed air crew if the effective dose from cosmic radiation may exceed 1 mSv per calendar year.

(3) The radiation protection executive shall ensure that every occupationally-exposed person under his or her authority is informed in writing, on request, of the occupational exposure received due to the employment relationship, unless a radiation passport is issued. The radiation protection executive shall furthermore ensure that the occupational exposure received by the persons deployed as air crew is communicated once per calendar year, as well as after their final assignment, in the case of the notifiable operation of an aircraft.

(4) If it cannot be ruled out that a person who is or has been in an area in which a practice is carried out has incorporated radioactive substances, the competent authority may order that it be determined through suitable measurements whether the person has incorporated radioactive substances.

(5) Subsection (1), first sentence, shall not apply to persons who spend time in a controlled area for the use of ionising radiation or radioactive substances on themselves.

Section 65

Procedure in establishment of the body dose

(1) The radiation protection executive shall ensure that the personal dose is measured in accordance with section 66 in order to establish the body dose. The competent authority may determine on the basis of the exposure conditions that, in order to establish the body dose, in addition to or in derogation from the first sentence, only

1. the ambient dose, the ambient dose rate, the concentration of radioactive substances in the air, or the contamination of the workplace, is measured,
2. the physical activity or the activity of excretions is measured, or
3. further properties of the radiation field or of the source of the ionising radiation be determined.

(2) In the event that a measurement is not carried out or is erroneous, the radiation protection executive shall ensure that

1. the competent authority is informed, and
2. the dose is estimated.

The competent authority shall determine the notional dose, and shall arrange for the notional dose to be transmitted to the radiation protection register in accordance with section 170 of the Radiation Protection Act. The competent authority may refrain from determining a notional dose in individual cases if the dose to be determined is 0 mSv, and the authority transmits this value to the radiation protection register in accordance with section 170 of the Radiation Protection Act. The transmission in accordance with the second or third sentence may take place via a measuring body determined in accordance with section 169 of the Radiation Protection Act.

(3) If, on the basis of the establishment of the body dose, there is a suspicion that one of the dose limits in section 78 of the Radiation Protection Act has been exceeded, the radiation protection executive shall ensure that the body dose is determined, taking the exposure conditions into account. He or she shall ensure that the determined body dose is transmitted to the competent authority without undue delay, together with the information on the exposure conditions. The competent authority shall arrange for the determined body dose and the information on the exposure conditions to be transmitted to the radiation protection register in accordance with section 170 of the Radiation Protection Act. This may take place via a measuring body determined in accordance with section 169 of the Radiation Protection Act.

(4) The radiation protection executive shall ensure that the measurement of physical activity or of the activity of excretions, as well as the establishment of the body dose implemented on the basis of this measurement, is conducted by a measuring body designated in accordance with section 169 of the Radiation Protection Act.

Section 66

Measurement of the personal dose

(1) The measurement of the personal dose in accordance with section 65 subsection (1), first sentence, shall be carried out with

1. a dosimeter that is to be requested from a measuring body determined in accordance with section 169 of the Radiation Protection Act body, or
2. a dosimeter that is analysed subject to the responsibility of the radiation protection executive and the use of which was permitted by the competent authority subsequent to consent from a measuring body determined in accordance with section 169 of the Radiation Protection Act.

(2) The radiation protection executive shall ensure that the dosimeter is worn on a part of the body's surface that is considered to be representative for the exposure, generally the front of the torso. The measurement value of the dosimeter shall be considered the

gauge for the effective dose, insofar as the body dose for individual body parts, organs or tissues has not been determined more precisely. If it is foreseeable that the equivalent dose for the hands, forearms, feet and ankles, or the local skin dose, could exceed 150 mSv, or that the equivalent dose for the ocular lens could exceed 15 mSv per calendar year, the radiation protection executive shall ensure that the personal dose is also determined by additional dosimeters on individual body parts. The competent authority may order on the basis of the exposure conditions that the personal dose be measured in accordance with another appropriate procedure, or with two independent procedures.

(3) The radiation protection executive shall ensure that

1. the dosimeters in accordance with subsection (1) no. 1 and subsection (2), third sentence, are submitted without undue delay to the measuring body at the end of each month, or
2. in cases falling under subsection (2) no. 2, the measurement values are provided to the measuring body for assessment and determination.

The competent authority may permit dosimeters to be submitted to the measuring body at intervals of up to three months if the exposure conditions do not preclude this.

(4) The radiation protection executive shall ensure that the quality of the measurements in accordance with subsection (2) no. 2 is secured through regular internal assessments. He or she shall ensure that the results of the assessments are communicated to the competent authority on request.

(5) The radiation protection executive shall ensure that a person to be supervised is provided with a dosimeter on his or her request which can be used to measure the personal dose and determine it at any time.

Section 67

Establishment of the body dose of air crew

(1) In derogation from section 65, the radiation protection executive shall ensure that a calculation program or measuring instrument specified under section 50 subsection (3) no. 4 of the Radiation Protection Act is used to establish the body dose of persons deployed as air crew in the case of the notifiable operation of an aircraft. With the approval of the competent authority, a different calculation program that is recognised by it, or a different appropriate meter, can be used than that designated in accordance with section 50 subsection (3) no. 4 of the Radiation Protection Act.

(2) Section 65 subsections (2) and (3), as well as section 66 subsection (4), shall apply mutatis mutandis in case of determination with a measuring instrument.

(3) The radiation protection executive shall ensure that the results of the establishment are available at the latest six months after deployment and are submitted to the Federal Aviation Office without undue delay in accordance with section 168 subsection (2) of the Radiation Protection Act.

Section 68

Employment with a radiation passport

(1) Anyone who is a radiation protection executive on the basis of a licence in accordance with section 25 subsection (1), on the basis of a notification in accordance with section 26 subsection (1) or section 59 subsection (2) of the Radiation Protection Act, shall ensure that persons under his or her supervision are only employed in third-party radiation protection areas if each occupationally-exposed person possesses a complete radiation passport that is registered with the competent authority. The first sentence shall not apply to radiation protection areas in which the establishment of the body dose may be waived. The first and second sentences shall apply mutatis mutandis if a radiation protection executive is personally active in accordance with the first sentence in third-party radiation protection areas.

(2) Subsection (1) shall apply mutatis mutandis to persons who may receive an effective dose of more than 1 mSv, an equivalent dose exceeding 15 mSv for the ocular lens, or a local skin dose of more than 50 mSv per calendar year, when conducting a practice that is not connected with the stay in a radiation protection area.

(3) The radiation protection executive responsible for establishing a radiation protection area shall ensure that occupationally-exposed persons in accordance with subsection (1), first and third sentences, are only employed in the radiation protection area if they submit the radiation passport and wear a dosimeter in accordance with section 66 subsection (1). The first sentence shall not apply to radiation protection areas in which it is possible to waive the establishment of the body dose.

(4) The competent authority may issue an exemption from the obligation to carry a radiation passport in accordance with subsection (1), and from the obligation to present same in accordance with subsection (3), in an individual case if the occupationally-exposed person is not employed in more than one third-party installation or facility.

Section 69

Protection of pregnant and breastfeeding women

As soon as the radiation protection executive has been informed that a person who may be occupationally exposed is pregnant or is breastfeeding, the supervisor shall ensure that

1. the occupational exposure of the pregnant woman is determined every working week, and
2. the working conditions of the pregnant or breastfeeding woman are designed in such a way that an internal occupational exposure is ruled out.

The radiation protection executive shall ensure that the assessed exposure of the pregnant woman is communicated without undue delay.

Section 70

Protection when handling unsealed radioactive substances; employment restrictions

(1) The radiation protection executive shall ensure that persons handling unsealed radioactive substances the activity and specific activity of which exceed the exemption levels of Annex 4 Table 1 columns 2 and 3

1. wear the requisite protective clothing and use the requisite protective equipment, and
2. behaviour is prohibited through which they can absorb radioactive substances, in particular through food, drink, smoking and the use of healthcare or cosmetic products.

The radiation protection executive shall ensure that no persons under 18 years of age may handle unsealed radioactive substances the activity and specific activity of which exceed the exemption levels of Annex 4 Table 1 columns 2 and 3 where handling is subject to a licence. The first sentence nos. 1 and 2 shall apply mutatis mutandis to time spent in areas in which substances are handled as designated in the first sentence, unless this is unreasonable for patients or carers and comforters given the length of stay.

(2) The competent authority may permit exceptions from subsection (1), second sentence, for trainees and students between 16 and 18 years of age if this is necessary to achieve the training goal, and if constant supervision and guidance by a person who has the requisite specialist knowledge in radiation protection is ensured.

Division 2

Special provisions for the protection of occupationally-exposed persons

Section 71

Categories of occupationally-exposed persons

(1) The radiation protection executive shall ensure that occupationally-exposed persons are assigned to one of the following categories for the purpose of control and medical surveillance before taking up their practices:

1. Category A occupationally-exposed persons: persons who have occupational exposure due to practices that may result in an effective dose of more than 6 mSv, an equivalent dose of more than 15 mSv for the ocular lens, or of more than 150 mSv for hands, forearms, feet or ankles, or a local skin dose of more than 150 mSv per calendar year;
2. Category B occupationally-exposed persons: persons who are not assigned to Category A and have occupational exposure due to activities that may result in an effective dose of more than 1 mSv, an equivalent dose exceeding 50 mSv for hands, forearms, feet or ankles, or a local skin dose of more than 150 mSv per calendar year.

(2) The radiation protection executive shall ensure in the case of the notifiable operation of an aircraft that the occupationally-exposed persons deployed by him or her as air crew are allocated to the following categories prior to taking up their activity:

1. Category A occupationally-exposed persons: persons whose deployment as air crew may result in an effective dose of more than 6 mSv per calendar year from cosmic radiation;
2. Category B occupationally-exposed persons: persons who are not allocated to Category A and whose deployment as air crew may result in an effective dose of more than 1 mSv per calendar year from cosmic radiation.

(3) The radiation protection executive shall ensure that the categorisation is adjusted if it can be expected that a person who was allocated to Category B reaches the limits for allocation to Category A.

Section 72

Dose constraints for activities

(1) The radiation protection executive shall ensure within six months after the start of an activity that it will be verified whether the determination of dose constraints for occupationally-exposed persons is an appropriate instrument for optimising radiation protection. For occupationally-exposed persons who perform tasks in the context of employment requiring an authorisation or notification in accordance with section 25 or 26 of the Radiation Protection Act, the radiation protection executive shall provide for this test jointly with the radiation supervisor of the external installation or facility, X-ray equipment or stray radiation emitter.

(2) If dose constraints are determined, they shall be determined for the effective dose or for an equivalent dose for individual persons, and relating to a time period.

(3) The determination of dose constraints is in particular to be included in planning for operational radiation protection if the practices performed are connected with exposures that require the allocation of the occupationally-exposed persons to Category A, and it is not already guaranteed by other radiation protection planning measures that radiation protection is optimised.

(4) The radiation protection executive shall ensure that the results of the test and

the determination of the dose constraints are recorded and submitted to the competent authority on request. The records shall be retained, namely for a period of at least five years after the end of the activity or a new assessment and determination of dose constraints.

Section 73

Dose limitation for exceeding limits

If a limit was exceeded during the calendar year in violation of section 78 of the Radiation Protection Act, continued employment as an occupationally-exposed person shall only be permissible if the radiation protection executive ensures that exposure is restricted in the following four calendar years, taking into account the exceedance of the limits that has taken place, in such a way that the sum of the doses does not exceed five times the applicable limit. If the limit has been exceeded to such an extent that the application of the first sentence means that the previous employment cannot be continued, the competent authority may permit exceptions, in consultation with an authorised doctor.

Section 74

Specially-authorised exposures

(1) In exceptional circumstances, which are to be evaluated on an individual basis, the competent authority may permit occupational exposures deviating from section 78 subsections (1), (2) and (4), first sentence, of the Radiation Protection Act for the purpose of implementing necessary specific work processes. The limit for this specially-authorised exposure for a person in a professional life shall be deemed to be

1. the limit of the effective dose, 100 mSv,
2. the limit of the equivalent dose for the ocular lens, 100 mSv,
3. the limit of the equivalent dose for hands, forearms, feet and ankles, 1 Sievert each, and
4. the limit for local skin, 1 Sievert.

The radiation protection executive shall ensure that the limit values in accordance with the second sentence are complied with.

(2) A specially-authorised exposure may only be imposed on volunteers who are Category A occupationally-exposed persons. Trainees and students, as well as pregnant women and, if the possibility of the incorporation of radioactive substances or contamination cannot be ruled out, breastfeeding women, shall be excluded from such exposures.

(3) The radiation protection executive shall ensure that specially-authorised exposure is examined in advance in terms of its justification. He or she shall ensure that persons who are exposed to specially-authorised exposure are informed of the risks associated with the work processes and the exposure and of the protection measures to be taken during the operations. The works council or the staff committee, the occupational health and safety specialists, the occupational physician and the authorised doctor, shall be involved.

(4) The radiation protection executive shall ensure that the body dose caused by a specially-authorised exposure is determined, taking account of the exposure conditions. The body dose determined shall be entered separately from the other results of the measurements and establishments of the body dose in the records in accordance with section 167 of the Radiation Protection Act and in the records of the authorised doctor. The specially-authorised exposure shall be taken into account in the sum of all effective doses determined over all calendar years in accordance with section 77 of the Radiation Protection Act.

(5) If the limits in accordance with section 78 subsection (1), (2) or (4), first sentence, of the Radiation Protection Act have been exceeded in a specially-authorised exposure, this exceedance alone shall not constitute a reason to exclude the person from their previous employment without their consent.

Section 75

Other protective measures

(1) The radiation protection executive shall ensure that the protection of occupationally-exposed persons from external and internal exposure is primarily secured by structural and technical equipment or by appropriate work processes.

(2) The radiation protection executive shall ensure that unsealed radioactive substances may only be present in workplaces as long as, and in such activities required by, the work procedure.

(3) In the case of the notifiable operation of an aircraft, the radiation protection executive shall ensure that the obligation to reduce the dose is taken into consideration, particularly when drawing up working rotas. Subsection (1) shall not apply.

Section 76

Special rules for the protection of space crew

In derogation from sections 64 and 65, in the case of the notifiable operation of a spacecraft, the body dose received by the space crew from cosmic radiation during their deployment shall be determined by a method that is appropriate to the special exposure conditions. Section 64 subsection (3), first sentence, shall apply mutatis mutandis. Section 45, 46, 63, 71, 72 or 69 shall only apply insofar as the competent authority appropriately arranges the measures designated therein for the protection of the deployed space crew. Section 81 shall not apply.

Division 3

Medical surveillance of occupationally-exposed persons

Section 77

Medical surveillance of occupationally-exposed persons

(1) The radiation protection executive shall ensure that a Category A occupationally-exposed person only performs tasks for which classification into this category is required if he or she has been examined by a doctor authorised in accordance with section 175 subsection (1), first sentence, within one year before the first performance of the task, and the radiation protection executive has been provided with a certificate issued by this doctor in accordance with which performance of the tasks is not precluded by any health concerns.

(2) The radiation protection executive shall ensure that the Category A occupationally-exposed person only continues tasks in accordance with subsection (1) if he or she has been examined by a doctor authorised in accordance with section 175 subsection (1), first sentence, within one year of the last examination, and the radiation protection executive has been provided with a certificate issued by this doctor in accordance with which the continued performance of the tasks is not precluded by any health concerns. In place of a repeated examination, an evaluation may be made without an examination if an examination has been conducted in the previous twelve months.

(3) At the proposal of the authorised doctor who carried out the examination in accordance with subsection (1) or (2), the competent authority may reduce the deadline for re-examination if the working conditions or state of health of the exposed person make this necessary.

(4) In corresponding application of subsections (1) and (3), the competent authority may order measures for the medical surveillance of a Category B occupationally-exposed person if the working conditions or state of health of the exposed person so require.

(5) The competent authority may order that persons under 18 years of age who have received an occupational exposure but are not categorised as Category A or B occupationally-exposed persons be examined by a doctor authorised in accordance with section 175 subsection (1), first sentence, if the working conditions or state of health of the exposed person so require.

Section 78

Medical surveillance subsequent to ending of activity

(1) The radiation protection executive shall ensure that medical surveillance with the consent of the affected person continues after the task as an occupationally-exposed person is completed for as long as a doctor authorised in accordance with section 175 subsection (1), first sentence, considers this to be necessary for the protection of the person (follow-up examination).

(2) The obligation to offer follow-up examinations shall no longer apply if the competent statutory accident insurance institution initiates the follow up examination with the consent of the affected person after the end of the employment relationship. This shall be conditional on a copy of the requisite documents being submitted to the accident insurance institution; the affected person shall be notified of this precondition in writing before giving consent.

Section 79

Medical certificate

(1) In order to issue the medical certificate in accordance with section 77 subsection (1), (2) or (3), the doctor authorised in accordance with section 175 subsection (1), first sentence, shall request the following documents:

1. the medical records previously created by other authorised doctors for medical surveillance in accordance with section 175 subsection (1), first sentence, insofar as these are required for the evaluation,
2. the previously issued medical certificates,
3. the official decisions in accordance with section 80, and
4. the expert reports underlying the official decisions.

The requested documents shall be submitted to the requesting authorised doctor without undue delay.

(2) The level of fitness of the occupationally-exposed person for the performance of the respective task shall be divided on the medical certificate into the levels “fit”, “fit for limited obligations” and “unfit”. The activity-related restrictions associated with this level for the medically-supervised person shall be presented in the case of fitness for limited obligations.

(3) The doctor authorised in accordance with section 175 subsection (1), first sentence, may make the issuance of the medical certificate dependent on being provided in advance with the following information in writing:

1. the nature of the tasks of the occupationally-exposed person and the working conditions associated with these tasks,
2. every change in the type of tasks and the working conditions associated with these tasks,
3. the content of the records in accordance with section 167 subsection (1) of the Radiation Protection Act, and
4. the content of the most recent medical certificate if it was not issued by him or her.

The occupationally-exposed person may request a transcript of the communications by the radiation protection executive.

(4) The doctor authorised in accordance with section 175 subsection (1), first sentence, shall also send the medical certificate to the radiation protection executive, the occupationally-exposed person and, if there are any health concerns also to the competent authority, without undue delay. Transmission to the occupationally-exposed person may be substituted by entering the contents of the certificate in the radiation passport.

(5) The radiation protection executive shall ensure that the medical certificate is retained for the duration of the performance of their task as an occupationally-exposed person, and provided to the competent authority on request.

Section 80

Official decision

(1) If the radiation protection executive for the occupationally-exposed person considers the evaluation made by the authorised doctor in the medical certificate to be incorrect, he or she may apply for a decision on the part of the competent authority. The decision of the competent authority shall replace the medical certificate.

(2) Before taking its decision, the competent authority may seek the expert opinion of an authorised medical expert. The costs related to the medical report shall be met by the radiation protection executive.

Section 81

Special medical surveillance

(1) If it cannot be ruled out that, due to an exposure in accordance with section 74 or due to different, extraordinary circumstances, a person has received exposures per calendar year that exceed the effective dose of 20 mSv or the equivalent dose of 20 mSv for the ocular lens or of 500 mSv for the hands, forearms, feet or ankles, or a local skin dose of 500 mSv, the radiation protection executive shall ensure that the person is examined without undue delay by a doctor authorised in accordance with section 175 subsection (1), first sentence, and that a certificate is issued by the latter as to whether there continue to be no health reservations regarding the performance of the task.

(2) If the result of the special medical surveillance raises a concern that the health of the person is at risk if they again perform or continue a task as an occupationally-exposed person, the competent authority may order that they may not perform this task, or that they may only perform it with restrictions. Section 80 subsection (2) shall apply *mutatis mutandis*.

(3) If the radiation protection executive or the occupationally-exposed person considers the result of the special medical surveillance in accordance with subsection (1) to be incorrect, he or she may apply for a decision on the part of the competent authority. Section 80 subsection (1), first sentence, and subsection (2) shall apply *mutatis mutandis*.

(4) Section 78 shall apply *mutatis mutandis* to the continuation of medical surveillance after termination of performance of the task.

Division 4

Special rules on radiation protection in schools and relating to apprenticeship and training relationships

Section 82

Radiation protection in schools and relating to apprenticeship and training relationships

(1) X-ray equipment may only be operated in connection with instruction given in general schools if it is school X-ray equipment.

(2) The radiation protection executive shall ensure that pupils and apprentices only work under the direct supervision of an instructor when performing the following practices in schools:

1. when operating school X-ray equipment or a full-protection device,
2. when operating other X-ray equipment or a stray radiation emitter requiring a licence, and
3. when handling radioactive substances requiring a licence.

The radiation protection executive shall furthermore ensure in the case of practices in accordance with the first sentence, nos. 2 and 3, that the instructor in accordance with the first sentence has the requisite specialist knowledge in radiation protection.

(3) The person responsible for an apprenticeship or training relationship shall ensure that appropriate protective measures are applied to rule out internal exposure due to substances the handling of which does not require a licence in accordance with Annex 3 Part B no. 8.

Division 5
Security of radiation sources

Sub-division 1
Highly-radioactive sources

Section 83
Limits for highly active radiation sources

Annex 4 Table 1 column 4 shall apply to the determination of the activity from which a sealed radioactive substance constitutes a highly active radiation source.

Section 84
Register of highly active radiation sources

(1) The Federal Office for Economic Affairs and Export Control shall transmit information in accordance with Annex 9 to the register of highly active radiation sources without undue delay in a secure electronic form on licences granted in accordance with section 3 subsection (1) of the Atomic Energy Act or section 12 subsection (1) for the cross-border transportation of a highly active radiation source from a country that is not a Member State of the European Union into the territorial scope of this Ordinance. It shall inform the competent authority of the notification in accordance with the first sentence without undue delay.

(2) The competent authority may transmit records that it requests of the radiation protection executive to the register of highly active radiation sources.

(3) On request, the Federal Office for Radiation Protection shall issue an authorisation for personal access to the register of highly active radiation sources to the radiation protection executive who is obliged to effect a communication in accordance with section 85 subsection (4), first sentence, or section 167 subsection (2), or to the persons authorised by him or her, for inspection of the data stored concerning them. The radiation protection executive, or the persons authorised by the supervisor, shall be granted access to

1. personal user data for the purpose of updating,
2. their own reports on highly active radiation sources for correction, on request by the competent authority, and
3. data on their own registered highly active radiation sources.

(4) The Federal Office for Radiation Protection shall summarise the transmitted data in the register of highly active radiation sources. It shall inform the following without undue delay

1. the Federal Ministry responsible for nuclear safety and radiation protection, and the Federal Criminal Police Office, of the receipt of a communication forwarded to the register of highly active radiation sources in accordance with section 167 subsection (2), or section 168 subsection (2), relating to discovery, acquisition, loss, unlawful removal or retrieval of a highly active radiation source,
2. the competent authority if data that have been transmitted are not complete, or a highly active radiation source has been found.

(5) The Federal Office for Radiation Protection shall determine the data format, and shall establish the technical framework conditions for data transfer in agreement with the Federal Office for Radiation Protection.

Sub-division 2

Safety and security of radiation sources

Section 85

Accounting and notification

(1) The radiation protection executive shall ensure that, when radioactive substances are handled,

1. the competent authority is informed within one month of the extraction, production, acquisition, relinquishment and other fate of radioactive substances; the type and activity of the substances shall be stated in doing so,
2. the extraction, production, acquisition, relinquishment and other fate of radioactive substances; the type and activity of the substances shall be listed in so doing, and
3. the competent authority shall be informed of the stock of radioactive substances with half-lives exceeding 100 days at the end of the calendar year by 31 January of the following year.

The radiation protection executive shall ensure that the communication of the acquisition of sealed radioactive substances includes the certificate in accordance with section 94 subsection (2). The first sentence shall not apply to practices that do not require a licence in accordance with section 5 subsection (1).

(2) The competent authority may exempt from the obligation to keep records and notify in accordance with subsection (1), in full or in part, in individual cases where no danger to people or the environment may result from the nature and activity of radioactive substances. In the case of an exemption from the obligation to notify in accordance with subsection (1), first sentence, no. 1, the competent authority may determine in individual cases that the quantity of radioactive substances with half-lives of less than 100 days at the end of the calendar year is notified to the competent authority by 31 January of the following year.

(3) The radiation protection executive shall ensure that the documents in accordance with subsection (1), first sentence, no. 2

1. are kept for 30 years after completion of the extraction or generation, or from the time of the acquisition, relinquishment or other fate, and are deposited with the competent authority at its request, or
2. are given without undue delay to a body designated by the competent authority if the practice is ended prior to expiry of the retention period in accordance with no. 1.

(4) In the case of highly active radiation sources, the radiation protection executive shall ensure, in addition to the obligation in accordance with subsection (1), first sentence, that the following is also communicated to the register of highly active radiation sources at the Federal Office for Radiation Protection in a secure electronic form:

1. in the case of the acquisition and relinquishment of highly active radiation sources, without undue delay, the information in accordance with Annex 9 as well as any changes in the recorded information, and
2. within one month, the date of the leakage test in accordance with section 89 subsection (2).

The radiation protection executive shall ensure that the competent authority is informed of the notification without undue delay.

(5) The competent authority shall examine the transmitted data in accordance with subsection (4), first sentence, within a period of one month for completeness and

correspondence with the licence issued in accordance with section 9 of the Atomic Energy Act or section 12 subsection (1) no. 3 of the Radiation Protection Act. It shall mark the data as examined and correct if the results are positive.

(6) The radiation protection executive shall ensure that the measurement reports proving that they are free from contamination or non-activation taken in accordance with section 31 subsection (5) are retained for five years. They shall be handed over without undue delay to a body designated by the competent authority if the practice is ended prior to expiry of the retention period.

Section 86

Record-keeping and notification of clearance

1) The radiation protection executive who is the holder of the clearance in accordance with section 33 subsection (1) shall ensure that, for the substances which were determined to correspond with the content of the clearance notice,

1. a record is made, which shall include the following information:
 - a) the determinations in accordance with Annexes 4 and 8, in particular the specific activity, the radionuclides, the averaging mass and the averaging area,
 - b) the mass of the substances,
 - c) the clearance measurement procedure,
 - d) the date of the determination, and
2. the competent authority is informed of the following information at least annually:
 - a) the mass of the substances,
 - b) each specific type of clearance in accordance with section 35, 36 or 37 subsection (1), and
 - c) the actual destination in the case of specific clearance for disposal and specific clearance of scrap metal for recycling.

(2) The radiation protection executive who is the holder of the clearance in accordance with section 33 subsection (1) shall ensure that the documents in accordance with subsection (1) no. 1

1. are retained for 30 years from the time of the determination in accordance with section 42 subsection (1), and are deposited with the competent authority on request, or
2. if the practice ends before the expiry of the retention period in accordance with no. 1, are submitted without undue delay to a body designated by the competent authority.

(3) In individual cases, the competent authority may provide a full or partial exemption from the recording and notification obligation in accordance with subsection (1) if

1. the half-life of the radionuclides does not exceed seven days, and
2. the nature and activity of the radioactive substances cannot not lead to a risk to humans or to the environment.

Section 87

Safekeeping and storage of radioactive substances

(1) The radiation protection executive shall ensure that

1. radioactive substances the activity of which exceeds the exemption level in

accordance with Annex 4 Table 1 column 2, and the specific activity of which exceeds the exemption level in accordance with Annex 4 Table 1 column 3, are secured against loss, misuse and access by unauthorised persons, and

2. radioactive substances the activity of which exceeds the exemption level in accordance with Annex 4 Table 1 column 2, and the specific activity of which exceeds the exemption level of Annex 4 Table 1 column 3 by 100 times, are additionally stored in protective rooms or containers, unless they are being processed, handled or used in other ways.

(2) The radiation protection executive shall ensure that nuclear fuels are stored in such a way that a critical state cannot occur during storage.

(3) The radiation protection executive shall ensure that radioactive substances that are subject to safety measures due to international obligations are stored in such a way that the implementation of the safety measures is not adversely affected.

Section 88

Maintenance and testing

- (1) The radiation protection executive shall ensure that
 1. installations for the generation of ionising radiation, irradiation facilities and devices for gamma radiography
 - a) are maintained at least once per year, and
 - b) are tested between the maintenance works for safety functions, safety and radiation protection by an authorised expert appointed in accordance with section 172 subsection (1), first sentence, no. 3 of the Radiation Protection Act, and
 2. the test report in accordance with no. 1(b) is submitted to the competent authority on request.

The first sentence shall not apply to the installations listed in section 17 subsection (1) of the Radiation Protection Act and to section 7.

(2) The competent authority may extend the period for the inspection by an authorised expert in accordance with subsection (1), first sentence, no. 1(b) by up to three years for

1. irradiation facilities for the use of ionising radiation on humans in which the contained activity is less than 1,000 times the value for highly active radiation sources in accordance with Annex 4 Table 1 column 4,
2. irradiation facilities that are used for blood or product irradiation and in which the contained activity is less than 1,000 times the value for highly active radiation sources of Annex 4 Table 1 column 4, and
3. devices for gamma radiography.

(3) The competent authority may exempt from the obligation in accordance with subsection (1), first sentence, no. 1 (b) in individual cases if

1. the inspection by an authorised expert would be disproportionate given the slight inspection effort required and the only slightly detailed inspection needed, or the slight risk potential posed by the installation, equipment or device, and
2. the safety function, safety and radiation protection of the installation, equipment or device is regularly inspected by other suitable means; the inspection reports shall be submitted to the competent authority on request.

(4) The radiation protection executive shall ensure that

1. X-ray equipment is inspected at least every five years, in particular for safety

functions, safety and radiation protection, by an authorised expert appointed in accordance with section 172 subsection (1), first sentence, no. 1 of the Radiation Protection Act, and

2. the test report is submitted to the competent authority on request.

(5) For the purpose of protecting persons or the general public, the competent authority may order that stray radiation emitters the operation of which requires an authorisation, and installations for the generation of ionising radiation that are notifiable in accordance with section 17 subsection (1), first sentence, of the Radiation Protection Act, are checked for safety functions, safety and radiation protection by an authorised expert appointed in accordance with section 172 subsection (1), first sentence, no. 1 or 3, of the Radiation Protection Act, and that the test is repeated at set intervals. The radiation protection executive shall ensure that the test report is made available to the competent authority on request.

Section 89

Leakage test

(1) The radiation protection executive shall ensure that the integrity and leak tightness of the casing of sealed radioactive substances the activity of which exceeds the exemption levels of Annex 4 Table 1 column 2 are tested in an appropriate way, and that the test is repeated at specific intervals. The competent authority may order the test to be conducted by an authorised expert appointed in accordance with section 172 subsection (1), first sentence, no. 4 of the Radiation Protection Act, and at what intervals. The radiation protection executive shall ensure that the test report is made available to the competent authority on request. The first sentence shall not apply to sealed radioactive substances that are relinquished as radioactive waste. In individual cases, the competent authority may issue a full or partial exemption from the obligation in accordance with the first sentence that this cannot cause any risk to ensue to human beings and to the environment.

(2) The radiation protection executive shall ensure that the leakage test takes place at least once every year in the case of highly active radiation sources, insofar as the competent authority does not designate a different period. Subsection (1), second to fourth sentences, shall apply mutatis mutandis.

(3) If the casing of enclosed radioactive substances, or the device containing the radioactive substances, is mechanically damaged or corroded or has been exposed to fire, the radiation protection executive shall ensure that

1. the casing of the sealed radioactive substance is checked for leak tightness before continuing to be used by an authorised expert appointed in accordance with section 172 subsection (1), first sentence, no. 4 of the Radiation Protection Act, and
2. the test report is submitted to the competent authority on request.

(4) The radiation protection executive shall ensure that any leaks and lack of integrity that are detected are communicated to the competent authority without undue delay.

Section 90

Radiation measurement equipment

(1) The radiation protection executive shall ensure that suitable radiation measurement equipment is used to measure the personal dose, the ambient dose, the ambient dose rate, the surface contamination and the activity of air and water.

- (2) The radiation protection executive shall ensure that measurement equipment

for photon radiation of the type designated in section 1 subsection (1) no. 13 of the Measuring and Calibration Ordinance (*Mess- und Eichverordnung*) are only used for the following purposes if they comply with the Measuring and Calibration Act (*Mess- und Eichgesetz*):

1. for physical radiation protection control by means of measurement
 - a) of the personal dose in accordance with section 65 subsection (1), first sentence, section 66 subsection (2), fourth sentence, or subsection (5), or
 - b) of the ambient dose or ambient dose rate in accordance with section 65 subsection (1), second sentence, no. 1,
2. for measurements that delimitate radiation protection areas or determine the time spent exposed in radiation protection areas,
3. for X-ray equipment for measurements to verify compliance with
 - a) the authorisation conditions in accordance with section 13 subsection (1) no. 6(b) of the Radiation Protection Act, or
 - b) of the notification conditions in accordance with section 19 subsection (1) no. 1(c) of the Radiation Protection Act, or
4. for measurements forming part of quality assurance in accordance with section 115 with X-ray equipment for examining humans.

If no measurement equipment complying with the Measuring and Calibration Act is available for photon radiation in accordance with the first sentence for specific measurement purposes, the competent authority may permit other radiation measurement equipment to be used in individual cases if it is suitable for the measurement purposes.

(3) The radiation protection executive shall ensure that radiation measurement equipment which is intended to measure continuously in order to give warning of dangers to human beings and the environment in the event of emergencies, hazardous incidents or other significant incidents, is only used if their failure is indicated by a clearly-audible signal, unless two or more independent measurement devices serve the same measurement purpose.

(4) The radiation protection executive who is the holder of clearance in accordance with section 33 subsection (1) shall ensure that appropriate measurement equipment is used for a clearance measurement in accordance with section 42 subsection (2).

(5) The radiation protection executive shall ensure that

1. the radiation measurement equipment in accordance with subsections (1) to (4)
 - a) meets the requirements of the measurement purpose,
 - b) is available in sufficient quantity, and
 - c) is regularly tested and maintained in terms of its functionality,
2. the date and result of the function test and maintenance check are recorded,
3. records are retained for ten years from the time of the function test or maintenance, and are submitted to the competent authority on request or deposited at a body to be stipulated by it.

In the case of a clearance measurement in accordance with section 42 subsection (2), the radiation protection executive who is the holder of the clearance in accordance with section 33 subsection (1) shall ensure compliance with the obligations in accordance with the first sentence.

Section 91

Marking obligation

(1) The radiation protection executive shall ensure that the following articles, installations and areas are marked in accordance with Annex 10:

1. rooms, apparatus, devices, protective containers, storage containers and casings for radioactive substances that may only be handled on the basis of a licence in accordance with section 6 subsection (1), first sentence, or subsection (3), first sentence, section 7 subsection (1), first sentence, subsection (3), first sentence, or subsection (5), section 9 subsection (1) or section 9b subsection (1a), first sentence, of the Atomic Energy Act, a plan approval decision in accordance with section 9b subsection (1), first sentence, of the Atomic Energy Act, or a licence in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act,
2. installations for the generation of ionising radiation,
3. controlled areas and exclusion areas,
4. areas in which the contamination exceeds the limits designated in section 57 subsection (2), first sentence.

The radiation symbols shall be visibly and permanently applied and in sufficient quantity. With the exception of controlled areas and exclusion areas, the marking shall contain the words "Caution – Radiation", "Radioactive", "Nuclear Fuels" or "Contamination", insofar as this is possible depending on the size and properties of the object to be marked.

(2) The marking shall not be required in the case of containers or devices that are used within a controlled area in areas intended therefor, as long as

1. the person who is tasked with this use is present in these areas, or
2. these areas are secured against unintentional entry.

The first sentence shall not apply to containers and devices which contain highly active radiation sources.

(3) The radiation protection executive shall ensure that protective containers and storage containers that are marked in accordance with subsection (1) are only used to store radioactive substances.

Section 92

Special marking obligations

(1) The radiation protection executive shall ensure that

1. highly active radiation sources, where technically possible, and their protective containers or storage containers, are visibly and permanently designated during manufacture with a distinctive identification number in addition to the marking with the radiation symbol in accordance with Annex 10, and
2. the identification number applied is communicated to the Federal Office for Radiation Protection within a one-month period.

If additional marking of the highly active radiation sources is not technically possible, or if reusable protective containers or storage containers are used, they shall be additionally affixed with the information "highly-radioactive".

(2) The radiation protection executive shall ensure that all storage containers which contain unsealed radioactive substances the activity of which exceeds 10^4 times the limits of Annex 4 Table 1 column 2 are marked in such a way that the following details can be identified:

1. radionuclide,

2. chemical compound,
3. filling date,
4. activity on the filling date or on a reference date to be specified separately and adjacently,
5. radiation protection executive at the time of filling, and
6. name of the party which filled the radioactive substances.

Identification numbers, references and other abbreviations may only be used if these are generally known or can easily be taken from the records in accordance with section 85 subsection (1), first sentence, no. 2.

(3) Subsection (2) shall apply mutatis mutandis to devices that contain enclosed radioactive substances non-fixed in unenclosed form, the activity of which exceeds the limits of Annex 4 Table 1 column 4.

Section 93

Removal of markings

(1) The radiation protection executive shall ensure that markings in accordance with section 91 subsection (1) are removed from articles that have been removed from radiation protection areas in accordance with section 58 subsection (2), first sentence.

(2) The radiation protection executive who is the holder of clearance in accordance with section 33 subsection (1) shall ensure that markings in accordance with section 91 subsection (1) are removed after clearance is issued in accordance with section 31 subsection (1).

Section 94

Relinquishment of radioactive substances

(1) The radiation protection executive shall ensure that substances that may only be handled on the basis of a licence in accordance with section 6 subsection (1), first sentence, or subsection (3), first sentence, section 7 subsection (1), first sentence, subsection (3), first sentence, or subsection (5), section 9 subsection (1) or section 9b subsection 8(1a), first sentence, of the Atomic Energy Act, of a plan approval decision in accordance with section 9b subsection (1), first sentence, of the Atomic Energy Act, or of a licence in accordance with section 12 subsection (1) no. 1 or 3 of the Radiation Protection Act, may only be relinquished to persons who have the requisite licence.

(2) When enclosed radioactive substances are relinquished for further use, the radiation protection executive shall ensure that the acquirer in accordance with the second sentence receives a certificate stating that the casing is leak-proof and free of contamination. The certificate shall specify the body that performed the test, as well as the date, type and result of the test.

(3) The radiation protection executive shall ensure that highly active radiation sources are only relinquished on condition that documentation from the manufacturer is attached, which shall include the following:

1. the identification number,
2. information on the type and activity of the radiation source, and
3. photographs or technical drawings
 - a) of the type of radiation source,
 - b) of a typical protective container or storage container, and
 - c) of an appropriate transport container.

If documentation from the manufacturer in accordance with the first sentence is not available, the radiation protection executive shall ensure that highly active radiation sources are only relinquished if the certificate of an authorised expert containing the information in accordance with the first sentence, nos. 1 and 2, as well as own photographs or technical drawings in compliance with the first sentence no. 3, are attached thereto.

(4) The radiation protection executive shall ensure that highly active radiation sources which are no longer handled, or are no longer to be handled once their use is ended,

1. are relinquished to the manufacturer, supplier or another licence-holder, or
2. are relinquished or stored as radioactive waste.

(5) The radiation protection executive shall ensure that radioactive substances that are released for transportation or transshipment on public traffic routes, or on traffic routes that are accessible to the public, without prejudice to section 4 of the Ordinance on the Disposal of Radioactive Waste (*Atomrechtliche Entsorgungsverordnung*), are conveyed by persons who are entitled to transport goods in accordance with section 4 of the Atomic Energy Act or with sections 27 or 28 of the Radiation Protection Act. The radiation protection executive shall also ensure that, when they are handed over, the radioactive substances are packed in accordance with the legal provisions applicable to the respective mode of transport. If there are no such legal provisions, the radioactive substances shall be packed according to the requirements for the intended mode of transport according to the scientific and technical state-of-the-art. The substances may not be surrendered for transshipment if the packaging is obviously damaged or leaking.

(6) Anyone who transports radioactive substances shall ensure that these substances are only relinquished to the recipient or to a person authorised by the recipient to receive them. The transporting party shall safeguard the requisite protection against loss, disruptive action or other third-party interference until handover. The competent authority may permit exceptions from the first sentence in individual cases insofar as the necessary protection against loss, disruptive action or other interference by third parties is ensured.

Section 95

Take-back of highly active radiation sources

Anyone who has manufactured highly active radiation sources or imported them from a country which is not a Member State of the European Union into the territorial scope of this Ordinance, or brought them from a Member State of the European Union into the territorial scope of this Ordinance, shall take them back, or shall ensure that they can be taken back by third parties.

Section 96

Surrender of stray radiation emitters

(1) The manufacturer and importer may only transfer a stray radiation emitter to another person for operation not requiring an authorisation if the emitter satisfies the conditions set out in accordance with Annex 3 Part D nos. 1 to 3.

(2) The manufacturer and the importer may only transfer a stray radiation emitter the operation of which requires a licence to another person if the stray radiation emitter bears a clearly-visible indication of the licence requirement.

(3) For the protection of persons or of the general public, the competent authority may order the manufacturer or importer to have the essential radiation protection features of a stray radiation emitter that can be operated without a licence and that is not type-

approved tested before transferring the stray radiation emitter to another person.

Section 97

Storage and availability of documents

(1) The radiation protection executive shall ensure that, with regard to practices which require an authorisation in accordance with section 12 subsection (1) of the Radiation Protection Act, a copy of the licence certificate is permanently stored.

(2) The radiation protection executive shall also ensure that the operating manual is kept available with

1. installations for the generation of ionising radiation,
2. X-ray equipment,
3. stray radiation emitters, and
4. equipment or devices containing sealed radioactive substances.

(3) The radiation protection executive shall furthermore ensure that the following are kept at the ready:

1. in the case of installations for the generation of ionising radiation requiring an authorisation, the most recent test report in accordance with section 88 subsection (1), first sentence, no. 1 (b),
2. in the case of notifiable installations for the generation of ionising radiation, the most recent test report in accordance with section 88 subsection (5),
3. in the case of irradiation facilities and devices for gamma radiography, in each case the most recent test report in accordance with section 88 subsection (1), first sentence, no. 1 (b) and section 89 subsection (1),
4. in the case of X-ray equipment requiring a licence, the most recent test report in accordance with section 88 subsection (4) no. 1,
5. in the case of notifiable X-ray equipment
 - a) a certificate from an officially-appointed authorised expert in accordance with section 19 subsection (3), first sentence, no. 1 of the Radiation Protection Act,
 - b) the most recent test report in accordance with section 88 subsection (4) no. 1, and
 - c) the certificates on tests carried out by authorised experts after significant amendments to the operation of the X-ray equipment, and
6. in the case of stray radiation emitters requiring a licence, the most recent test report in accordance with section 88 subsection (5).

Section 98

Instruction in practices with radioactive sources

The radiation protection executive shall ensure that, in connection with use on people or use on animals in veterinary medicine,

1. the persons employed in the operation of an installation for the generation of ionising radiation, of an irradiation device, or of X-ray equipment, are instructed in proper handling with a German-language operating manual by a suitably-qualified person,
2. the instruction is carried out on first start-up by a suitably-qualified person of the manufacturer or supplier,
3. records are made without undue delay regarding the instruction, and
4. the records are retained for the duration of operation.

The first sentence shall also be applied when X-rays are used outside use on people or use on animals in veterinary medicine, as well as in connection with the operation of stray

radiation emitters.

Division 6

Protection of the public and of the environment

Section 99

Limitation of the discharge of radioactive substances

(1) For the planning, construction, operation, decommissioning, safe enclosure and dismantling of nuclear installations, installations within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation and installations, the limits of the effective dose of exposure for members of the public due to discharges of radioactive substances into the air or water from such installations or facilities shall be 0.3 mSv per calendar year.

(2) If several activities are taken into account for compliance with the dose level in accordance with section 80 subsection (1) of the Radiation Protection Act, the competent authority shall endeavour to ensure that the totality of discharges of radioactive substances from these practices into the air or water also complies with the dose levels stipulated in subsection (1).

(3) The radiation protection executive shall ensure compliance with the limits of subsection (1).

(4) The radiation protection executive shall ensure that radioactive substances are not discharged into the environment in an uncontrolled manner.

Section 100

Establishment of the expected exposure of members of the public

(1) Within the framework of the licensing or notification procedure for practices in accordance with section 4 subsection (1) no. 1 and nos. 3 to 8 of the Radiation Protection Act, as well as of remaining residues left behind in the monitoring in accordance with section 63 subsection (1) of the Radiation Protection Act, the radiation protection executive shall assess the expected exposure of a representative person, taking account of the pathways of exposure, living habits of the representative person and other assumptions designated in Annex 11, Parts A to C or, in the case of residues left behind in the monitoring, of the pathways of exposure designated in Annex 6. The competent authority may assume that the limits of section 80 of the Radiation Protection Act, and section 99 of this Ordinance, are complied with if this is proven on the basis of the general administrative provisions in accordance with subsection (3), first sentence.

(2) The establishment in accordance with subsection (1) shall not be necessary

1. in the case of practices in accordance with section 4 subsection (1) no. 7 of the Radiation Protection Act that are notifiable in accordance with section 17 subsection (1) of the Radiation Protection Act,

2. in the case of practices in accordance with section 4 subsection (1) no. 8 of the Radiation Protection Act,

- a) which are exercised in connection with use on people or use on animals in veterinary medicine, or
- b) which are notifiable in accordance with section 19 subsection (1) no. 2 of the Radiation Protection Act, or
- c) which are not covered by (a) or (b) insofar as there are no indications that the limits designated in section 99 subsection (1), or the limits of section 80 subsection (1) and 2 of the Radiation Protection Act, may be exceeded on the basis of practices in accordance with section 4 subsection (1), first sentence, of the Radiation Protection

Act at this location, or at other locations to be included in accordance with section 99 subsection (2), or

3. if the competent authority in accordance with section 102 subsection (2), first sentence, refrains from the determination of activity quantities and activity concentrations.

(3) With the consent of the Bundesrat, the Federal Government shall issue general administrative provisions on the assumptions to be used as the basis and on the calculation methods for the establishment of the expected exposure of a representative person. The criteria for the consideration of other practices required in accordance with section 80 subsection (4) of the Radiation Protection Act and section 99 subsection (2) of this Ordinance shall also be incorporated into the general administrative provisions.

(4) To establish the expected exposure, the competent authority may request the following information from other authorities on other practices that have already been approved or notified, as well as on practices in other ongoing licensing or notification procedures:

1. actual or expected discharges in exhaust air or waste water,
2. data on meteorological or hydraulic dispersion conditions,
3. actual or expected body doses from direct radiation.

Section 101

Establishment of the exposure received by members of the public

(1) The competent authority shall annually assess the body doses received in the previous calendar year by a representative person in accordance with section 80 subsections (1) and (2) of the Radiation Protection Act, taking into account the pathways of exposure in Annex 11 Parts A to C or, in the case of residues left behind in the monitoring, of the pathways of exposure, living habits of the representative person, and other assumptions for the following authorised or notified practices designated in Annex 6:

1. practices in accordance with section 4 subsection (1) nos. 3 to 6 of the Radiation Protection Act,
2. disposal or recovery of residues left in the monitoring in accordance with section 63 subsection (1) of the Radiation Protection Act.

The exposure shall be established in a realistic manner. With the approval of the Bundesrat, the Federal Government shall issue general administrative provisions on further assumptions to be made and on the calculation methods to be applied for the establishment of the exposure received by a representative person.

(2) The establishment in accordance with subsection (1) shall not be necessary in the case of

1. practices in connection with use on people for non-medical purposes in relation to the exposure of the person on whom the ionising radiation or the radioactive substance is applied,
2. practices in connection with use on animals in veterinary medicine, including subsequent to the release of the animal, in relation to the exposure of the person accompanying animals,
3. practices in accordance with section 4 subsection (1) no. 7 of the Radiation Protection Act which are notifiable in accordance with section 17 subsection (1) of the Radiation Protection Act,
4. practices in accordance with section 4 subsection (1) nos. 1 and 7 of the Radiation Protection Act in cases in which the effective dose does not exceed 0.1 mSv per calendar year.

(3) If the competent authority has indications that the limits in accordance with section 80 of the Radiation Protection Act are exceeded, all other practices which were

also included in the licensing procedure shall be included in the establishment of body doses in accordance with section 80 subsections (1) and (2) of the Radiation Protection Act.

(4) To establish the exposure received by a representative person, the competent authority may order the radiation protection executive to determine and communicate the following data on practices in accordance with subsection (1) at least once per year:

1. if radioactive substances are discharged, the data required to describe the meteorological and hydrological dispersion conditions, in addition to the information in accordance with section 103 subsection (1),
2. data which are appropriate for establishing the exposure to the representative person which is generated by direct radiation.

(5) The competent authority shall document the exposures to the representative person determined by it. They shall be made available to all stakeholders on request. In any case, the determined exposures for the practices in accordance with subsection (1), first sentence, no. 1 shall be published annually.

(6) The Federal Office for Radiation Protection shall be competent for the establishment in accordance with subsection (1), first sentence, no. 1 insofar as the practices designated therein are carried out on the operating site of installations or facilities in accordance with section 6, 7, 9 or section 9b of the Atomic Energy Act.

Section 102

Permissible discharges of radioactive substances

(1) For the operation, decommissioning, safe enclosure and dismantling of nuclear installations, installations within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation and equipment, the competent authority shall determine the permissible discharges of radioactive substances into the air and water by limiting the activity concentrations or quantities. Proof of compliance with the limits of section 99 subsection (1) shall be deemed to have been provided if these limits are not exceeded.

(2) In the case of installations or facilities in accordance with subsection (1) that do not require a licence in accordance with section 6, 7, 9 or 9b of the Atomic Energy Act, or a plan approval decision in accordance with section 9b of the Atomic Energy Act, the competent authority may refrain from determining activity amounts and concentrations, and may consider proof in accordance with section 100 subsection (1) that the annual average limits specified in section 99 subsection (1) have been complied with if the activity concentrations for discharges of radioactive substances into the air or water from radiation protection areas of the installations or facilities concerned that are permissible in accordance with Annex 11 Part D are not exceeded. If the values of Annex 11 Part D are complied with, it shall be presumed that the effective dose from discharges of radioactive substances from this practice in the air or water does not exceed, respectively, the range of 10 mSv per calendar year. Unless otherwise determined by the competent authority, the permissible activity concentrations shall be complied with at the boundary of the radiation protection area. The first sentence shall not apply if the competent authority has indications that the limits designated in section 99 subsection (1), or the limits of the section 80 subsection (1) and (2) of the Radiation Protection Act, can be exceeded at a location due to discharges or direct irradiation from the installations or facilities designated in subsection (1) at this location, or at other locations to be included in accordance with section 99 subsection (2).

Section 103

Emissions and immissions monitoring

(1) The radiation protection executive shall ensure that discharges from nuclear installations, installations within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation and equipment

1. are monitored, and
2. are communicated to the competent authority at least annually; the discharges shall be specified by type and activities.

The competent authority may fully or partially exempt from the notification obligation if it is able to sufficiently estimate by other means that the limits of section 99 subsection (1), taking account of section 99 subsection (2), are not exceeded. The second sentence shall not apply to installations for the fission of nuclear fuels for the commercial generation of electricity, or to installations for processing irradiated nuclear substances,

(2) The competent authority may order that, in the case of the operation, decommissioning, safe enclosure and dismantling of nuclear installations, installations within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation and installations, the activity of samples from the surrounding area, as well as ambient doses for monitoring exposure by direct irradiation, shall be determined by measurement in accordance with a plan that is to be established, and that the measurement results are to be recorded, provided to the competent authority on request and made accessible to the public. The competent authority may designate the body which is to conduct the measurements.

(3) To ensure a uniform national quality standard in emissions and immissions monitoring, the federal administrative authorities designated in Annex 12 shall, as control centres, conduct comparative measurements and comparative analyses. The control centres shall furthermore be tasked with developing and determining sampling, analysis and measurement procedures, in addition to summarising, processing and documenting the data on emissions and immissions monitoring. The National Meteorology Institute (*Physikalisch-Technische Bundesanstalt*) shall provide radioactivity standards for measurements of the gamma ambient dose rate of the background radiation.

(4) The Federal Office for Radiation Protection shall conduct control measurements to review the emission measurements in accordance with subsection (1), and shall communicate the results of the measurements to the competent authority. The radiation protection executive and the measuring bodies commissioned by him or her shall permit the control measurements to be performed. In order to ensure the quality of his or her emission measurements, the radiation protection executive shall participate in comparative measurements and comparative analyses by the Federal Office for Radiation Protection. The quality of the control measurements shall also be ensured by participating in these ring trials.

Section 104

Limiting exposure due to hazardous incidents

(1) The radiation protection executive shall ensure, in the planning of structural or other technical protection measures against hazardous incidents in or to a nuclear power plant for the generation of electricity, until decommissioning in accordance with section 7 subsection (3) of the Atomic Energy Act, without prejudice to the requirements of section 8 of the Radiation Protection Act, that no higher body doses should be used in the vicinity of the installation because of the discharge of radioactive substances into the surrounding are:

1. an effective dose of 50 mSv,
2. an equivalent dose of the thyroid of 150 mSv,
3. an equivalent dose of the skin, hands, forearms, feet and ankles of 500 mSv each,
4. an equivalent dose of the ocular lens, the gonads, uterus and bone marrow (red) of 50 mSv each,
5. an equivalent dose of the bone surface of 300 mSv, and
6. an equivalent dose of the large intestine, lungs, stomach, bladder, chest, liver, oesophagus, the other organs or tissues as in accordance with Annex 18 Part C no. 2 footnote 1, unless listed in no. 4, of 150 mSv each.

The scientific and technical state-of-the-art shall govern the adequacy of precautions against hazardous incidents in accordance with the first sentence. The authorising authority may, in particular, consider these precautions to have been taken if the applicant has based the design of the nuclear power plant on the hazardous incidents which, in accordance with the published safety requirements for nuclear power plants and the interpretations of the safety requirements for nuclear power plants, must determine the design of a nuclear power plant.

(2) Subsection (1), first and second sentences, shall also apply to the storage of irradiated nuclear fuels in accordance with section 6 of the Atomic Energy Act at the respective locations of the nuclear power plants licensed in accordance with section 7 of the Atomic Energy Act, as well as for facilities of the Federation for securing and final disposal of radioactive waste in accordance with section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act.

(3) The radiation protection executive shall ensure that, in the planning of facilities in accordance with section 7 subsection (1) of the Atomic Energy Act other than those listed in subsection (1), first sentence, as well as in planning for the decommissioning, the safe enclosure of the finally decommissioned facilities, and the dismantling of the facilities or parts thereof in accordance with section 7 subsection (3), first sentence, of the Atomic Energy Act, structural or technical protection measures are taken which take into account the potential magnitude of damage in order to limit exposure from hazardous incidents due to the discharge of radioactive substances into the surrounding area. The authorising authority shall define the type and scope of the protective measures in consideration of the individual case, in particular of the potential risk associated with the facility and the probability of the occurrence of a hazardous incident.

(4) Subsection (3) shall apply mutatis mutandis to

1. the other activities in accordance with section 6 subsection (1) and section 9 subsection (1) of the Atomic Energy Act,
2. dismantling and decommissioning measures in the context of activities in accordance with section 6 subsection (1) and section 9 subsection (1) of the Atomic Energy Act,
3. for activities in accordance with section 12 subsection (1) no. 3 of the Radiation

Protection Act in conjunction with section 12 subsection (4) of the Radiation Protection Act, in which more than 10^7 times the exemption levels of Annex 4 Table 1 column 2 are handled as an unsealed radioactive substance, or more than 10^{10} times the exemption levels in accordance with Annex 4 Table 1 column 2 are handled as enclosed radioactive substances, unless

- a) the radioactive substances in an individual establishment or independent branch establishment, or at the place of activity of the applicant in the case of non-commercial operators, are handled in several buildings or parts thereof, installations or facilities that are spatially separated,
- b) the activity of radioactive substances in the individual buildings or parts thereof, installations or facilities does not exceed the stated multiples of the exemption levels, and
- c) it is adequately ensured that the radioactive substances from the buildings or parts thereof, installations or facilities cannot interact with each other.

(5) Subsections (1) to (4) shall not apply to goods that are conveyed as dangerous goods in accordance with section 2 of the Transport of Dangerous Goods Act.

(6) With the consent of the Bundesrat, the Federal Government shall issue general administrative provisions in which protective goals are determined for the prevention of hazardous incidents in accordance with subsections (3) and (4). These shall take into account the likelihood of the occurrence of the magnitude of damage and, in the case of practices in accordance with section 12 subsection (1) no. 3 of the Radiation Protection Act, the multiple of the exemption levels for unsealed and enclosed radioactive substances.

Division 7

Incidents

Section 105

Preparatory measures for the prevention, detection and limitation of the effects of an incident during use on humans

(1) The radiation protection executive shall ensure during the use of ionising radiation or radioactive substances on humans that appropriate measures are taken systematically

1. to prevent an incident,
2. to detect an incident, and
3. in the event of an incident, to keep the negative impact as small as possible.

(2) The selection of measures shall take into consideration the risk associated with the practice.

Section 106

Preparatory measures for emergencies or hazardous incidents

(1) The radiation protection executive shall ensure that the authorities competent for disaster protection and public safety are provided with the necessary information and requisite consultation for their planning for the prevention of risks from ionising radiation and for the restriction or removal of negative effects of an emergency or hazardous incident. In addition, the radiation protection executive shall ensure that the authorities and organisations competent in accordance with section 115 subsection (1) nos. 2 and 3 of the Radiation Protection Act are provided with the information and consultation that they need for the information, basic and further training of persons identified as emergency workers or as persons responsible for emergency operations in accordance with section 113 subsection (1) no. 2 or 3 of the Radiation Protection Act for deployment in emergencies in connection with activities of the radiation protection executive.

(2) The radiation protection executive shall furthermore ensure that the requisite trained personnel and tools required for limiting and eliminating the dangers resulting from emergencies or hazardous incidents on the operating site are kept available. He or she shall prove their operational capability vis-à-vis the competent authority. This may also be done by proving an entitlement to the use of an institution appropriate for carrying out these tasks.

(3) Subsections (1) and (2) shall not apply

1. to the handling of radioactive substances the activities of which do not exceed the exemption levels of Annex 4 Table 1 column 2 by more than

1. 10^7 times, in the case of unsealed radioactive substances,
2. 10^{10} times, in the case of enclosed radioactive substances, and

2. to the operation of X-ray equipment, stray radiation emitters as well as installations for the generation of ionising radiation, if their erection does not require a licence in accordance with section 10 of the Radiation Protection Act.

The first sentence shall also apply if, in an independent establishment or independent branch establishment, in the case of non-commercial operators at the place of activity of the applicant, radioactive substances are handled in several installations or facilities that are spatially separated, the activity of the radioactive substances in the individual installations or facilities does not exceed the values of the first sentence, and it is adequately ensured that the radioactive substances from the individual installations or

facilities cannot interact with each other.

(4) Insofar as the authority competent for disaster response or public safety has created an external emergency response plan in accordance with section 101 subsection (1) of the Radiation Protection Act for the event of an emergency, the radiation protection executive shall furthermore ensure that members of the public who could be affected by an emergency are suitably informed at least every five years without request about the safety measures, planned measures for warning and protection of the public, as well as recommendations for behaviour in the case of possible emergencies. The radiation supervisor shall ensure that this information is made generally accessible and can be accessed online at any time. The information shall supplement the information of the competent authorities of the Federation and of the *Länder* in accordance with section 105 of the Radiation Protection Act, and must include the information designated in Annex 13. The radiation protection executive shall ensure that his or her information is updated in the event of significant changes that could have an impact on the safety or protection of the public. Insofar as the information is intended for the protection of the public, the radiation protection executive shall coordinate it with the authorities competent for disaster response and public safety. The radiation protection executive shall coordinate the manner in which the information is provided, repeated and updated with the authorities competent for disaster response and those responsible for public safety.

Section 107

Measures in the event of an emergency or hazardous incident

Beyond the scope of section 72 subsection (3) of the Radiation Protection Act, the radiation protection executive shall ensure that, in the event of an emergency or hazardous incident, all necessary measures are taken to reduce the consequences of the emergency or hazardous incident.

Section 108

Reporting a significant incident

(1) The radiation protection executive shall ensure that the occurrence of an emergency, hazardous incident or another significant incident is reported in accordance with section (2) without undue delay. Another incident shall in particular be deemed to be significant if one of the criteria designated in Annex 14 or 15 is satisfied.

(2) The report shall include all available information that is required for the assessment of the significant incident. Insofar as is possible, the causes and effects, as well as the measures for eliminating the effects and preventing this kind of incident, shall be stated.

(3) The radiation protection executive shall ensure that additional information needed for a complete evaluation is submitted to the competent authority without undue delay after completion of the investigation in accordance with section 109 subsection (1). He or she shall ensure that the competent authority is provided with a complete summary report at the latest six months after the occurrence of the significant incident, including the presentation of the measures for eliminating the effects and preventing this kind of incident. The competent authority may agree to a later submission.

(4) The radiation protection executive shall ensure that the occurrence of an emergency, hazardous incident or, if necessary, another significant incident, is reported to the authorities competent for disaster response and public safety without undue delay after becoming aware thereof. The radiation protection executive shall furthermore ensure that the occurrence of a significant incident that could lead to or has led to a transregional or regional emergency is reported to the Radiological Situation Centre of the Federation (*Radiologisches Lagezentrum des Bundes*) without undue delay in accordance with

section 106 of Radiation Protection Act.

Section 109

Investigation, recording and retention

(1) The radiation protection executive shall ensure that the causes and effects of an incident are investigated without undue delay and in a systematic manner.

(2) Without prejudice to section 90 subsection (2), first sentence, of the Radiation Protection Act, the radiation protection executive shall ensure that the occurrence of an incident, the results of the investigation in accordance with subsection (1), as well as the measures taken to remedy the effects and prevent an incident, are recorded without undue delay.

(3) Without prejudice to section 90 subsection (2), third sentence, of the Radiation Protection Act, the radiation protection executive shall ensure that the records in accordance with subsection (2) are protected against unauthorised access.

(4) Without prejudice to section 90 subsection (2) second, fourth and fifth sentences, of the Radiation Protection Act, the radiation protection executive shall ensure that the records in accordance with subsection (2) are retained for 30 years and submitted to the competent authority on request. The retention period shall begin on the occurrence of the incident.

Section 110

Tasks of the competent supervisory authorities

(1) Within the framework of supervision under radiation protection law, the competent authority shall collect, assess and evaluate reports in accordance with section 108.

(2) The competent authority

1. shall inform the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety about any significant incident without undue delay, and
2. in the case of a significant incident involving medical exposure and exposure of the person examined in the case of a non-medical use, shall transmit the information on the significant incident without undue delay in pseudonymised form to the central body in accordance with section 111.

Should an authority of the *Länder* have competence, the information transmission in accordance with the first sentence shall be effected by the competent highest *Land* authority.

(3) If a significant incident involving medical exposure relates to a use of radioactive substances or ionising radiation for the purpose of medical research, the competent authority shall inform the authority competent for the licence or notification of the facts without undue delay. In doing so, it shall also transmit the information on the radiation protection executive and the licence in accordance with section 31 subsection (1) or the notification in accordance with section 32 subsection (1) of the Radiation Protection Act.

Section 111

Tasks incumbent on the central body

(1) The central body

1. shall establish and operate an electronic system for the collection, processing

and evaluation of information on significant incidents involving medical exposure and in the case of the exposure of the examined person with a non-medical use,

2. shall define the procedures, form and content of the transmission of information in accordance with section 110 subsection (2), first sentence, no. 2,
3. shall record and process information on a significant incident, and shall evaluate this, in particular with respect to the transferability and significance of the knowledge for other uses and other users,
4. shall inform the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety without undue delay of the information at its disposal and of its evaluation of a significant incident,
5. shall make the information in the system in accordance with no. 1 available to the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, as well as to the competent authorities, insofar as this is required for the performance of their tasks,
6. shall conduct regular systematic scientific research of the evaluations performed, and shall publish the results, including the recommendations for radiation protection derived therefrom, and
7. shall exchange information with the bodies competent for the notification procedures in accordance with the law on medical devices and on medicinal products, as well as with other bodies acting in the area of medicinal product safety and medical device safety, and shall take their knowledge into consideration in its evaluation and scientific analysis.

- (2) The central body shall be the Federal Office for Radiation Protection.

Section 112

Reporting and recording of incidents in accordance with other legal provisions

(1) The provisions on the reporting and recording of incidents in accordance with the law on medicinal products and the law on medical devices shall remain unaffected thereby.

(2) Sections 108 to 110 shall not apply within the territorial scope of the Nuclear Safety Commissioner and Reporting Ordinance (*Atomrechtliche Sicherheitsbeauftragten- und Meldeverordnung*).

Section 113

Exception

This Division shall not apply to the notifiable operation of an aircraft or spaceship.

Division 8

Use of ionising radiation or radioactive substances on humans

Sub-division 1

Technical requirements

Section 114

Requirements for equipment in use on humans

(1) The radiation protection executive shall ensure that X-ray equipment is only used on humans if it

1. has a function that displays the parameters for establishing the exposure received by the person examined or treated through the use, or, if this is not possible with the state-of-the-art, allowing the exposure received by the person examined or treated to be ascertained by other means,
2. has a function that electronically records the parameters that are required for establishing the exposure of the person examined or treated and that is electronically usable for quality assurance,
3. in the case of use for screening, has a function for electron image amplification and for automatic dose regulation, or another at least equivalent function,
4. in the case of use for screening in interventions, has a function in addition to the device or function under no. 1 that continuously displays the parameters for establishing the exposure of the person examined to the person in accordance with section 145.

(2) The radiation protection executive shall ensure that an installation for the generation of ionising radiation or an irradiation device, each providing a photon or particle energy of at least 1 MeV, is only used for treating persons if it permits the parameters to determine the dose distribution to be verified.

(3) The radiation protection executive shall ensure that an installation for the generation of ionising radiation is only used for the examination of persons if it has a function that shows the parameters for establishing the exposure of the person being examined to the person in accordance with section 145, or, if this is not possible with the state-of-the-art, which is able to directly show by other means the exposure received by the person being examined or treated.

Section 115

Quality assurance before start-up; acceptance test

(1) In installations for the generation of ionising radiation, irradiation facilities, X-ray equipment and other devices or equipment used for the use of radioactive substances or ionising radiation on humans, the radiation protection executive shall ensure that the requisite quality for the use as defined in section 14 subsection (1) no. 5 of the Radiation Protection Act is achieved prior to start-up, and that an acceptance test is conducted with his or her involvement by the respective manufacturer or supplier of the individual components for this purpose.

(2) The radiation protection executive shall ensure that the reference levels for the constancy assessment in accordance with section 116 are determined as part of the acceptance test.

(3) If the installation for the generation of ionising radiation, the irradiation device,

the X-ray equipment or other device or apparatus is part of an overall system for use on humans, the radiation protection executive shall also use a test to ensure that the quality of the overall system required for the use within the meaning of section 14 subsection (1), no. 5 of the Radiation Protection Act has been achieved.

(4) Subsections (1) to (3) shall apply mutatis mutandis after every change to an installation for the generation of ionising radiation, irradiation device, X-ray equipment, another device, or equipment in accordance with subsection (1) which can influence the required quality for use as defined in section 14 subsection (1) no. 5 of the Radiation Protection Act. In this case, the test may be limited to the change and its effects. If the final assessment by the manufacturer or supplier is no longer possible, the radiation protection executive shall ensure that an equivalent test is conducted by a person with the requisite specialist knowledge in radiation protection.

Section 116

Constancy assessment

(1) The radiation protection executive shall ensure that installations for the generation of ionising radiation, irradiation facilities, X-ray equipment or other devices or equipment in accordance with section 115 subsection (1) are checked after start-up regularly and at the required intervals for continued compliance with the requisite quality within the meaning of section 14 subsection (1) no. 5 of the Radiation Protection Act (constancy assessment). It shall particularly be verified in so doing whether the reference levels collected in accordance with section 115 subsection (2) are complied with.

(2) The radiation protection executive shall ensure that the test equipment is used in the constancy assessment which was used in the acceptance test for the determination of the reference levels in accordance with section 115 subsection (2). The competent authority may consent to the use of other test equipment in individual cases if the use of the test equipment used in the acceptance test would lead to a disproportionate impairment of the notified or licensed operation.

(3) It shall furthermore be verified in cases falling under section 115 subsection (3) whether the overall system also continues to achieve the required quality for the use as defined in section 14 subsection (1) no. 5 of the Radiation Protection Act.

(4) If the required quality within the meaning of section 14 subsection (1) no. 5 of the Radiation Protection Act is no longer achieved, the radiation protection executive shall ensure that the causes are identified and eliminated without undue delay.

Section 117

Records

(1) The radiation protection executive shall ensure that the contents, result and time of the tests in accordance with sections 115 and 116 subsections (1) and (3) are recorded without undue delay.

(2) The radiation protection executive shall ensure that records are retained

1. in the case of tests in accordance with section 115, for the duration of the operation, but at least three years after completion of the next complete acceptance test,
2. in the case of tests in accordance with section 116, ten years after completion of the test.

The competent authority may determine derogations from the retention periods.

(3) The radiation protection executive shall present the records to the competent authority and to the medical or dental authority on request.

Section 118

Stock inventory

The radiation protection executive shall ensure that an up-to-date stock inventory is retained of the apparatus, devices and equipment used in the use of radioactive substances or ionising radiation on humans, and submitted to the competent authority on request; the stock inventory in accordance with section 13 of the Ordinance on the installation, operation and use of medical devices may be consulted.

Sub-division 2

Requirements in connection with use on humans

Section 119

Justifying indication

(1) The doctor or dentist providing the justifying indication shall test, in addition to compliance with the requirements in accordance with section 83 subsection (3) of the Radiation Protection Act, whether the envisaged use of ionising radiation or of radioactive substances is a recognised procedure in consideration of the requirements of medical science or an attempted cure the implementation of which requires special justification on the part of the doctor or dentist.

(2) A justifying indication shall also be provided if a request by a referring doctor or dentist is present.

(3) The doctor or dentist providing the justifying indication shall consult the available information on previous medical knowledge prior to the use, where necessary in collaboration with the referring doctor or dentist, in order to prevent any unnecessary exposure. For this purpose, the person to be examined or treated shall be questioned on previous uses of ionising radiation or radioactive substances that may be significant for the envisaged use.

Section 120

Protection of special groups

(1) The radiation protection executive shall ensure that the practising doctor or dentist within the context of the justifying indication asks a woman of child-bearing age whether she is or could be pregnant prior to a use of ionising radiation and radioactive substances, if necessary in collaboration with a referring doctor. If she is pregnant, or if this cannot be ruled out, the urgency of the use shall be reviewed. The second sentence shall apply mutatis mutandis to breastfeeding women in case of the use of unsealed radioactive substances.

(2) With persons who are offered the use of ionising radiation or radioactive substances despite being pregnant or with regard to whom pregnancy cannot be ruled out, the practising doctor or dentist shall use all options for reducing the exposure of such person, and in particular of the unborn child. Where unsealed radioactive substances are used, the first sentence shall apply mutatis mutandis to breastfeeding women.

(3) The radiation protection executive shall ensure that, in the use of ionising radiation or radioactive substances on persons under 18 years of age, appropriate procedures as well as equipment, devices and instruments are available and are used in order to do justice to the particular sensitivity of such persons to radiation.

Section 121

Measures during use

(1) The radiation protection executive shall ensure that written work instructions are drawn up for examinations and treatment with ionising radiation or radioactive substances. These shall be kept available for inspection at all times by the persons involved in such examinations and treatment, and shall be submitted to the competent authority, and to the medical or dental authority, on request.

(2) The radiation protection executive shall ensure that a doctor in accordance with section 145 subsection (1) no. 1, and a medical physics expert for persons whose treatment with ionising radiation or radioactive substances is to be individually determined, define a written irradiation plan relating to this person. The irradiation plan shall incorporate all treatment conditions, particularly the individually-determined dose in the target volume or the activity of the radioactive substance used in consideration of the requirements of medical science.

(3) The radiation protection executive shall ensure that, with treatments on the basis of an individual irradiation plan, compliance with all conditions determined in the irradiation plan is inspected. The inspection shall take place before the start

1. of the first irradiation, or subsequent to an amendment of the irradiation plan, by a doctor in accordance with section 145 subsection (1) no. 1 and a medical physics expert,
2. of each additional irradiation by a doctor in accordance with section 145 subsection (2) no. 2 or 3.

(4) The radiation protection executive shall ensure that a log is kept of every treatment.

Section 122

Restriction of exposure

(1) The radiation protection executive shall ensure that measures are taken to limit the exposure of carers and comforters. He or she shall ensure, within six months after the start of a practice, that an assessment is carried out of whether the determination of dose constraints for the exposure of carers and comforters is an appropriate instrument for optimising radiation protection. The radiation protection executive shall also ensure that a guideline is drawn up for the exposure of carers and comforters.

(2) The radiation protection executive shall ensure that the exposure of persons on whom ionising radiation or radioactive substances are applied is regularly evaluated and assessed for every kind of examination and treatment.

(3) The radiation protection executive shall ensure that the diagnostic reference levels in accordance with section 125 subsection (1) are taken as a basis in examinations of persons with radioactive substances or ionising radiation.

(4) The radiation protection executive shall ensure that a person who has been treated with radioactive substances is not released from the radiation protection area until it can be assumed that an effective dose of no more than 1 mSv can result therefrom for relatives and third parties. In the event of it being necessary in individual cases to release for medical reasons prior to this time, the radiation protection executive shall ensure that this is reasoned in writing and that the competent authority is notified accordingly.

Section 123

Requirements in connection with the operation of X-ray equipment for teleradiology

(1) When conducting the examination, the teleradiologist shall

1. provide the justifying indication after detailed consultation with the doctor, who

must be present at the site of technical implementation in accordance with section 14 subsection (2) no. 3 of the Radiation Protection Act,

2. determine the results of the examination, and

3. be in direct contact with the person who is to carry out the technical implementation of the examination in accordance with section 14 subsection (2) no. 2 of the Radiation Protection Act, and with the doctor who must be present at the site of the technical implementation of the examination in accordance with section 14 subsection (2) no. 3 of the Radiation Protection Act by means of electronic data transmission and telecommunications, in particular for the justifying indication and diagnosis.

(2) The doctor who must be present at the site of technical implementation in accordance with section 14 subsection (2) no. 3 of the Radiation Protection Act shall in particular identify the information needed to determine the justifying indication when conducting the teleradiological examination, and shall forward it to the teleradiologist.

(3) The radiation protection executive shall ensure that, when applying X-ray radiation to humans, the technical teleradiological examination is conducted by persons authorised in accordance with section 145 subsection (2) no. 2 or 3.

(4) When operating X-ray equipment for teleradiology, the radiation protection executive shall ensure that copies of the quality assurance records prior to start-up and in accordance with section 115, and of the constancy assessments in accordance with section 116, as well as of the expert tests in accordance with section 88 subsection (4) no. 1 of all X-ray facilities belonging to the system, are available for inspection at the other facility involved in the teleradiology system. The obligation may also be fulfilled by providing the records in electronic form.

Section 124

Information obligations

(1) The radiation protection executive shall ensure that a person subjected to ionising radiation or radioactive substances is informed about the risk of the use of radiation prior to the use.

(2) Before entering the controlled area, the radiation protection executive shall ensure that carers or comforters are

1. informed of possible risks of exposure, and
2. offered, and where desired given, appropriate written instructions.

(3) The radiation protection executive shall ensure that, after the use of radioactive substances, the person on whom the substances are used, as well as the carer or comforter, are given appropriate written instructions in order to keep exposure emanating from the person, or the contamination of relatives, third parties or the environment, as low as possible. This shall not apply if such exposure or contamination can be ruled out or the person continues in in-patient treatment.

(4) The radiation protection executive shall ensure that, after treatment with ionising radiation or radioactive substances requiring verification of the long-term success of the radiation treatment, a person is informed about appropriate intervals for the check-ups.

Section 125

Diagnostic reference levels, population dose

(1) The Federal Office for Radiation Protection shall determine, prepare and publish diagnostic reference levels for examinations with ionising radiation and radioactive

substances. For the establishment, the Federal Office for Radiation Protection may use the data provided to the competent authority by the medical and dental bodies in accordance with section 130 subsection (3), first sentence, no. 2 for the determination. For this purpose, the competent authority shall transmit the exposure data recorded by the medical and dental bodies to the Federal Office for Radiation Protection once per year.

(2) The Federal Office for Radiation Protection shall check at least every three years after the most recent publication whether the diagnostic reference levels need to be updated, and shall update them if necessary.

(3) The Federal Office for Radiation Protection shall determine the medical exposure of the public and of selected population groups at least every two years.

Section 126

Risk analysis before radiation treatments

(1) Before the first use or significant change of a treatment procedure with radioactive substances or ionising radiation, the radiation protection executive shall ensure that an analysis is conducted to identify and evaluate the risk of unintended exposure to the treated person.

(2) The radiation protection executive shall ensure that the results of the analysis

1. are recorded,
2. are retained for ten years, and
3. are presented to the competent authority on request.

Section 127

Storage, passing on and transmission of records, X-ray images, digital image data and other examination data

(1) The radiation protection executive shall ensure that records in accordance with section 85 subsection (1), first sentence, of the Radiation Protection Act, X-ray images, digital image data and other examination data are stored in such a manner that it is guaranteed for the duration of the retention period in accordance with section 85 subsection (2) of the Radiation Protection Act, that

1. they are available at any time within a reasonable time period and can be made readable directly in the case of electronic storage, and
2. no information changes or losses can occur.

(2) The radiation protection executive shall ensure when storing records in accordance with section 85 subsection (1), first sentence, of the Radiation Protection Act, as well as when storing personal data, X-ray images, digital image data and other examination data on electronic data media that

1. the creator, the source and the time of origin are clearly recognisable,
2. subsequent changes or additions are recognisable as such and stored with information on the creator and time of subsequent changes or additions, and
3. for the duration of the storage, the personal data can be linked at any time to the findings made, the data describing the image creation and processing procedure, the image data and the other records in accordance with section 85 subsection (1), first sentence, of the Radiation Protection Act.

(3) The radiation protection executive shall ensure that it is guaranteed in case of the storage of X-ray images, digital image data and other examination data on electronic data media that

1. all data are retained that were collected which were used for analysis of the findings, or which are stored according to the requirements of medical knowledge for the analysis of the findings, for progression assessment or to avoid further exposure, and
2. data describing the process of the generation and processing of the X-ray images, digital image data and other examination data, insofar as they serve to understand the content of the data designated in no. 1.

Data may be compressed if it is ensured that the diagnostic validity is maintained.

(4) The radiation protection executive shall ensure when passing on or transmitting data in accordance with section 85 subsection (3) of the Radiation Protection Act that the data correspond with the source data and can be read by the addressees. The X-ray images, digital image data and other examination data shall be suitable for an analysis of the findings.

Section 128

Designation of medical and dental bodies for quality assurance

(1) The competent authority shall designate medical and dental bodies for their area of competence in order to assure the quality of the use of ionising radiation or of radioactive substances on humans.

(2) A medical or dental body may only be designated if

1. there are no facts which give rise to concerns about the necessary independence for the performance of their task,
2. the staff, technical and organisational equipment are available that are required in order to carry out its tasks,
3. the persons working for the body have the requisite qualification and experience to carry out the tasks of the medical or dental authority,
4. the modus operandi of the medical or dental authority, and the manner in which the examinations in accordance with section 130 subsections (1) and (2) are carried out, permit one to presume that the tasks will be carried out properly, including compliance with the requirements of medical knowledge, and
5. suitable measures are available for the quality assurance of its examinations.

Section 129

Notification of the commencement and discontinuation of a practice with a medical or dental body

(1) The radiation protection executive shall ensure that

1. the commencement of a practice in connection with the use of ionising radiation or of radioactive substances on people which requires a licence in accordance with section 12 subsection (1), no. 1, 2, 3 or 4 of the Radiation Protection Act, or of a notification in accordance with section 19 subsection (1) of the Radiation Protection Act, is reported to a medical or dental body designated by the competent authority without undue delay, and
2. a copy of the report is sent to the competent authority.

The first sentence shall apply mutatis mutandis in the case of a major modification of a practice.

- (2) The radiation protection executive shall ensure that
 1. the discontinuation of a practice in accordance with subsection (1) no. 1 is communicated without undue delay to a medical or dental body designated by the competent authority, and
 2. a copy of the deregistration is sent to the competent authority.

Section 130

Quality assurance measures by medical and dental bodies

(1) The radiation protection executive shall be subject to the quality assurance test to be conducted by the medical and dental bodies. In particular, the medical and dental bodies shall examine as part of quality assurance whether

1. the respective use of ionising radiation or radioactive substances on humans is justified and the requirements of medical science are respected in the use,
2. the facilities used for generating ionising radiation, irradiation facilities, other devices or installations, as well as the procedures applied in connection therewith, correspond to the quality standards required in accordance with the scientific and technical state-of-the-art in order to keep their exposure as low as possible,
3. the X-ray equipment and the procedures used in connection therewith correspond to the respective requisite quality standards according to the technical state-of-the-art in order to keep their exposure as low as possible,
4. the diagnostic reference levels are not unjustifiably exceeded,
5. a procedure is available with which incidents are systematically detected and processed when ionising radiation or radioactive substances are used on humans, and
6. written work instructions were drawn up in accordance with section 121 subsection (1).

Insofar as radioactive substances or ionising radiation are used by the radiation protection executive for the purpose of medical research, the medical and dental bodies shall verify whether the research project has been carried out properly in compliance with the requirements of medical science with regard to radiation protection.

(2) The medical and dental bodies shall propose options to the radiation protection executive for optimising the use of ionising radiation or radioactive substances on humans, and shall check whether and to what extent the proposals are implemented.

(3) The medical and dental bodies shall inform the competent authority of the following:

1. the results of the tests,
2. a summary of the exposure data collected in the tests,
3. any continuous, unjustified exceedance of the diagnostic reference levels used as a basis in the examination, and
4. any non-compliance with the optimisation proposals.

Personal data of the person examined or treated may not be transmitted.

(4) The medical and dental bodies may transmit the results of the tests, including the name and address of the radiation protection executive, to the body competent for the quality assessment in accordance with the Ninth Division of the Fourth Chapter of Book Five of the Social Code (*Sozialgesetzbuch*). Personal data of the persons treated or examined may not be transmitted.

(5) The medical and dental bodies shall be subject to medical confidentiality with

respect to personal data of persons examined or treated.

(6) The radiation protection executive shall ensure that the medical or dental body is provided on request with all the information that it needs to perform its tasks. The medical or dental body may only process the data transmitted to it in accordance with the first sentence for the purposes designated in subsections (1) and (2).

Section 131

Medical physics expert

(1) The radiation protection executive shall ensure that, in treatment with radioactive substances or ionising radiation that is based on an individual irradiation plan, a medical physics expert is brought in for close cooperation in determining the irradiation plan and the implementation of the treatment.

(2) The radiation protection executive shall ensure that in

1. standardised treatment with radioactive substances or ionising radiation,
2. examinations with unsealed radioactive substances,
3. examinations with ionising radiation which are conducted with a computer tomograph or with devices for three-dimensional imaging of articles with low X-ray contrast, with the exception of tomosynthesis, and
4. interventions in which the X-ray equipment is used for fluoroscopy and which involve considerable exposure

a medical physics expert shall be consulted and brought into cooperation. The extent of the consultation of the medical physics expert shall be determined on the basis of the type and number of examinations or treatment, as well as of the number of devices used.

(3) The radiation protection executive shall ensure that, with all further uses with radioactive substances or ionising radiation, a medical physics expert is consulted to give advice insofar as this is required in order to optimise radiation protection or to guarantee the necessary quality.

Section 132

Tasks of medical physics experts

The radiation protection executive shall ensure that a medical physics expert, if he or she is to be consulted in accordance with section 131, assumes responsibility for the dosimetry of persons on whom radioactive substances or ionising radiation are used, and in particular shall cooperate when implementing the optimisation of radiation protection and the following tasks:

1. quality assurance in the planning and implementation of uses of radioactive substances or ionising radiation on humans, including physical-technical quality assurance,
2. selecting the apparatus, devices and equipment to be used,
3. monitoring the exposure of persons on whom radioactive substances or ionising radiation are used,
4. monitoring compliance with the diagnostic reference levels,
5. investigating incidents,
6. performing risk analyses for treatments, and
7. training and instructing persons involved in use.

Division 9

Special requirements for the use of radioactive substances or ionising radiation for medical research

Section 133

The principle of consent after information and questioning

The radiation protection executive shall ensure that the use of radioactive substances or ionising radiation on humans for the purpose of medical research is only done with consent after information and questioning in accordance with sections 134, 135 and 136 subsection (1) no. 4, as well as subsections (2) and (3).

Section 134

Consent of the person involved in the research project

(1) The radiation protection executive shall ensure that the written consent of the person included in the research project is obtained which states that he or she agrees to the following:

1. the use of radioactive substances or ionising radiation on his or her person, and
2. the examinations that are needed on his or her person before, during and after the use of radioactive substances for monitoring and safeguarding his or her health.

The declarations in accordance with the first sentence may be informally revoked at any time by the person included in the research project.

(2) The radiation protection executive shall furthermore ensure that the consent of the person included in the research projects is obtained and proven:

1. the communication of his or her participation in the research project to the competent authority, and
2. the communication to the competent authority of information regarding his or her exposure caused by the use.

(3) The consent in accordance with subsection (1), first sentence, and subsection (2), shall be provided in person, and shall only be effective if the person included in the research project has reached the age of majority and is able to recognise the type, significance, scope and risks arising from the use of radioactive substances or ionising radiation, and to express his or her intentions accordingly.

(4) If the person is unable to submit the consent in accordance with subsection (1), first sentence, in writing, it may be declared and recorded in another appropriate way in the presence of an impartial witness. The witness shall have been present at the provision of information in accordance with section 135 subsection (2), and shall sign the record of the consent declared in another appropriate way.

(5) The revocation of consent in accordance with subsection (1), first sentence, or subsection (2) shall not impact on the processing of data that was carried out on the basis of the respective consent prior to its revocation, or to the further processing of such data as was collected on the basis of the respective consent prior to its revocation, insofar as

1. the achievement of the research purposes would otherwise be made impossible or seriously impeded,
2. the processing of the data is required in order to ensure that interests in need of protection of the person included in the research project are not harmed, or
3. the processing of the data is required in order to follow the exposure of the person involved in the research project in order to

- a) comply with the obligation to draw up the final report, or
- b) to enable supervision under radiation protection law and quality assurance to be carried out by medical and dental bodies.

Section 135

Information and questioning

(1) The radiation protection executive shall ensure that the person included in the research project is given written information which is understandable to that person on the use before submitting the declarations in accordance with section 134 subsection (1), first sentence, and subsection (2), first sentence, presenting the type, significance, scope and risks of the use of the radioactive substances or the ionising radiation, as well as informing of the conditions and duration of the use, and of the option of revoking the declarations in accordance with section 134 subsection (1), first sentence.

(2) The radiation protection executive shall ensure that the person included in the research project is informed and asked by a doctor or dentist who is in charge of the uses or assigned by the radiation protection executive whether radioactive substances or ionising radiation have already been used on him or her in the past, before submitting the declarations in accordance with section 134 subsection (1), first sentence, and subsection (2). In case of uses requiring a licence, the appointed doctor or dentist shall have the requisite specialist knowledge in radiation protection. The information provided shall include the aspects listed in subsection (1). The radiation protection executive shall ensure that records are prepared on the information and questioning.

Section 136

Use on persons who are incapable of giving consent and on minors

(1) The radiation protection executive shall ensure that radioactive substances or ionising radiation are only used on a person who is not able to recognise the type, significance, scope and risks of the use of the radioactive substances or of the ionising radiation for himself or herself, and to express his or her intentions accordingly, as well as on a minor, if

1. the goal of the research cannot otherwise be attained,
2. it is used on a person who has an illness or suspected illness relating to the research project,
3. the goal is pursued within the framework of the research project to detect this illness, save the life of the person, restore their health, ease their suffering or improve procedures for their examination or treatment in connection with this illness,
4. the legal representative or authorised representative submitted the declarations in accordance with section 134 subsection (1), first sentence, and subsection (2) after they were given the written information in accordance with section 135 subsection (1) and correspondingly informed and questioned in accordance with section 135 subsection (2), first sentence, and
5. the declaration on the part of the person, or their will not to take part in the research project expressed by other means, is complied with.

The first sentence nos. 3 and 5 shall not apply to a research project for which a licence in accordance with the law on medicinal products or on medical devices is required.

(2) The radiation protection executive shall ensure that, in addition to his or her legal representative or authorised representative, the person intended for inclusion in the research project should be appropriately informed. If the minor is able to recognise the type, significance, scope and risks of the use of the radioactive substances or the ionising

radiation for himself or herself, and to express his or her intentions accordingly, his or her personal declarations in accordance with section 134(1), first sentence, and subsection (2) shall also be required.

(3) Section 134 subsection (1), second sentence, subsections (4) and (5), and section 135 subsection (2), fourth sentence, shall apply mutatis mutandis to the consent of the legal representative or authorised representative in accordance with subsection (1) no. 4, as well as to the declarations of the minor in accordance with subsection (2), second sentence.

Section 137

Other prohibitions and restrictions on use

(1) The radiation protection executive shall ensure that radioactive substances or ionising radiation are not used for the purpose of medical research on a pregnant woman or on a person who is interned in an institution in accordance with a judicial or administrative order. The radiation protection executive shall ensure that radioactive substances are not used on a breastfeeding woman for the purpose of medical research.

(2) The radiation protection executive shall ensure that the effective dose as determined by the research project for a healthy person within the meaning of the research project does not exceed the limit of 20 mSv.

(3) The radiation protection executive shall ensure that a healthy person as defined by the research project is excluded from the use on whom a use of radioactive substances or ionising radiation has taken place in the previous ten years for the purpose of medical research or treatment, if it is expected that the renewed use for the purpose of medical research will cause an effective dose that is higher than 10 mSv.

(4) The radiation protection executive shall ensure that radioactive substances or ionising radiation are only used for the purpose of medical research on a healthy person within the meaning of the research project who has not reached the age of 50 if this is particularly necessary in order to achieve the research goal.

Section 138

Special protection obligations

(1) In the case of a use in accordance with section 32 subsection (1) of the Radiation Protection Act, the radiation protection executive shall, prior to the first use, designate a doctor or dentist who is in charge of the uses who has the requisite specialist knowledge in radiation protection and at least two years' experience in the use of radioactive substances or ionising radiation on humans.

(2) The radiation protection executive shall ensure the constant availability of a doctor or dentist who is in charge of the uses within the meaning of section 31 subsection (4) no. 6 of the Radiation Protection Act or of subsection (1) (doctor or dentist who is in charge of the uses) during the use of radioactive substances or of ionising radiation for the purpose of medical research (doctor or dentist who is in charge of the use), or the constant availability of a deputy who has the same qualifications.

(3) The radiation protection executive shall ensure that radioactive substances or ionising radiation are only used on humans for the purpose of medical research by a doctor or dentist who is in charge of the uses, or a doctor or dentist commissioned by him or her and with the requisite specialist knowledge in radiation protection. Section 145 subsection (2) shall remain unaffected thereby.

(4) The radiation protection executive shall ensure that the person included in the research project is examined by a doctor or dentist before radioactive substances or ionising radiation are used. He or she shall ensure that the findings are recorded without

undue delay.

(5) Before the use of radioactive substances or ionising radiation for the purpose of medical research, the radiation protection executive shall ensure that

1. the activity of the radioactive substances to be used is determined,
2. in the case of uses requiring an authorisation, the exposure for each person included in the research project is individually estimated by means of appropriate procedures, and
3. in the case of uses requiring a notification, the exposure for the persons included in the research project is estimated by means of appropriate procedures.

The radiation protection executive shall ensure that the exposure is monitored by means of appropriate procedures and is evaluated with reference to the estimate for each person included in the research project. The radiation protection executive shall ensure that the results of the estimation, as well as the type and result of the monitoring measures, are recorded.

(6) Section 122 subsection (3) shall apply *mutatis mutandis* to uses for examinations for medical research. The authorising authority may determine otherwise in the case of uses requiring an authorisation for examination for the purpose of medical research insofar as the use of the diagnostic reference levels is not suitable for the research project.

Section 139

Quality assurance

(1) The person entitled to conduct medical research and the doctor or dentist who is in charge of the uses shall ensure that, in the use of radioactive substances or ionising radiation for the purpose of medical research, the health and safety as well as the rights and interests of the persons included in the research project are given priority, in particular over the economic and societal interests in the research project.

(2) In the case of a multi-centre study, the person entitled to conduct medical research shall transmit the licence certificate or the significant content of the notification, the determinations regarding the aims, organisation, methods and progression of the research project, as well as other information and instructions for implementing the uses relating to the research project, to the respective radiation protection executives.

(3) The radiation protection executive shall ensure that the licence certificate or the significant content of the notification, the determinations regarding the aims, organisation, methods and progression of the research project, as well as other information and instructions needed to implement the uses relating to the research project, are communicated to the following persons:

1. the doctor or dentist who is in charge of the use,
2. the doctor or dentist assigned by the doctor or dentist who is in charge of the use to explain or implement the use and is appointed to carry out the information or use, and
3. insofar as is needed according to the type of use, the medical physics experts.

(4) The person entitled to conduct medical research shall ensure that the uses of radioactive substances or ionising radiation on people shall be designed in such a way that reliable, authoritative results can be obtained on achieving the purposes of the research. The party entitled to carry out medical research shall retain the results in such a way that complete reporting and review is possible, and shall grant inspection to the competent authority and to the medical or dental body inspection on request.

(5) The person entitled to conduct medical research, and the doctor or dentist who is in charge of the use, shall continuously monitor the performance of the uses on humans

for the purpose of medical research. The monitoring shall in particular be appropriate

1. when recording expected and unexpected radiation effects, to recognise that risks caused by radiation or benefits included in the research project, where appropriate in consideration of the medical benefit for the persons included in the research project, deviate from the information that formed the basis for the authorisation or notification,
2. to ensure compliance with the determinations regarding the aims, organisation, methods and progression of the research project, and the extraction of results, and
3. in the case of a multi-centre study, to ensure compliance with the authorised or notified number of persons included in the research project.

(6) Subsections (1) and (4) shall not apply to a research project for which an authorisation exists in accordance with medicinal product legislation or medical product legislation.

Section 140

Record-keeping obligations; further rules on records

(1) The radiation protection executive shall ensure that

1. the consent in accordance with section 134 subsection (1), first sentence, and subsection (2), also in conjunction with section 136 subsection (1), first sentence, no. 4, and subsection (2), second sentence, are retained for 30 years after being declared,
2. the records in accordance with section 135 subsection (2), fourth sentence, also in conjunction with section 136 subsection (3), and in accordance with section 138 subsection (4), second sentence, and subsection (5), third sentence, are retained for 30 years after the date of the last use, and
3. the consent in accordance with no. 1 and the records in accordance with no. 2 are submitted to the competent supervising authority on request.

(2) Section 85 subsection (1), third sentence, subsection (2), second sentence, and subsection (3), first sentence, nos. 2 and 3, second and third sentences, of the Radiation Protection Act, as well as section 127, shall apply mutatis mutandis to the records in accordance with section 135 subsection (2), fourth sentence, also in conjunction with section 136 subsection (3) and section 138 subsection (4), second sentence, and subsection (5), second sentence, as well as subsection (5), third sentence.

Section 141

Reporting obligations

- (1) The radiation protection executive shall ensure that the competent supervisory authority is informed without undue delay of the completion of the use of radioactive substances or ionising radiation for the purpose of medical research.
- (2) The person entitled to conduct medical research shall ensure that the following is notified to the authorisation or notifying authority without undue delay:
 1. the departure of a radiation protection executive in a multi-centre study, and
 2. the completion of the research project.

(3) The person entitled to conduct medical research shall ensure that the following is notified to the authorisation or notifying authority without undue delay:

1. the discontinuation or interruption of the uses in order to protect the persons

included in the research project against the effects of radiation or because of a change in the risk-benefit analysis, and

2. in the case of authorised uses, the availability of significant new knowledge regarding the benefits associated with the research project, where appropriate in consideration of the medical benefits for the persons included in the research project, or regarding the risks associated with the radiation.

(4) Anyone who has reported a use of radioactive substances or ionising radiation on humans for the purpose of medical research in accordance with section 32 of the Radiation Protection Act shall inform the supervisory authority of a change relating to the proof of necessary financial provision without undue delay in accordance with section 32 subsection (3) in conjunction with section 35 of the Radiation Protection Act, and shall include any available up-to-date evidence.

Section 142

Final report

(1) The person entitled to conduct medical research shall submit a final report to the supervisory authority competent for him or her at the latest twelve months after the completion of the research project, showing in particular the exposure determined for each person included in the research project.

(2) In the case of a multi-centre study,

1. the respective radiation protection executives shall provide the person entitled to conduct medical research without undue delay on completion of the uses under their responsibility with the information needed to prepare the final report in accordance with subsection (1),
2. the final report shall also designate for each facility involved the number of persons on whom radioactive substances or ionising radiation were used within the territorial scope of this Ordinance, and shall list information specific to the facility in such a way that it can be attributed to the individual facilities,
3. the final report must also contain the total number of persons on whom radioactive substances or ionising radiation was used in the territorial scope of this Ordinance, and
4. the supervisory authority competent for the party entitled to carry out medical research shall inform the supervisory authority competent for the radiation protection executive insofar as a considerable deviation from the licence or notification, or a breach of provisions of radiation protection law, emerges from the final report.

(3) The supervisory authority competent for the person entitled to conduct medical research shall inform the authorising or notifying authority insofar as there is any significant deviation between the authorisation or notification and the final report.

(4) The personal data of persons included in the research project shall be pseudonymised in cases falling under subsection (1), and subsection (2) no. 1.

Section 143

Official protection order

(1) If there is concern that the health of a person included in the research project will be harmed due to exceedance of the authorised or notified dose level for the use of radioactive substances or ionising radiation for the purpose of medical research, or if harm to health has already occurred on the basis of an exceedance of the authorised or notified

dose levels, the competent authority shall order that the person be examined by a doctor authorised in accordance with section 175 subsection (1), first sentence. If there is concern about damage to health without an exceedance of the dose levels, the competent authority may order an examination by a doctor authorised in accordance with section 175 subsection (1), first sentence. Section 78 subsection (1) shall apply mutatis mutandis.

(2) If the authority competent in accordance with subsection (1), first or second sentence, has ordered the examination of a person, a further use of radioactive substances or ionising radiation on this person may only be carried out within the framework of the research project with the approval of the competent authority.

Division 10

Use of ionising radiation or radioactive substances on animals in veterinary medicine

Section 144

Use-related requirements

(1) The radiation protection executive shall ensure that, in the use of radioactive substances or ionising radiation on animals in veterinary medicine, a person accompanying animals is only present if this is required due to the circumstances of the individual case. No persons other than the person accompanying animals may accompany the animal. A pregnant woman may not act as a person accompanying animals.

(2) The radiation protection executive shall ensure that a maximum dose constraint of 100 µSv is established per use when planning operational radiation protection to protect the person accompanying animals. The dose constraint shall be determined for the effective dose of the person accompanying animals.

(3) The radiation protection executive shall ensure that an animal on which radioactive substances were used is not released from the radiation protection area until the person accompanying animals can only receive an effective dose in the range of 100 µSv.

(4) Animal welfare provisions shall remain unaffected thereby.

Division 11

Authorised persons

Section 145

Authorised persons relating to use on humans

(1) The radiation protection executive shall ensure that ionising radiation and radioactive substances are only used on humans by persons who are entitled to practice the medical or dental profession, or who are temporarily permitted to practice the medical or dental profession, and who

1. either have the specialist knowledge in radiation protection required for the use, or
2. have the requisite knowledge in radiation protection in their particular area of work for the use of radioactive substances and ionising radiation, and work under the constant supervision and responsibility of one of the persons

designated at no. 1.

(2) The radiation protection executive shall ensure that, in addition to the persons specified in accordance with subsection (1), technical implementation in the use of ionising radiation and radioactive substances on humans is exclusively carried out by the following persons:

1. persons who may use ionising radiation and radioactive substances on humans in accordance with subsection (1),
2. persons with a permit in accordance with section 1 subsection (1) no. 2 of the Act on Technical Assistants in Medicine of 2 August 1993 (Federal Law Gazette Part I p. 1402), most recently amended by Article 21 of the Act of 18 April 2016 (Federal Law Gazette Part I p. 886),
3. persons who have successfully completed state-regulated, state-recognised or state-monitored training, if technical implementation was the subject of their training and assessment and they have the requisite specialist knowledge in radiation protection,
4. persons in professional training imparting the required conditions for technical implementation, if they carry out the work under the constant supervision and responsibility of a person in accordance with subsection (1) no. 1 who is assigned to them in the context of their training and who has the requisite knowledge in radiation protection,
5. persons who have successfully completed other medical training, if they work under the constant supervision and responsibility of a person in accordance with subsection (1) no. 1, and have the requisite knowledge in radiation protection,
6. medical physics experts, if they work under the constant supervision and responsibility of a person in accordance with subsection (1) no. 1.

Section 146

Entitled persons in veterinary medicine

(1) The radiation protection executive shall ensure that ionising radiation and radioactive substances are only used in veterinary medicine by

1. persons who are entitled to practice the veterinary, medical or dental profession, or who are permitted to temporarily exercise the medical or dental profession, and have the specialist knowledge in radiation protection necessary for the use,
2. persons who are entitled to practice the veterinary, medical or dental profession and do not have the necessary specialist knowledge in radiation protection, if they have the requisite knowledge of radiation protection in their particular area of work necessary for the use, and work under the constant supervision and responsibility of one of the persons designated in no. 1.

(2) The radiation protection executive shall ensure that, when using ionising radiation and radioactive substances in veterinary medicine, the technical implementation is exclusively carried out by the following persons:

1. persons who may use ionising radiation and radioactive substances in veterinary medicine in accordance with subsection (1),
2. persons with a permit in accordance with section 1 subsection (1) no. 2 of the Act on Technical Assistants in Medicine,
3. persons who have successfully completed state-regulated, state-recognised or state-monitored training, if the technical implementation was the subject of their

training and assessment and they have the requisite specialist knowledge in radiation protection,

4. medical physics experts,
5. persons with the requisite knowledge in radiation protection if they work under the constant supervision and responsibility of a person in accordance with subsection (1) no. 1.

Section 147

Entitled persons outside the use on humans or in veterinary medicine

The radiation protection executive shall ensure that in cases other than for use on humans or for use on animals in veterinary medicine, X-ray radiation is only used by persons who

1. have the requisite specialist knowledge in radiation protection, or
2. have the requisite knowledge in radiation protection for the case of use within their area of work.

The first sentence shall not apply to the operation of a full-protection device in accordance with section 45 subsection (1) no. 5 of the Radiation Protection Act.

Chapter 7

Manufacturers' information obligations

Section 148

Information obligations of the manufacturer of devices

(1) The manufacturer of one of the devices designated in section 91, first sentence, of the Radiation Protection Act shall ensure that documents are enclosed with the device when it is handed over to the radiation protection executive which contain the following:

1. appropriate information on the potential radiological risks connected with the operation or use of the device, and on proper use, assessment and maintenance, as well as
2. proof that the design of the device allows exposure to be restricted to a level that is as low as reasonably achievable in accordance with the technical state-of-the-art.

The first sentence, no. 2, shall not apply to stray radiation emitters the operation of which does not require a licence, and also not to installations for the generation of ionising radiation which may be operated without a licence or notification.

(2) If the devices designated in section 91, first sentence, of the Radiation Protection Act are intended for use on humans, additional suitable information including available results of the clinical evaluation shall be enclosed which allow an assessment of the risks for persons examined or treated.

(3) The documents must be drafted in German or in another language that the user of the device can easily understand.

Chapter 8

Supervisory programme

Section 149

Supervisory programme

(1) In the supervisory programme in accordance with section 180 subsection (1), first sentence, of the Radiation Protection Act, the competent authority shall define the implementation and conditions of supervisory inspections, in particular of on-site inspections.

(2) The intervals at which regular on-site inspections take place shall be aligned to the type and extent of the risk associated with the respective practice. The criteria in accordance with Annex 16 shall be used as the basis when assessing the type and extent of the risk. Regular on-site inspections shall occur as a rule at intervals of between one and six years. For low-risk practices, the supervisory programme may waive the implementation of regular on-site inspections and determine a different procedure for the selection of the time for on-site inspections.

(3) Subsections (1) and (2) shall not be applicable to practices in accordance with section 4 subsection (1), first sentence, nos. 3 to 6 of the Radiation Protection Act.

Part 3

Radiation protection in emergency exposure situations

Section 150

Dosimetry for emergency workers

(1) The person responsible for the protection of emergency workers involved in emergency response measures in accordance with section 115 subsection (2) of the Radiation Protection Act shall ensure that the exposure that an emergency worker receives in an emergency exposure situation or when deployed to combat other hazardous situations is determined or estimated. The establishment or estimation is to be carried out by

1. a measurement of the personal dose of the emergency worker, or
2. if a measurement in accordance with no. 1 is not possible, by means of assumption of the results of the measurement of the personal dose of another person with comparable exposure conditions, or
3. alternatively by an estimation of the body dose, in particular on the basis of measurements of the ambient dose, of the ambient dose rate, of the concentration of radioactive substances in the air, or of the contamination of the surrounding area or of other physical parameters, in each case in conjunction with the period of time spent.

(2) If a relevant incorporation of radioactive substances is to be feared, in order to estimate the body dose, in addition to the methods designated in subsection (1), second sentence, a measurement of the physical activity or of the activity of the excretions or of other biological parameters shall be carried out by a measuring body designated in accordance with section 169 of the Radiation Protection Act.

(3) The competent authority may determine another or additional method for the calculation or estimation of the body dose if this is suitable in light of missing, incomplete or erroneous measurements or of uncertainties with regard to the results in accordance with subsection (1) or (2).

(4) The provisions on the measurement of the personal dose in section 66 subsections (1) and (2), first and second sentences, shall apply *mutatis mutandis*. The dosimeters may be retained for 12 months if a reference dosimeter is additionally used to take account of the deduction of natural exposure. After the use of a dosimeter in an emergency exposure situation or another risk situation, the dosimeter and the reference dosimeter shall be submitted to the measuring body within one month.

(5) If the determined or estimated effective dose exceeds 1 mSv, or the equivalent dose calculated for the ocular lens exceeds 15 mSv, or 50 mSv for local skin, the person responsible for the protection of workers involved in emergency response in accordance with section 115 subsection (2) of the Radiation Protection Act shall ensure that the results of the determination or estimation of the body dose are transmitted to the radiation protection register in accordance with section 170 subsection (4) of the Radiation Protection Act.

Section 151

Special medical surveillance of emergency workers

If it cannot be ruled out that, due to an exposure in accordance with section 114 of the Radiation Protection Act, or due to a different risk situation in accordance with section 116 of the Radiation Protection Act, a person has received exposures per calendar year that exceed the effective dose of 20 mSv or the equivalent dose of 20 mSv for the ocular lens or of 500 mSv for the skin, hands, forearms, feet or ankles, section 81 shall apply *mutatis mutandis* to the person responsible in accordance with section 115

subsection (2) of the Radiation Protection Act.

Section 152

Support from and consultation with authorities, aid organisations and emergency workers in an emergency

(1) In order to fulfil the obligations in accordance with section 72 subsection (3) of the Radiation Protection Act, and in accordance with section 107 of this Ordinance, the radiation protection executive shall ensure in particular that, in the event of an emergency, the competent authorities and organisations involved in an emergency are supported in decisions, protective measures and other measures in accordance with section 97 subsection (1), third sentence, of the Radiation Protection Act.

(2) The radiation protection executive shall in particular ensure in accordance with subsection (1) that, in the case of an emergency, hazardous incident or other significant incident that is notifiable in accordance with section 108 subsection (1) and (2), or of an event that is notifiable in accordance with section 6 subsections (1) and (2) of the Nuclear Safety Officer and Reporting Ordinance, after the occurrence of an emergency subsequent to the report in accordance with section 108 subsection (4) or the notification in accordance with section 6 subsection (3) of the Nuclear Safety Officer and Reporting Ordinance, the following authorities are sent an initial evaluation of the emergency and of its effects without undue delay:

1. the authority to be notified of the significant incident in accordance with section 108 subsections (1) and (2), or of a notifiable event in accordance with section 6 subsections (1) and (2) of the Nuclear Safety Officer and Reporting Ordinance,
2. the disaster response authority,
3. the authority competent for public security, and
4. in the case of a trans-regional or regional emergency, the Federal Radiological Situation Centre in accordance with section 106 of the Radiation Protection Act.

The radiation protection executive shall furthermore ensure that new or amended relevant data for estimates are transmitted to the authorities designated in the first sentence without due delay after becoming known to the authorities designated in the first sentence.

(3) In the case of a trans-regional or regional emergency, the radiation protection executive shall ensure that the provisional initial assessment in accordance with subsection (2), first sentence, and its updates in accordance with subsection (2), second sentence, as far as possible also include the data on the facilities or radioactive source, on the radiological inventory and on clearances, as well as clearance estimates and forecasts that are relevant in accordance with sections 107 and 108 of the Radiation Protection Act for the assessment of the radiological situation. In the case of the practices listed in section 106 subsection (3), the radiation protection executive shall not be obliged to transmit clearance estimates and forecasts.

(4) The radiation protection executive shall furthermore ensure in particular in accordance with subsection (1) that

1. the authorities competent for disaster response and for public safety, as well as the authorities and organisations involved in emergency response, are given all the information and consultation that is necessary
 - a) to prevent risks to people or the environment, or
 - b) to limit or eliminate deleterious effects, and
2. the authorities and organisations competent for the protection of emergency workers in accordance with section 115 subsection (2), second sentence, no. 2 of the Radiation Protection Act, the authorities and organisations involved in the

emergency response, and the head of operations at the place of deployment, are given all the information and advice necessary for informing the emergency workers in accordance with section 114 subsection (2), second or third sentence, of the Radiation Protection Act.

Part 4

Radiation protection in existing exposure situations

Chapter 1

Protection against radon

Division 1

Common provisions for recreation rooms and workplaces

Section 153

Determination of areas in accordance with section 121 subsection (1), first sentence, of the Radiation Protection Act

(1) The competent authority shall determine the areas in accordance with section 121 subsection (1), first sentence, of the Radiation Protection Act by using a scientifically-sound method that allows forecasts with respect to exceedance of the reference level in accordance with section 124 or section 126 of the Radiation Protection Act in the air of recreation rooms or workplaces on the basis of appropriate data. Appropriate data shall be deemed to include in particular geological data, measurement data of radon 222 activity concentrations in soil vapour, measurement data of soil permeability, measurement data of radon 222 activity concentrations in recreation rooms or at workplaces, and remote sensing data.

(2) The competent authority may assume that the radon 222 activity concentration averaged over the year exceeds the reference level in accordance with section 124 or section 126 of the Radiation Protection Act in a considerable number of buildings in the air of recreation rooms or workplaces in an area, if a forecast in accordance with subsection (1) states that the reference level will be exceeded in at least 75 % of the respective area to be designated in at least ten percent of the number of buildings.

(3) The areas shall be determined within the administrative boundaries existing in the *Land*.

(4) The competent authority shall conduct the measurements and take the samples necessary to determine the areas in accordance with section 121 subsection (1), first sentence, of the Radiation Protection Act, and to review the definition of areas in accordance with section 121 subsection (1), third sentence, of the Radiation Protection Act. To this end, it shall implement the requisite measurements and samples, or shall use existing data.

Section 154

Measures for the protection of new buildings from radon in areas in accordance with section 121, subsection 1, first sentence, of the Radiation Protection Act

In areas in accordance with section 121 subsection (1), first sentence, of the Radiation Protection Act, the obligation in accordance with section 123 subsection (1), first sentence, of the Radiation Protection Act to take appropriate measures to prevent or significantly impede the entry of radon from the building land shall be deemed to have been met if, in addition to the measures in accordance with section 123 subsection (1), first sentence, no. 1 of the Radiation Protection Act, at least one of the following measures is carried out:

1. reduction of radon 222 activity concentrations under the building,
2. targeted manipulation of the air pressure differential between the inside of the building and the soil vapours on the outside of walls and floors with ground

contact insofar as the diffusive radon discharge is restricted on the basis of the location or construction,

3. restriction of the development of cracks in walls and floors with ground contact and selection of diffusion-resistant concrete types with the required thickness of the components,
4. suctioning of radon at edge joints or under seals,
5. the use of diffusion-resistant, convection-inhibiting materials or constructions.

Division 2

Radon at workplaces in internal areas

Section 155

Measurement of radon 222 activity concentrations, recognised body

(1) The measurements of the radon 222 activity concentrations in accordance with section 127 subsection (1) and section 128 subsection (2) of the Radiation Protection Act shall be conducted in accordance with generally-accepted technique over a total duration of 12 months. The measurement locations shall be selected in such a way that they are representative of the radon 222 activity concentration at the workplace. Notwithstanding the above, exceedances of the reference level in the case of the measurement in accordance with section 127 subsection (1) of the Radiation Protection Act may also be determined on the basis of a shorter measurement period if it can be assumed, on the basis of an estimate of radon 222 activity concentrations averaged over a year, that the reference level will be exceeded.

(2) The execution of the measurement shall be recorded; the records shall be submitted to the competent authority on request together with the records in accordance with section 127 subsection (3) and section 128 subsection (2), second sentence, of the Radiation Protection Act.

(3) The meters needed to determine the radon 222 activity concentration shall be requested from a body recognised by the Federal Office for Radiation Protection for the measurement of radon 222 activity concentrations and adjusted in accordance with their stipulations. The evaluation of the measurement devices shall be carried out by the recognised body. This shall not apply if the measurement result can be evaluated under the responsibility of the responsible party in accordance with section 127 subsection (1) of the Radiation Protection Act.

(4) The Federal Office for Radiation Protection shall recognise a body for the measurement of radon 222 activity concentrations if the body

1. can provide appropriate measurement equipment,
2. has appropriate equipment and procedures for evaluating the measurement equipment,
3. has a suitable quality assurance system, and
4. ensures participation in quality assurance measures by the Federal Office for Radiation Protection.

The Federal Office for Radiation Protection shall publish a list of recognised bodies.

Section 156

Workplace-related estimation of exposure

The competent authority may issue stipulations for conducting the estimation in accordance with section 130 subsection (1) of the Radiation Protection Act in order to ensure the requisite quality of the estimate.

Section 157

Determination of exposure and body dose

- (1) The determination of the body dose in accordance with section 131 subsection (1) no. 2 of the Radiation Protection Act shall be implemented by a measuring body designated in accordance with section 169 subsection (1) no. 4 of the Radiation Protection Act.
- (2) The person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act shall ensure that the exposure is measured with measurement equipment
 1. which shall be requested from the measuring body in accordance with subsection (1), and which is evaluated by this measuring body, or
 2. which is used to ascertain measurement values under his or her responsibility if its use was permitted by the competent authority after consent was given by the measuring body in accordance with subsection (1).
- (3) The person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act shall ensure that the exposure conditions are recorded. He or she shall ensure that the measuring body, in order to determine the body dose after completion of three months,
 1. the measurement equipment in accordance with subsection (2) no. 1 are made available together with the records in accordance with the first sentence, or
 2. in cases falling under subsection (2) no. 2, the measurement values are provided together with the records in accordance with the first sentence.

The competent authority may permit the measurement devices to be submitted to the measuring body at intervals of up to six months, if this is not precluded by the exposure conditions.

(4) The person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act shall endeavour to ensure that the results of the determination of the body dose are made available to the employees at a workplace requiring registration at the latest nine months after the exposure has taken place.

(5) The person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act shall ensure that

1. the competent authority is informed, and
2. the dose is estimated

in the event of a measurement having being omitted or of it being erroneous.

The competent authority shall determine a notional dose, and shall see to it that the notional dose is transmitted to the radiation protection register in accordance with section 170 of the Radiation Protection Act. The competent authority may refrain from determining a notional dose in individual cases if the dose to be determined is 0 mSv and it transmits this value to the radiation protection register in accordance with section 170 of the Radiation Protection Act. The transmission in accordance with the second or third sentence may take place via a measuring body appointed in accordance with section 169 of the Radiation Protection Act.

Section 158

Further requirements for occupational radiation protection

(1) The person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act, who was obliged to make the estimation as a third party in accordance with section 130 subsection (1), second half of the first sentence, of the Radiation Protection Act, shall ensure that he or she personally, and persons under his or her supervision, only work subject to a notification obligation in external locations if every person possesses a completed radiation passport that is registered with the competent authority. The competent authority may exempt in individual cases from the obligation to carry a radiation passport in accordance with the first sentence if the person does not engage in a professional activity in workplaces requiring registration in more than one set of third-party premises.

(2) If a limit was exceeded during the calendar year in violation of section 78 subsection (1) or (3) of the Radiation Protection Act, continued employment of the person shall only be permissible if the person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act ensures that the exposure is restricted in the following four calendar years, taking into account the exceedance of the limits that has taken place, so that the sum of the doses does not exceed five times the limit. If the limit has been exceeded to such a degree that the application of the first sentence means that the previous employment cannot be continued, the competent authority may permit exceptions, in consultation with a doctor authorised in accordance with section 175 subsection (1), first sentence.

(3) The person responsible in accordance with section 131 subsection (1) of the Radiation Protection Act may only permit persons who engage in a practice falling under section 130 subsection (3) of the Radiation Protection Act to be employed or to continue to be employed if they have been examined within the respective calendar year by a doctor authorised in accordance with section 175 subsection (1), first sentence, and the person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act has a certificate issued by the doctor authorised in accordance with which no health concerns preclude the employment. This shall apply mutatis mutandis to persons who work on their own responsibility in their own or in other business premises. Section 77 subsection (3) and sections 79 and 80 shall apply mutatis mutandis. The documents requested in accordance with section 79 subsection (1), first sentence, shall be given to the authorised doctor. The authorised doctor shall send the medical certificate without undue delay to the person responsible in accordance with section 131 subsection (1) of the Radiation Protection Act, to the person exposed and, if there are any health concerns, to the competent authority.

(4) Insofar as the exposure conditions so require, the competent authority, for activities falling under section 130 subsections (3) of the Radiation Protection Act, may order the person obliged in accordance with section 131 subsection (1) of the Radiation Protection Act to take measures in accordance with sections 45, 46, 52, 53, 55, 56, 63, 75 subsection (1) and 91 subsection (1), first sentence, no. 3.

Chapter 2

Protection from radioactivity in construction products

Section 159

Determination of the specific activity

The person obliged in accordance with section 135 subsection (1) of the Radiation Protection

1. shall calculate the activity index in accordance with Annex 17, and
2. shall ensure that the activity index does not exceed the values designated in Annex 17

in order to prove that the reference level in accordance with section 133 of the Radiation Protection Act has not been exceeded.

Chapter 3

Radioactively-contaminated sites

Section 160

Determination of public exposure

(1) Realistic pathways of exposure and exposure assumptions shall be used when determining the exposure of members of the public. Insofar as the pathways of exposure as in accordance with Annex 11 Part A are considered, the assumptions in accordance with Annex 11 Part B Table 1 columns 1 to 7 and Table 2 shall be used as a basis. The type and concentration of the radionuclides and the possibility of their dispersion in the environment shall be taken into consideration, without prejudice to section 136 subsection (3) of the Radiation Protection Act.

(2) The current exposure shall be determined, and the expected future exposures shall be assessed. Exposure shall be assessed for periods of time

1. in which non-negligible exposures are likely to occur, and
2. which include the maximum anticipated exposure.

If the estimation of exposure for the period resulting from the second sentence cannot be carried out with sufficient reliability, it shall be sufficient to provide an estimate for the period for which sufficiently reliable statements can be made. An estimate shall be conducted for a maximum period of 1,000 years.

(3) The dose coefficients from the compilation in the Federal Gazette no. 160a and b of 28 August 2001, Parts I and II, shall be used for members of the public. The dose coefficients from the compilation in Federal Gazette no. 160a and b of 28 August 2001, Parts I and II, shall be used for workers.

(4) In the use, decommissioning, remediation and subsequent use of mining equipment and facilities, in particular the operational installations and sites of uranium ore mining, as well as other plots of land which are contaminated by mining legacies, the competent authority may assume that the requirements in accordance with subsection (1) are met if the exposure has been determined on the calculation basis for determining exposure due to environmental radioactivity due to mining (Calculation base – mining).

Section 161

Test levels for radioactively-contaminated sites and for the decommissioning and remediation of uranium ore mining equipment and facilities

(1) In the determination of radioactively-contaminated sites in accordance with section 136 subsection (1) of the Radiation Protection Act, a test level of 0.2 becquerels per gram of dry matter shall apply to natural radionuclides of the decay series of uranium 238 and thorium 232 with anthropogenic interventions.

(2) In derogation from subsection (1), a test level of 1 becquerel per gram of dry matter shall apply if the following can be ruled out:

1. the use or contamination of the groundwater,
2. permanent use of the contaminated site for housing or other purposes related to the permanent presence of humans, and
3. the consumption of agricultural or horticultural products generated on the contaminated site.

The first sentence shall not apply to mining waste.

(3) The determination shall be made on the basis of representative values of the highest specific activities.

(4) If the test levels designated in subsection (1) or (2), first sentence, have not been exceeded, the competent authority may assume that the site is not radioactively contaminated. In the case of artificial radionuclides, it shall be tested in individual cases whether the site is radioactively contaminated.

(5) A licence in accordance with section 149 subsection (1) of the Radiation Protection Act for the decommissioning and remediation of uranium ore mining equipment and facilities shall not be required if the test levels in accordance with subsection (1), first sentence, are not exceeded.

Section 162

Emissions and immissions monitoring for the decommissioning and remediation of uranium ore mining equipment and facilities

(1) At the time of decommissioning and remediation of uranium ore mining equipment and facilities, the holder of the licence shall ensure that the emissions and immissions emanating from the equipment and facilities

1. are monitored, and
2. are notified to the competent authority at least annually.

The holder of the licence shall in particular create a measurement programme for monitoring pollution.

(2) The competent authority shall determine measuring bodies to carry out the emissions and immissions monitoring. These shall have the following tasks:

1. control of the emissions monitoring to be conducted by the holder of the licence,
2. implementation of a measurement programme for immissions monitoring which serves the extension and control of the measurement programme to be created by the licence holder.

(3) The competent authority may assume that the measures required in accordance with subsection (1) and subsection (2), second sentence, for emissions and immissions monitoring have been taken if the emissions and immissions monitoring is carried out on the basis of the Guideline on Emissions and Immissions Monitoring of Mining Activities (*Richtlinie zur Emissions- und Immissionsüberwachung bei*

bergbaulichen Tätigkeiten - REI-Bergbau).

- (4) Section 103 subsection (3) shall apply mutatis mutandis.

Section 163

Principles for the optimisation of remediation measures

(1) In optimisation of the nature, scope and duration of the remediation, protection and restriction measures in accordance with section 139 subsection (2), second sentence, of the Radiation Protection Act, the advantages and disadvantages of the various measures shall be weighed up against each other.

(2) In particular, consideration shall be paid in weighing up to:

1. the characteristics of the hazardous waste and of the location, including the use and exposure conditions,
2. current exposure to the hazardous waste and forecasts of the future development of the exposure,
3. reduction of exposure to be achieved by the measures,
4. additional exposure of employees and the public from the measures,
5. costs for the implementation of the measures as well as for aftercare,
6. changes in the hazardous waste, the barriers created and the dispersion conditions which influence the effectiveness of the measures, as well as their respective consequences for the exposure and costs; hydraulic, geochemical and geo-mechanical processes within the hazardous waste shall be taken into consideration, as shall external geological, climatic and biological influences,
7. the stability of the measures taken in order to counter inadequate or omitted aftercare and the resulting consequences for exposure and costs,
8. the long-term negative effects of the measures on the environment, and
9. the effects of the measures on the interests of persons concerned.

Section 164

Contents of remediation plans

(1) The remediation plan shall illustrate the measures in accordance with section 143 subsection (1), second sentence, no. 3 of the Radiation Protection Act in full in text and graphics. It shall be demonstrated that these measures are appropriate, that the reference level in accordance with section 136 subsection (1) of the Radiation Protection Act is constantly adhered to or, if it is not possible to consistently remain below this value, that the envisaged measures are appropriate to permanently keep the exposure as low as possible, in consideration of the optimisation principles in accordance with section 163. In particular, the predicted costs shall also be presented in addition to the licensing, notification and reporting requirements, including when a binding remediation plan in accordance with section 143 subsection (2), second sentence, of the Radiation Protection Act cannot include such costs.

(2) In addition to the tasks stated in accordance with section 143 subsection (1), second sentence, of the Radiation Protection Act, a remediation plan is in particular to include information on

1. the conditions at the site and characteristics of the contaminated site,
2. the outer perimeter of the remediation plan and the area which is already affected by the contaminated site, or which is forecast to be affected as the

result of the envisaged measures,

3. the technical design of remediation measures, the type and scope of other measures to prevent or reduce exposure, the elements and the procedure followed in the remediation,
4. specific technical calculations on the individual components of the measures,
5. the self-monitoring measures to assess the proper execution and effectiveness of the envisaged measures,
6. the quantities to be treated and the transportation, methods of recovery and disposal,
7. the official decisions that were made and the public-law contracts that were concluded which impact the fulfilment of the duty to remediate the radioactively-contaminated site,
8. the information and documents required by the competent authority for a declaration of bindingness in accordance with section 143 subsection (2), second sentence, of the Radiation Protection Act,
9. the schedule for the remediation and aftercare of the contaminated site,
10. the responsibility for aftercare and the criteria for ending the aftercare,
11. the criteria for the proof of successful remediation, and
12. the perspectives that were taken into account in the weighing up of optimisation in accordance with section 139 subsection (2), second sentence, of the Radiation Protection Act.

Section 165

Protection of workers at radioactively-contaminated sites

(1) The following provisions shall apply mutatis mutandis to the protection of workers in connection with the implementation of measures in accordance with section 145 subsection (1) of the Radiation Protection Act:

1. for the person obliged to notify in accordance with section 145 subsection (2) of the Radiation Protection Act: sections 63 and 64 subsections (1) to (3), section 65 subsection (1), first sentence, and subsections (2) to (4), section 66 subsections (1) and (2), first to third sentences, and subsections (3) to (5), sections 68, 69, 70 subsection (1), sections 71 and 73, first sentence, section 75 subsection (1), section 77 subsections (1) and (2), sections 78 and 81 subsection (1) and section 90 subsections (1) and (2), first sentence, nos. 1 and 2, subsections (3) and (5), first sentence,
2. for the competent authority: section 64 subsections (4), section 65 subsection (1), second sentence, section 66 subsection (2), fourth sentence, section 70 subsection (2), section 73, second sentence, section 77 subsections (3) to (5) and section 81 subsection (2), and
3. sections 77, 80 and 81 subsection (3).

(2) Insofar as the exposure conditions so require, the competent authority may order appropriate measures for the protection of workers

1. in accordance with sections 45, 46, 52, 53 and 55 to 58, in accordance with section 75 subsection (2), in accordance with section 91, in accordance with section 91 subsections (2) and (3), and in accordance with section 93 subsection (1), and

2. order that a radiation passport be carried.

- (3) The person obliged to notify in accordance with section 145 subsection (2) of

the Radiation Protection Act shall consult persons who have the requisite specialist knowledge in radiation protection in connection with the performance of measures in accordance with section 145 subsection (1) of the Radiation Protection Act. This shall not apply if the person obliged to notify has the requisite specialist knowledge in radiation protection himself or herself.

Chapter 4

Other existing exposure situations

Section 166

Protection of workers in other existing exposure situations

(1) The following provisions shall apply mutatis mutandis to the protection of workers in other existing notifiable exposure situations:

1. for the person responsible in accordance with section 153 subsection (1) of the Radiation Protection Act: sections 63, 64 subsections (1) to (3), section 65 subsection (1), first sentence, and subsections (2) to (4), section 66 subsections (1) and (2), first to third sentences, and subsections (3) to (5), sections 68, section 69, 70 subsection (1), sections 71, 73, first sentence, section 75 subsection (1), section 77 subsection (1) and (2), sections 78, 81 subsection (1) and section 90 subsection (1) nos. 1 and 2, first sentence, nos. 1 and 2, as well as subsections (3) and (5), first sentence,
2. for the competent authority: section 64 subsection (4), section 65 subsection (1), second sentence, section 66 subsection (2), fourth sentence, section 70 subsection (2), section 73, second sentence, section 77 subsections (3) to (5) and section 81 subsection (2), and
3. sections 79, 80 and 81 subsection (3).

(2) Insofar as the exposure conditions so require, the competent authority may, for the protection of workers,

1. order appropriate measures in accordance with sections 45, 46, 52, 53 and 55 to 58, in accordance with section 75 subsection (2), in accordance with section 91, in accordance with section 92 subsections (2) and (3), and in accordance with section 93 subsection (1), and
2. order that a radiation passport be carried.

(3) The person responsible in accordance with section 153 subsection (1) of the Radiation Protection Act shall consult persons with the requisite specialist knowledge in radiation protection in connection with the fulfilment of their obligations. This shall not apply if the person responsible has the requisite specialist knowledge in radiation protection.

Part 5

Cross-exposure situation provisions

Chapter 1

Loss, finding and acquisition; contaminated metal

Section 167

Loss

(1) The previous holder of actual physical control of a radioactive substance in accordance with section 3 of the Radiation Protection Act shall notify the loss of this substance to the nuclear or radiation protection supervisory authority, or to the police authority competent in accordance with *Land* law, without undue delay. The first sentence shall apply mutatis mutandis in the event of the loss of a type-approved device containing a radioactive substance, or of a consumer product to which a radioactive substance has been added, insofar as the activity and specific activity of the contained or added radioactive substance exceeds the levels of Annex 4 Table 1 columns 2 and 3. The first and second sentences shall also apply to the retrieval of the radioactive substance or of the articles designated in the second sentence. The authorities listed in the first sentence shall respectively inform each other without undue delay regarding the message received by them.

(2) In addition to the communication in accordance with subsection (1), first sentence, the radiation protection executive shall ensure that the loss of a highly active radiation source is transferred in a secure electronic form without undue delay to the register of highly active radiation sources at the Federal Office for Radiation Protection in accordance with Annex 9 no. 11, and that the competent authority is informed of such report without undue delay. The first sentence shall also apply in the event of the retrieval of a highly active radiation source.

Section 168

Finding and acquisition

(1) Anyone who

1. finds a radioactive substance in accordance with section 3 of the Radiation Protection Act, or
2. unwillingly obtains actual physical control of a radioactive substance in accordance with section 3 of the Radiation Protection Act, or
3. has obtained actual physical control of a radioactive substance in accordance with section 3 of the Radiation Protection Act without knowing that this substance was radioactive,

shall notify this to the nuclear or radiation protection supervisory authority, or to the police authority competent in accordance with *Land* law, without undue delay as soon as he or she becomes aware that this substance is radioactive. The first sentence shall apply mutatis mutandis to the party who presumes to have found a radioactive substance in accordance with section 3 of the Radiation Protection Act or to exercise actual physical control of a radioactive substance in accordance with section 3 of the Radiation Protection Act. The authorities designated in the first sentence shall inform each other to the required degree without undue delay regarding the message received by them.

(2) The competent authority shall transmit the finding or acquisition of a highly active radiation source without undue delay to the register of highly active radiation

sources at the Federal Office for Radiation Protection in a secure electronic form in accordance with Annex 9 no. 11, at the latest two working days after becoming aware thereof.

(3) The notification obligation in accordance with subsection (1) shall also apply to anyone who obtains actual physical control of water that contains radioactive substances as the owner of a water supply facility that does not fall within the territorial scope of the Drinking Water Ordinance or as the owner of a waste water plant, if its concentration of activity in cubic metres of water from

1. water supply systems exceeds three times the values of Annex 11 Part D no. 2, or
2. sewage treatment plants exceeds 60 times the values of Annex 11 Part D no. 2.

Subsection (1), third sentence, shall apply *mutatis mutandis*.

(4) A licence in accordance with sections 4, 6 or 9 of the Atomic Energy Act, or in accordance with section 12 subsection (1) no. 3, also in conjunction with subsection (2), or section 27 subsection (1) of the Radiation Protection Act, shall not be required for anyone who stores the substance in cases falling under subsection (1), or the water in cases falling under subsection (3), after notification without undue delay until the decision of the competent authority, or on their order, stores it, or transports or handles it for compelling reasons for the protection of life and health.

Section 169

Contaminated metal

(1) Anyone who becomes aware or presumes that an orphaned radiation source has been melted down or otherwise used in metallurgical processing shall notify the nuclear or radiation protection supervisory authority or the authority competent for public safety thereof without undue delay.

(2) The authorities listed in subsection (1) may inform each other at its reasonable discretion without undue delay regarding the report received by them.

(3) The holder of actual physical control of actual or possibly contaminated metal may only use, bring into circulation or dispose thereof in accordance with the stipulations of the competent authority.

Section 170

Information of the competent Federal Ministry

The supervisory authority responsible under nuclear protection or radiation protection law shall inform the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety without undue delay of a notification received in accordance with section 167 subsection (1), first and second sentences, section 168 subsection (1), first and second sentences, and subsection (3), first sentence, as well as section 169 subsection (1), first sentence. Should a *Land* authority be competent, the information shall be provided by the competent highest *Land* authority.

Chapter 2

Dose and measured values

Section 171

Dose and measured values

The measured values, doses, weighting factors, dose coefficients and the

associated calculation bases that are relevant to the measurement and determination of exposure shall be determined in accordance with Annex 18.

Chapter 3

Common provisions for occupational exposure

Section 172

Measuring bodies

(1) The measuring body designated in accordance with section 169 subsection (1) of the Radiation Protection Act shall provide the following on request:

1. to the radiation protection executive: the personal dosimeters for determining the body dose in accordance with section 65 subsection (1), first sentence, and section 66 subsection (1) no. 1,
2. to the party obliged in accordance with section 145 subsection (2) of the Radiation Protection Act: the personal dosimeters for determining the body dose in accordance with section 165 subsection (1) no. 1, in conjunction with section 65 subsection (1), first sentence, and section 66 subsection (1) no. 1,
3. to the party responsible in accordance with section 153 subsection (1) of the Radiation Protection Act: the personal dosimeters for determining the body dose in accordance with section 166 subsection (1) no. 1, in conjunction with section 65 subsection (1), first sentence, and section 66 subsection (1) no. 1, and
4. to the party obliged in accordance with section 131 subsection (1) of the Radiation Protection Act: the measurement equipment for determining exposure in accordance with section 157 subsection (2) no. 1.

(2) The measuring body designated in accordance with section 169 subsection (1) of the Radiation Protection Act may avail itself of the services of a body recognised in accordance with section 155 subsection (3) to evaluate the measurement equipment in accordance with section 157 subsection (2) no. 1 insofar as the measuring body continues to satisfy the requirements in accordance with section 169 subsection (2) of the Radiation Protection Act.

(3) The measuring bodies designated in accordance with section 169 subsection (1) of the Radiation Protection Act shall participate in quality control measures. These shall be conducted

1. by the Federal Physical-Technical Institute for determining the body dose in accordance with section 66 subsections (1) and (2), third sentence, and
2. by the Federal Office for Radiation Protection for determining the body dose in accordance with section 65 subsection (4) and section 157 subsection (3).

Section 173

Radiation protection register

(1) The Federal Office for Radiation Protection shall determine the technical procedure for generating and composing the personal identification number in accordance with section 170 subsection (3) of the Radiation Protection Act.

(2) The Federal Office for Radiation Protection may use an identification number provided by a competent authority outside the territorial scope of the Radiation Protection Act as a personal identification number if the identification number

1. can be unambiguously attributed to the monitored person,

2. stays unchanged during the lifetime of the monitored person, and
3. is available from the monitored person or the company employing him or her.

(3) The Federal Office for Radiation Protection shall determine the data format as well as the transmission procedure in accordance with section 170 subsection (4), and the provision of information in accordance with section 170 subsection (5), first sentence, of the Radiation Protection Act.

Section 174

Radiation passport

(1) Anyone who is responsible for ensuring that the persons identified in accordance with section 68 subsection (1), section 158 subsection (1), first sentence, section 165 subsection (2) no. 2 or section 166 subsection (2) no. 2, are employed only with a radiation passport, shall be responsible for the carrying of radiation passports. He or she shall ensure that the radiation passport is registered by the authority competent in accordance with subsection (2) for the person for whom it is carried (radiation passport holder). In the event of the loss of a valid radiation passport, he or she shall ensure that the authority is notified thereof without undue delay.

(2) The authority in whose area of competence the person responsible for maintaining the radiation passport has his or her office shall register a radiation passport for a period of six years if

1. the information required in accordance with subsection (3) no. 1 (a) to (c) has been entered,
2. the radiation passport has been signed personally by the radiation passport holder and by the person responsible for issuing the radiation passport, and
3. sufficient space has been provided in the radiation passport for the further entries that are necessary in accordance with subsection (3).

The competent authority may assume that the requirement in accordance with the first sentence no. 3 has been complied with if the passport corresponds to the template of a radiation passport in accordance with general administrative provisions.

(3) The persons designated below, or the authority in accordance with subsection (2), shall ensure that at least the following information is entered in the radiation passport:

1. the person obliged to carry the radiation passport:
 - a) the personal data of the radiation passport holder and the personal identification number in accordance with section 170 subsection (3) of the Radiation Protection Act,
 - b) the information about the person obliged to carry the radiation passport, including the operating number and contact details,
 - c) the accounting of the official dose levels from occupational exposure for every calendar year and for every month of the calendar year,
 - d) any exceedance of limits for the body dose,
2. the person responsible for the external facility or installation or for the external place of operation: information on exposure in the external facility, installation or place of operation,
3. the person obliged for the carrying of the radiation passport in accordance with subsection (1), or the authorised doctor: the information on the completed medical surveillance, in particular the content of the certificate in accordance with section 79 subsection (1),
4. the authority in accordance with subsection (2)

- a) information about the issuance of the radiation passport, and
- b) information about the authority.

(4) The person obliged for the carrying of the radiation passport shall ensure that the entries in the radiation passport are complete before the radiation passport holder begins work in an external facility or installation, or in an external establishment.

(5) The person responsible for the external facility or installation for the external establishment shall ensure that work-related information in accordance with subsection (3) no. 2 is entered without undue delay after the end of the work of the radiation passport holder in the external facility or installation, or in the external place of operation, in particular the designation of the external facility, installation or place of operation, the period of time of the external operation, as well as the exposure during this period.

(6) The radiation passport shall be the property of the radiation passport holder, and shall not be transferable. On termination of the employment relationship, the person obliged for the carrying of the radiation passport shall ensure that the radiation passport is returned to the radiation passport holder. A radiation passport that cannot be returned to the radiation passport holder shall be handed over to the authority that registered the radiation passport.

(7) A radiation passport registered outside of the territorial scope of the Radiation Protection Act may be used if it fulfils the conditions for registration in accordance with subsection (2), first sentence.

Section 175

Authorised doctors

(1) The competent authority shall authorise doctors to conduct medical surveillance in accordance with sections 77, 78, 79 and 81, also in conjunction with sections 151, 158 subsection (3), and section 165 or 166. The authorisation may only be granted to a doctor who proves that he or she has the requisite specialist knowledge in radiation protection with occupational exposure. It shall be time-limited to five years.

(2) The authorised doctor shall have the task of conducting the initial examinations, the renewed examinations and the assessments in accordance with sections 77 and 78, as well as the special medical surveillance in accordance with section 81. He or she shall propose measures that are required for the prevention of harm to health in the event of increased exposure and to avert same. Persons who are employed at workplaces at which the ocular lens is particularly exposed shall be examined in order to see whether a cataract has formed.

(3) The authorised doctor shall be obliged to keep a medical record in accordance with section 79 subsection (2) of the Radiation Protection Act for every person who is subject to medical surveillance.

Section 176

Obligations to tolerate

(1) Persons who are subject to medical surveillance in accordance with sections 77 and 78, also in conjunction with section 158 subsection (3), section 165 subsection (1) or section 166 subsection (1), or to special medical surveillance in accordance with section 81, also in connection with sections 151, 158 subsection (3), section 165 subsection (1), or section 166 subsection (1), shall tolerate the necessary medical examinations.

(2) Persons for whom the body dose is to be determined in accordance with section 64 subsection (1), first sentence, or subsection (2), section 65 subsection (1), first or second sentence, or subsection (3), section 66 subsection (1), sections 67 and 74 subsection (1), first sentence, section 76, first sentence, section 150 subsection (1),

sections 157 and 165 subsection (1), or section 166 subsection (1), or for whom contamination is to be determined in accordance with section 57 subsection (1) or section 58 subsection (1), shall tolerate the necessary measurements and determinations.

(3) Subsections (1) and (2) shall also apply to persons for whom the competent authority in accordance with section 64 subsection (4), section 66 subsection (2), fourth sentence, section 77 subsections (4) and (5), in each case also in conjunction with section 165 subsection (1) no. 2, or section 166 subsection (1) no. 2, or section 143, has ordered medical examinations, measurements or determinations.

Chapter 4

Appointment of authorised experts

Section 177

Appointment of authorised experts

(1) On request, the competent authority shall appoint individual authorised experts in accordance with section 172 subsection (1) of the Radiation Protection Act if

1. there are no facts that give rise to concerns about the reliability or independence of the applicant,
2. the applicant fulfils the necessary requirements in accordance with section 181 on training, professional expertise and skills, and
3. the required technical and organisational equipment is available for the proper execution of the assessment assignment.

(2) On request, the competent authority shall appoint expert organisations in accordance with section 172 subsection (1) of the Radiation Protection Act if

1. there are no facts leading to concerns with regard to the independence of the expert organisation,
2. there are no facts leading to concerns with regard to the reliability or independence of the persons authorised by law, statutes or articles of association as representatives,
3. there are no facts leading to concerns with regard to the reliability of the person carrying out the examination,
4. the inspector fulfils the necessary requirements in accordance with section 181 relating to training, professional expertise and skills, and
5. the required technical and organisational equipment is available for the proper execution of the assessment order.

(3) The required documents for assessment shall be attached to the application. In the case of an expert organisation, the request shall in particular list the individual inspectors and the areas in which they are to act.

(4) The appointment as an authorised expert shall be limited to five years.

Section 178

Extension of the appointment

The addition of an inspector in an expert organisation, or the extension of the scope of activity of the individual authorised expert or of the inspector shall require the approval of the competent authority. The requisite documents for the examination shall be appended to the application for extension of the scope.

Section 179

Verification of reliability

(1) To prove reliability, the applicant shall, with every request for the appointment of an authorised expert, apply without undue delay for a current proof of good conduct in accordance with section 30 subsection (5) of the Act on the Federal Central Register (*Bundeszentralregistergesetz*) for presentation to the authority. This shall apply mutatis mutandis if an examination of reliability is required for other reasons.

(2) It shall not be necessary to resubmit the documents if the scope of work of the individual authorised expert or of the inspector is to be expanded during a determination that is still valid.

Section 180

Independence

(1) The independence required for appointment as an authorised expert shall be deemed to exist if the individual authorised expert, or in the case of expert organisations, the organisation itself, as well as the person entitled to act as representative, is not subject to economic, financial or other interference that influences its judgment or may raise questions with regard to the impartial performance of tasks. No commitments may be entered into that have or could have a negative effect on professional freedom of choice.

(2) The requisite independence shall be deemed not to exist if the individual authorised expert, or in the case of expert organisations the organisation itself, or the persons entitled to act as representatives, participate in the development, manufacturing, sale or maintenance of devices or equipment, or parts thereof, or of enclosed radioactive substances that are to be tested within the framework of the expert activity. This shall also apply if the persons listed in the first sentence themselves operate the equipment or devices to be tested.

(3) The required independence shall generally also not be deemed to exist if the individual authorised expert, or in the case of expert organisations, the organisation itself, or the persons entitled to act as representatives, are organisationally, economically, personally or financially intertwined with third parties to such an extent that their influence on the respective tasks cannot be ruled out.

(4) A declaration shall be submitted with each application that the requirements as to independence be met and the individual authorised expert, or in the case of authorised expert organisations of the inspectors, are not subject to any specialist instructions with regard to the expert activity. Section 179 subsection (2) shall apply mutatis mutandis.

Section 181

Expert qualifications

(1) Anyone who carries out expert activities as an individual authorised expert or inspector shall

1. hold a degree from a University or University of Applied Sciences in a scientific or technical subject,
2. have the requisite specialist knowledge in radiation protection,
3. have been instructed in the expert activity by a person who has been active for at least three years as an individual authorised expert or inspector, and
4. have conducted tests as in accordance with Annex 19 during the training.

(2) Proof of training in the expert activity shall be provided, and shall contain the following:

1. a list of the tested systems or workplaces with exposure by naturally-occurring radioactivity,
2. the date of the test, and
3. the number of the respective test report.

In addition, a final assessment shall be submitted which shows that the necessary technical qualification for practising the expert activity exists.

(3) The assessment of systems that are not listed in Annex 19 shall require at least five years' experience in the assessment of technically-related systems. Subsection (1) nos. 3 and 4 shall not be applicable. Subsection (2), first sentence, shall apply *mutatis mutandis* to proof of the tests.

(4) If a renewed appointment as an authorised expert is applied for and the scope of the activity of the appointment applied for is identical to that of the most recent appointment, the individual authorised expert or the inspector shall,

1. in cases falling under section 172 subsection (1), first sentence, nos. 1, 3 and 4 of the Radiation Protection Act within the framework of the most recent appointment, have conducted tests in accordance with Annex 19 Part 1 Table 1 column 3 and Table 2 column 3, and
2. in cases falling under section 172 subsection (1), first sentence, no. 2, of the Radiation Protection Act within the framework of the most recent appointment have conducted at least two tests in one or several fields of activity in accordance with Annex 3 of the Radiation Protection Act.

Subsection (1) nos. 3 and 4 shall not apply. Subsection (2), first sentence, shall apply *mutatis mutandis* to the proof of the tests.

Section 182

Criteria for tests

(1) The individual authorised expert or the inspector shall test the extent to which the safety-related design and the function and safety of the inspected device, equipment or enclosed radioactive substance, as well as the structural conditions, ensure the protection of personnel, the public and persons examined or treated.

(2) In the case of workplaces with exposure due to naturally-occurring radioactivity, it shall be tested whether the envisaged radiation protection measures ensure the protection of personnel and of the public.

(3) The individual authorised expert or the inspector shall take into account the

state-of-the-art in tests in accordance with section 172 subsection (1), first sentence, nos. 1 and 2 of the Radiation Protection Act, and the scientific and technical state-of-the-art in tests in accordance with section 172 subsection (1), first sentence, nos. 3 and 4 of the Radiation Protection Act.

Section 183

Obligations incumbent on authorised experts appointed by the authority

- (1) The individual authorised expert appointed by the authority shall be obliged to
1. inform the authority competent for the appointment without undue delay after becoming aware of changes that relate to the conditions of the appointment,
 2. ensure that the measuring devices and test equipment used in the expert activity are properly made, appropriate for the respective measuring task and available in the appropriate quantity,
 3. regularly test and maintain the measuring equipment with respect to its proper quality and functionality,
 4. participate in the measures for the exchange of opinion and experience for authorised experts as determined in the notice of appointment,
 5. regularly carry out and document the quality assurance measures stipulated in the notice of appointment,
 6. provide a copy of the test report to the authority competent for the party obliged to have the test carried out by the authorised expert within four weeks of a test having been carried out,
 7. provide a report regularly or on an ad hoc basis to the authority in the area of competence of which he or she is active on the subject and scope of his or her expert activity; in particular
 - a) provide a summary of the records made within the framework of each test once every year, and submit same to the authority on request,
 - b) hold records on the measuring equipment available,
 - c) within three months of the completion of a calendar year, provide the authority with a summary of the fundamental conclusions for the improvement of the safety of the tested devices, equipment and radioactive substances or workplaces with exposure due to naturally-occurring radioactivity,
 8. to inform the authority which is responsible for having the test carried out by the authorised expert, as well as the radiation protection executive or the radiation protection supervisor, without undue delay if he or she has determined, or there is justified suspicion, that there is a risk to the life or health of human beings or to the environment arising from the tested equipment, device, enclosed radioactive substance or workplace with exposure due to naturally-occurring radioactivity, and
 9. use appropriate measures to ensure, taking account of existing provisions of the law on confidentiality, the protection of operational and company secrets, as well as of secrets for reasons of public safety, of which they become aware in connection with their activity.

The authority competent for the appointment shall be provided on request with appropriate proof of compliance with the obligations in accordance with the first sentence, nos. 2 to 5.

(2) If the individual authorised expert exercises an expert activity outside the area of competence of the authority that appointed him or her, he or she shall communicate same to the authority in whose area of responsibility he or she works

1. without undue delay after commencing the activity, and
2. send a copy of the notice of appointment.

(3) Subsection (1), first sentence, subsections (1) to (3) and (5) to (9) shall apply mutatis mutandis to the expert organisation appointed by the authority. It shall furthermore be obliged to

1. communicate the departure of an inspector from their function to the authority competent for the appointment,
2. ensure the participation of inspectors in the measures for the exchange of opinion and experience for authorised experts determined by the competent authority in the notice of appointment,
3. keep a record for each inspector regarding the
 - a) type and number of tests conducted, and
 - b) their participation in measures for the exchange of opinion and experience,
4. submit the records in accordance with no. 3 to the authority competent for the appointment on request,
5. pass on information that is significant to the area of work of the inspectors to the latter without undue delay,
6. remove an inspector from his or her function without undue delay after learning that one of the conditions listed in section 177 subsection (2) no. 3 or no. 4 was not satisfied from the start, or ceased to be satisfied at a later time, and
7. oblige the personnel to exercise confidentiality with regard to operational and commercial secrets, as well as secrets for reasons of public safety, of which the personnel becomes aware in connection with their work.

On request, the authority competent for the appointment shall be provided with appropriate proof of compliance with the obligations in accordance with the first sentence in conjunction with subsection (1), first sentence, subsections (2), (3) and (5).

(4) If an inspector carries out an expert activity outside the area of competence of the authority which appointed the expert organisation, the latter shall

1. notify this without undue delay after commencing the activity, and
2. send a copy of the notice of appointment to the authority in the area of competence of which the inspector is active.

Part 6

Final provisions

Chapter 1

Regulatory offences

Section 184

Regulatory offences

(1) In accordance with section 194 subsection (1) no. 1 (a) of the Radiation Protection Act, a regulatory offence shall be deemed to have been committed by anyone who intentionally or negligently commits the following acts:

1. in contravention of section 24 no. 2, fails to implement quality control, or fails to do so completely or in good time,

2. in contravention of section 24 no. 3, fails to have quality control monitored,
3. in contravention of section 24 no. 4, fails to affix a marking, or fails to affix it correctly, completely, in the prescribed manner, or in good time,
4. in contravention of section 24 no. 5, also in conjunction with section 25 subsection (1), second sentence, fails to issue a document, or fails to issue it correctly, completely or in good time,
5. in contravention of section 25 subsection (1), first sentence, fails to maintain available a document designated therein,
6. in contravention of section 25 subsection (3), fails to cease the operation of a device, or fails to do so correctly, completely or in good time, fails to decommission a device, or fails to do so correctly, completely or in good time, or fails to perform a protective measure, or fails to do so in good time,
7. in contravention of section 25 subsection (4), first sentence, fails to have a device tested, or fails to do so correctly, completely or in good time,
8. in contravention of section 25 subsection (5), fails to return a device, or fails to do so correctly or in good time, or fails to surrender it, or fails to do so correctly or in good time,
9. in contravention of section 31 subsection (1), uses, recycles, disposes of, possesses or passes on a substance or article designated in that provision as a non-radioactive substance,
10. fails to comply with an enforceable obligation in accordance with section 33 subsection (4), first sentence, in conjunction with section 17 subsection (1), second or third sentence, of the Atomic Energy Act,
11. in contravention of section 34, brings about, causes or facilitates adherence to a requirement or compliance by mixing or diluting,
12. in contravention of section 52 subsection (1), fails to ensure that a radiation protection area is established,
13. in contravention of section 53 subsection (1), first sentence, subsection (2), first sentence, or subsection (3), first sentence, fails to ensure that a controlled area or an exclusion area is delimited or marked,
14. in contravention of section 56 subsection (1), fails to ensure that a measurement designated therein is carried out,
15. in contravention of section 57 subsection (1), fails to ensure that a determination of the contamination is made,
16. in contravention of section 57 subsection (2), first sentence, or section 58 subsection (1), second sentence, fails to ensure that a measure is taken,
17. in contravention of section 58 subsection (1), fails to ensure that a that test is conducted,
18. in contravention of section 58 subsection (2), second sentence, fails to ensure that an object is not removed from the controlled area,
19. in contravention of section 60 subsection (1), or of section 61 subsection (1), fails to ensure that X-ray equipment or a device is only used in a room designated therein,
20. in contravention of section 64 subsection (1), first sentence, also in conjunction with subsection (2), fails to ensure that the body dose is determined,
21. violates an enforceable order in accordance with section 64 subsection (4), section 66 subsection (2), fourth sentence, section 77 subsection (4) or (5), section 81 subsection (2), first sentence, section 88 subsection (5), first

- sentence, section 89 subsection (1), second sentence, also in conjunction with subsection (2), second sentence, or section 103 subsection (2),
22. in contravention of section 68 subsection (3), first sentence, fails to ensure that a person designated therein is only employed subject to the conditions designated therein,
 23. in contravention of section 69 subsection (1), first sentence, no. 1, fails to ensure that the occupational exposure is determined,
 24. in contravention of section 69, first sentence, no. 2, fails to ensure that the working conditions are structured in the prescribed manner,
 25. in contravention of section 70 subsection (1), first sentence, no. 1, fails to ensure that a person wears protective clothing or uses protective equipment,
 26. in contravention of section 70 subsection (1), second sentence, fails to ensure that no person under 18 years of age handles a radioactive substance designated therein,
 27. in contravention of section 73, first sentence, fails to ensure that the exposure is restricted,
 28. in contravention of section 77 subsection (1), third sentence, or section 99 subsection (3), fails to ensure that a limit is complied with,
 29. in contravention of section 77 subsection (1) or (2), first sentence, fails to ensure that a person designated therein only performs or continues a task if the preconditions designated therein are complied with,
 30. in contravention of section 82 subsection (1), operates X-ray equipment,
 31. in contravention of section 82 subsection (2), fails to ensure that a pupil or trainee only participates under the supervision or in the presence of one of the persons designated therein,
 32. in contravention of section 86 subsection (1), no. 1, fails to ensure that records are kept
 33. in contravention of section 86 subsection (1) no. 2, or of section 103 subsection (1), first sentence, no. 2 fails to ensure that a notification is made,
 34. in contravention of section 86 subsection (2) no. 12, fails to ensure that a document designated therein is retained or deposited for at least 30 years,
 35. in contravention of section 86 subsection (1) no. 2, fails to ensure that a document is handed over,
 36. in contravention of section 87 subsection (1) no. 2, fails to ensure that a radioactive substance is secured,
 37. in contravention of section 87 subsection (1) no. 2, or of subsection (2) or (3), fails to ensure that a radioactive substance or nuclear fuel is stored in the designated manner,
 38. in contravention of section 88 subsection (1), first sentence, no. 1(b), subsection (4) no. 1 or section 89 subsection (2), first sentence, or subsection (3) no. 1, fails to ensure that a test designated therein is conducted,
 39. in contravention of section 90 subsection (3), fails to ensure that a measuring device designated therein is used,
 40. in contravention of section 94 subsection (1), fails to ensure that a substance designated therein is relinquished to a person designated therein,
 41. in contravention of section 94 subsection (2), first sentence, fails to ensure that a certificate is issued,

42. in contravention of section 94 subsection (3), fails to ensure that a radioactive source is only relinquished if documentation is enclosed,
43. in contravention of section 94 subsection (4), fails to ensure that a radioactive source designated therein is relinquished or stored as radioactive waste,
44. in contravention of section 96 subsection (1) or (2), relinquishes a stray radiation emitter to another person,
45. in contravention of section 99 subsection (4), fails to ensure that radioactive substances are not discharged uncontrolled,
46. in contravention of section 104 subsection (1), first sentence, fails to ensure that body doses named therein are used as a basis in planning,
47. in contravention of section 104 subsection (3), first sentence, fails to ensure that a protective measure is taken,
48. in contravention of section 114 subsection (1), (2) or (3), fails to ensure that X-ray equipment or a facility is only used where the conditions designated therein are complied with,
49. in contravention of section 115 subsection (1), also in conjunction with subsection (4), first sentence, fails to ensure that an acceptance test is carried out,
50. in contravention of section 116 subsection (4), fails to ensure that the cause is remedied,
51. in contravention of section 117 subsection (1), fails to ensure that a record is made,
52. in contravention of section 117 subsection (3), fails to submit a record, fails to do so correctly, completely or in good time,
53. in contravention of section 121 subsection (2), first sentence, fails to ensure that a radiation treatment plan is determined,
54. in contravention of section 122 subsection (4), first sentence, fails to ensure that a person is released once the conditions designated therein are complied with,
55. in contravention of section 123 subsection (3), of section 145 subsection (2) or of section 146 subsection (2), fails to ensure that the technical implementation is carried out by a person designated therein,
56. in contravention of section 136 subsection (1), first sentence, fails to ensure that radioactive substances or ionising radiation are used subject to the conditions designated therein,
57. in contravention of section 137 subsection (1), fails to ensure that radioactive substances or ionising radiation are not used,
58. in contravention of section 137 subsection (2), fails to ensure that the limit designated therein is not exceeded,
59. in contravention of section 137 subsection (3), fails to ensure that a person designated therein is excluded from the use,
60. in contravention of section 138 subsection (3) first sentence, section 145 subsection (1) or section 146 subsection (1), fails to ensure that radioactive substances or ionising radiation are used by a person designated therein,
61. in contravention of section 138 subsection (4), first sentence, fails to ensure that an examination designated therein is carried out,
62. in contravention of section 138 subsection (5), second sentence, fails to ensure that monitoring and evaluation are carried out,

63. in contravention of section 144 subsection (3), fails to ensure that an animal is released from the radiation protection area if the conditions designated therein are complied with, or
64. in contravention of section 169 subsection (3), uses, places on the market or disposes of a metal.

(2) In accordance with section 194 subsection (1) no. 1(b) of the Radiation Protection Act, a regulatory offence shall be deemed to have been committed by anyone who, intentionally or negligently, commits the following acts:

1. in contravention of section 42 subsection (3), fails to transmit information, or fails to do so correctly, completely or in good time,
2. in contravention of section 44 subsection (1), first sentence, section 65 subsection (2), first sentence, no. 1, of section 85 subsection (4), second sentence, of section 157 subsection (5), first sentence, no. 1 or of section 167 subsection (2), first sentence, also in conjunction with the second sentence, fails to ensure that training or information takes place,
3. in contravention of section 56 subsection (2), first sentence, or section 57 subsection (3), first sentence, fails to make a record, fails to do so correctly, completely or in good time,
4. in contravention of section 56 subsection (2), second sentence, fails to retain a record, or fails to do so for at least five years, or fails to submit same correctly, completely or in good time,
5. in contravention of section 56 subsection (2), third sentence, fails to ensure that a record is deposited, or fails to do so correctly, completely or in good time,
6. in contravention of section 57 subsection (3), second sentence, fails to ensure that a record is retained for at least ten years, or that it is presented, or fails to ensure that it is presented correctly, completely or in good time,
7. in contravention of section 63 subsection (6), first sentence, of section 98, first sentence, no. 3, also in conjunction with the second sentence, of section 109 subsection (2), of section 138 subsection (4), second sentence, or subsection (5), third sentence, or of section 157 subsection (3), first sentence, fails to ensure that a record is made,
8. in contravention of section 63 subsection (3), third sentence, fails to ensure that a record designated therein is retained for one year or for five years or is presented,
9. in contravention of section 65 subsection (2), second sentence, fails to ensure that a notification is made,
10. in contravention of section 66 subsection (2), first sentence, fails to ensure that a measurement value is provided,
11. in contravention of section 66 subsection (4), second sentence, section 85 subsection (1), first sentence, no. 1, also in conjunction with the second sentence, in contravention of section 85 subsection (4), first sentence, no. 1 or 2, section 89 subsection (4), section 141 subsection (1) or section 167 subsection (2), first or second sentence, fails to ensure that a notification is made,
12. in contravention of section 85 subsection (3) no. 1, fails to ensure that a document is retained or deposited for 30 years,
13. in contravention of section 85 subsection (3), no. 2, fails to ensure that a certificate is handed over,
14. in contravention of section 88 subsection (1), first sentence, no. 2,

- subsection (4) no. 2 or subsection (5), second sentence, section 89 subsection (1), third sentence, also in conjunction with subsection (2), second sentence, or subsection (3) no. 2, fails to ensure that a test report is presented,
15. in contravention of section 90 subsection (5), first sentence, no. 3, fails to ensure that a record is retained, presented or deposited for ten years,
 16. in contravention of section 91 subsection (1), or of section 92 subsection (1), first sentence, no. 1 or section 92 subsection (1), second sentence, or of section 92 subsection (2), also in conjunction with subsection (3), fails to ensure that marking is effected,
 17. in contravention of section 91 subsection (3), fails to ensure that a protective container or a storage container is only used to store radioactive substances,
 18. in contravention of section 97 subsection (1), fails to ensure that storage is carried out,
 19. in contravention of section 97 subsection (2) or (3), fails to ensure that an operating manual, a test report or a certificate is kept available,
 20. in contravention of section 98 subsection (1), first sentence, no. 4, also in conjunction with the second sentence, fails to ensure that a record is retained,
 21. acts in contravention of an enforceable order in accordance with section 101 subsection (4) or section 158 subsection (4),
 22. in contravention of section 108 subsection (1), first sentence, subsection (3), second sentence, or section 108 subsection (4), first or second sentence, fails to ensure that a report is made,
 23. in contravention of section 109 subsection (4), first sentence, fails to ensure that a record is retained for ten years or presented,
 24. in contravention of section 127 subsection (1), subsection (2), first sentence, or subsection (3), also in conjunction with section 140 subsection (2), fails to ensure that retention designated therein is ensured,
 25. in contravention of section 129 subsection (1), first sentence, no. 1, also in conjunction with the second sentence, or in contravention of section 129 subsection (2) no. 1, fails to ensure that a report is made,
 26. in contravention of section 129 subsection (1), first sentence, no. 2, also in conjunction with the second sentence, or in contravention of section 129 subsection (2) no. 2, fails to ensure that a transfer is effected,
 27. in contravention of section 133, fails to ensure that the use of radioactive substances or of ionising radiation takes place in the prescribed manner on humans,
 28. in contravention of section 134 subsection (1), first sentence, also in conjunction with section 136 subsection (2), first sentence, no. 4 or subsection (2), second sentence, fails to ensure that the consent designated therein is obtained,
 29. in contravention of section 135 subsection (1), also in conjunction with section 136 subsection (1), first sentence, no. 4, fails to ensure that information is handed out,
 30. in contravention of section 135 subsection (2), first sentence, also in conjunction with section 136 subsection (1), first sentence, no. 4, fails to ensure that information is provided and questions asked in the manner prescribed therein,
 31. in contravention of section 142 subsection (1), also in conjunction with subsection (2), fails to present a final report, fails to do so correctly, completely or in good time,
 32. in contravention of section 147, first sentence, fails to ensure that X-rays, ionising radiation or a radioactive substance designated therein is used or

deployed by a person designated therein,

33. in contravention of section 158 subsection (3), first sentence, also in conjunction with the second sentence, permits employment or continued employment,
34. in contravention of section 158 subsection (3), fourth sentence, fails to pass on a document, fails to do so correctly, completely or in good time,
35. in contravention of section 158 subsection (3), fifth sentence, fails to forward a certificate, fails to do so correctly, completely or in good time,
36. in contravention of section 175 subsection (3), fails to keep a health record, or fails to keep it correctly,
37. in contravention of section 183 subsection (1), first sentence, no. 1, also in conjunction with subsection (3), first sentence, or subsection (3), second sentence, no. 1, fails to make a report, or fails to do so correctly, completely or in good time,
38. in contravention of section 183 subsection (1), first sentence, no. 6, also in conjunction with subsection (3), first sentence, or subsection (3), second sentence, no. 4, fails to submit a copy of the test report or a record, or fails to do so correctly, completely or in good time,
39. in contravention of section 183 subsection (1), first sentence, no. 8, also in conjunction with subsection (3), first sentence, fails to provide training, or fails to do so correctly, completely or in good time,
40. in contravention of section 183 subsection (2) or (4), fails to make a report, fails to do so correctly, completely or in good time, or fails to transmit a copy of the notice of appointment, or fails to do so correctly, completely or in good time, or
41. in contravention of section 183 subsection (2), second sentence, no. 3 fails to keep accounts, or fails to do so correctly or completely.

(3) In accordance with section 194 subsection (1) no. 1(c) of the Radiation Protection Act, a regulatory offence shall be deemed to have been committed by anyone who, intentionally or negligently, commits the following acts:

1. transports a highly active radiation source, or another radioactive substance, without a licence in accordance with section 12 subsection (1) or (2), or
2. in contravention of section 13 subsection (1), first sentence, or subsection (2), fails to make a registration, fails to do so correctly, completely or in the prescribed manner or in good time, or
3. in contravention of section 13 subsection (3), fails to take precautions, or fails to take the correct precautions.

Chapter 2

Transitional provisions

Section 185

Type approval (sections 16 to 26)

The owner of type-approved equipment containing or having contained other radioactive substances in accordance with section 3 subsection (1) of the Radiation Protection Act, and which continue to be operated in accordance with section 208 subsections (2) and (3), second clause, or subsection (4) of the Radiation Protection Act, shall have it inspected for integrity and leak tightness every ten years after the expiry of the type approval, unless shorter periods are prescribed in the approval certificate, in accordance

with section 25 subsection (4), first sentence. If the expiry of the type approval took place more than ten years previously on 31 December 2018, the integrity and leakage test shall take place at the latest by 31 December 2021. The first and second sentences shall not apply if the activity of the substances contained in the equipment is below the exemption level in accordance with Annex 4 Table 1 column 2.

Section 186

Residue (section 29)

A release issued in accordance with section 98 subsection (1), first sentence, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, shall continue to be effective as release in accordance with section 29 if the authority competent in accordance with section 29 subsection (3) for release from the monitoring in the local jurisdiction of which the future waste is to be recovered or disposed of gives its consent by 30 June 2019.

Section 187

Clearance (sections 31 to 42)

(1) Clearance issued in accordance with section 29 subsection (2), first sentence, in conjunction with the second sentence no. 1(a) of the Radiation Protection Ordinance, in the version effective until 31 December 2018, on which the values of Annex III Table 1 column 5 of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, were based, shall be considered to continue to constitute clearance in accordance with section 33, in conjunction with section 35, subject to the proviso that the values of Annex 4 Table 1 column 3 of the Radiation Protection Ordinance are complied with from 1 January 2021 onwards.

(2) Clearance issued in accordance with section 29 subsection (2), first sentence, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, in which in accordance with section 29 subsection (2), third sentence, proof of compliance with the dose criterion has been retained in individual cases, shall be considered to continue to constitute clearance in accordance with section 33 in conjunction with section 37.

(3) Clearance issued in accordance with section 29 subsection (2), second sentence, no. 1 (b), (c) or (d), or in accordance with no. 2 (a), (b), (c) or (d) of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, shall be considered to continue to constitute clearance in accordance with section 33 in conjunction with section 36.

(4) Determinations in accordance with section 29 subsection (6), first sentence, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, that were effected up to 31 December 2018 shall continue to apply.

(5) The values of Annex III Table 1 column 5 of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, shall continue to apply to clearance in accordance with section 33 in conjunction with section 35, which is issued between 1 January 2019 and 31 December 2020, until 31 December 2020, and from 1 January 2021 onwards the values of Annex 4 Table 1 column 3.

(6) Clearance rules issued up to 31 December 2018 in

1. licences in accordance with sections 6, 7 or 9 of the Atomic Energy Act which relate to the decommissioning of facilities and equipment,
2. a licence in accordance with section 7 or section 11 subsection (2) of the Radiation Protection Ordinance in the version applicable until 31 December 2018, or
3. a separate notice in accordance with section 29 subsection (4) of the Radiation Protection Ordinance in the version applicable until 31 December 2018

which are based on the values of Annex III Table 1 column 5 of the Radiation Protection Ordinance in the version applicable until 31 December 2018, shall continue to be effective with the proviso that the limits of Annex 4 Table 1 column 3 shall be complied with from 1 January 2021 onwards.

Section 188

Operational organisation of radiation protection (sections 44 and 45)

(1) For an installation for the generation of ionising radiation, X-ray equipment or a stray radiation emitter that was already operated by several radiation protection executives before 31 December 2018, the agreement in accordance with section 44 subsection (2), first sentence, shall be signed by 31 December 2019. The first sentence shall apply *mutatis mutandis* to the handling of radioactive substances approved before 31 December 2018.

(2) For practices that were commenced before 31 December 2018, the radiation protection order in accordance with section 45 subsection (1), first sentence, shall be drawn up by 1 January 2020 if no radiation protection order was previously required. A radiation protection order that was issued before 31 December 2018 shall be updated by 1 January 2020, in consideration of section 45 subsection (2).

Section 189

Requisite specialist and general knowledge in radiation protection (sections 47, 48 and 51)

(1) For radiation protection supervisors who were

1. appointed before 1 August 2001 in accordance with the Radiation Protection Ordinance in the version applicable until 30 July 2001, or
2. prior to 1 July 2002 in accordance with the X-ray Ordinance (*Röntgenverordnung*) in the version effective until 30 June 2002,

the requisite specialist knowledge in radiation protection shall be considered to have been acquired and certified in accordance with section 47 subsection (1), first sentence. For individual authorised experts or inspectors in an expert organisation who were designated in accordance with section 66 of the Radiation Protection Act in the version effective until 31 December 2018, or section 4a of the Radiation Protection Ordinance in the version effective until 31 December 2018, and which continued to act as such until 31 December 2018, the requisite specialist knowledge in radiation protection shall be deemed to have been obtained and certified in accordance with section 47 subsection (1), first sentence. Section 48 subsection (1), first sentence, shall remain unaffected thereby. A certificate of specialist knowledge issued prior to 31 December 2018 shall continue to be effective as a certificate in accordance with section 47 subsection (1), first sentence, in other respects.

(2) If the authority competent in accordance with section 18a subsection (1), fifth sentence, of the X-ray Ordinance, in the version applicable until 31 December 2018, has determined that the training and practical experience in radiation protection for the respective area of application, as well as the theoretical knowledge corresponding to the recognised courses, was imparted in state or state-recognised vocational training, this determination shall continue to be effective as a finding in accordance with section 47 subsection (5), first sentence. If the requisite specialist knowledge in radiation protection in accordance with section 18a subsection (1), fifth sentence, of the X-ray Ordinance in the version applicable until 31 December 2018 was regarded as tested and certified, it shall continue to be effective as tested and certified. Section 48 subsection (1), first sentence, shall remain unaffected thereby.

(3) A certificate issued before 31 December 2018 on the requisite knowledge in radiation protection shall continue to be effective as a certificate in accordance with

section 49 subsection (2), first sentence in conjunction with section 47 subsection (1), first sentence. If the authority competent in accordance with section 30 subsection (4), third sentence, of the Radiation Protection Act, in the version applicable until 31 December 2018, or in accordance with section 18a subsection (3), third sentence, of the X-ray Ordinance in the version applicable until 31 December 2018, has determined that the requisite knowledge in radiation protection has been obtained by passing the final examination of a recognised course, this determination shall continue to be effective as approval in accordance with section 49 subsection (2), second sentence. If the requisite knowledge in radiation protection is regarded as having been tested and certified in accordance with section 30 subsection (4), third sentence, of the Radiation Protection Ordinance in the version effective until 31 December 2018, or in accordance with section 18a subsection (3), third sentence, of the X-ray Ordinance in version applicable until 31 December 2018, it shall continue to be effective as tested and certified. Section 49 subsection (3) in conjunction with section 48 subsection (1), first sentence, shall remain unaffected thereby.

(4) If the authority competent in accordance with section 18a subsection (3), second sentence, in conjunction with section 18a subsection (1), fifth sentence, of the X-ray Ordinance, in the version applicable until 31 December 2018, has determined that the appropriate theoretical knowledge and practical experience in radiation protection were imparted in state or state-recognised vocational training for the respective area of use, as well as in the recognised courses, this determination shall continue to be effective as a determination in accordance with section 49 subsection (2), first sentence, in conjunction with section 47 subsection (5), first sentence. If the requisite knowledge in radiation protection in accordance with section 18a subsection (3), second sentence, in conjunction with section 18a subsection (1), fifth sentence, of the X-ray Ordinance in the version applicable until 31 December 2018 were regarded as tested and certified, it shall continue to be effective as tested and certified. Section 49 subsection (3) in conjunction with section 48 subsection (1), first sentence, shall remain unaffected thereby.

(5) Courses recognised by the competent authority before 31 December 2018 to impart the requisite specialist or general knowledge shall continue to be effective as recognised in accordance with section 51 until 31 December 2023, insofar as the recognition does not contain a shorter period.

Section 190

Transitional provisions in connection with radiation protection areas (sections 52 to 62)

(1) The holder of a licence which continues to be applicable in accordance with section 197 or 198 of the Radiation Protection Act, of a licence issued before 31 December 2018 in accordance with sections 6, 7, 9 or 9b of the Atomic Energy Act, or of a plan approval decision in accordance with section 9b of the Atomic Energy Act, as well as the person required to notify a declaration continuing to apply in accordance with sections 199, 200 or 210 of the Radiation Protection Act, shall establish a controlled area in accordance with section 52 subsection (2) no. 2 by 1 January 2020 if no controlled area has yet been established, insofar as the equivalent dose for the ocular lens may exceed 15 mSv per calendar year.

(2) The holder of a licence continuing to apply in accordance with section 198 subsection (1) or (4) of the Radiation Protection Act, as well as the person required to notify a declaration continuing to apply in accordance with section 200 subsection (1) of the Radiation Protection Act, insofar as an exclusion area in accordance with section 52 subsection (2), first sentence, no. 3 is necessary, shall establish same by 31 December 2019.

(3) The operation of an irradiation device approved before 31 December 2018, which contains radioactive substances the activity of which exceeds 50 Gigabecquerel

(Gbg), may be continued until 31 December 2019 outside an irradiation area in accordance with section 61.

Section 191

Dose constraints for practices (section 72)

For practices which were already commenced before 31 December 2018, the test in accordance with section 72 subsection (1) of whether the determination of dose constraints is an appropriate instrument for optimising radiation protection shall take place by 1 January 2020.

Section 192

**Register of
highly active radiation sources
(section 84)**

With regard to highly active radiation sources which were recorded by 31 December 2018 in the register of highly active radiation sources, and which in accordance with section 83 continue to be effective as constituting highly active radiation sources, the information in the register of highly active radiation sources required in accordance with Annex 9 shall be completed by 1 January 2020.

Section 193

**Determination of the exposure expected and received for members of the public
(sections 99, 100, 101 and Annex 11)**

(1) Section 99 subsection (1) and section 100 subsections (1) and (4) shall not be applied to the

1. licensing procedures for which an application for authorisation is made from the first day of the 13th calendar month following the entry into force of general administrative provisions in accordance with section 100 subsection (3),
2. notification procedures for which a notification is made from the first day of the 19th calendar month following the entry into force of general administrative provisions in accordance with section 100 subsection (3).

Section 47 subsection (2) in conjunction with subsection (1) and Annex VII of the Radiation Protection Ordinance in the version applicable until 31 December 2018 shall continue to apply until the respective time stated in the first sentence, nos. 1 and 2.

(2) The establishment of the exposure received by members of the public shall be

1. implemented for the first time for the calendar year 2020 in accordance with section 101 subsection (1) and documented in accordance with section 101 subsection (5), first sentence,
2. made available and published on request for the first time for the calendar year 2021 in accordance with section 101 subsection (5), second and third sentences.

Section 194

Restriction of exposure due to hazardous incidents (section 104)

Until the entry into force of general administrative provisions on the prevention of hazardous incidents in accordance with section 104 subsections (6), the exposure from hazardous incidents shall be restricted when planning the facilities and equipment designated in section 104 subsections (3) and (4) in such a way that an effective dose of 50 mSv is not exceeded by the discharge of radioactive substances into the surrounding area.

Section 195

Equipment for use on humans (section 114)

(1) Section 114 subsection (1) no. 12 shall apply from 1 January 2024 onwards to X-ray equipment that was first put into service prior to 1 July 2002.

(2) Section 114 subsection (1) no. 2 shall apply, subject to the proviso of the second sentence, only to X-ray equipment which is first put into service prior 1 January 2023. Section 114 subsection (1) no. 2 shall apply from 1 January 2023 onwards to X-ray equipment which is used for computer tomography or fluoroscopy, and which was first put into service before 31 December 2018. Section 114 subsection (1) no. 2 shall apply from 1 January 2021 onwards to X-ray equipment which is used for computer tomography or fluoroscopy, and which was first put into service from 31 December 2018 onwards.

(3) Section 114 subsection (1) no. 4 shall only apply from 1 January 2021 onwards to X-ray equipment that was first put into service before 31 December 2018.

(4) Section 114 subsection (2) shall only apply from 1 January 2021 onwards to installations for the generation of ionising radiation and irradiation facilities that were put into service before 31 December 2018.

(5) Section 114 subsection (3) shall not apply to installations for the generation of ionising radiation that were first put into service before 31 December 2018.

Section 196

Medical and dental bodies (section 128)

A determination by a medical or dental body made before 31 December 2018 shall continue to be effective as a determination in accordance with section 128 subsection (1) if it is proven to the competent authority by 31 December 2020 that the prerequisites in accordance with section 128 subsection (2) are satisfied.

Section 197

**Dose and measured values
(section 171 and Annex 18)**

(1) The measured value designated in Annex 18 Part A no. 1 (b) shall be used at the latest from 1 January 2022 onwards in the case of measurements of the personal dose in accordance with section 65 subsection (1), first sentence, and section 66 subsection (2), fourth sentence, and subsection (5). The measured value designated in Annex 18 Part A no. 2 (b) shall be used at the latest from 1 January 2022 onwards in measurements of the ambient dose and ambient dose rate in accordance with sections 56 and 65 subsection (1), second sentence, no. 1.

(2) The values of the radiations weighting factor and of the tissue weighting factor stated in Annex 18 Part C nos. 1 and 2 shall be used from 1 January 2021 at the latest.

Section 198

Radiation passport (section 174)

A valid radiation passport issued before 31 December 2018 may continue to be used until the expiration of validity specified therein, until 31 December 2024 at most, insofar as the personal identification number of the radiation passport holder in accordance with section 170 subsection (3) of the Radiation Protection Act has been entered into this radiation passport by 30 June 2019.

Section 199

Authorised doctors (section 175)

The authorisation of a doctor to conduct preventive occupational medicine in accordance with section 64 subsection (1), first sentence, of the Radiation Protection Ordinance in the version effective until 31 December 2023, or in accordance with section 41 subsection (1), first sentence, of the X-ray Ordinance in the version effective until 31 December 2018, shall continue to be effective as an authorisation to conduct medical surveillance in accordance with section 175 subsection (1), first sentence. If the authorisation was time-limited at an earlier date, the date designated in the time limitation shall be material.

Section 200

Officially-appointed authorised experts (section 181)

(1) For individual authorised experts or inspectors who were designated in accordance with section 66 of the Radiation Protection Ordinance in the version applicable until 31 December 2018 or in accordance with section 4a of the X-ray Ordinance in the version applicable until 31 December 2018, and who were still acting as such until 31 December 2018, the requisite specialist qualification in accordance with section 181 subsection (1) shall apply to the appointment as an authorised expert in accordance with section 172 subsection (1), first sentence, of the Radiation Protection Act for the groups of practices to which the previous provision applies.

(2) In derogation from section 181 subsection (1) nos. 2 to 4, persons or organisations who apply for the first time for appointment as an authorised expert in accordance with section 172 subsection (1), first sentence, no. 2 of the Radiation Protection Act may provide proof of the technical qualification by 1 January 2022 by demonstrating that the person who is to conduct tests has comprehensive knowledge in general radiation protection and advanced knowledge of radiation protection in workplaces with exposure due to naturally-occurring radioactivity.

List of non-justified types of practice

Part A: The non-justified use of radioactive substances or ionising radiation – not including the use of radioactive substances or ionising radiation on humans

The following shall be deemed not to be justified

1. the use of surge arrestors with radioactive substances on pylons,
2. the use of unsealed radioactive substances for leak tightness detection (water, heating, ventilation), insofar as these substances are not subsequently re-collected,
3. use of unsealed radioactive substances for retention time spectroscopy insofar as this does not take place in sealed systems and with radionuclides which given their half-lives cannot be released into the environment and the exposure of third parties cannot be ruled out,
4. the use of substances containing uranium or thorium in the production of dyes for glazes, insofar as contact of the product with food cannot be ruled out,
5. the use of gaseous tritium light sources in night-vision instruments, targeting instruments and binoculars, insofar as, in consideration of all aspects of the individual case, the use is not necessary in order to carry out public service tasks,
6. the use of devices with radioactive luminous pigments that firmly adhere to the surface, with the exception of
 - a) markings with luminous pigments containing tritium in professional areas that are not accessible to the public,
 - b) emergency exit notices in aircraft with an aeronautical type approval,
7. the use of highly active radiation sources in the examination of containers and vehicles outside material testing,
8. the use of ionisation smoke detectors with type approval as in accordance with Annex IV no. 1 of the Radiation Protection Ordinance in the version of the notice of 30 June 1989 (Federal Law Gazette Part I p. 1321) in the version applicable until 30 July 2001.

Part B: Non-authorised use of radioactive substances or of ionising radiation on humans

The following shall be deemed not to be justified

1. the use of
 - a) iodine 131 in the form of I-131-orthoiodine hippuric acid (OIH), and
 - b) iodine 125 in the form of I-125-iothalamate (IOT), I-125-orthoiodine hippuric acid and I-125-diethylenetriamine pentaacetic acid (DTPA) for examining the kidneys,
2. the use of iodine 125 in the form of I-125 fibrinogen for the examination of deep vein thrombosis,
3. the use of radium 226 in enclosed form for the treatment of humans,
4. the use of X-ray radiation on humans to show dental condition with intraoral anodes,
5. the use of X-ray radiation on humans for pneumoencephalography,
6. the use of X-ray radiation on humans to test the fit of articles of clothing and shoes,
7. the use of sealed radioactive substances or of ionising radiation on humans for access controls or to search for articles which a person conceals on or in his or her body, insofar as the use is not
 - a) performed on the basis of a law, and is necessary to carry out public service tasks, in consideration of all the circumstances of the individual case, or
 - b) essential, in the sphere of the Federal Ministry of Defence, for the purpose of defence or the fulfilment of international commitments.

Annex 2

(re sections 3 and 4)

Required documents for assessing the justification of types of practice

Part A: Required documents for assessing the justification in accordance with sections 7 and 38 of the Radiation Protection Act

The following shall be required:

1. information that makes it possible to assess whether the type of practice is appropriate as a matter of principle in order to provide a benefit,
2. information on the exposure caused by the type of practice, broken down into medical exposure of examined or treated persons as well as carers and comforters, exposure of members of the public and occupational exposures,
3. information on the radiological risk resulting from exposure in accordance with section 148,
4. information on the risk of the type of practice of placing the health or safety of persons at risk or causing contamination from accident-related or unintended exposure,
5. information on current approvals or licences on the basis of other national or international provisions that are closely associated with the type of activity to be assessed.

Part B: Additional documents for assessing the justification in accordance with section 38 of the Radiation Protection Act

The following shall be required:

1. information on the intended area of application, the intended use conditions and frequency of use, the expected duration of use and the expected distribution of consumer products or devices requiring a type approval,
2. justification of the selection of the radionuclide used, particularly relating to the associated risks, as well as information on other radionuclides that may be present that are not used in a target-orientated manner,
3. information that enables the assessment of
 - a) whether and if so how the consumer product or the device requiring a type approval can also be used outside the scope of the intended use,
 - b) whether the integrity of consumer products or devices requiring a type approval is sufficient in the case of use as intended, as well as in the event of possible misuse or accident-related damage.

Annex 3

(re sections 5, 6, 7, 8, 9, 14, 82 and 95)

Practices not requiring a licence

Part A

The use of substances on humans shall not require a licence in accordance with section 5 subsection (1) if the specific activity of the substances does not exceed 500 µBq per gram.

Part B:

The following shall not require a licence in accordance with section 5 subsection (1):

1. handling substances the activity of which does not exceed the exemption levels of Annex 4 Table 1 column 2,
2. handling substances the specific activity of which does not exceed the exemption levels of Annex 4 Table 1 column 3,
3. using, storing and disposing of medicinal products that were placed on the market in accordance with section 2 subsection (1), second sentence, of the Ordinance on Radioactive Medicinal Products or Medicinal Products treated with Ionising Radiation (*Verordnung über radioaktive oder mit ionisierenden Strahlen behandelte Arzneimittel* - AMRA_{AdV}),
4. using devices the type of which is approved in accordance with section 45 subsection (1) of the Radiation Protection Act, with the exception of the installation, removal and maintenance of such devices,
5. storing devices the type of which is approved in accordance with section 45 subsection (1) of the Radiation Protection Act, insofar as the total activity of the radioactive substances does not exceed 1,000 times the exemption levels of Annex 4 Table 1 column 2,
6. extracting, using and storing noble gases obtained from the air, if the isotope ratio in the gas corresponds to that in the air,
7. using and storing consumer products, medicinal products within the meaning of section 2 of the Medicinal Products Act, pesticides, plant protection products within the meaning of section 2 of the Plant Protection Act (*Pflanzenschutzgesetz*), and substances in accordance with section 2, first sentence, nos. 1 to 8 of the Fertiliser Act (*Düngegesetz*) the manufacture of which is authorised in accordance with section 40 of the Radiation Protection Act, or the transportation of which is authorised in accordance with section 42 of the Radiation Protection Act, or the manufacture of which does not require authorisation in accordance with section 40 subsection (3) of the Radiation Protection Act, or the transportation of which does not require authorisation in accordance with section 42 subsection (2) of the Radiation Protection Act; section 55 in conjunction with Annex 3 of the Radiation Protection Act shall remain unaffected thereby,
8. handling natural radioactive substances for the purpose of using the radioactivity for teaching and training purposes, if the ambient dose rate of each substance does not exceed 1 µSv per hour at a distance of 0.1 metres from the accessible surface, or
9. handling depleted uranium in the shape of uranyl compounds for chemical-analytical or for chemical-preparatory purposes with a total mass of the uranium of up to 30 grams.

Part C:

Operation of installations for the generation of ionising radiation not requiring an authorisation or notification in accordance with section 7, where the

1. type is approved in accordance with section 17, or
2. the potential difference is no more than 30 kilovolt (kV) and the ambient dose rate under normal operating conditions does not exceed 1 µSv per hour at a distance of 0.1 m from the accessible surface. The operation of installations for the generation of ionising radiation in which the impingement of laser radiation on material in accordance with section 2 subsection (3), first sentence, of the Ordinance on Health and Safety at Work

(*Arbeitsschutzverordnung*) can be used to generate ionising radiation for artificial optical radiation if the irradiation intensity of the laser radiation does not exceed 1×10^{13} Watt per square centimetre, and the ambient dose rate at 0.1 metres from the accessible surface does not exceed 1 mSv per hour, shall not require a licence or notification.

Part D:

The operation of stray radiation emitters shall not require a licence in accordance with section 8

1. where the voltage to accelerate the electrons does not exceed 30 kV if
 - a) the ambient dose rate during an hour at normal operating conditions at a distance of 0.1 m from the accessible surface of the device does not exceed 1 μ Sv, and
 - b) it is sufficiently indicated on the stray radiation emitter that
 - aa) X-ray radiation is generated, and
 - bb) the voltage to accelerate the electrons may not exceed the maximum value indicated by the manufacturer or importer,
2. where the voltage to accelerate the electrons exceeds 30 kV if the type is approved in accordance with section 45 subsection (1) no. 1 of the Radiation Protection Act,
3. if a cathode-ray tube is operated to present images in which the voltage to accelerate electrons does not exceed 40 kV if the ambient dose rate at an hour of normal operating conditions at a distance of 0.1 m from the accessible surface of the device does not exceed 1 μ Sv, or
4. that is operated as an image intensifier in connection with X-ray equipment requiring an authorisation or notification.

Part E:

The transportation of the following shall not require authorisation or notification in accordance with section 14:

1. substances the activity of which does not exceed the exemption levels of Annex 4 Table 1 column 2,
2. substances the specific activity of which does not exceed the exemption levels of Annex 4 Table 1 column 3,
3. medicinal products that were sold in accordance with section 2 subsection (1), second sentence, of the Ordinance on Radioactive Medicinal Products or Medicinal Products Treated with Ionising Radiation,
4. devices the type of which is approved in accordance with section 45 subsection (1) of the Radiation Protection Act, or
5. noble gases obtained from air if the isotope ratio in the gas corresponds to that in the air.

Annex 4

(re sections 5, 10, 11, 12, 16, 31, 35, 36, 37, 52, 57, 58, 61, 70, 83, 87, 88, 89, 92, 104, 106, 167 and 187 and Annex 3)

Exemption levels, clearance levels for different clearance types, levels of high-activity radioactive sources, limits for surface contamination, list of radionuclides and daughter nuclides considered in the calculations

***Table 1:* Exemption levels, clearance levels for different clearance types, levels of high-activity radioactive sources, limits for surface contamination**

[...]

Table 2: List of radionuclides and daughter nuclides considered in the calculation

[...]

Annex 5

(re section 27 and Annex 7)

Monitoring limits as well as methods of recovery and disposal for the determination of the monitoring requirement of residues

1. In the case of the recovery or disposal of residues, the following sum formula shall apply to the representative determined values $C_{U238max}$ and $C_{Th232max}$ of the highest specific activities of the radionuclides of nuclide chains U-238sec and Th-232sec in becquerels per gram (Bq/g), each relating to dry mass:

$$C_{U238max} + C_{Th232max} \leq C \text{ with the monitoring limit } C = 1 \text{ Bq/g.}$$

2. In derogation from no. 1, $C_{U238max} + C_{Th232max} \leq 0.5 \text{ Bq/g}$ shall apply if
- more than 5,000 tonnes of residues are deposited in the catchment area of a usable aquifer per calendar year, or
 - more than 50% residues are incorporated in construction materials in the case of recovery in road, path, landscape or hydraulic construction, in sports and play areas, or in other areas.

The first sentence shall not apply to the disposal of slags in road, path, landscape or hydraulic construction in other areas.

3. In derogation from no. 1, $C_{U238max} + C_{Th232max} \leq 5 \text{ Bq/g}$ shall apply in underground recovery or landfilling of residues.
4. If the greatest specific activity of Pb-210+ radionuclides exceeds the greatest specific activity of the other radionuclides of the U-238sec nuclide chain by a factor A larger than 5, the following shall apply in derogation from nos. 1 to 3: $R \cdot C_{U238max} + C_{Th232max} \leq C$. The factor R shall have the value 0.5 with above-ground recovery or disposal. The factor R shall be taken from the following table for underground recovery or disposal.

Factor A	Factor R
$5 < A \leq 10$	0.3
$10 < A \leq 20$	0.2
$20 < A$	0.1

5. In derogation from nos. 1 and 2, the conditions $C_{U238max} \leq 0.2 \text{ Bq/g}$ and $C_{Th232max} \leq 0.2 \text{ Bq/g}$ shall apply if a surface of more than 1 hectare is occupied with leftover rock in the case of landfilling or recovery in road, path or landscape construction, including in sport and play areas, in the catchment area of a usable aquifer.

Exposures by radionuclides of the U-235 decay series shall be taken into account in the nuclide chain U-238sec, and do not need to be separately considered. If, additionally, the specific activity of each radionuclide in one of the U-238sec or Th-232sec nuclide chains is less than 0.2 becquerels per gram (Bq/g), the respective nuclide chain shall not be taken into consideration.

Annex 6

(re 28, 100 and 101)

Principles for the determination of exposures from residues

1. Realistic pathways of exposure and exposure assumptions shall be used in each case when assessing the exposure of members of the public and of occupational workers. To the extent that the pathways of exposure in accordance with Annex 11 Part A are considered, the assumptions in accordance with Annex 11 Part B Table 1 columns 1 to 7 and Table 2 shall be used as a basis.
2. In the case of recovery of residues, when determining the exposure of members of the public and of occupational workers, all exposures shall be taken into consideration that could occur via the envisaged method of recovery, in particular through the manufacture and sale of products and through the disposal of further residues that have occurred in this process.
3. In the case of the disposal of residues, when determining the exposure of members of the public and of occupational workers, all exposures shall be taken into consideration that may occur on the envisaged method of disposal through the treatment, storage and deposition of the residues.
4. In the case of properties that are contaminated by residues, all exposure scenarios that could occur with realistic use assumptions in consideration of the natural site conditions shall be incorporated into the determination of exposure in accordance with section 64 subsection (1), second sentence, of the Radiation Protection Act.

The dose coefficients from the compilation in the Federal Gazette no. 160a and b of 28 August 2001, Parts I and II, shall be used for members of the public. The dose coefficients from the compilation in Federal Gazette no. 160a and b of 28 August 2001, Parts I and II, shall be used for occupational workers.

Annex 7

(re 29 subsection (4))

Preconditions for release from monitoring in the case of joint landfilling of residues requiring monitoring with other residues and waste

For the release of residues from monitoring for the purpose of joint landfilling with other residues and waste, the competent authority can assume under the following conditions that exposures that can occur due to this joint landfilling will not exceed the constraint of an effective dose of 1 mSv per calendar year for members of the public without further measures:

1. The following sum formula shall apply to the mean values $C_{U238max}^M$ and $C_{Th232max}^M$ of the specific activities of the radionuclides in the nuclide chains U-238sec and Th-232sec in becquerels per gram (Bq/g): $C_{U238max}^M + C_{Th232max}^M \leq C^M$. The mean values $C_{U238max}^M$ and $C_{Th232max}^M$ of the specific activities may be determined as the total activity of the residues requiring monitoring which are deposited on the landfill within 12 months in accordance with Annex 1 of the Radiation Protection Act and Annex 5 of this Ordinance, divided by the total mass of all residues and waste deposited on the landfill within this period. The highest activity of the radionuclides in the nuclide chains U-238sec and Th-232sec shall be used as a basis for the determination of total activity. C^M shall assume the following limits:
 - a) $C^M = 0.05$ Bq/g for landfills with an area exceeding 15 hectares,
 - b) $C^M = 0.1$ Bq/g for landfills with an area of up to 15 hectares,
 - c) $C^M = 1$ Bq/g regardless of the landfill area for landfills that can be excluded due to the specific site-based groundwater pollution, and
 - d) $C^M = 5$ Bq/g for underground disposal.

The specific activity of no radionuclide in the nuclide chains U-238sec and Th-232sec shall exceed 10 becquerels per gram (Bq/g), or 50 becquerels per gram (Bq/g) in landfill on landfill sites for waste requiring special monitoring.

2. If in a residue batch, the highest specific activity of the Pb-210+ radionuclides exceeds the specific activity of the other radionuclides of the U-238sec nuclide chain by a factor A greater than 5, the activity of the radionuclides of the U-238sec nuclide chain may be multiplied by a factor R for this batch in the determination of the total activity in accordance with no. 1. For disposal on landfills, factor R assumes the value 0.3. For underground disposal, the factor R shall be taken from the table in Annex 5 no. 4.

Exposures from radionuclides of the U-235 decay series shall be taken into consideration in the nuclide chain U-238sec, and need not be considered separately. Additionally, if the specific activity of each radionuclide in one of the U-238sec or Th-232sec nuclide chains in individual batches of residues is less than 0.2 becquerels per gram (Bq/g), the respective nuclide chain shall not be taken into consideration for this batch in the determination of the total activity in accordance with no. 1.

Determinations for clearance

Part A: General

1. Unless otherwise specified in Parts B to G below, the following shall apply:
 - a) The procedure for proving compliance with the clearance levels shall depend on the type and characteristics of the substances.
 - b) The proof of compliance with the clearance levels shall be provided using measurements. Additionally, where a solid surface is available on which a contamination measurement can be carried out, compliance with the limits for surface contamination shall be proved if a solid surface is present on which a contamination measurement is possible; this proof too shall be provided on the basis of measurements. The competent authority may also permit other verification methods in individual cases.
 - c) The averaging mass to be used as a basis in the determination of the specific activity may not significantly exceed 300 kg.
 - d) The averaging area for surface contamination may be up to 1,000 cm².
 - e) For several radionuclides, the sum of the ratios C_i / R_i from the specific activity (C_i) to be cleared, and the respective clearance levels (R_i) of the individual radionuclides in accordance with Annex 4 Table 1 columns 3, 6 to 11, and 14, shall be calculated (sum formula), whereby i shall be the respective radionuclide. This sum may not exceed value 1:

$$\sum_i \frac{C_i}{R_i} \leq 1.$$

In the case of several radionuclides, the sum of the ratios $A_{s,i} / O_i$ from the existing activity per area unit ($A_{s,i}$) and the respective limits for surface contamination (O_i) of the individual radionuclides shall be calculated in accordance with Annex 4 Table 1 columns 5, 12 and 13 (sum formula):

$$\sum_i \frac{A_{s,i}}{O_i} \leq 1.$$

Radionuclides do not need to be taken into account in the sum total if the proportion of the nuclides that are not considered vis-à-vis the sum of all C_i / R_i or $A_{s,i} / O_i$ ratios does not exceed 10 percent.

2. If the proof of compliance with the dose criterion for clearance in accordance with section 31 subsection (2) is maintained in the individual case, the determinations of Annex 11 Parts B and C no. 1, in particular the determinations of Annex 11, Part B Table 1 columns 1 to 7 shall be taken as a basis, insofar as the pathways of exposure as specified in Annex 11 Part A are significant for the individual case in accordance with section 37. In individual cases in accordance with section 37, the clearance of liquid substances shall be based at most on the limits of Annex 11 Part D Table 4 column 3, insofar as they can be discharged. In the case of the clearance of a floor area, only those pathways of exposure may be disregarded which have been eliminated due to the existing site-related circumstances, in particular the geographic location and the geogenic conditions.

Part B: Unrestricted clearance of solid substances, oils and liquids containing oil, organic solvents and coolants

The levels of Annex 4 Table 1 column 3 shall apply to

1. solid substances,
2. rubble from the demolition of buildings, including adhering soil, if the mass to be cleared is

no more than 1,000 Mg per calendar year, and

3. oils and liquids containing oil, organic solvents and coolants.

Part C: Specific clearance for disposal

1. A specific clearance for disposal shall be contingent on the substances for which an effective determination was made in accordance with section 42 subsection (1) being deposited on a landfill, or disposed of in an incineration facility. Recovery or re-use outside of a landfill or incineration facility, as well as the re-entry of the substances into the economy, shall be ruled out.
2. The levels of Annex 4 Table 1 columns 8 to 11 shall not apply to rubble and to rubble including adhering soil if the mass to be cleared can be more than 1,000 Mg per calendar year.
3. Only landfills shall be suited for the disposal of cleared substances as waste disposal facilities which
 - a) at least comply with the requirements of landfill categories in accordance with section 2 nos. 7 to 10 of the Landfill Ordinance (*Deponieverordnung*) of 27 April 2009 (Federal Law Gazette Part I p. 900), most recently amended by Article 2 of the Ordinance of 27 September 2017 (Federal Law Gazette Part I p. 3465), and
 - b) which have an annual capacity of at least 10,000 Mg per calendar year (Mg/a) or 7,600 cubic metres per calendar year (m³/a) with regard to the stored quantity of waste, averaged over the last three years.
4. In derogation from no. 2 and Part A no. 1(e), first sentence, if more than 1,000 Mg are to be discharged per calendar year and disposed of via a waste disposal facility, with several radionuclides the sum of the ratios C_i/R_i from the specific activity (C_i) to be cleared and the respective clearance level (R_i) of the individual radionuclides in accordance with Annex 4 Table 1 columns 10 or 11, multiplied by a thousandth of the mass to be cleared, shall be calculated. This sum may not exceed the value 1:

$$\sum_i \frac{C_i}{R_{i,Sp.10,Sp.11}} \cdot \frac{m}{1000} \leq 1.$$

If in a calendar year, both masses with radionuclides are to be cleared for disposal on a landfill in accordance with Annex 4 Table 1 column 8 and with Annex 4 Table 1 column 10, in derogation from Part A no. 1(e), first sentence, with several radionuclides the sum of the products of the ratios C_i/R_i from the specific activity (C_i) to be cleared and the respective clearance level (R_i) of the individual radionuclides i in accordance with Annex 4 Table 1 column 8, multiplied by one-hundredth of the mass to be cleared and the product of the ratios C_i/R_i from the specific activity (C_i) to be cleared and the respective clearance levels (R_i) of the individual radionuclides in accordance with Annex 4 Table 1 column 10, multiplied by one-thousandth of the mass to be cleared, shall be calculated. This sum may not exceed the value 1:

$$\sum_i \left(\frac{C_{i,Sp.8}}{R_{i,Sp.8}} \cdot \frac{m_{Sp.8}}{100} + \frac{C_{i,Sp.10}}{R_{i,Sp.10}} \cdot \frac{m_{Sp.10}}{1000} \right) \leq 1.$$

The third and fourth sentences shall apply mutatis mutandis for clearance for disposal in an incineration facility in accordance with the provision under column 9 or column 11, i.e. the following applies for the sum:

$$\sum_i \left(\frac{C_{i,Sp.9}}{R_{i,Sp.9}} \cdot \frac{m_{Sp.9}}{100} + \frac{C_{i,Sp.11}}{R_{i,Sp.11}} \cdot \frac{m_{Sp.11}}{1000} \right) \leq 1.$$

Where

- C_i is the average specific activity of the radionuclide i that has been cleared and is to be cleared in the current calendar year is in Bq/g and $C_i < R_i$

- m is the mass of the substances that have been cleared and are to be cleared in the current calendar year in Mg
- R_i is the clearance level in accordance with Annex 4 Table 1 columns 8, 9, 10 or 11 for each radionuclide i in Bq/g.

Part D: Specific clearance of buildings, rooms and parts thereof, as well as construction parts

1. The clearance measurement of a building, of a room or parts thereof, or of construction parts, is to be conducted on the standing structure as a matter of principle. The measurements may be conducted on the basis of an appropriate sampling technique.
2. The averaging area to be used as a basis may be up to 1 m².
3. If the subsequent reuse or continued use of the building cannot be ruled out, the surface contamination levels may not exceed the limits of Annex 4 Table 1 column 12.
4. If the building or parts thereof is to be demolished after the clearance measurement, the surface contamination levels may not exceed the limits in accordance with Annex 4 Table 1 column 13. The competent authority may permit higher averaging areas than 1 m² on request if it is proven that the required detection limit will be achieved with the larger averaging area. The clearance of buildings, rooms or parts thereof and construction parts for demolition shall be conditional on their being processed into rubble after clearance.
5. No separate clearance shall be required for rubble occurring subsequent to the clearance of a building, of a room or parts thereof or of construction parts by means of demolition.
6. Part B, C or F shall apply in the event of volume-supported activity through activation.

Part E: Specific clearance of soil areas

1. In the case of use of clearance levels for surface areas, the averaging area for surface contamination may be up to 100 m². Alternatively, in the use of clearance levels related to mass, the underlying averaging mass for determination of the specific activity may be up to 1 Mg.
2. Only contamination that has been caused by facilities or installations on the operating site shall be taken into account.
3. If no clearance levels are stated in accordance with Annex 4 Table 1 column 7, proof of the dose criterion shall be furnished in the individual case. In doing so, the uses of the soil areas to be cleared shall be taken into account in accordance with the respective local conditions and the pathways of exposure relevant thereto.
4. The proof in accordance with no. 3 shall be furnished through dose calculations on the basis of measurements.
5. The clearance levels in accordance with Annex 4 Table 1 column 7 may be converted into area-based clearance levels according to the following ratio:

$$O_i = R_i \times \rho \times d.$$

Where:

O_i is the clearance level for ground areas for the respective radionuclide i in Bq/cm²,

R_i is the clearance level for ground areas for the respective radionuclide i in Bq/g in accordance with Annex 4 Table 1 column 7,

ρ is the mean ground density in g/cm³ at depth d, and

d is the mean penetration depth in cm.

Part F: Specific clearance of rubble from the demolition of buildings

1. The levels of Annex 4 Table 1 column 6 shall apply to rubble occurring during current operational activities or after the demolition of buildings or parts of installations insofar as the prerequisites of a clearance measurement of the standing structure in accordance with Part D have not been met. Soil adhering to rubble may be considered as rubble.

2. For a clearance measurement of rubble, the averaging mass may be up to 1 Mg. The competent authority may permit larger averaging masses on request if it is proven that the dose criterion of clearance will also be achieved with the larger averaging mass.
3. In derogation from the applicability of the clearance levels of Annex 4 Table 1 column 6 on masses of building rubble exceeding 1,000 Mg, the clearance level for Cs-137 for masses between zero and 10,000 Mg per calendar year shall be used as the basis for clearance.

Part G: Specific clearance of scrap metal for recycling

1. Clearance of scrap metal for recycling shall be conditional on the scrap metal for which a determination was made in accordance with section 42 subsection (1) being melted down.
2. The levels of Annex 4 Table 1 column 14 shall not apply to composite materials from metallic and non-metallic components.
3. Only smelting operations that can ensure a mixing ratio of 1:10 of cleared scrap metal to other metals, or that have a throughput of at least 40,000 tonnes per calendar year, shall be deemed appropriate.
4. In the case of the clearance of scrap metal for recycling that is contaminated with only one of the radionuclides Be-7, C-14, Mn-53, Mn-54, Co-57, Ni-59, Ni-63, Nb-93m, Mo-93, Tc-97, Tc-99, Ru-103, Ag-105, Ag-108m, Cd-109, Sb-125, Te-132, I-129, Eu-155, Ti-204, Pa-231, Es-254 or Fm-255, the mass shall be limited to 10 Mg per calendar year. Contamination with a single radionuclide shall be deemed to be present if all other radionuclides together do not exceed a proportion of one thousandth of the activity.

(re sections 84, 85, 167, 168 and 192)

List of data on highly active radiation sources (HASS) which are recorded in the register of highly active radiation sources (HASS Register)

1	Holder of the licence (owner)
Manufacturer, user or	The holder of a licence to handle highly active radiation sources in accordance with section 9 of the Atomic Energy Act or section 12 subsection (1) no. 3 of the Radiation Protection Ordinance or sections 6, 7 and 9b of the Atomic Energy Act (on the basis of the territorial scope in accordance with section 10a subsection (2) of the Atomic Energy Act)
Supplier	Holder of a licence in accordance with section 3 of the Atomic Energy Act or section 12
Name	Name of the company or institution
Address	Complete postal address
Contact person	Name, telephone number, e-mail address
<i>Land</i>	
2	Information regarding the licence
Number	
Date of issue	
Date of expiry	
Licensing authority/competent supervisory authority	
3	Information regarding the HASS
HASS identification number	Identification number of the highly active radiation source in accordance with section 92 subsection (1)
Use	Information regarding the use of the highly active radiation source, e.g. blood irradiation or industrial radiography
Manufacturer's device number	
4	Information regarding the manufacturer/supplier
	If the manufacturer of the highly-radioactive source is established outside the European Atomic Energy Community, the name and address of the transporting party or of the supplier shall additionally be indicated.
Name	Name of company or institution
Address	Complete postal address

Land

5	HASS characteristics
Radionuclide	
Date of manufacture or when first placed on the market	
Activity at the date of manufacture or other reference date for the activity	if applicable, activity at the time when the highly active radiation source is first placed on the market or with regard to another reference date, if activity at the time of manufacture is unknown
Source type	
Capsule type	
Chem./phys. characteristics	
ISO classification	
ANSI classification	
Certificate of special form	Information regarding the date when a special form approval was granted and its extensions, if applicable
IAEA source category	Cat. 1, 2 or 3
Neutron source	yes/no
Neutron source target	
Neutron flux	
6	Type of use
Fixed use, storage or mobile use	
Information insofar as a mobile highly active radiation source is used, and if the highly active radiation source does not remain in another location for more than four weeks	
7	Location of HASS (use, storage or permanent storage location in case of mobile use)
if different from (1)	
Name	Name of company or institution
Address	Complete postal address
<i>Land</i>	
Competent supervisory authority	
Authorisation number, if appropriate	

8	Receipt of the HASS	
Date of receipt	Date of acquisition of possession	
acquired from		
Manufacturer, other user or supplier		
Name	Name of company or institution	
Address	Complete postal address	
Contact person	Name, telephone number, e-mail address	
<i>Land</i>		
9	Transfer of HASS	
Date of transfer	Date of relinquishment of physical control	
Transfer to		
Manufacturer, other user, supplier or		
Disposal installation	<i>Länder</i> -level collecting facility or federal installation for the safekeeping and disposal of radioactive waste in accordance with section 9a subsection (3), first sentence, of the Atomic Energy Act	
Name	Name of company or institution	
Address	Complete postal address	
Contact person	Name, telephone number, e-mail address	
<i>Land</i>		
Licence number		
Date of issue of licence		
Date of expiry of licence		
10	Assessment of HASS	
Respective type and date of inspections for integrity and leak tightness	Date of integrity and leakage test in accordance with section 82 subsection (2)	
11 Other information		
Loss of a HASS		
Date		
Unlawful misappropriation of a HASS – e.g. theft		
Date		

Retrieval of a HASS

Date

Location

Finding of a HASS

Date

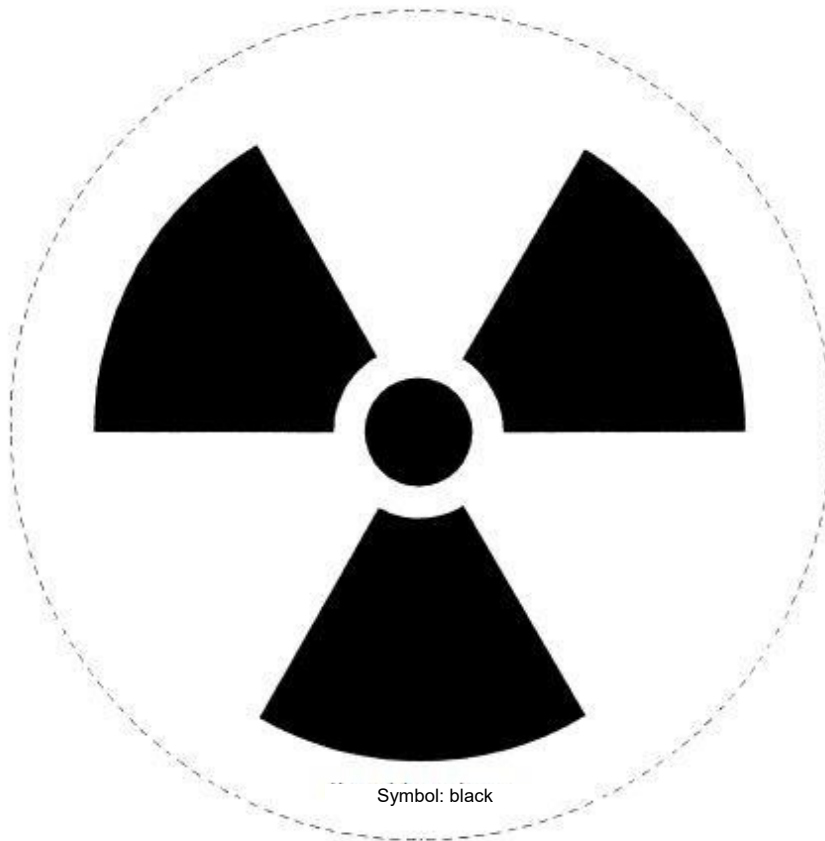
Location

12 Additional observations

Annex 10

(re section 91 and 92)

Radiation symbol



Symbol: black
Background: yellow

Annex 11

(re sections 100, 101, 102, 160 and 168, as well as Annex 6 and Annex 8)

Assumptions in the calculation of exposure

Part A: Pathways of exposure

1. For discharge with air:
 - 1.1. Exposure through beta radiation in the exhaust air plume (beta submersion)
 - 1.2. Exposure through gamma radiation in the exhaust air plume (gamma submersion)
 - 1.3. Exposure through gamma radiation of the radioactive substances stored on the ground (terrestrial gamma radiation)
 - 1.4. Exposure through intake of radioactive substances with respiratory air (inhalation)
 - 1.5. Exposure through intake of radioactive substances with food (ingestion) on the pathway
 - 1.5.1. Air – plant
 - 1.5.2. Air – feed plant – cow – milk
 - 1.5.3. Air – feed plant – animal – meat
 - 1.5.4. Air – mother's milk
 - 1.5.5. Air – food – mother's milk
2. Discharge with water:
 - 2.1. Exposure through time spent on sediment (terrestrial gamma radiation)
 - 2.2. Exposure through intake of radioactive substances with food (ingestion) on the pathway
 - 2.2.1. Drinking water
 - 2.2.2. Water – fish
 - 2.2.3. Cattle watering trough – cow – milk
 - 2.2.4. Cattle watering trough – animal – meat
 - 2.2.5. Rain/spray irrigation – feed plant – cow – milk
 - 2.2.6. Rain/spray irrigation – feed plant – animal – meat
 - 2.2.7. Rain/spray irrigation – plant
 - 2.2.8. Mother's milk through intake of radioactive substances by the mother via the abovementioned ingestion paths
3. Ionising radiation from nuclear installations, facilities as defined in section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation, and other equipment:
 - 3.1. gamma radiation
 - 3.2. X-ray radiation
 - 3.3. neutron radiation
4. In case of soil areas that were contaminated in other ways:
 - 4.1. Exposure by spending time on contaminated soil or next to contaminated deposits (terrestrial gamma radiation)
 - 4.2. Exposure through intake of resuspended soil or material of deposits with the air (dust inhalation)
 - 4.3. Exposure through intake of contaminated soil or material of deposits through the

mouth (soil ingestion)

- 4.4. Exposure through intake of radioactive substances with food produced in private gardens next to contaminated deposits (dust pathway) or on contaminated soils (soil ingestion)

Pathways of exposure shall remain unconsidered, or additional pathways of exposure (e.g. seepage water with contaminated deposits) shall be taken into consideration, if this is justified on the basis of the local circumstances of the site, or of the type of nuclear installation, of the type of installation within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, of the type of installation for the generation of ionising radiation or the type of other equipment or of the particularity of the soil areas contaminated by other means.

Part B: Living habits

**Table 1:
Consumption rates**

Median consumption rates of reference persons in kg/a							
1	2	3	4	5	6	7	8
Age group	≤ 1 year	> 1 - ≤ 2 years	> 2 - ≤ 7 years	> 7 - ≤ 12 years	> 12 - ≤ 17 years	> 17 years	
Foodstuff							
Drinking water	55 ¹²⁾	100	100	150	200	350	2
Mother's milk, processed milk products with drinking water	200 ¹³⁾	-	-	-	-	-	1.6
Milk, dairy products	45	160	160	170	170	130	3
Fish ⁴⁾	0.5	3	3	4.5	5	7.5	5
Meat, sausage, eggs	5	13	50	65	80	90	2
Cereals, cereal products	12	30	80	95	110	110	2
Local fresh fruit, fruit products, juices	25	45	65	65	60	35	3
Potatoes, root vegetables, juices	30	40	45	55	55	55	3
Leafy vegetables	3	6	7	9	11	13	3
Vegetables, vegetable products, juices	5	17	30	35	35	40	3

It shall be presumed with regard to the food groups "Drinking water" and "Mother's milk, processed milk products with drinking water" that 100 percent of the products are contaminated. 50 percent shall be presumed for all other food groups. The food group "Cereals, cereal products", as well as contaminations via the dust pathway for the food group "Potatoes, root vegetables, juices" may remain unconsidered as a matter of principle with radionuclides of the natural decay series uranium 238 and thorium 232.

-
- 2) Quantity specification in [l/a].
Another 160 l/a are added to the annual 55 l/a infant drinking water quantity if it is assumed that the infant is not being breastfed but is only given processed milk products that are produced nationally, and can be considered not to be contaminated. It shall be assumed here that 0.2 kg of concentrate (equivalent to 1 l of milk) are dissolved in 0.8 l of water.
- 3) Depending on the nuclide composition, the least favourable nutritional variant shall be taken as the basis.
- 4) The proportion of fresh water fish among total fish consumption amounts to an average of approx. 17 %, and shall be adapted to regional circumstances.

In the determination of the expected exposure in accordance with section 100 subsection (1) within the framework of the licensing or notification procedure for practices in accordance with section 4 subsection (1) nos. 1 and 3 to 8 of the Radiation Protection Act, and in the determination of the exposure received in accordance with section 101 subsection (1) no. 1 or 2, for the food group which leads to the highest ingestion dose with medium consumption rates, the average consumption rate shall be multiplied by the factor in column 8. All vegetable products other than leafy vegetables shall be combined to form one food group in to determine the dose-dominating food group. The average consumption rates should be set for all other food groups.

Table 2: Respiration rates

Age group	≤ 1 year	> 1 - ≤ 2 years	> 2 - ≤ 7 years	> 7 - ≤ 12 years	> 12 - ≤ 17 years	> 17 years
Breathing rate in m ³ /year	1,100	1,900	3,200	5,640	7,300	8,100

Table 3: Periods of stay, locations of stay and reduction factors

Pathway of exposure	Periods and locations of stay	Reduction factor
Radiation within the exhaust air plume	1,760 hours per year outdoors 7,000 hours per year in buildings	- -
Gamma radiation from the exhaust air plume	1,760 hours per year outdoors 7,000 hours per year in buildings	- 0.3
Gamma radiation from the radioactive substances stored on the ground	1,760 hours per year outdoors 7,000 hours per year in buildings	- 0.3
Inhalation of radioactive substances	1,760 hours per year outdoors 7,000 hours per year in buildings	- -
Stay on sediment	760 hours per year	-
Direct radiation ¹	1,760 hours per year outdoors 7,000 hours per year in buildings	- case-specific ²

²

The numeric values listed in Table 3 for the respective pathways of exposure shall be used for the prospective calculation of the exposure. The following cases shall be taken into consideration for the time spent outdoors:

The representative person stays outdoors, either for 760 hours per calendar year on sediment, and

¹ Ionising radiation from nuclear installations, facilities within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, installations for the generation of ionising radiation and other facilities.

² Case-specific reduction factors for direct radiation (gamma direct radiation and direct X-ray radiation) with time spent in buildings:

0.3 for nuclear installations, facilities within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act,

0.3 for installations for the generation of ionising radiation and other facilities that are not located in the same residential building as the representative person,

1 for installations for the generation of ionising radiation and other facilities that are located in the same residential building as the representative person.

Reduction factor 1 shall be used for neutron direct radiation.

the remaining 1,000 hours per calendar year in other locations, or 1,760 hours per calendar year in other locations outdoors. The least favourable variant overall shall be used as a basis for the prospective calculation of the exposure.

The actual durations and locations of the stay during the time in question, if known or ascertainable with a reasonable amount of effort, shall be used as a basis for the retrospective calculation of the exposure. In other cases, the procedure shall be as in the prospective calculation.

Part C: Other assumptions

1. The dose coefficients and stipulations made in the in Annex 18 Part B no. 4, as well as other dose coefficients designated in the general administrative provisions, shall be used to calculate the exposure.
2. All effective sources in accordance with the criteria in the general administrative provisions shall be taken into account to calculate the exposure.
3. Models describing an equilibrium condition shall be used as the basis to calculate exposure. The expected fluctuations in radioactive discharges shall be taken into consideration in this process by making a suitable selection of calculation parameters.
4. For discharges with air, the dispersion calculation shall be based on the Lagrangian particle model. The prospective calculation of the exposure shall be based on long-term weather statistics or on the time series of a representative year, while the retrospective calculation of the exposure shall be based on the meteorological data for the period under review. In individual cases, the authority competent for considering the characteristics of the site or of the nuclear facility, the facility within the meaning of section 9a subsection (3), first sentence, second clause of the first half-sentence of the Atomic Energy Act, the installation for the generation of ionising radiation, or the other installation, can order or permit other procedures to be used. For discharges with water, the prognostic calculation of the exposure shall be based on long-term mean values of the water level of the draining canal. The retrospective calculation of the exposure shall be based on the mean value of the water level of the draining canal for the period under review.
5. The determination of parameters shall be effected in conjunction with the calculation models, and in such a manner that no underestimation of radiation exposure can be expected to occur in the overall result. If parameters are to be taken into consideration when exposure is calculated the numeric values of which are subject to a fluctuation range, extreme values of the individual parameters may only be selected in justified exceptional cases.
6. In the retrospective calculation of the exposure, the specific local conditions shall be taken into consideration, where appropriate also with the specific local model parameters, as well as current representative statistical data for the period under review. The following procedure shall apply:
 - a) The measured or balanced actual emissions and the measured or calculated direct radiation in the area surrounding the site shall be taken into consideration.
 - b) Only those pathways of exposure shall be used as a basis that actually contributed to the exposure due to the real circumstances in the area surrounding the site. The actual usage (not the usage possibilities) in the surrounding area shall be particularly taken into consideration therein.
 - c) To calculate the ingestion dose from food, only those food groups that were produced in the period under review in the area surrounding the site shall preferably be taken into account. Insofar as this information cannot be obtained with a reasonable amount of effort, the procedure shall be followed as with the prospective calculation of the exposure.
 - d) For the enrichment of radioactive substances in the soil and in other environmental media, the actual total duration of the emissions shall be assumed for the individual case (productive phase and also post-operational phase where appropriate).
 - e) The real stay times and locations during the period under review shall preferably be taken into account. Insofar as this information cannot be obtained with a reasonable amount of effort, the procedure shall be followed as with the prospective calculation of the exposure.
7. When calculating the expected exposure in accordance with section 100 subsection (1) as part of the licensing or notification procedure for practices in accordance with section 4

subsection (1) no. 1 and nos. 3 to 8 of the Radiation Protection Act, the calculated effective doses caused by the discharge of radioactive substances into the air or water shall be multiplied by the following generic radionuclide-specific factors and exposure pathway-specific factors.

Table 4
Generic radionuclide-specific factors

Pathway of exposure	Factor	Radionuclide
Terrestrial gamma radiation	2 1	I-125 I-131
Gamma submersion	2	I-125, I-131
Ingestion	7	I-125, I-131
Beta submersion and inhalation	7	I-125, I-131

Table 5
Exposure pathway-specific factors

Pathway of exposure	Factor
In case of discharge with air:	
– beta submersion	1
– gamma submersion	2
– terrestrial gamma radiation	2
– inhalation	1
– ingestion of food	3
In case of discharge with water:	
– terrestrial gamma radiation on sediment	1
– ingestion of food	3

Part D: Maximum permissible activity concentrations from radiation protection areas

In the event of several radionuclides, the sum of the ratios from the mean annual concentration of radionuclides in the air or in the water in Bq/cbm ($C_{i,a}$), and the respective calculated mean annual concentration value of the respective radionuclide (C_i) of Table 6 or 7, shall be determined (sum formula), whereby i is the respective radionuclide. This sum shall not exceed the value 1:

$$\sum_i \frac{\bar{C}_{i,a}}{C_i} \leq 1$$

Daughter nuclides shall be taken into account.

1. Maximum permissible activity concentrations in the air from radiation protection areas
 - 1.1 Inhalation

The average annual activity of radionuclide i per cubic metre of air

 - 1.1.1 for exhaust air streams $Q \leq 10^4 \text{ m}^3 \text{ h}^{-1}$ may not be higher than ten times the respective values of Table 6 column 2 or Table 8 column 2, or
 - 1.1.2 for exhaust air streams $10^4 \text{ m}^3 \text{ h}^{-1} < Q \leq 10^5 \text{ m}^3 \text{ h}^{-1}$ may not be higher than the respective values of column 2 of Table 4 or 6;
 - 1.2 Submersion

The average annual activity of radionuclide i per cubic metre of air

 - 1.2.1 for exhaust air streams $Q \leq 10^4 \text{ m}^3 \text{ h}^{-1}$ may not be higher than ten times the values of Table 5 column 2, or
 - 1.2.2 for exhaust air streams $10^4 \text{ m}^3 \text{ h}^{-1} < Q \leq 10^5 \text{ m}^3 \text{ h}^{-1}$ may not be higher than the values of column 2 of Table 7.
2. Maximum permissible activity concentration in water that is discharged from radiation protection areas into sewers
 - 2.1 Ingestion

The average annual activity of radionuclide i per cubic metre of water

 - 2.1.1 for waste water quantities $\leq 10^5 \text{ m}^3 \text{ a}^{-1}$ may not be higher than ten times the respective values of Table 6 column 3 or Table 8 column 4, or
 - 2.1.2 for waste water quantities $>10^5 \text{ m}^3 \text{ a}^{-1}$ may not be higher than the respective values of Table 4 column 3 or Table 6 column 4.

**Table 6: Activity concentration C_i from radiation protection areas
(re Part D nos. 1.1 and 2)**

Radionuclide		C_i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
H-3	A	1 E+2	1 E+7
H-3	O		7 E+6
Be-7	A	6 E+2	5 E+6
Be-10	A	1	6 E+4
C-11	A	6 E+2	3 E+6
C-14	A	6	6 E+5
F-18	A	5 E+2	2 E+6
Na-22	A	1	4 E+4
Na-24	A	9 E+1	3 E+5
Mg-28	A	2 E+1	7 E+4
Al-26	A	5 E-1	1 E+4
Si-31	A	3 E+2	5 E+5
Si-32	A	3 E-1	1 E+5
P-32	A	1	3 E+4
P-33	A	2 E+1	3 E+5
S-35	A	2 E+1	7 E+5
S-35	O		1 E+5
Cl-36	A	1 E-1	1 E+4
Cl-38	A	5 E+2	6 E+5
Cl-39	A	6 E+2	9 E+5
K-42	A	2 E+2	2 E+5
K-43	A	2 E+2	4 E+5
K-44	A	1 E+3	9 E+5
K-45	A	2 E+3	1 E+6
Ca-41	A	3	3 E+5
Ca-45	A	2	8 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Ca-47	A	2 E+1	7 E+4
Sc-43	A	2 E+2	5 E+5
Sc-44	A	1 E+2	3 E+5
Sc-44m	A	2 E+1	4 E+4
Sc-46	A	5	8 E+4
Sc-47	A	4 E+1	1 E+5
Sc-48	A	3 E+1	7 E+4
Sc-49	A	7 E+2	9 E+5
Ti-44	A	3 E-1	2 E+4
Ti-45	A	3 E+2	6 E+5
V-47	A	8 E+2	1 E+6
V-48	A	1 E+1	6 E+4
V-49	A	8 E+2	2 E+6
Cr-48	A	1 E+2	6 E+5
Cr-49	A	8 E+2	1 E+6
Cr-51	A	8 E+2	3 E+6
Mn-51	A	6 E+2	8 E+5
Mn-52	A	2 E+1	7 E+4
Mn-52m	A	8 E+2	1 E+6
Mn-53	A	2 E+2	2 E+6
Mn-54	A	2 E+1	2 E+5
Mn-56	A	2 E+2	3 E+5
Fe-52	A	4 E+1	7 E+4
Fe-55	A	2 E+1	1 E+5
Fe-59	A	8	2 E+4
Fe-60	A	1 E-1	1 E+3
Co-55	A	5 E+1	2 E+5
Co-56	A	5	4 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Co-57	A	3 E+1	3 E+5
Co-58	A	2 E+1	1 E+5
Co-58m	A	2 E+3	4 E+6
Co-60	A	1	2 E+4
Co-60m	A	2 E+4	4 E+7
Co-61	A	6 E+2	1 E+6
Co-62m	A	1 E+3	1 E+6
Ni-56	A	3 E+1	2 E+5
Ni-57	A	5 E+1	1 E+5
Ni-59	A	8 E+1	1 E+6
Ni-63	A	3 E+1	6 E+5
Ni-65	A	3 E+2	4 E+5
Ni-66	A	2 E+1	3 E+4
Cu-60	A	7 E+2	1 E+6
Cu-61	A	4 E+2	1 E+6
Cu-64	A	3 E+2	2 E+6
Cu-67	A	5 E+1	4 E+5
Zn-62	A	5 E+1	2 E+5
Zn-63	A	7 E+2	1 E+6
Zn-65	A	3	3 E+4
Zn-69	A	1 E+3	3 E+6
Zn-69m	A	9 E+1	7 E+5
Zn-71m	A	2 E+2	6 E+5
Zn-72	A	2 E+1	1 E+5
Ga-65	A	1 E+3	2 E+6
Ga-66	A	5 E+1	7 E+4
Ga-67	A	1 E+2	5 E+5
Ga-68	A	5 E+2	7 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Ga-70	A	2 E+3	2 E+6
Ga-72	A	5 E+1	9 E+4
Ga-73	A	2 E+2	3 E+5
Ge-66	A	3 E+2	1 E+6
Ge-67	A	1 E+3	1 E+6
Ge-68	A	3	7 E+4
Ge-69	A	1 E+2	4 E+5
Ge-71	A	2 E+3	7 E+6
Ge-75	A	8 E+2	2 E+6
Ge-77	A	9 E+1	3 E+5
Ge-78	A	3 E+2	7 E+5
As-69	A	1 E+3	1 E+6
As-70	A	4 E+2	7 E+5
As-71	A	8 E+1	3 E+5
As-72	A	3 E+1	8 E+4
As-73	A	3 E+1	3 E+5
As-74	A	2 E+1	9 E+4
As-76	A	3 E+1	9 E+4
As-77	A	8 E+1	3 E+5
As-78	A	3 E+2	4 E+5
Se-70	A	3 E+2	9 E+5
Se-73	A	1 E+2	6 E+5
Se-73m	A	1 E+3	3 E+6
Se-75	A	2	4 E+4
Se-79	A	4 E-2	5 E+3
Se-81	A	2 E+3	3 E+6
Se-81m	A	6 E+2	2 E+6
Se-83	A	8 E+2	2 E+6

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Br-74	A	6 E+2	1 E+6
Br-74m	A	4 E+2	6 E+5
Br-75	A	5 E+2	1 E+6
Br-76	A	7 E+1	2 E+5
Br-77	A	3 E+2	1 E+6
Br-80	A	2 E+3	2 E+6
Br-80m	A	4 E+2	6 E+5
Br-82	A	5 E+1	1 E+5
Br-83	A	7 E+2	2 E+6
Br-84	A	7 E+2	9 E+5
Rb-79	A	1 E+3	2 E+6
Rb-81	A	6 E+2	2 E+6
Rb-81m	A	3 E+3	8 E+6
Rb-82m	A	2 E+2	1 E+6
Rb-83	A	2 E+1	8 E+4
Rb-84	A	2 E+1	4 E+4
Rb-86	A	1 E+1	3 E+4
Rb-87	A	8 E-1	6 E+4
Rb-88	A	1 E+3	8 E+5
Rb-89	A	2 E+3	2 E+6
Sr-80	A	2 E+2	2 E+5
Sr-81	A	7 E+2	1 E+6
Sr-82	A	3	1 E+4
Sr-83	A	8 E+1	3 E+5
Sr-85	A	4 E+1	1 E+5
Sr-85m	A	6 E+3	2 E+7
Sr-87m	A	1 E+3	4 E+6
Sr-89	A	4	3 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Sr-90	A	1 E-1	4 E+3
Sr-91	A	6 E+1	2 E+5
Sr-92	A	1 E+2	3 E+5
Y-86	A	5 E+1	1 E+5
Y-86m	A	9 E+2	2 E+6
Y-87	A	7 E+1	2 E+5
Y-88	A	8	1 E+5
Y-90	A	2 E+1	3 E+4
Y-90m	A	3 E+2	5 E+5
Y-91	A	4	3 E+4
Y-91m	A	3 E+3	1 E+7
Y-92	A	1 E+2	2 E+5
Y-93	A	5 E+1	6 E+4
Y-94	A	8 E+2	9 E+5
Y-95	A	2 E+3	2 E+6
Zr-86	A	6 E+1	1 E+5
Zr-88	A	1 E+1	3 E+5
Zr-89	A	5 E+1	1 E+5
Zr-93	A	1	4 E+5
Zr-95	A	6	1 E+5
Zr-97	A	3 E+1	4 E+4
Nb-88	A	9 E+2	1 E+6
Nb-89	A	2 E+2	3 E+5
Nb-90	A	4 E+1	8 E+4
Nb-93m	A	2 E+1	6 E+5
Nb-94	A	8 E-1	6 E+4
Nb-95	A	2 E+1	2 E+5
Nb-95m	A	4 E+1	1 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Nb-96	A	4 E+1	1 E+5
Nb-97	A	6 E+2	1 E+6
Nb-98m	A	4 E+2	7 E+5
Mo-90	A	8 E+1	5 E+5
Mo-93	A	2 E+1	1 E+5
Mo-93m	A	2 E+2	1 E+6
Mo-99	A	3 E+1	2 E+5
Mo-101	A	1 E+3	2 E+6
Tc-93	A	7 E+2	3 E+6
Tc-93m	A	1 E+3	4 E+6
Tc-94	A	2 E+2	7 E+5
Tc-94m	A	5 E+2	7 E+5
Tc-95	A	2 E+2	9 E+5
Tc-95m	A	3 E+1	2 E+5
Tc-96	A	4 E+1	1 E+5
Tc-96m	A	4 E+3	9 E+6
Tc-97m	A	8	1 E+5
Tc-97	A	2 E+1	9 E+5
Tc-98	A	8 E-1	4 E+4
Tc-99	A	3	9 E+4
Tc-99m	A	2 E+3	4 E+6
Tc-101	A	2 E+3	4 E+6
Tc-104	A	8 E+2	9 E+5
Ru-94	A	5 E+2	1 E+6
Ru-97	A	3 E+2	7 E+5
Ru-103	A	1 E+1	1 E+5
Ru-105	A	2 E+2	3 E+5
Ru-106	A	6 E-1	1 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Rh-99	A	4 E+1	2 E+5
Rh-99m	A	6 E+2	2 E+6
Rh-100	A	7 E+1	2 E+5
Rh-101	A	7	2 E+5
Rh-101m	A	1 E+2	5 E+5
Rh-102	A	2	5 E+4
Rh-102m	A	5	7 E+4
Rh-103m	A	1 E+4	2 E+7
Rh-105	A	9 E+1	2 E+5
Rh-106m	A	2 E+2	6 E+5
Rh-107	A	2 E+3	3 E+6
Pd-100	A	4 E+1	1 E+5
Pd-101	A	4 E+2	1 E+6
Pd-103	A	8 E+1	4 E+5
Pd-107	A	6 E+1	2 E+6
Pd-109	A	8 E+1	1 E+5
Ag-102	A	1 E+3	2 E+6
Ag-103	A	1 E+3	2 E+6
Ag-104	A	7 E+2	2 E+6
Ag-104m	A	9 E+2	2 E+6
Ag-105	A	1 E+1	2 E+5
Ag-106	A	2 E+3	2 E+6
Ag-106m	A	9	9 E+4
Ag-108m	A	4 E-1	4 E+4
Ag-110m	A	1	4 E+4
Ag-111	A	3	6 E+4
Ag-112	A	1 E+2	2 E+5
Ag-115	A	9 E+2	1 E+6

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Cd-104	A	7 E+2	2 E+6
Cd-107	A	4 E+2	1 E+6
Cd-109	A	4	4 E+4
Cd-113	A	1 E-1	9 E+3
Cd-113m	A	2 E-1	7 E+3
Cd-115	A	3 E+1	6 E+4
Cd-115m	A	5	2 E+4
Cd-117	A	2 E+2	3 E+5
Cd-117m	A	1 E+2	3 E+5
In-109	A	6 E+2	2 E+6
In-110	A	2 E+2	6 E+5
In-111	A	1 E+2	4 E+5
In-112	A	4 E+3	7 E+6
In-113m	A	1 E+3	3 E+6
In-114m	A	2	2 E+4
In-115m	A	5 E+2	9 E+5
In-116m	A	6 E+2	2 E+6
In-117	A	1 E+3	3 E+6
In-117m	A	4 E+2	6 E+5
In-119m	A	1 E+3	2 E+6
Sn-110	A	1 E+2	3 E+5
Sn-111	A	2 E+3	4 E+6
Sn-113	A	1 E+1	1 E+5
Sn-117m	A	1 E+1	1 E+5
Sn-119m	A	2 E+1	2 E+5
Sn-121	A	1 E+2	3 E+5
Sn-121m	A	4	2 E+5
Sn-123	A	3	4 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Sn-123m	A	1 E+3	2 E+6
Sn-125	A	1 E+1	3 E+4
Sn-126	A	1	2 E+4
Sn-127	A	2 E+2	4 E+5
Sn-128	A	3 E+2	6 E+5
Sb-115	A	2 E+3	4 E+6
Sb-116	A	2 E+3	3 E+6
Sb-116m	A	5 E+2	2 E+6
Sb-117	A	2 E+3	6 E+6
Sb-118m	A	2 E+2	7 E+5
Sb-119	A	5 E+2	1 E+6
Sb-120	A	3 E+1	1 E+5
Sb-122	A	3 E+1	5 E+4
Sb-124	A	4	4 E+4
Sb-124m	A	5 E+3	1 E+7
Sb-125	A	3	8 E+4
Sb-126	A	4 E-1	4 E+4
Sb-126m	A	1 E+3	2 E+6
Sb-127	A	2 E+1	5 E+4
Sb-128	A	6 E+1	1 E+5
Sb-129	A	1 E+2	2 E+5
Sb-130	A	5 E+2	1 E+6
Sb-131	A	6 E+2	8 E+5
Te-116	A	2 E+2	6 E+5
Te-121	A	7 E+1	3 E+5
Te-121m	A	4	3 E+4
Te-123	A	7 E-2	3 E+4
Te-123m	A	6	5 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Te-125m	A	8	7 E+4
Te-127	A	2 E+2	6 E+5
Te-127m	A	2	2 E+4
Te-129	A	7 E+2	1 E+6
Te-129m	A	4	2 E+4
Te-131	A	8 E+2	1 E+6
Te-131m	A	2 E+1	4 E+4
Te-132	A	9	2 E+4
Te-133	A	8 E+2	1 E+6
Te-133m	A	2 E+2	3 E+5
Te-134	A	4 E+2	8 E+5
I-120	E	5 E+1	2 E+5
I-120m	E	1 E+2	4 E+5
I-121	E	2 E+2	1 E+6
I-123	E	7 E+1	4 E+5
I-124	E	1	7 E+3
I-125	E	5 E-1	2 E+4
I-126	E	3 E-1	4 E+3
I-128	E	4 E+2	2 E+6
I-129	E	3 E-2	4 E+3
I-130	E	8	4 E+4
I-131	E	5 E-1	5 E+3
I-132	E	5 E+1	3 E+5
I-132m	E	5 E+1	4 E+5
I-133	E	3	2 E+4
I-134	E	2 E+2	8 E+5
I-135	E	1 E+1	9 E+4
Cs-125	A	1 E+3	2 E+6

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Cs-127	A	7 E+2	5 E+6
Cs-129	A	3 E+2	2 E+6
Cs-130	A	2 E+3	3 E+6
Cs-131	A	6 E+2	2 E+6
Cs-132	A	1 E+2	3 E+5
Cs-134	A	2	2 E+4
Cs-134m	A	6 E+2	4 E+6
Cs-135	A	4	2 E+5
Cs-135m	A	2 E+3	7 E+6
Cs-136	A	1 E+1	6 E+4
Cs-137	A	9 E-1	3 E+4
Cs-138	A	6 E+2	8 E+5
Ba-126	A	2 E+2	3 E+5
Ba-128	A	2 E+1	4 E+4
Ba-131	A	4 E+1	2 E+5
Ba-131m	A	4 E+3	2 E+7
Ba-133	A	4	4 E+4
Ba-133m	A	7 E+1	2 E+5
Ba-135m	A	8 E+1	3 E+5
Ba-139	A	4 E+2	6 E+5
Ba-140	A	6	3 E+4
Ba-141	A	8 E+2	1 E+6
Ba-142	A	1 E+3	3 E+6
La-131	A	1 E+3	3 E+6
La-132	A	1 E+2	2 E+5
La-135	A	2 E+3	3 E+6
La-137	A	4	8 E+5
La-138	A	2 E-1	1 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
La-140	A	3 E+1	4 E+4
La-141	A	2 E+2	2 E+5
La-142	A	3 E+2	5 E+5
La-143	A	1 E+3	1 E+6
Ce-134	A	2 E+1	3 E+4
Ce-135	A	6 E+1	1 E+5
Ce-137	A	2 E+3	3 E+6
Ce-137m	A	7 E+1	1 E+5
Ce-139	A	2 E+1	3 E+5
Ce-141	A	9	1 E+5
Ce-143	A	4 E+1	7 E+4
Ce-144	A	6 E-1	1 E+4
Pr-136	A	2 E+3	2 E+6
Pr-137	A	1 E+3	2 E+6
Pr-138m	A	3 E+2	9 E+5
Pr-139	A	1 E+3	3 E+6
Pr-142	A	4 E+1	6 E+4
Pr-142m	A	3 E+3	4 E+6
Pr-143	A	1 E+1	6 E+4
Pr-144	A	1 E+3	1 E+6
Pr-145	A	1 E+2	2 E+5
Pr-147	A	1 E+3	2 E+6
Nd-136	A	5 E+2	9 E+5
Nd-138	A	9 E+1	1 E+5
Nd-139	A	2 E+3	4 E+6
Nd-139m	A	2 E+2	4 E+5
Nd-141	A	5 E+3	1 E+7
Nd-147	A	1 E+1	7 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Nd-149	A	3 E+2	6 E+5
Nd-151	A	2 E+3	3 E+6
Pm-141	A	2 E+3	2 E+6
Pm-143	A	2 E+1	5 E+5
Pm-144	A	4	1 E+5
Pm-145	A	1 E+1	6 E+5
Pm-146	A	2	9 E+4
Pm-147	A	7	3 E+5
Pm-148	A	1 E+1	3 E+4
Pm-148m	A	6	6 E+4
Pm-149	A	4 E+1	7 E+4
Pm-150	A	2 E+2	3 E+5
Pm-151	A	6 E+1	1 E+5
Sm-141	A	2 E+3	2 E+6
Sm-141m	A	8 E+2	1 E+6
Sm-142	A	3 E+2	4 E+5
Sm-145	A	2 E+1	4 E+5
Sm-146	A	3 E-3	6 E+2
Sm-151	A	9	6 E+5
Sm-153	A	5 E+1	1 E+5
Sm-155	A	2 E+3	3 E+6
Sm-156	A	1 E+2	3 E+5
Eu-145	A	5 E+1	2 E+5
Eu-146	A	4 E+1	1 E+5
Eu-147	A	3 E+1	2 E+5
Eu-148	A	1 E+1	1 E+5
Eu-149	A	1 E+2	9 E+5
Eu-150	A	7 E-1	3 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Eu-152	A	9 E-1	5 E+4
Eu-152m	A	1 E+2	2 E+5
Eu-154	A	7 E-1	4 E+4
Eu-155	A	5	2 E+5
Eu-156	A	1 E+1	4 E+4
Eu-157	A	8 E+1	1 E+5
Eu-158	A	5 E+2	8 E+5
Gd-145	A	1 E+3	2 E+6
Gd-146	A	5	9 E+4
Gd-147	A	7 E+1	2 E+5
Gd-148	A	1 E-3	5 E+2
Gd-149	A	4 E+1	2 E+5
Gd-151	A	3 E+1	4 E+5
Gd-153	A	1 E+1	3 E+5
Gd-159	A	1 E+2	2 E+5
Tb-147	A	3 E+2	6 E+5
Tb-149	A	7	4 E+5
Tb-150	A	2 E+2	4 E+5
Tb-151	A	1 E+2	3 E+5
Tb-153	A	1 E+2	4 E+5
Tb-154	A	8 E+1	2 E+5
Tb-155	A	2 E+2	5 E+5
Tb-156	A	3 E+1	1 E+5
Tb-156m	A	2 E+2	6 E+5
Tb-157	A	3 E+1	2 E+6
Tb-158	A	8 E-1	4 E+4
Tb-160	A	5	6 E+4
Tb-161	A	3 E+1	1 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Dy-155	A	4 E+2	9 E+5
Dy-157	A	8 E+2	2 E+6
Dy-159	A	9 E+1	9 E+5
Dy-165	A	5 E+2	7 E+5
Dy-166	A	2 E+1	5 E+4
Ho-155	A	1 E+3	2 E+6
Ho-157	A	6 E+3	2 E+7
Ho-159	A	5 E+3	1 E+7
Ho-161	A	4 E+3	6 E+6
Ho-162	A	1 E+4	3 E+7
Ho-162m	A	1 E+3	4 E+6
Ho-164	A	4 E+3	7 E+6
Ho-164m	A	3 E+3	4 E+6
Ho-166	A	4 E+1	6 E+4
Ho-166m	A	3 E-1	2 E+4
Ho-167	A	4 E+2	1 E+6
Er-161	A	5 E+2	1 E+6
Er-165	A	3 E+3	5 E+6
Er-169	A	3 E+1	2 E+5
Er-171	A	1 E+2	2 E+5
Er-172	A	3 E+1	9 E+4
Tm-162	A	2 E+3	3 E+6
Tm-166	A	2 E+2	4 E+5
Tm-167	A	3 E+1	2 E+5
Tm-170	A	5	6 E+4
Tm-171	A	3 E+1	6 E+5
Tm-172	A	3 E+1	5 E+4
Tm-173	A	2 E+2	3 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Tm-175	A	1 E+3	3 E+6
Yb-162	A	2 E+3	4 E+6
Yb-166	A	4 E+1	1 E+5
Yb-167	A	5 E+3	1 E+7
Yb-169	A	1 E+1	1 E+5
Yb-175	A	4 E+1	2 E+5
Yb-177	A	4 E+2	9 E+5
Yb-178	A	4 E+2	6 E+5
Lu-169	A	8 E+1	3 E+5
Lu-170	A	4 E+1	1 E+5
Lu-171	A	4 E+1	2 E+5
Lu-172	A	2 E+1	9 E+4
Lu-173	A	1 E+1	3 E+5
Lu-174	A	8	3 E+5
Lu-174m	A	8	1 E+5
Lu-176m	A	3 E+2	4 E+5
Lu-177	A	3 E+1	1 E+5
Lu-177m	A	2	5 E+4
Lu-178	A	1 E+3	2 E+6
Lu-178m	A	8 E+2	2 E+6
Lu-179	A	2 E+2	4 E+5
Hf-170	A	9 E+1	2 E+5
Hf-172	A	1	5 E+4
Hf-173	A	2 E+2	5 E+5
Hf-175	A	3 E+1	2 E+5
Hf-177m	A	3 E+2	1 E+6
Hf-178m	A	1 E-1	1 E+4
Hf-179m	A	9	7 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Hf-180m	A	2 E+2	6 E+5
Hf-181	A	7	7 E+4
Hf-182	A	1 E-1	2 E+4
Hf-182m	A	7 E+2	2 E+6
Hf-183	A	5 E+2	1 E+6
Hf-184	A	9 E+1	2 E+5
Ta-172	A	8 E+2	2 E+6
Ta-173	A	2 E+2	4 E+5
Ta-174	A	7 E+2	1 E+6
Ta-175	A	2 E+2	6 E+5
Ta-176	A	1 E+2	4 E+5
Ta-177	A	3 E+2	9 E+5
Ta-178	A	4 E+2	1 E+6
Ta-179	A	6 E+1	1 E+6
Ta-180m	A	7 E+2	2 E+6
Ta-182	A	3	6 E+4
Ta-182m	A	1 E+3	6 E+6
Ta-183	A	2 E+1	6 E+4
Ta-184	A	7 E+1	2 E+6
Ta-185	A	6 E+2	1 E+6
Ta-186	A	1 E+3	2 E+6
W-176	A	6 E+2	1 E+6
W-177	A	1 E+3	2 E+6
W-178	A	3 E+2	5 E+5
W-179	A	2 E+4	3 E+7
W-181	A	4 E+2	1 E+6
W-185	A	6 E+1	2 E+5
W-187	A	1 E+2	2 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
W-188	A	3 E+1	4 E+4
Re-177	A	2 E+3	4 E+6
Re-178	A	2 E+3	3 E+6
Re-181	A	1 E+2	2 E+5
Re-182	A	2 E+1	6 E+4
Re-184	A	2 E+1	1 E+5
Re-184m	A	5	5 E+4
Re-186	A	3 E+1	5 E+4
Re-186m	A	1	3 E+4
Re-187	A	7 E+2	1 E+7
Re-188	A	4	5 E+4
Re-188m	A	E+1	2
Re-189	A	2	E+6
Os-180	A	E+3	9
Os-181	A	6	E+4
Os-182	A	E+1	6 E+6
Os-185	A	2	1 E+6
Os-189m	A	E+3	2
Os-191	A	4 E+2	E+5
Os-191m	A	8 E+1	2
Os-193	A	2 E+1	E+5
Os-194	A	4 E+3	4 E+6
Ir-182	A	2 E+1	1 E+5
Ir-184	A	2 E+2	8 E+5
Ir-185	A	6 E+1	1 E+5
Ir-186	A	4 E+1	3 E+4
Ir-187	A	1 E+3	2 E+6
Ir-188	A	2 E+2	6 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Ir-189	A	2 E+2	4 E+5
Ir-190	A	9	2 E+5
Ir-190m	A	E+1	8
Ir-192	A	4	E+5
Ir-192m	A	E+2	2
Ir-193m	A	7 E+1	E+5
Ir-194	A	6 E+1	4 E+5
Ir-194m	A	1 E+1	9 E+4
Ir-195	A	3 E+2	9 E+5
Ir-195m	A	5	7 E+4
Pt-186	A	9 E-1	7 E+4
Pt-188	A	3 E+1	3 E+5
Pt-189	A	1 E+1	6 E+4
Pt-191	A	3	5 E+4
Pt-193	A	4 E+2	7 E+5
Pt-193m	A	2 E+2	4 E+5
Pt-195m	A	7 E+2	1 E+6
Pt-197	A	6 E+1	1 E+5
Pt-197m	A	5	8 E+5
Pt-199	A	E+2	3 E+5
Pt-200	A	9 E+1	6 E+4
Au-193	A	3 E+2	7 E+5
Au-194	A	1 E+2	3 E+5
Au-195	A	2 E+1	4 E+5
Au-198	A	4 E+1	9 E+4
Au-198m	A	2 E+1	7 E+4
Au-199	A	4 E+1	2 E+5
Au-200	A	8 E+2	1 E+6

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Au-200m	A	4 E+1	1 E+5
Au-201	A	2 E+3	3 E+6
Hg-193	A	4 E+2	3 E+6
Hg-193	O	9 E+2	1 E+6
Hg-193m	A	1 E+2	3 E+5
Hg-193m	O	2 E+2	8 E+5
Hg-194	A	1	1 E+5
Hg-194	O	4 E-1	7 E+3
Hg-195	A	4 E+2	9 E+5
Hg-195	O	9 E+2	3 E+6
Hg-195m	A	6 E+1	2 E+5
Hg-195m	O	2 E+2	4 E+5
Hg-197	A	1 E+2	4 E+5
Hg-197	O	4 E+2	9 E+5
Hg-197m	A	6 E+1	2 E+5
Hg-197m	O	2 E+2	6 E+5
Hg-199m	A	9 E+2	2 E+6
Hg-199m	O	2 E+3	3 E+6
Hg-203	A	1 E+1	2 E+5
Hg-203	O	1 E+1	6 E+4
Tl-194	A	5 E+3	1 E+7
Tl-194m	A	1 E+3	2 E+6
Tl-195	A	2 E+3	4 E+6
Tl-197	A	2 E+3	4 E+6
Tl-198	A	4 E+2	2 E+6
Tl-198m	A	6 E+2	2 E+6
Tl-199	A	1 E+3	4 E+6
Tl-200	A	2 E+2	7 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Tl-201	A	5 E+2	1 E+6
Tl-202	A	1 E+2	3 E+5
Tl-204	A	1 E+1	7 E+4
Pb-195m	A	1 E+3	3 E+6
Pb-198	A	4 E+2	2 E+6
Pb-199	A	7 E+2	3 E+6
Pb-200	A	9 E+1	4 E+5
Pb-201	A	2 E+2	9 E+5
Pb-202	A	2	3 E+4
Pb-202m	A	3 E+2	1 E+6
Pb-203	A	1 E+2	6 E+5
Pb-205	A	4 E+1	4 E+5
Pb-209	A	5 E+2	2 E+6
Pb-210	A	7 E-3	1 E+2
Pb-211	A	3	3 E+5
Pb-212	A	2 E-1	6 E+3
Pb-214	A	2	3 E+5
Bi-200	A	8 E+2	2 E+6
Bi-201	A	4 E+2	9 E+5
Bi-202	A	5 E+2	1 E+6
Bi-203	A	1 E+2	3 E+5
Bi-205	A	3 E+1	1 E+5
Bi-206	A	2 E+1	6 E+4
Bi-207	A	1	9 E+4
Bi-210	A	4 E-1	6 E+4
Bi-210m	A	1 E-2	4 E+3
Bi-212	A	1	3 E+5
Bi-213	A	1	4 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Bi-214	A	2	6 E+5
Po-203	A	7 E+2	3 E+6
Po-205	A	4 E+2	3 E+6
Po-207	A	3 E+2	2 E+6
Po-210	A	8 E-3	3 E+1
At-207	A	1 E+1	4 E+5
At-211	A	3 E-1	7 E+3
Fr-222	A	3	1 E+5
Fr-223	A	2 E+1	3 E+4
Ra-223	A	4 E-3	2 E+2
Ra-224	A	1 E-2	3 E+2
Ra-225	A	4 E-3	1 E+2
Ra-226	A	4 E-3	2 E+2
Ra-227	A	8 E+1	8 E+5
Ra-228	A	2 E-3	3 E+1
Ac-224	A	3 E-1	9 E+4
Ac-225	A	4 E-3	2 E+3
Ac-226	A	3 E-2	6 E+3
Ac-227	A	7 E-5	3 E+1
Ac-228	A	9 E-1	1 E+5
Th-226	A	5 E-1	2 E+5
Th-227	A	3 E-3	3 E+1
Th-228	A	9 E-4	2 E+2
Th-229	A	2 E-4	8 E+1
Th-230	A	4 E-4	2 E+2
Th-231	A	9 E+1	2 E+5
Th-232	A	3 E-4	2 E+2
Th-234	A	5	2 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Pa-227	A	5 E-1	2 E+5
Pa-228	A	5 E-1	7 E+4
Pa-230	A	4 E-2	3 E+4
Pa-231	A	3 E-4	7 E+1
Pa-232	A	4	1 E+5
Pa-233	A	8	9 E+4
Pa-234	A	8 E+1	2 E+5
U-230	A	2 E-3	1 E+3
U-231	A	8 E+1	3 E+5
U-232	A	1 E-3	4 E+2
U-233	A	4 E-3	2 E+3
U-234	A	4 E-3	2 E+3
U-235	A	4 E-3	3 E+3
U-236	A	4 E-3	3 E+3
U-237	A	2 E+1	1 E+5
U-238	A	5 E-3	3 E+3
U-239	A	1 E+3	3 E+6
U-240	A	5 E+1	7 E+4
Np-232	A	3 E+2	1 E+7
Np-233	A	1 E+4	4 E+7
Np-234	A	5 E+1	1 E+5
Np-235	A	5 E+1	1 E+6
Np-236	A	5 E-3	5 E+3
Np-237	A	7 E-4	4 E+2
Np-238	A	1 E+1	9 E+4
Np-239	A	3 E+1	1 E+5
Np-240	A	3 E+2	1 E+6
Pu-234	A	1	4 E+5

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Pu-235	A	2 E+4	4 E+7
Pu-236	A	9 E-4	4 E+2
Pu-237	A	9 E+1	8 E+5
Pu-238	A	3 E-4	2 E+2
Pu-239	A	3 E-4	2 E+2
Pu-240	A	3 E-4	2 E+2
Pu-241	A	2 E-2	2 E+4
Pu-242	A	3 E-4	2 E+2
Pu-243	A	4 E+2	9 E+5
Pu-244	A	3 E-4	2 E+2
Pu-245	A	6 E+1	1 E+5
Pu-246	A	4	3 E+4
Am-237	A	1 E+3	5 E+6
Am-238	A	2 E+2	4 E+6
Am-239	A	1 E+2	3 E+5
Am-240	A	7 E+1	2 E+5
Am-241	A	4 E-4	2 E+2
Am-242	A	2	2 E+5
Am-242m	A	4 E-4	3 E+2
Am-243	A	4 E-4	3 E+2
Am-244	A	1 E+1	2 E+5
Am-244m	A	2 E+2	2 E+6
Am-245	A	6 E+2	1 E+6
Am-246	A	4 E+2	1 E+6
Am-246m	A	1 E+3	2 E+6
Cm-238	A	7	1 E+6
Cm-240	A	1 E-2	4 E+3
Cm-241	A	9 E-1	8 E+4

Radionuclide		C _i	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Cm-242	A	6 E-3	2 E+3
Cm-243	A	5 E-4	3 E+2
Cm-244	A	6 E-4	3 E+2
Cm-245	A	4 E-4	2 E+2
Cm-246	A	4 E-4	2 E+2
Cm-247	A	4 E-4	3 E+2
Cm-248	A	1 E-4	6 E+1
Cm-249	A	9 E+2	2 E+6
Cm-250	A	2 E-5	1 E+1
Bk-245	A	2 E+1	1 E+5
Bk-246	A	9 E+1	2 E+5
Bk-247	A	5 E-4	1 E+2
Bk-249	A	2 E-1	4 E+4
Bk-250	A	4 E+1	6 E+5
Cf-244	A	3	9 E+5
Cf-246	A	7 E-2	2 E+4
Cf-248	A	4 E-3	6 E+2
Cf-249	A	5 E-4	1 E+2
Cf-250	A	1 E-3	2 E+2
Cf-251	A	5 E-4	1 E+2
Cf-252	A	2 E-3	2 E+2
Cf-253	A	2 E-2	9 E+3
Cf-254	A	8 E-4	8 E+1
Es-250	A	6 E+1	4 E+6
Es-251	A	2 E+1	5 E+5
Es-253	A	1 E-2	5 E+3
Es-254	A	4 E-3	6 E+2
Es-254m	A	7 E-2	2 E+4

Radionuclide		Ci	
A = aerosol (air) E = elemental (air) O = organic		in air in Bq/cbm	in water in Bq/cbm
1		2	3
Fm-252	A	1 E-1	2 E+4
Fm-253	A	8 E-2	4 E+4
Fm-254	A	5 E-1	2 E+5
Fm-255	A	1 E-1	3 E+4
Fm-257	A	5 E-3	9 E+2
Md-257	A	1	3 E+5
Md-258	A	6 E-3	1 E+3

Table 7: Activity concentration Ci from controlled areas (relating to Part D, no. 1.2)

Radionuclide	Ci in air in Bq/cbm
1	2
C-11	3 E+3
N-13	2 E+3
O-15	1 E+3
Ar-37	2 E+8
Ar-39	6 E+3
Ar-41	2 E+2
Kr-74	2 E+2
Kr-76	5 E+2
Kr-77	2 E+2
Kr-79	9 E+2
Kr-81m	5 E+6
Kr-81	4 E+4
Kr-83m	4 E+6
Kr-85	4 E+3
Kr-85m	1 E+3
Kr-87	2 E+2

Radionuclide	C _i in air in Bq/cbm
1	2
Kr-88	1 E+2
Xe-120	6 E+2
Xe-121	1 E+2
Xe-122	3 E+3
Xe-123	3 E+2
Xe-125	9 E+2
Xe-127	9 E+2
Xe-129m	1 E+4
Xe-131m	2 E+4
Xe-133	7 E+3
Xe-133m	7 E+3
Xe-135m	5 E+2
Xe-135	9 E+2
Xe-138	2 E+2

Table 8:
Activity concentration C_i from radioactivity protection areas
(re Part D nos. 1.1 and 2)

Radionuclide mixture	C _i in air in Bq/cbm	Radionuclide mixture	C _i in water in Bq/cbm
1	2	3	4
Any mixture	1 E-5	Any mixture	1 E+1
Any mixture, if Ac-227 and Cm-250 may remain unconsidered	1 E-4	Any mixture, if Po-210, Ra-228, Ac-227 and Cm-250 may remain unconsidered	5 E+1
Any mixture, if Ac-227, Th-229, Th-230, Th-232, Pa-231, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Am-241, Am-242m, Am-243, Cm-245, Cm-246, Cm-247, Cm-248 and Cm-250 may remain unconsidered	5 E-4	Any mixture, if Po-210, Ra-228, Ac-227, Th-229, Pa-231, Cm-248, Cm-250, Bk-247, Cf-249, Cf-251 and Cf-254 may remain unconsidered	1 E+2

Radionuclide mixture	C _i in air in Bq/cbm	Radionuclide mixture	C _i in water in Bq/cbm
1	2	3	4
Any mixture, if Ac-227, Th-228, Th-229, Th-230, Th-232, Pa-231, U-232, Np-237, Pu-236, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Am-241, Am-242m, Am-243, Cm-243, Cm-244, Cm-245, Cm-246, Cm-247, Cm-248, Cm-250, Bk-247, Cf-249, Cf-251 and Cf-254 may remain unconsidered	1 E-3	Any mixture, if Sm-146, Gd-148, Pb-210, Po-210, Ra-223, Ra-224, Ra-225, Ra-226, Ra-228, Ac-227, Th-228, Th-229, Th-230, Th-232, Pa-231, U-232, Np-237, Pu-236, Pu-238, Pu-239, Pu-240, Pu-242, Pu-244, Am-241, Am-242m, Am-243, Cm-243, Cm-244, Cm-245, Cm-246, Cm-247, Cm-248, Cm-250, Bk-247, Cf-248, Cf-249, Cf-250, Cf-251, Cf-252, Cf-254, Es-254 and Fm-257 may remain unconsidered	1 E+3

Annex 12

(re section 103 subsection (3))

**Central offices of the Federation for emissions
and immissions monitoring**

Central office	Environmental area
German Meteorological Service	Air, precipitation
Federal Institute for Hydrology	Inland waters: surface water, sediment
Federal Maritime and Hydrographic Agency	Coastal waters: surface water, sediment
Max Rubner Institute, Federal Research Centre for Nutrition and Food	Soil, plants, vegetation, animal feed, food of plant and animal origin
Johann Heinrich von Thünen Institute, Federal Research Institute for Rural Areas, Forestry and Fisheries	Fish and fishery products
Federal Office for Radiation Protection	Ambient dose, ambient dose rate, soil surface, groundwater, drinking water, waste water, sewage sludge, exhaust air

Public information in preparation for an emergency

Public information shall include the following:

1. the name of the radiation protection executive and information on the location of the installation or facility for the area surrounding which the authority competent for disaster response or for public security has drawn up an external emergency response plan in accordance with section 101 subsection (1) of the Radiation Protection Act,
2. the designation of the office issuing the information,
3. a generally-comprehensible brief description of the type and purpose of the facility or installation and of the practice,
4. the basic concepts of radioactivity and effects of radioactivity on humans and the environment,
5. the emergencies considered in the external emergency response plan and their impact on the public and the environment
6. the planned measures to protect the public and provide assistance,
7. information on how the public that might be affected will be warned in an emergency and receive continuous information on the progress of an emergency,
8. recommendations on how persons who might be affected should act and behave in an emergency,
9. a confirmation that the radiation protection executive has taken suitable measures and precautions at the location, including the measures and precautions for the contacts with authorities competent for disaster control and for public safety in order to be prepared at the onset of an emergency and to keep its effects to a minimum,
10. an indication regarding external emergency response plans that have been created for the impact of an emergency in the area surrounding the location or the installation,
11. information regarding the authorities competent for disaster response as well as for public security,
12. an indication regarding the emergency response plans, as well as the information and recommendations of the competent authorities of the Federation and of the *Land* in which the location of the installation or facility is located, published in accordance with section 105 of the Radiation Protection Act, as well as where appropriate the competent authorities of other *Länder* concerned, including information on where such information and recommendations can be found,
13. an indication that the information regarding the holder of the licence must be updated in the event of significant amendments that have an impact on security or on the protection of the public, and information as to how this information can be accessed by anyone in its respectively current version and accessed on the Internet at any time.

Criteria for the significance of an incident involving medical exposure and exposure of the person examined in the case of a non-medical use

I. Examinations with ionising radiation and radioactive substances – not including interventions – with the exception of examinations using conventional projection radiography and using digital volume tomography of the teeth and jaw

1) relating to a group of persons

each time a mean value is exceeded by more than 100 % of the respective diagnostic reference level over the last 20 consecutive examinations of the same type, as soon as the diagnostic reference level of an individual examination was exceeded by 200 %.

2) relating to an individual person

a) each time the volume-related computed tomography dose index of a computed tomographic use to the brain of 120 milligray and another computed tomographic use to the body of 80 milligray is exceeded, and each time the total dose area product of an X-ray fluoroscopy of 20,000 centigrays times square centimetres is exceeded. The value first exceeded by computed tomography or fluoroscopy shall apply to uses with digital volume tomography equipment,

each time the intended effective dose is exceeded by more than 20 mSv as a result of radioactive substances, or by more than 100 mSv, or of an organoleptic dose in a single study; to verify compliance with these values, the radiation protection executive may refer to the action thresholds for activities published by the Federal Office for Radiation Protection in Megabecquerel for studies with radioactive substances,

b) each time a use is repeated, in particular due to a misidentified body part, a setting error or a previous fault in the device, if the criterion in accordance with (a) is satisfied for the resulting total additional exposure,

c) each misidentified person, if the criterion in accordance with (a) has been met for the resulting total additional exposure,

d) each occurrence of a deterministic effect that was not expected for the examination that was determined.

II. Interventions

1) relating to a group of persons

each time a mean value is exceeded by more than 100 % of the respective diagnostic reference level over the last 20 consecutive interventions of the same type of examination, as soon as the diagnostic reference level of an individual examination was exceeded by 200 %

2) relating to an individual person if the intervention takes place for the purpose of examining the person

a) each time the total dose area product of 20,000 centigrays times square centimetres is exceeded,

b) each time a use is repeated, in particular due to a misidentified body part, a setting error or a previous fault in the device, if the criterion under (a) is satisfied for the resulting total additional exposure,

c) each misidentified person,

d) each occurrence of a deterministic effect that was not expected for the intervention that was determined.

- 3) relating to an individual person if the intervention is carried out for the purpose of treating the person
 - a) each time the total dose area product has been exceeded by 50,000 centigray per cubic centimetre if second- or higher-degree deterministic skin damage occurs on an acute basis or within 21 days after the interventional examination,
 - b) each misidentified person or body part,
 - c) each occurrence of a deterministic effect that was not expected for the intervention that was determined.

III. Treatments with ionising radiation and enclosed radioactive substances

- 1) each deviation of the total dose in the target volume or at the reference point by more than 10 % from the dose determined in the radiation plan, provided the deviation is at least 4 Gray,
- 2) each unplanned exceedance of the dose restriction determined in the work instruction for organs at risk, insofar as it is exceeded by more than 10 %,
- 3) each deviation from the average total dose by more than 10 % of the average dose determined in the target volume or for organs at risk,
- 4) each deviation from the total treatment time determined in the irradiation plan by more than one week, insofar as the deviation is not caused by the person being treated,
- 5) each misidentified person or treatment plan,
- 6) each occurrence of a deterministic effect that was not expected for the treatment that was determined.

IV. Treatments with unsealed radioactive substances

- 1) each deviation of the administered total activity of the determined activity by more than 10 %,
- 2) each occurrence of a deterministic effect that was not expected in the treatment that was determined,
- 3) each misidentified person or body part or misidentification of the radioactive substance,
- 4) each occurrence of an extravasation after the injection of a radioactive substance, insofar as more than 15 % of the specified activity was erroneously applied,
- 5) each contamination by a radioactive substance if it leads to an unintended exposure of the person treated and the resulting effective dose exceeds 20 mSv or the equivalent dose of 100 mSv.

V. Carers and comforters in accordance with section 2 subsection (8) no. 3 of the Radiation Protection Act

Each unintended exceedance of the effective dose of 1 mSv for a carer and comforter

VI. Use of ionising radiation or radioactive substances on humans for the purpose of medical research

- 1) for uses licensed in accordance with section 31 of the Radiation Protection Act, each significant incident in accordance with the criteria listed in Divisions I to V; insofar as the licensing authority in accordance with section 138 subsection (6), second sentence, determines deviating values, these values shall be used in place of the diagnostic reference levels, in application of Division I no. 1 and Division II no. 1,
- 2) for uses notified in accordance with section 32 of the Radiation Protection Act, each significant incident according to the criteria designated in Divisions I, II and V,
- 3) for examinations for the purpose of medical research, each exceedance of the dose levels in accordance with section 137 subsection (2) or (3).

VII. Incidents where exposure almost occurred

Each incident discovered outside the quality assurance measures involving exposure that almost occurred to which one of the criteria of Divisions I to VI would apply if the exposure had actually occurred.

Criteria for the significance of an incident in a planned exposure situation

1. Exposure of an occupationally-exposed person which exceeds a limit of the body dose - effective dose or equivalent dose - in accordance with section 78 of the Radiation Protection Act, insofar as the exposure does not constitute a specifically-approved exposure in accordance with section 74.
2. Exposure of an individual member of the public which exceeds a limit in accordance with section 80 of the Radiation Protection Act.
3. Exceedance of the permissible discharge of radioactive substances into the air or water.
4. Discharges of radioactive substances:
 - a) within an area marked as a controlled area, insofar as it is not marked as an exclusion area, if the ambient dose rate exceeds the value of 3 mSv per hour for more than 24 hours,
 - b) within a monitoring area, so that the establishment of a new controlled area is required, or
 - c) into the surrounding area with activities that are higher than the exemption levels in accordance with Annex 4 Table 1 column 2.
5. Contaminations:
 - a) contamination within a controlled area, in an area which, in accordance with its intended use, must not be polluted, which exceeds 1,000 times the values in Annex 4 Table 1 column 5, and the overall activity of which in becquerels is more than 100 times the values of Annex 4 Table 1 column 2,
 - b) contamination within a monitoring area, in an area that must not be polluted during the intended operation, which exceeds 100 times the values of Annex 4 Table 1 column 5, and the overall activity in becquerels of which is more than 10 times the values in Annex 4 Table 1 column 2, or
 - c) contamination that is not covered by (a) or (b) that exceeds ten times the values in Annex 4 Table 1 column 5, and the overall activity of which in becquerels exceeds the values in Annex 4 Table 1 column 2.
6. Unusual sequence of events or operational state that is of substantial significance for safety, in the operation of X-ray equipment, of a stray radiation emitter requiring a licence, of installations for the generation of ionising radiation, or when handling or carrying radioactive substances.

Annex 16
(re section 149)

Criteria to determine the type and extent of the risk associated with a practice

The intervals at which regular on-site inspections are to be conducted by a radiation protection executive shall be governed by a systematic assessment of the risks associated with the practice, in particular on the basis of the following criteria:

1. Level of expected exposure from the proper use of ionising radiation or radioactive substances on humans,
2. Level of expected exposure from the proper use of ionising radiation or radioactive substances in uses without the targeted exposure of persons,
3. Level of activity of the licensed handling of enclosed and unsealed radioactive substances,
4. Risk of incorporations when handling unsealed radioactive substances,
5. Risk of unintended exposures,
6. Existing protection devices to prevent unintended exposure with X-ray equipment, stray radiation emitters, installations for the generation of ionising radiation and enclosed radioactive substances, as well as the extent of the necessary radiation protection measures for the safe implementation of practices, and
7. Further risk-related conditions for practices in accordance with section 4 subsection (1) of the Radiation Protection Act in planned exposure situations.

Annex 17

(re section 159)

Activity index and values not to be exceeded in accordance with section 135 subsection (1), third sentence, of the Radiation Protection Act

Under consideration of the density of the construction materials $\rho \cdot d$ with a construction material density ρ in kilogrammes per cubic metre and a material thickness in the structure d in metres, with the specific activities of the radionuclides radium 226 C_{Ra226} , thorium 232 (or its decay product Ra-228) C_{Th232} and potassium 40 C_{K40} in the construction material in becquerels per kilogram, the activity index I shall amount to:

$$I = \left[\begin{array}{l} [281 + 16,3\rho \cdot d - 0,0161(\rho \cdot d)^2] \cdot C_{Ra} \\ + [319 + 18,5\rho \cdot d - 0,0178(\rho \cdot d)^2] \cdot C_{Th} \\ + [22,3 + 1,28\rho \cdot d - 0,00114(\rho \cdot d)^2] \cdot C_K \end{array} \right] \cdot 10^{-6} - 0,29$$

If the density $\rho \cdot d$ exceeds the value of 500 kg/m², the formula for the value $\rho \cdot d$ with 500 kg/m² shall be used in its place. The reference level of 1 mSv per year shall be considered to have been complied with if activity index I does not exceed a value of 1.

For thin-layered materials, i.e. construction materials with a thickness of up to 0.03 m, which are only used in combination with a surface bracing or bearing the room whilst restricting it – wall, ceiling, floor –, a contribution of 0.48 shall be added to the index for generic consideration of the surface behind it.

If the thickness of the construction material in the structure is not known, $d=0.2$ m shall be used.

Dose and measured values

Part A Measured values for external radiation

The measured values for external radiation

1. for personal dosimetry are the depth personal dose $H_p(10)$, the ocular lens personal dose $H_p(3)$, and the surface personal dose $H_p(0.07)$.
 - a) the depth personal dose $H_p(10)$ is the equivalent dose at a depth of 10 millimetres in the body at the site of the dosimeters intended for the measurement.
 - b) the ocular lens personal dose $H_p(3)$ is the equivalent dose at a depth of 3 millimetres in the body at the site of the dosimeters intended for the measurement.
 - c) the surface personal dose $H_p(0.07)$ is the equivalent dose at a depth of 0.07 millimetres in the body at the site of the dosimeters intended for the measurement;
2. for local dosimetry are the ambient equivalent dose $H^*(10)$, the directional equivalent dose at a depth of 3 millimetres $H'(3 \Omega)$, and the directional equivalent dose at a 0.07 millimetre depth $H'(0.07 \Omega)$.
 - a) the ambient equivalent dose $H^*(10)$ at the point of interest in the actual radiation field is the equivalent dose that would be generated in the associated focussed and expanded radiation field at a depth of 10 millimetres on the radius of the ICRU sphere that has the opposite orientation to the direction of the incoming radiation;
 - b) the directional equivalent dose $H'(3 \Omega)$ at the point of interest in the actual radiation field is the equivalent dose that would be generated in the associated expanded radiation field at a depth of 3 millimetres on a radius orientated in a determined direction Ω of the ICRU sphere;
 - c) the directional equivalent dose $H'(0.07 \Omega)$ at the point of interest in the actual radiation field is the equivalent dose that would be generated in the associated expanded radiation field at a depth of 0.07 millimetres on a radius orientated in a determined direction Ω of the ICRU sphere.

Where

1. an expanded radiation field is an idealised radiation field in which the particle flow density and the energy and direction distribution of the radiation at all points of a sufficiently large volume show the same levels as the actual radiation field at the point of interest,
2. an expanded, aligned field is an idealised radiation field that is expanded and, in addition, in which the radiation is focused in one direction,
3. the ICRU sphere constitutes a spherical phantom of 30 centimetres in diameter of ICRU soft tissue (tissue-equivalent material with a density of 1 g/cm³, composition: 76.2 % oxygen, 11.1 % carbon, 10.1 % hydrogen and 2.6 % nitrogen).

Part B: Calculation of the body dose

1. Calculation of the equivalent dose H_T :

The equivalent dose $H_{T,R}$ which is generated through the radiation R is the product of the energy dose averaged through the tissue or organ T , the organ energy dose $D_{T,R}$, which is generated through the radiation R , and the radiation weighting factor w_R in accordance with Part C no. 1:

$$H_{T,R} = w_R D_{T,R}$$

In the case of several types and energies of radiation with different values of w_R , the individual contributions shall be added together. The following shall then apply to the total equivalent dose H_T :

$$H_T = \sum_R H_{T,R} = \sum_R w_R D_{T,R}$$

Organ equivalent dose values shall be determined for an idealised person (reference person) and ascertained separately for the male and female reference persons (H_T^M bzw. H_T^F) due to their differing characteristics.

The average energy dose of the skin at a tissue depth of 0.07 millimetres shall be used to calculate the local skin dose.

In the case of an internal exposure, the equivalent dose shall also take into account the exposure occurring after the reference time on the basis of the fate of the radionuclides in the body (subsequent equivalent dose).

The subsequent equivalent dose $HT(\tau)$ shall be the time integral of the organ equivalent dose rate in tissue or organ T which a person receives as the result of the incorporation of radioactive substances at time t_0 :

$$HT(\tau) = \int_{t_0}^{t_0+\tau} H \cdot T(t) dt$$

$HT(t)$ refers to the medium organ equivalent dose rate in tissue or organ T at time t.

Whereby τ refers to the time over which the integration takes place. A period of 50 years shall be taken as a basis for adults, and for children the period from the respective age until reaching the age of 70, unless a different value is stated.

2. Calculation of the effective dose E:

The effective dose in accordance with section 5 subsection (11) of the Radiation Protection Act shall be the weighted mean of the equivalent dose for the consideration of the radiation effect on different organs or tissue; the sensitivity to radiation of different organs or tissue shall be taken into consideration with the weighting factors w_T in accordance with Part C, no. 2. The sum of all organs and tissue listed in Part C, no. 2 shall be established thereby and averaged over the equivalent doses for the male and female reference person:

$$E = \sum_T \frac{w_T}{2} (H_T^M + H_T^F)$$

In the case of internal exposure, the effective dose shall also take into account the exposure occurring after the reference time on the basis of the fate of the radionuclides in the body (effective follow-up dose).

The effective subsequent dose $E(\tau)$ shall be the sum of the subsequent equivalent doses $HT(\tau)$ in accordance with no. 1, in each case multiplied by the appropriate tissue-weighting factor w_T in accordance with Part C no. 2, whereby it shall be totalled over all organs and tissue listed in Part C no. 2:

$$E(\tau) = \sum_T w_T HT(\tau)$$

Whereby τ shall refer to the period during which integration takes place. A period of 50 years shall be taken as a basis for adults, and for children the period from the respective age up to the age of 70, insofar as no other value is stated.

When calculating the effective dose, the energy dose of the skin at a tissue depth of 0.07 mm shall be averaged over the whole skin.

3. Calculation of the effective dose through inhalation of radon at indoor workplaces: It shall be assumed that an effective dose of 1 mSv is caused by

- a) a radon 222 exposure of 0.32 megabecquerel per cubic metre per hour; a value of 0.4 shall be used as a basis for the equilibrium factor between radon 222 and its short-lived decay products, or
- b) a potential exposure to alpha energy of 0.71 millijoules per cubic metre per hour. The competent authority may determine conversion factors deviating from the first sentence (a) due to the exposure conditions.

4. Calculation of the effective dose in the event of incorporation, submersion or soil contamination:

The dose respective coefficients from the compilation in the Federal Gazette no. 160a and b of 28 August 2001, Parts I, II and III as well as IV and V, shall be used when calculating the exposure. The competent authority may determine other dose coefficients in accordance with the scientific and technical state-of-the-art, in consideration of the exposure conditions.

5. Calculation of the effective dose for an unborn child:

- a) calculation of the contribution of an external exposure of the unborn child: In the case of external exposure, the equivalent dose of the uterus of the pregnant woman shall be regarded as the effective dose of the unborn child.
- b) calculation of the contribution of an internal exposure of the unborn child on the basis of the incorporation of radionuclides of a pregnant woman:

In the case of internal exposure, the effective dose of the pregnant woman which is related to the activity dose shall be regarded as the effective dose of the unborn child unless determined otherwise by the competent authority on the basis of the exposure conditions.

Part C: Values of the radiation weighting factor and of the tissue weighting factor

1. Radiation weighting factor w_R :

The values of the radiation weighting factor w_R shall depend on the type and quality of the external radiation field or on the type and quality of the radiation emitted from an incorporated radionuclide.

Radiation type	Radiation weighting factor w_R
Photons	1
Electrons and muons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, energy $E_n < 1$	$2.5 + 18.2 e^{-[\ln(E_n)]^2/6}$
Neutrons, $1 \text{ MeV} \leq \text{Energy } E_n \leq 50$	$5.0 + 17.0 e^{-[\ln(2E_n)]^2/6}$
Neutrons, energy $E_n > 50$	$2.5 + 3.25 e^{-[\ln(0.04E_n)]^2/6}$

E_n is the numerical value of the neutron energy in MeV.

2. Tissue weighting factor w_T

Tissue or organs	Tissue weighting factors w_T
1. Bone marrow (red)	0.12
2. Large intestine	0.12
3. Lung	0.12
4. Stomach	0.12
5. Breast	0.12
6. Gonads	0.08
7. Bladder	0.04
8. Oesophagus	0.04
9. Liver	0.04
10. Thyroid	0.04
11. Skin	0.01
12. Bone surface	0.01
13. Brain	0.01
14. Salivary glands	0.01
15. Other organs or tissue ¹⁾	0.12

1) The tissue weighting factor for other organs or tissue relates to the arithmetic mean of the doses of the 13 organs and tissue for each gender, which are listed below. Remaining tissue: Adrenals, extrathoracic (ET) region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate (male), small intestine, spleen, thymus, uterus/cervix (female).

Part D: Quality factor Q

The values of the quality factor Q of the ICRU, depending on the unrestricted linear energy transfer L in water, shall be determined in accordance with the recommendations of the International Commission on Radiological Protection (ICRP) of 2007: ICRP publication 103, which shall be published in the Digital Online Repository and Information System (DORIS) of the Federal Office for Radiation Protection under ID urn:nbn:de:0221-2009082154, as follows:

L	Q(L)
< 10	1
$10 \leq L \leq 100$	$0.32 \cdot L^{-0.2}$
$L > 100$	$300/L$

L shall be the numerical value of the linear energy transfer in water in keV/μm.

Annex 19
(re section 181)

Tests for obtaining and retaining the requisite expert qualifications for practising an activity as an officially-appointed authorised expert in accordance with section 172 subsection (1) of the Radiation Protection Act

Part 1: Authorised experts in accordance with section 172 subsection (1), first sentence, nos. 1, 3 and 4 of the Radiation Protection Act

In order to obtain the requisite expert qualifications in accordance with section 181 subsection (1) no. 4 for tests in accordance with section 172 subsection (1), first sentence, nos. 1, 3 and 4 of the Radiation Protection Act, tests on systems in accordance with column 1 of Tables 1 and 2 shall require the performance of tests in accordance with column 2 of Tables 1 and 2 under the supervision of a person in accordance with section 181 subsection (1) no. 3.

Table 1: Tests in accordance with section 172 subsection (1), first sentence, no. 1 of the Radiation Protection Act

1		2	3	4
System		Number of systems to be tested in order to obtain the qualification	Number of systems to be tested in order to retain the qualification	Comments
A	Medical and dental X-ray equipment			
A 1	Imaging devices			
A 1.1	Imaging devices	20	10	To obtain the qualification, fixed - at least 5 - and mobile imaging devices must be tested.
A 1.2	Mammography devices	10	5	For systems in accordance with A 1.2, the qualification may only be gained in connection with the required number of systems in accordance with A 1.1.
A 2	Scanning devices			
A 2.1	Scanning devices	30	15	These include angiography, digital subtraction angiography (DSA) and cardiac catheter workstations, as well as C-arm devices used for cardiac catheterisation, DSA or interventions.

1		2	3	4
System		Number of systems to be tested in order to gain the qualification	Number of systems to be tested in order to retain the qualification	Comments
A 2.2	C-arm devices	10	5	These include mobile C-arm devices with which examinations can be performed on localisations at the trunk, at extremities, shoulders and hip joints, as well as implantations of catheters and port systems.
A 3	Computer tomography devices	10	5	The qualification may only be obtained in connection with the requisite number of systems in accordance with A 2.1.
A 4	Dental X-ray equipment			
A 4.1	Dental imaging devices with a tube	10	5	
A 4.2	Specialised dental imaging devices	10	5	To obtain the qualification, tomography, teleradiology as well as at least three DVT devices must be tested.
A 5	Therapy devices	10	5	To obtain the qualification, up to three systems in accordance with D 1 may be taken into account.
B	Non-medical X-ray equipment and stray radiation emitters			
B 1	Fine structure and broad structure examination devices	20	10	To obtain the qualification, at least three fine structure, fixed and mobile broad structure examination devices shall be tested in each case.
B 2	High-, full- and basic-protection and X-ray equipment for training purposes	5	2	The qualification for the testing of systems in accordance with B 2 may only be obtained in connection with the requisite number of systems in accordance with B 1.

1		2	3	4
System		Number of systems to be tested in order to gain the qualification	Number of systems to be tested in order to retain the qualification	Comments
B 3	Stray radiation emitters	5	2	These include e.g. electron microscopes and excimer lasers. Electron beam welding devices shall be assigned to device category B 1.
C	Veterinary X-ray equipment			
C 1	Fixed and mobile imaging and scanning devices	10	5	Human medical systems in accordance with A 1 and A 2 may be counted as comparable systems.
C 2	Computer tomography devices	5	2	Human medical systems in accordance with A 3 may be counted as comparable systems.

Table 2: Tests in accordance with section 172 subsection (1), first sentence, nos. 3 and 4 of the Radiation Protection Act

The tests shall be conducted on different systems or in different areas of application.

1		2	3	4
System		Number of systems to be tested in order to obtain the qualification	Number of systems to be tested in order to retain the qualification	Comments
D	Medically-used systems (uses on humans) ¹			
D 1	Installations for the generation of ionising radiation which do not require a construction authorisation	10	5	Accelerators To obtain the qualification, three tests must cover the scope of an initial test, including structural radiation protection.

¹ These also include comparable devices used on animals.

1		2	3	4
System		Number of systems to be tested in order to gain the qualification	Number of systems to be tested in order to retain the qualification	Comments
D 2	Irradiation facilities for brachytherapy	5	2	If the qualification is gained independently of D 1, two tests for obtaining the qualification must cover the scope of an initial test, including structural radiation protection.
E	Non-medically-used systems			
E 1	Installations for the generation of ionising radiation which require a construction authorisation	2	2	To obtain the qualification, one test must cover the scope of an initial test, including structural radiation protection.
E 2	Installations for the generation of ionising radiation, with the exception of E 1	5	2	To obtain the qualification, two tests must cover the scope of an initial test, including structural radiation protection.
E 3	Irradiation facilities with radioactive sources	2	2	To obtain the qualification, both tests must cover the scope of an initial test, including structural radiation protection. Corresponding tests in accordance with D 1, D 2 or E 1 will be taken into account.
E 4	Devices for gamma radiography	5	2	
F	Enclosed radioactive substances (leakage tests)	100	50	To obtain the qualification, the leakage tests must cover all relevant test methods.

Part 2:

Authorised experts in accordance with section 172 subsection (1), first sentence, no. 2 of the Radiation Protection Act

In order to obtain the requisite expert qualification in accordance with section 181 subsection (1) no. 4 for tests in accordance with section 172 subsection (1), first sentence, no. 2 of the Radiation Protection Act, five tests must be conducted under the supervision of a person in accordance with section 181 subsection (1) no. 3 into two or more fields of activity in accordance with Annex 3 of the Radiation Protection Act.