

Act on Protection against the Harmful Effects of Ionising Radiation – Radiation Protection Act

(Gesetz zum Schutz vor der schädlichen Wirkung ionisierender Strahlung – Strahlenschutzgesetz – StrlSchG)

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Part 1

General provisions

Section 1

Scope and coverage

(1) This Act lays down provisions concerning the protection of people and, in so far as concerns the long-term protection of human health, the environment against the harmful effects of ionising radiation, in particular in:

1. planned exposure situations,
2. emergency exposure situations, and
3. existing exposure situations.

(2) This Act does not lay down provisions concerning

1. exposure of members of the public or workers, with the exception of air or space crew, to cosmic radiation,
2. aboveground exposure to radionuclides naturally present in the undisturbed earth's crust,
3. exposure to radionuclides naturally present in the human body and via cosmic radiation close to the ground.

(3) This Act and the statutory ordinances issued on the basis of this Act shall also apply, within the framework of the stipulations laid down in the United Nations Convention on the Law of the Sea of 10 December 1982 (Federal Law Gazette [BGBl.] 1994 Part II, p. 1799), to Germany's exclusive economic zone and continental shelf.

Section 2

Exposure; exposure situations; categories of exposure

(1) 'Exposure' means the action on the human body of ionising radiation from radiation sources outside the body (external exposure) and within the body (internal exposure), or the extent of such action.

(2) 'Planned exposure situation' means an exposure situation that arises from practices in which exposure is or may be caused.

(3) 'Emergency exposure situation' means an exposure situation that arises as a result of an emergency, provided that said situation does not fall within the scope of subsection (4).

(4) 'Existing exposure situation' means an exposure situation that already exists when a decision on its control has to be taken.

(5) A distinction is drawn between the following categories of exposure

1. public exposure,
2. occupational exposure, and

3. medical exposure.

(6) 'Public exposure' means exposure of individuals, with the exception of occupational or medical exposure.

(7) 'Occupational exposure' means exposure of

1. a person who is in an employment relationship with a person who carries out a practice in accordance with this Act, or who carries out such practice himself or herself,
2. air or space crew,
3. a person who carries out a task in accordance with section 19 or section 20 of the Atomic Energy Act (*Atomgesetz* – AtG) in accordance with section 172 or section 178,
4. a person who, in an existing exposure situation, is in an employment relationship with a person carrying out an occupational activity, or who carries out said activity himself or herself (workers), or
5. emergency workers during deployment in an emergency exposure situation or other hazardous situation.

A training relationship or the voluntary or unsalaried performance of comparable activities shall be deemed to be equivalent to an employment relationship.

(8) 'Medical exposure' means exposure of

1. a patient or asymptomatic individual on whom radioactive substances or ionising radiation are applied as part of his or her medical or dental examination or treatment with the intention of being beneficial to his or her health,
2. a person on whom radioactive substances or ionising radiation are applied, with his or her consent or that of his or her legal or authorised representative, for the purposes of medical research, or
3. a person who is capable of giving consent, or acting with the consent of his or her legal or authorised representative, who knowingly and willingly incurs exposure to ionising radiation by voluntarily, other than as part of his or her occupation, supporting and comforting persons on whom radioactive substances or ionising radiation are applied as part of their medical or dental examination or treatment or in the course of medical research (carers and comforters).

Section 3

The term 'radioactive substances'

(1) For the purposes of this Act, 'radioactive substances' (nuclear fuels and other radioactive materials) means all substances containing one or more radionuclides the activity or specific activity of which precludes their being disregarded under the provisions contained in this Act or in a statutory ordinance issued by the Federal Government with the consent of the Bundesrat on the basis of this Act. 'Nuclear fuels' means highly-fissile substances in forms of

1. plutonium 239 and plutonium 241,
2. uranium enriched in isotope 235 or 233,

3. any substance containing one or more of the substances referred to in nos. 1 and 2 above,
4. substances which permit a self-sustaining chain reaction to be maintained in a suitable installation and which are determined in a statutory ordinance issued by the Federal Government with the consent of the Bundesrat.

The term 'uranium enriched in isotope 235 or 233' means uranium containing isotopes 235 or 233, or both, in such quantities that the sum total of the quantities of these two isotopes is greater than the quantity of isotope 238 multiplied by the ratio of isotope 235 to isotope 238 occurring in nature.

(2) The activity or specific activity of a substance may be disregarded in accordance with subsection (1), first sentence, above insofar as, in accordance with this Act or a statutory ordinance issued by the Federal Government on the basis of this Act with the consent of the Bundesrat

1. it falls below specified exemption levels
2. if the substance concerned occurs within the context of a practice subject to licensing in accordance with this Act, with the Atomic Energy Act or with a statutory ordinance issued on the basis of either of said Acts, it falls below specified clearance levels, and clearance has been given for the substance in question,
3. if the substance concerned is of natural origin, is not used as a nuclear fuel or to generate nuclear fuel because of its radioactivity, and is not subject to monitoring under the provisions of the Atomic Energy Act, this Act or a statutory ordinance issued by the Federal Government on the basis of this Act with the consent of the Bundesrat.

By way of derogation from the first sentence above, a statutory ordinance issued by the Federal Government on the basis of this Act with the consent of the Bundesrat and concerning the use of substances on people or the purposive addition of substances in the production of medicinal products, medical devices, plant protection products, pesticides, substances in accordance with section 2, first sentence, nos. 1 to 8 of the German Fertiliser Act (*Düngengesetz*), or consumer products or the activation thereof, may stipulate in what cases the activity or specific activity of a substance may not be disregarded.

(3) For the application of licensing provisions in accordance with this Act or with the statutory ordinances issued on the basis of this Act, substances in which the proportion of isotopes uranium 233, uranium 235, plutonium 239 and plutonium 241 does not exceed 15 grams in total, or the concentration of the isotopes stated does not exceed 15 grams per 100 kilograms, are classified as 'other radioactive substances'. The first sentence shall not apply to solidified high-activity fission product solutions derived from the reprocessing of nuclear fuel.

(4) Subsections (1)-(3) above shall not apply to substances that occur in connection with existing exposure situations and emergency exposure situations.

Section 4

Practices, types of practice

(1) 'Practices' means

1. handling in accordance with section 5 subsection (39),
2. the acquisition of artificially-produced radioactive substances and of naturally-occurring radioactive substances that, as on the basis of their radioactivity, are used as a nuclear fuel or to generate nuclear fuel, the transfer of such substances to others, their carriage and their cross-border transportation,
3. the custody of nuclear fuels in accordance with section 5 of the Atomic Energy Act and the holding of nuclear fuels in accordance with section 6 of the Atomic Energy Act,
4. the construction, operation, otherwise possession, decommissioning and safe enclosure of an installation, as well as the dismantling of an installation or parts thereof in accordance with section 7 of the Atomic Energy Act,
5. the treatment, processing and other utilisation of nuclear fuels in accordance with section 9 of the Atomic Energy Act,
6. the construction, operation and decommissioning of installations of the Federation for the safekeeping and disposal of radioactive waste in accordance with section 9b of the Atomic Energy Act,
7. the construction and operation of installations for the generation of ionising radiation,
8. the operation and the verification, testing, maintenance or repair of X-ray equipment and stray radiation emitters,
9. the addition of radioactive substances in the manufacture of consumer products, medicinal products within the meaning of the Medicinal Products Act (*Arzneimittelgesetz*), of plant protection products within the meaning of the Plant Protection Act (*Pflanzenschutzgesetz*), of pesticides and substances in accordance with section 2, first sentence, nos. 1-8 of the Fertiliser Act, as well as the activation of the aforementioned products, and
10. activities that, whilst not falling within the scope of nos. 1-9, could increase exposure or contamination in connection with naturally-occurring radioactivity
 - a) insofar as they are carried out in connection with exploration, extraction, generation, storage, treatment, processing and other use of materials,
 - b) insofar as they are carried out in connection with materials arising from operational processes, to the extent that such activities do not already fall under (a) above,
 - c) insofar as they are carried out in connection with the recovery or disposal of materials occurring by virtue of activities in accordance with (a) or (b) above,
 - d) insofar as natural terrestrial sources of radiation have an impact as a result, with the exception of exposure by radon emanating from the soil into the free atmosphere or emanating from the geogenic substratum and entering into recreation rooms and insofar as such activities do not already fall under (a) to (c) above and are not performed for a purpose referred to under (a) above, or

11. the operation of air and spacecraft in connection with the performance of the occupational duties of air and space crew.

The practices in accordance with the first sentence, nos. 1-10, shall also include the deployment of persons who perform such practices for third parties, as well as other activities that could increase exposure or contamination in connection with such practices. The term practice within the meaning of the first sentence, no. 10, shall not include agricultural, forestry or construction-related processing of the surface of the earth insofar as such activities do not take place for the purposes of decontamination in accordance with section 64 subsection (1).

(2) A 'type of practice' means the totality of practices that are to be assessed in essentially the same manner in respect of the principle of justification.

Section 5

Other definitions

(1) 'Waste' means all substances and articles that constitute waste within the meaning of section 3 subsection (1) of the Circular Economy Act (*Kreislaufwirtschaftsgesetz*), including waste that is excepted from the scope of the Circular Economy Act in accordance with section 2 subsection (2) nos. 1-4 or 7-15 of the Circular Economy Act. Residual material and installation components that must be rendered harmless through recovery, or disposed of in a controlled manner in accordance with section 9a subsection (1) of the Atomic Energy Act, as well as other radioactive waste, residues and other radioactive substances that are subject to the provisions of the Repository Site Selection Act (*Standortauswahlgesetz*) or of the Atomic Energy Act, shall not be regarded as waste within the meaning of this Act.

(2) 'Installations for the generation of ionising radiation' means equipment or devices that are suitable for generating particle or photon radiation with a particle or photon cut-off energy of at least five kiloelectron-volts, either intentionally or unintentionally, in particular electron accelerators, ion accelerators and plasma installations. In connection with use on people, 'installation for the generation of ionising radiation' shall also encompass application devices, ancillary equipment and accessories, the necessary software and equipment to monitor and evaluate the immediate results of the use of an application. X-ray equipment, stray radiation emitters, nuclear installations and installations within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act shall not be deemed installations for the generation of ionising radiation.

(3) 'Use of ionising radiation or radioactive substances on people' means the technical performance of

1. an examination using ionising radiation or radioactive substances and the analysis of the findings of said examination, or
2. treatment using ionising radiation or radioactive substances and the immediate review and evaluation of the outcome of said treatment.

(4) 'Workplace' means any place at which a worker is regularly or repeatedly present during the performance of his or her occupational duties.

(5) 'Recreation room' means an indoor space intended for non-temporary occupation by members of the public, for example in a school, hospital, kindergarten or residence.

(6) 'Construction products' means building materials, building kits, components and in-

stallations that are manufactured for the purpose of being permanently installed in buildings as the wall, floor or ceiling structures, including the coverings thereof, of recreation rooms. Finished products used on a small scale and in small volumes, such as patching mortar and grouting, shall not be deemed to constitute construction products.

(7) 'Occupationally-exposed person means a person who, as a result of practices, may incur occupational exposure which

1. exceeds an effective dose of 1 millisievert (mSv) in a given calendar year,
2. exceeds an equivalent dose for the lens of the eye of 15 mSv in a given calendar year, or
3. exceeds an equivalent dose for the skin, averaged over any area of 1 cm², regardless of the area exposed, of 50 mSv in a given calendar year.

Occupational exposures resulting from emergency exposure situations shall not be taken into account thereby. A person who receives occupational exposure exclusively in an emergency exposure situation or other hazardous situation shall not be deemed to be an occupationally-exposed person.

(8) 'Irradiation device' means shielded device which contains sealed radioactive substances or is part of an installation used for the fission of nuclear fuels and which temporarily emits ionising radiation when the shield is opened or when these radioactive substances are deployed

1. which is used in connection with use on people or on animals in veterinary medicine, or
2. by which an effect is to be caused for other purposes on the objects to be irradiated, and in which the activity of the radioactive substance exceeds 20 terabecquerels (TBq).

In connection with use on people, 'irradiation device' shall also encompass application equipment, ancillary equipment and accessories, the necessary software and equipment to analyse the findings of an examination, or to monitor and evaluate the outcome of a treatment.

(9) 'Operation of X-ray equipment' means the autonomous use or ensuring the availability of X-ray equipment for the generation of X-rays. The generation of X-rays in connection with the verification, testing, maintenance or repair of X-ray equipment for commercial purposes shall not be deemed to form part of operation. X-ray equipment shall also not be deemed to be operated where it is verified, tested, maintained, repaired or kept ready in connection with Germany's Federal Armed Forces (*Bundeswehr*), or with civil protection, exclusively for the use of the latter.

(10) 'Operation of a stray radiation emitter' means the autonomous use or ensuring the availability of a stray radiation emitter. The generation of X-rays in connection with the verification, testing, maintenance or repair of the stray radiation emitter for commercial purposes shall not be deemed to form part of operation. Stray radiation emitters shall also not be deemed to be in operation insofar as they are verified, tested, maintained, repaired or its availability is ensured in connection with Germany's Federal Armed Forces, or with civil protection, exclusively for the use of the latter.

(11) 'Effective dose' means the weighted average of equivalent doses in order to allow for the effects of radiation on various organs or tissues; the organs or tissues shall be taken account of with the weighting factors laid down in the statutory ordinance in accordance with

section 175 subsection (2) no. 2.

(12) 'Facilities' means buildings, parts of buildings, individual rooms or comparable delimited open spaces in which

1. radioactive substances are handled in accordance with section 5 or section 9 of the Atomic Energy Act or in accordance with section 12 subsection (1) no. 3 of that Act, with the exception of interim storage facilities within the meaning of section 2 subsection 3a no. 1(c) of the Atomic Energy Act, or
2. an installation for the generation of ionising radiation in accordance with section 12 subsection (1) no. 1, or X-ray equipment in accordance with section 12 subsection (1) no. 4 or a stray radiation emitter in accordance with section 12 subsection (1) no. 5 is operated.

(13) 'Emergency worker' means any person having a defined task in an emergency or in another hazardous situation who may be subject to exposure while being so deployed.

(14) 'Member of the public' means any person who is not subject to occupational or medical exposure.

(15) 'Exemption levels' means values for the activity and specific activity of radioactive substances as laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, and for practices in connection with such radioactive substances as a measure of the need for monitoring in accordance with this Act and with the statutory ordinances issued on the basis hereof.

(16) 'Screening' means the use of X-radiation or radioactive substances in connection with medical exposure in order to examine persons who do not exhibit any symptoms of disease or any concrete suspicion of disease (asymptomatic individuals) in order to detect a specific disease.

(17) 'Indoor' means enclosed, stationary spaces within and outside buildings which may be occupied by people, including caves and mines.

(18) 'Nuclear installation' means a nuclear installation in accordance with section 2 subsection (3a) no. 1 of the Atomic Energy Act.

(19) 'Body dose' is an overarching term for the effective dose and the equivalent dose.

(20) 'Consumer products' means articles of daily use within the meaning of the Food and Feed Code (*Lebensmittel- und Futtermittelgesetzbuch*) intended for end consumers, as well as goods and articles for daily use for household and occupational purposes. Construction products and type-approved devices shall not be deemed to constitute consumer products where such construction products or devices contain other radioactive substances.

(21) 'Contamination' means pollution caused by substances that contain one or more radionuclides.

(22) 'Materials' means substances that contain naturally-occurring radionuclides or are contaminated by such substances. The following shall not be deemed to constitute 'materials'

1. substances containing naturally-occurring and artificial radionuclides that are or were the subject of practices in accordance with section 4 subsection (1), first sentence,

nos. 1-9 and 11,

2. substances containing naturally-occurring and artificial radionuclides arising from emergencies, and
3. substances present in the environment that are contaminated as a result of nuclear weapons tests.

(23) 'Medical research' means the advancement of medical examination methods, treatment procedures or medical science. The use of radioactive substances or ionising radiation exclusively for the examination or treatment of an individual shall not be deemed to constitute medical research.

(24) 'Medical physics expert' means a person with a Master's degree in medical physics, or with equivalent training in medical physics plus a higher education degree, who possesses in each case the requisite specialist knowledge in radiation protection.

(25) 'Follow-up measures' means monitoring, maintaining and restoring the effectiveness of remedial measures or of other measures to prevent or reduce exposure in existing exposure situations.

(26) 'Emergency' means an event in which ionising radiation could result in significant deleterious effects on people, the environment or property. It shall not be regarded as an emergency where it can be foreseen that an event that has occurred in connection with a planned practice can be expected to be dealt with by the measures laid down for the planned exposure situations.

1. 'Supra-regional emergency' means an emergency taking place within Germany the deleterious effects of which cannot be expected to be restricted to the *Land* in which it took place, or an emergency taking place outside Germany which is expected to have not only local deleterious effects within the scope of this Act.
2. 'Regional emergency' means an emergency taking place within Germany the deleterious effects of which can be expected to be substantially restricted to the *Land* in which it took place.
3. 'Local emergency' means an emergency that can be expected to have substantially not only local deleterious effects within the scope of this Act.

(27) 'Equivalent dose' means the result of the multiplication of the energy deposited in an organ or tissue by ionising radiation, divided by the mass of the organ or tissue, by a weighting factor laid down by statutory ordinance in accordance with section 175 subsection (2) no. 1 in order to allow for the effect for the type or energy of radiation, versus photon and electron radiation. Where several types or energy of radiation are present, their contributions shall be summed.

(28) 'Radon' means the radionuclide Rn-222 and its progeny.

(29) 'Reference level', in an existing exposure situation or emergency exposure situation, means a stipulated level that serves as a yardstick by means of which to assess the appropriateness of measures. A reference level shall not constitute a limit.

(30) 'X-ray equipment' means equipment or a device

1. in which X-radiation with a cut-off energy of at least 5 kiloelectron-volts can be generat-

ed using accelerated electrons, where the acceleration of the electrons is limited to an energy of one megaelectron-volt, and

2. that is operated for the purpose of generating X-radiation.

The term 'X-ray equipment' shall also encompass application equipment, ancillary equipment and accessories, as well as the necessary software and equipment to analyse medical findings.

(31) 'X-ray tube assembly' means an X-ray equipment component consisting of an X-ray tube and the protective housing of said tube, as well as the high-voltage generator in the case of a single-chamber device.

(32) 'Residues' means materials that are generated during the industrial and mining processes referred to in Annex 1 and that meet the criteria referred to therein.

(33) 'Remedial measures' means measures that

1. serve to remove or reduce contamination, or
2. inhibit or reduce, on a long-term basis, the dispersion of radionuclides or ionising radiation emitted by same.

(34) 'Unsealed radioactive substances' means all radioactive substances except sealed radioactive substances.

(35) 'Sealed radioactive substances' means radioactive substances that are permanently enclosed on all sides by an impervious, solid, inactive casing that cannot be opened non-destructively or permanently incorporated into solid inactive substances such that, under normal conditions of use, the emission of radioactive substances is definitively prevented; the radioactive substance must measure at least 0.2 centimetres in enclosed form.

(36) 'High-activity radioactive sources' means sealed radioactive substances the activity of which corresponds to or exceeds the levels laid down in a statutory ordinance in accordance with section 24, first sentence, no. 11. Fuel rods and solidified high-activity fission product solutions derived from the reprocessing of nuclear fuels, as well as permanently-impervious, solid transport or storage containers containing radioactive substances, shall not be deemed to constitute high-activity radioactive sources.

(37) 'Stray radiation emitter' means a device or equipment in which X-radiation with a cut-off energy of at least 5 kiloelectron-volts can be generated exclusively using accelerated electrons, and in which the acceleration of the electrons is limited to an energy of 1 megaelectron-volt, without the device or equipment being operated for the purpose of generating X-radiation. Stray radiation emitters include electron microscopes the X-radiation from which is analysed by detectors.

(38) 'Teleradiology' means examination of a person using X-radiation under the responsibility of a doctor who possesses the requisite specialist knowledge in radiation protection and who is not present at the site where technical implementation takes place (teleradiologist).

(39) 'Handling' means

1. the extraction, generation, storage, treatment, processing, other use and disposal of
 - a) artificially-produced radioactive substances, and of
 - b) naturally-occurring radioactive substances due to their radioactivity, for use as a nuclear fuel or to generate nuclear fuels,
2. the operation of irradiation devices, and
3. exploration, extraction and treatment of radioactive mineral resources within the meaning of the Federal Mining Act (*Bundesberggesetz*).

(40) 'Addition of radioactive substances' means the purposive addition of radionuclides to substances in order to produce particular properties, where

1. the addition of artificially-produced radionuclides leads to their specific activity in the product exceeding 500 microbecquerels per gram ($\mu\text{Bq/g}$), or
2. the addition of naturally-occurring radionuclides leads to their specific activity in the product exceeding one-fifth of the exemption levels laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10.

It is irrelevant whether the addition is effected due to radioactivity or due to other properties.

Part 2

Radiation protection in planned exposure situations

Chapter 1

General principles of radiation protection

Section 6

Justification of types of practice; empowerment to issue ordinances

(1) New types of practice which may result in the exposure of people and the environment must be justified, with their economic, social or other benefit being weighed up against the potential health detriment caused. This justification shall take account of any occupational exposure, public exposure and medical exposure. Exposures resulting from use on people shall be taken into account in accordance with section 83 subsection (2).

(2) Justification of existing types of practice may be reviewed as soon as there are significant new findings on the benefits or effects of the practice or significant new information regarding other processes or techniques.

(3) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what types of practice are not justified.

Section 7

Procedure to verify the justification of a type of practice; empowerment to issue ordinances

(1) Should a competent authority find indications in the course of a licensing or notification procedure in accordance with sections 10, 12, 17, 19 subsection (1), first sentence, no. 1, or section 56 or 59, that raises doubts as to the justification of the practice within the meaning of section 6 subsections (1) and (2), the authority shall pass on the documents which present such indications to the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (in the case of *Länder*-level authorities, via the highest authority competent for radiation protection in the *Land* in question). Should the indications in question require further investigation, the Ministry shall have the Federal Office for Radiation Protection carry out a review. In appropriate application of the second sentence, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety may also arrange an investigation by the Federal Office for Radiation Protection beyond ongoing licensing and notification procedures for types of practice insofar as radiation protection so necessitates.

(2) The Federal Office for Radiation Protection shall examine the justification of the type of practice within the meaning of section 6 subsections (1) and (2) within 12 months of receiving the documents in question, and shall publish a scientific report. Trade and business secrets as well as personal data shall be rendered unrecognisable in said report.

(3) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, laying down

1. what documents must be submitted,
2. stipulations for the procedure to verify the justification of types of practice, and
3. rules governing how the Federal Office for Radiation Protection publishes its scientific report into the justification of the type of practice.

Section 8

Prevention of unnecessary exposure and dose reduction

(1) Anyone who plans or carries out a practice, or has it carried out, shall be obliged to avoid any unnecessary exposure or contamination of people and the environment.

(2) Anyone who plans or carries out a practice, or has it carried out, shall be obliged to keep any exposure or contamination of people and the environment, even below the limits, as low as possible. In addition, and taking into consideration all the circumstances of the individual case, such a person must also

1. take note of the scientific and technical state-of-the-art, insofar as practices in accordance with section 4 subsection (1), first sentence, nos. 1-7 and 9, are concerned;
2. take note of the technical state-of-the-art, insofar as practices in accordance with section 4 subsection (1), first sentence, nos. 8, 10 and 11, are concerned.

Section 9

Dose limitation

Anyone who plans or carries out a practice, or has it carried out, shall be obliged to ensure that the dose limits laid down in this Act and in the statutory ordinances issued on the basis of this Act are not exceeded.

Chapter 2

Prior verification in the case of radioactive substances or ionising radiation

Division 1

Construction of installations for the generation of ionising radiation

Section 10

Construction requiring a licence of installations for the generation of ionising radiation

Anyone constructing an installation for the generation of ionising radiation of one of the following types shall require a licence

1. an accelerator or plasma installation capable of generating more than 10^{12} neutrons per second,
2. an electron accelerator having a final electron energy of more than 10 megaelectron-volts, insofar as the mean radiated power may exceed 1 kilowatt,
3. an electron accelerator having a final electron energy of more than 150 megaelectron-volts,
4. an ion accelerator having a final ion energy of more than 10 megaelectron-volts per nucleon, insofar as the mean radiated power may exceed 50 watts,
5. an ion accelerator having a final ion energy of more than 150 megaelectron-volts per nucleon.

Section 11

Conditions for granting a licence; suspension of the licensing procedure

(1) The competent authority shall grant a licence for the construction of an installation in accordance with section 10 where

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,

2. it is guaranteed that a radiation protection supervisor is appointed for the construction of the installation who possesses the requisite specialist knowledge in radiation protection and is capable of constructing the installation, or having it constructed, in accordance with the licence; there may be no facts giving rise to reservations regarding the reliability of the radiation protection supervisor,
3. it is guaranteed that the exposure of people as a result of the operation of the installation does not exceed the permissible limits for members of the public in generally-accessible areas outside the operating site; in determining the exposure, the discharge of radioactive substances into the air and water, as well as escaping and scattered radiation, must be taken into account,
4. the statutory provisions governing environmental protection can be complied with both during the operation of the installation as intended, and in the event of hazardous incidents,
5. the requisite protection against disruptive action or other interference by third parties is ensured, and
6. the practice in question is not an unjustified type of practice in accordance with a statutory ordinance in accordance with section 6 subsection (3) or where, in consideration of a report published in accordance with section 7 subsection (2), there are no serious doubts as to the justification of the type of practice.

The first sentence, no. 2, shall not be applied where a person referred to in the first sentence, no. 1, possesses the requisite specialist knowledge in radiation protection and is able to construct the installation, or have it constructed, in accordance with the licence.

(2) Where the competent authority instigates a procedure to verify justification in accordance with section 7, it shall suspend the procedure to grant the licence for the duration of the procedure to verify justification.

Division 2

Operation of installations for the generation of ionising radiation; handling of radioactive substances; operation of X-ray equipment or stray radiation emitters

Section 12

Practices requiring a licence

(1) Anyone carrying out the following practices shall require a licence

1. operating an installation for the generation of ionising radiation; this shall not apply to installations for the operation of which notification in accordance with section 17 is sufficient or which may be operated without needing a licence or notification in accordance with the statutory ordinance in accordance with section 24, first sentence, no. 1,
2. using ionising radiation from an irradiation device that forms part of an installation for the fission of nuclear fuels that is licensed in accordance with section 7 subsection (1) no. 1 of the Atomic Energy Act, in connection with use on people or with use on animals in veterinary medicine,
3. handling other radioactive substances; this shall not apply to handling that does not require a licence in accordance with the statutory ordinance in accordance with section 24, first sentence, no. 1,
4. operating X-ray equipment; this shall not apply to X-ray equipment for the operation of which notification in accordance with section 19 subsection (1) is sufficient, the licence requirement in accordance with section 19 subsection (2) having been taken into account,
5. operating a stray radiation emitter; this shall not apply to stray radiation emitters that may be operated without a licence in accordance with the statutory ordinance in accordance with section 24, first sentence, no. 1.

(2) Anyone who significantly alters a practice requiring a licence referred to in the first half of any of nos. 1-5 of subsection (1) above shall also require a licence.

(3) A licence in accordance with subsection (1) no. 1 above may extend to a handling practice requiring a licence in accordance with subsection (1) no. 3.

(4) No licence in accordance with subsection (1) no. 3 above shall be required

1. where a licence in accordance with subsection (1) no. 1, 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 obtains, which licence or decision also extends in accordance with section 10a subsection (2) of the Atomic Energy Act to handling other radioactive substances in accordance with subsection (1) no. 3 above, or
2. for the exploration, extraction or treatment of radioactive mineral resources, where this is subject to an operating plan requirement in accordance with section 51 of the Federal Mining Act.

(5) Two or more practices that are carried out contiguously for a common purpose may

be covered by a single licence where

1. they satisfy two or more licensing criteria in accordance with subsection (1), and
2. the conditions for all licences are satisfied.

The first sentence shall apply *mutatis mutandis* to practices that require both a licence and notification under this Act, where the documents to be submitted with notification are handed over in the licensing procedure and there are no grounds for prohibiting the notifiable practice. The first and second sentences shall apply *mutatis mutandis* in the event of any significant changes.

Section 13

General conditions for granting a licence; suspension of the licensing procedure

(1) The competent authority shall grant a licence for the practices in accordance with section 12 subsection (1) where

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, where a radiation protection supervisor is not necessary, one of said natural persons possesses the requisite specialist knowledge in radiation protection,
2. there are facts giving rise to reservations regarding the reliability of the radiation protection supervisors, and the latter possess the requisite specialist knowledge in radiation protection,
3. the number of radiation protection supervisors necessary for the safe performance of the practice has been appointed, and they have been granted the powers necessary to perform their tasks,
4. it is guaranteed that the other persons involved in carrying out the practice possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented,
5. there are no facts giving rise to reservations regarding whether the necessary personnel are available for the safe execution of the practice,
6. it is guaranteed that such equipment is available and such measures have been implemented
 - a) that are necessary in accordance with the scientific and technical state-of-the-art for a practice in accordance with section 12 subsection (1) nos. 1-3 in order to ensure that regulations governing protection are complied with, or
 - b) that are necessary in accordance with the technical state-of-the-art for a practice in accordance with section 12 subsection (1) no. 4 or 5 in order to ensure that regulations governing protection are complied with,
7. the practice in question is not an unjustified type of practice in accordance with a statutory ordinance in accordance with section 6 subsection (3) or where, in consideration of

a report published in accordance with section 7 subsection (2), there are no serious doubts regarding the justification of the type of practice, and

8. this is not precluded by other provisions of public law.

(2) A licence for a practice in accordance with section 12 subsection (1) no. 1, 2 or 3 shall only be granted where the necessary financial provision has been made to satisfy statutory liabilities for damages.

(3) A licence for a practice in accordance with section 12 subsection (1) no. 1 or 3 shall only be granted where the requisite protection against disruptive action or other interference by third parties is ensured; in the case of a licence in accordance with section 12 subsection (1) no. 1, this shall only apply where the construction of the installation requires a licence in accordance with section 10.

(4) A licence in accordance with section 12 subsection (1) no. 3 for handling high-activity radioactive sources shall only be granted where procedures are in place for emergencies and suitable communications connections.

(5) If only trial operation or trial handling is able to reveal whether the conditions in accordance with subsections (1) and (3) are met, the competent authority may issue a licence for the practice in accordance with section 12 subsection (1) no. 1 or 3 on a time-limited basis. The radiation protection executive shall ensure that the provisions governing dose limits, exclusion areas, controlled areas and the limitation of discharges of radioactive substances are adhered to during the trial operation or trial handling. No use on people may take place during the trial operation or trial handling.

(6) Where the competent authority instigates a procedure to verify the justification in accordance with section 7, it shall suspend the procedure to grant a licence in accordance with section 12 subsection (1) for the duration of the procedure to verify the justification.

(7) The competent authority may require the holder of a licence in accordance with section 12 subsection (1) no. 3 to lodge a security for the disposal of radioactive material resulting from handling. The first sentence shall not apply if the licence-holder is the Federation, one or several *Länder*, or a third party which is fully financed by the Federation, by one or several *Länder*, or by the Federation together with one or several *Länder*.

Section 14

Special conditions for practices in connection with use on people

(1) A licence for a practice in accordance with section 12 subsection (1) no. 1, 2, 3 or 4 in connection with the use of ionising radiation or radioactive substances on people shall be granted only where, in addition to the applicable conditions in accordance with section 13 being satisfied,

1. the applicant or the radiation protection supervisor appointed by the latter is qualified as a medical doctor or dentist, or has been granted interim permission to practice medicine or dentistry,
2. it is guaranteed that
 - a) for treatment with radioactive substances or ionising radiation based on an individual radiation treatment plan, a medical physics expert can be called in for close co-operation in accordance with the statutory ordinance in accordance with section 86 subsection (2) no. 10,

- b) for treatment with radioactive substances or ionising radiation not based on an individual radiation treatment plan (standardised treatment), and for examinations using radioactive substances or ionising radiation that could be associated with significant exposure of the examinee, a medical physics expert can be called in for cooperation in accordance with the statutory ordinance under section 86 subsection (2) no. 10,
 - c) for all other uses of ionising radiation or radioactive substances on people, a medical physics expert can be called in for consultation where the use in question so requires.
3. it is guaranteed that
- a) for treatment in accordance with no. 2(a), a sufficient number of medical physics experts are appointed as additional radiation protection supervisors,
 - b) for treatment or examination in accordance with no. 2(b), a medical physics expert is appointed as an additional radiation protection supervisor where organisational or technical radiation protection reasons dictate that this is required.
4. it is guaranteed that the necessary personnel are available in sufficient numbers for the safe execution of the practice,
5. it is guaranteed that such equipment is available and such measures have been implemented as are necessary to ensure that the requisite quality for the use is achieved
- a) with the minimum possible exposure in the case of examinations,
 - b) with the dose distribution necessary for the intended purposes in treatments.

(2) The licence for a practice in accordance with section 12 subsection (1) no. 4 for teleradiology shall only be granted where, in addition to the applicable conditions under section 13 subsection (1) being satisfied,

- 1. the availability of the teleradiologist during the examination is guaranteed,
- 2. it is guaranteed that the technical implementation is carried out by a person in possession of the requisite specialist knowledge in radiation protection who is authorised for the technical performance of a teleradiology examination in accordance with the statutory ordinance in accordance with section 86 subsection (2) no. 6,
- 3. it is guaranteed that a medical doctor with the requisite knowledge of radiation protection is present at the site of technical implementation,
- 4. there is a master plan for teleradiological operations which
 - a) guarantees the necessary level of availability of the teleradiology system,
 - b) allows, where necessary in an individual case, for the teleradiologist to attend in person at the site of technical implementation within a requisite time frame for emergency care; where justified by particular cases, another medical doctor with the requisite specialist knowledge in radiation protection may also attend in person,
 - c) guarantees the regular and close involvement of the teleradiologist in the clinical operations of the radiation protection executive.

The licence for the operation of X-ray equipment for teleradiology shall be restricted to service during nights, weekends and public holidays. It may be granted for services over and above such night, weekend and public holiday services where patient care so requires. A licence in accordance with the third sentence shall be valid for no more than five years.

(3) The licence for a practice in accordance with section 12 subsection (1) nos. 3 and 4 in connection with screening shall be granted only where, in addition to the applicable conditions in accordance with section 13 and in accordance with subsection (1) above being satisfied

1. screening is sanctioned in accordance with section 84 subsection (1) or (4), and
2. compliance is ensured with such measures as are necessary in consideration of the requirements of medical science in order to achieve the requisite quality in screening with the minimum possible exposure.

The licence shall be valid for no more than five years.

Section 15

Special conditions for practices in connection with use

A licence for a practice in accordance with section 12 subsection (1) no. 1, 2, 3 or 4 in connection with use on animals in veterinary medicine shall only be granted where, in addition to the satisfaction of the respective conditions in accordance with section 13, the applicant or the radiation protection supervisor appointed by the latter is qualified as a veterinarian, medical doctor or dentist, or has been granted interim permission to practice veterinary medicine, medicine or dentistry.

Section 16

Required documents

A licence application for a practice in accordance with section 12 subsection (1) must be accompanied by the necessary documents for verification, in particular the documents specified in Annex 2.

Section 17

Notifiable operation of installations for the generation of ionising radiation

(1) Anyone who intends

1. to operate a plasma installation in the operation of which an ambient dose rate of 10 microsieverts (μSv) per hour at a distance 0.1 m from the walls of the area is not exceeded, that cannot be accessed during its operation for electrotechnical reasons, or
2. to operate an ion accelerator in the operation of which an ambient dose rate of 10 μSv per hour at a distance 0.1 m from the accessible surface is not exceeded,

shall notify the competent authority of this in writing by no later than four weeks prior to the

intended commencement. Once this period has expired, the notifying party may operate the installation for the generation of ionising radiation unless the competent authority has suspended the procedure in accordance with section 18 subsection (2) or has prohibited operation.

(2) The following documents shall be enclosed with the notification

1. proof that the installation satisfies the requirements of subsection (1), first sentence, no. 1 or 2,
2. proof that the number of radiation protection supervisors necessary for safe operation has been appointed, and that they have been granted the powers necessary in order to perform their tasks,
3. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not necessary, that the person required to notify, that person'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 possesses the requisite specialist knowledge in radiation protection.

(3) Subsections (1) and (2) shall apply *mutatis mutandis* in the event of a significant change to an installation in accordance with subsection (1) above or to its operation.

Section 18

Verification of the notified operation of an installation for the generation of ionising radiation

(1) The competent authority shall verify the documents within four weeks of receiving the notification. Should the authority inform the notifying party in writing prior to expiry of the deadline that all the proof in accordance with section 17 subsection (2) has been provided, the notifying party may commence operation of the installation for the generation of ionising radiation as soon as it receives the appropriate communication.

(2) Where the competent authority instigates a procedure to verify justification in accordance with section 7 within the deadline in accordance with subsection (1) above, it shall suspend the procedure to verify the notification for the duration of the justification verification procedure.

(3) The competent authority may prohibit the operation of the installation for the generation of ionising radiation or an alteration to such operation where

1. any of the requirements to be proven in accordance with section 17 subsection (2) is not satisfied, or is no longer satisfied; after the expiry of the deadline in accordance with subsection (1) above, this shall only apply where rectification is not effected within a reasonable period of time,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, that person'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, or the radiation protection supervisor,

3. the practice in question is an unjustified type of practice in accordance with a statutory ordinance under section 6 subsection (3) or where, in consideration of a report published in accordance with section 7 subsection (2), there are serious doubts as to the justification of the type of practice,
4. the provisions of this Act or of the statutory ordinances issued on the basis of this Act, or any orders and instructions from the supervisory authorities based thereon, are seriously or repeatedly violated and rectification is not effected within a reasonable period of time, or
5. so required due to a serious danger to employees, third parties or the general public.

Section 19

Operation of X-ray equipment requiring a licence and notification

(1) Anyone who intends

1. to operate X-ray equipment
 - a) the X-ray tube assembly of which is type-approved in accordance with section 45 subsection (1) no. 2,
 - b) the manufacture and first entry into service of which falls within the scope of the Medical Devices Act (*Medizinproduktegesetz*), or
 - c) that first entered into service in accordance with the provisions of the Medical Devices Act and is not used in connection with medical exposure,
2. to operate a basic-, high- or full-protection device or school X-ray equipment,

shall notify the competent authority in writing accordingly by no later than four weeks prior to the planned commencement, unless such operation requires a licence in accordance with subsection (2) below. Once this period has expired, the notifying party may operate the X-ray equipment unless the competent authority has suspended the procedure in accordance with section 20 subsection (2) or has prohibited operation.

(2) By way of derogation from subsection (1), first sentence, no. 1, above, a licence in accordance with section 12 subsection (1) no. 4 shall be required by anyone

1. who operates X-ray equipment in technical radiography for macrostructural analysis in material testing,
2. who operates X-ray equipment for the treatment of people,
3. who operates X-ray equipment for teleradiology,
4. who operates X-ray equipment in connection with screening,
5. who operates X-ray equipment other than in an X-ray room, except where, in a specific case, the condition or size of the person or animal to be examined makes it absolutely necessary for the X-ray equipment to be operated other than in the X-ray room,
6. who intends to operate X-ray equipment in an X-ray room which is listed in a test report

by an officially-appointed authorised expert or in a licence for other X-ray equipment, or

7. who operates X-ray equipment in a mobile X-ray room.

(3) The following documents shall be enclosed with the notification in accordance with subsection (1), first sentence, no. 1 above

1. a copy of the certificate from an officially-appointed authorised expert in accordance with section 172, including the test report, in which
 - a) the X-ray equipment and its intended operation are described,
 - b) it is established that the X-ray tube assembly is type-approved or the X-ray equipment first entered into service in accordance with the provisions of the Medical Devices Act,
 - c) it is established that such equipment is available and such measures have been implemented for the planned operation as are necessary in accordance with the technical state-of-the-art in order to ensure that regulations governing protection are complied with,
 - d) it is established, in the case of X-ray equipment for the use of X-radiation on people, that the conditions in accordance with section 14 subsection (1) no. 5(a) are satisfied and that the acceptance test required under a statutory ordinance in accordance with section 86, second sentence, no. 13 has been carried out,
 - e) it is established, in the case of X-ray equipment used for examination, the operation of which outside an X-ray room is absolutely necessary in a specific case in accordance with subsection (2) no. 5 above, that special precautions have been taken to protect third parties from X-radiation,
2. in the case of X-ray equipment in accordance with subsection (1), first sentence, no. 1(a), a copy of the approval certificate in accordance with section 47 for the type of X-ray tube assembly,
3. in the case of X-ray equipment in accordance with subsection (1), first sentence, no. 1(b) or (c), a copy of the EC declaration of conformity in accordance with section 11 subsection (3), in conjunction with Annex II, IV, V or VI of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169 of 12 July 1993, p. 1), most recently amended by Directive 2007/47/EC (OJ L 247 of 21 September 2007, p. 21),
4. proof that the number of radiation protection supervisors necessary for the safe operation of the X-ray equipment has been appointed and that they have been granted the powers necessary to perform their tasks,
5. proof that every radiation protection supervisor possesses the requisite specialist knowledge or, where a radiation protection supervisor is not necessary, that the person required to effect a notification, 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 possesses the requisite specialist knowledge in radiation protection,
6. proof that the other persons involved in the operation of the X-ray equipment possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be applied,

7. proof, in the case of X-ray equipment for use on people, that the conditions referred to in section 14 subsection (1) no. 1, no. 2(b) or (c), no. 3(b) and no. 4 are satisfied, and
8. proof, in the case of X-ray equipment for use on animals in veterinary medicine, that the conditions referred to in section 15 are satisfied.

Where the authorised expert refuses to issue the certificate in accordance with the first sentence, no. 1, the competent authority shall decide, on request, whether the requirements to be proven under the first sentence, no. 1, are satisfied. It may impose additional conditions on operation in such cases.

(4) The following documents shall be enclosed with the notification in accordance with subsection (1), first sentence, no. 2 above

1. the copy of the approval certificate in accordance with section 47 for the type of X-ray equipment in question, and
2. in the case of a basic- or high-protection device or of school X-ray equipment, the documentary proof in accordance with subsection (3), first sentence, nos. 4-6.

(5) Subsections (1) to (4) shall apply *mutatis mutandis* in the event of a significant change to the operation of X-ray equipment notified in accordance with subsection (1) above.

Section 20

Verification of the notified operation of X-ray equipment

(1) The competent authority shall verify the documents within four weeks of receiving the notification. Should the authority inform the notifying party in writing prior to the expiry of this deadline that all the proof in accordance with section 19 subsection (3) or (4) has been provided, the notifying party may operate the X-ray equipment as soon as it receives the communication.

(2) Where the competent authority instigates a procedure to verify the justification in accordance with section 7 within the deadline set out in subsection (1) above in the case of a notification in accordance with section 19 subsection (1), first sentence, no. 1, it shall suspend the procedure to verify the notification for the duration of the procedure to verify the justification.

(3) The competent authority may prohibit the operation of X-ray equipment in accordance with section 19 subsection (1), first sentence, no. 1 or a change to its operation in accordance with section 19 subsection (5) where

1. one of the requirements to be proven in accordance with section 19 subsection (3) is not satisfied or is no longer satisfied; after the expiry of the deadline in accordance with subsection (1) above, this shall only apply where rectification is not effected within a reasonable period of time,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, of the latter's legal representative or, in the case of legal persons or associations of persons without legal capacity, of the party entitled by law, articles or memorandum of association to effect representation or to manage the business, or of the radiation protection supervisor,

3. there are facts giving rise to reservations regarding whether the necessary personnel are available for the safe execution of the practice,
4. the practice in question is an unjustified type of practice in accordance with a statutory ordinance in accordance with section 6 subsection (3) or where, in consideration of a report published in accordance with section 7 subsection (2), there are serious doubts regarding the justification of the type of practice,
5. the provisions of this Act or of the statutory ordinances issued on the basis of this Act or the orders and instructions from the supervisory authorities based thereon are seriously or repeatedly violated and rectification is not effected within a reasonable period of time,
6. so required due to a serious danger to employees, third parties or the general public, or
7. the proposed practice is precluded by other provisions of public law.

(4) The competent authority may prohibit the operation of a basic- or high-protection device or school X-ray equipment in accordance with section 19 subsection (1) no. 2, or an alteration to operation in accordance with section 19 subsection (5), where one of the requirements to be proven in accordance with section 19 subsection (4) is not satisfied or is no longer satisfied. After the expiry of the deadline in accordance with subsection (1) above, this shall only apply where rectification is not effected within a reasonable period of time. Subsection (3) nos. 2, 4 and 7 shall apply *mutatis mutandis* in all other respects.

(5) The competent authority may prohibit the operation of a full-protection device in accordance with section 19 subsection (1), first sentence, no. 2 where there are facts giving rise to reservations regarding the reliability of the radiation protection executive, or where the approval certificate required under section 19 subsection (4) no. 1 is not enclosed with the notification.

Section 21

Termination of the licensed or notified operation or handling

Anyone who terminates the licensed or notified operation of an installation for the generation of ionising radiation, X-ray equipment or stray radiation emitter or the licensed handling of radioactive substances shall notify the competent authority thereof without undue delay.

Section 22

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

(1) Anyone who

1. verifies, tests, maintains or repairs X-ray equipment or stray radiation emitters on a commercial basis, or
2. verifies or tests X-ray equipment or stray radiation emitters in connection with their manufacture,

shall notify the competent authority thereof in writing prior to commencing the practice.

(2) The following documents shall be enclosed with the notification

1. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not necessary, that the person required to notify, 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 possesses the requisite specialist knowledge in radiation protection,
2. proof that the other persons involved in the verification, maintenance, testing or repair of the X-ray equipment possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented,
3. proof that such equipment is available and such measures have been implemented for the verification, maintenance, testing or repair of the X-ray equipment as are necessary in accordance with the technical state-of-the-art to ensure that regulations governing protection are complied with, and
4. proof that the number of radiation protection supervisors necessary for safe verification, testing, maintenance or repair has been appointed and that they have been granted the powers necessary to perform their tasks.

(3) The competent authority may prohibit practices in accordance with subsection (1), where

1. there are facts giving rise to reservations regarding the reliability of the person required to notify, 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, or the radiation protection supervisor,
2. one of the requirement to be proven in accordance with subsection (2) above is not satisfied or is no longer satisfied, or
3. there are facts giving rise to reservations regarding whether the necessary personnel are available for the safe execution of the practice.

Section 23

Relationship with the Medical Devices Act

The requirements concerning the characteristics of irradiation devices, radioactive substances, installations for the generation of ionising radiation and X-ray equipment that constitute medical devices or accessories within the meaning of the Medical Devices Act are orientated towards the applicable requirements of the Medical Devices Act. Requirements under the Medical Devices Act concerning the characteristics of devices and facilities for recording, storing, evaluating, reproducing and transferring X-ray images and digital examination and treatment data shall remain unaffected thereby.

Section 24

Empowerments to issue ordinances

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. that exceptions from the licensing or notification requirement for a practice may be granted insofar as, as a result of the quantity or nature of the radioactive substances, properties of the devices or specific protective measures, no harm will be caused by the effects of ionising radiation,
2. under what conditions the necessary financial provision to satisfy statutory liabilities for damages need not be made for the licence in accordance with section 12 subsection (1) no. 3,
3. under what conditions the manufacturer or importer may entrust a stray radiation emitter to another party,
4. what X-ray equipment may be operated in schools, what radioactive substances may be handled in schools, what type-approved devices containing radioactive substances may be used in schools, and what special requirements apply to practices in schools,
5. that, by what means and to what extent the proprietor of a nuclear installation, an installation within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act, or of an installation for the generation of ionising radiation in which radioactive substances are handled, or are intended to be handled, is obliged to inform the supervisory authority whether, and if so what, deviations have occurred from the details given in the licence application, including supporting documentation, or from the licence,
6. that, in cases in which the handling of radioactive substances or the operation of an installation for the generation of ionising radiation, X-ray equipment or a stray radiation emitter falls under the responsibility of several radiation protection executives, the competent authorities must be informed thereof, of who is required to do this and of what documents are to be presented in this regard,
7. that radioactive substances may not
 - a) be used or placed on the market in a specific manner or for specific purposes, or
 - b) be transported across borders,

insofar as such prohibition is required in order to protect the life and health of the public against the dangers emanating from radioactive substances, or to implement decisions taken by international organisations of which the Federal Republic of Germany is a member,

8. that, and in what manner, the protection of radioactive substances, of installations for the generation of ionising radiation, of X-ray equipment and of stray radiation emitters against disruptive action and other interference by third parties must be guaranteed,
9. under what conditions a licence in accordance with section 12 subsection (1) no. 3 may be granted
 - a) for an interim storage facility for radioactive waste that deviates from the obligation to surrender radioactive waste to the *Länder*-level collection centres and to the installations of the Federation in accordance with section 9a subsection (3) of the Atomic Energy Act in view of the level of the associated danger, or
 - b) by granting other exceptions from the obligation to surrender,
10. what levels apply as the exemption levels for the activity and specific activity of radioactive substances,
11. from what level of activity a sealed radioactive substance is to be regarded as a high-activity radioactive source.

The statutory ordinance may also stipulate with regard to which provisions of the statutory ordinance the radiation protection executive is to ensure compliance.

Division 3

Employment in external installations or facilities or in connection with the operation of external X-ray equipment or stray radiation emitters

Section 25

Employment requiring a licence at external installations or facilities

(1) Anyone who employs people under his or her supervision in third-party nuclear installations, installations within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act, installations for the generation of ionising radiation or facilities, or undertakes such tasks himself or herself, shall require a licence where such practice may give rise to an effective dose for himself or herself or the employees exceeding 1 mSv per calendar year. A licence in accordance with the first sentence may be dispensed with in connection with third-party facilities in which X-ray equipment or stray radiation emitters are operated where notification is effected in accordance with section 26 subsection (1).

(2) The documents required for verification, in particular the documents listed in Annex 2, Part E, shall be enclosed with the licence application.

(3) The competent authority shall grant the licence where

1. the conditions in accordance with section 13 subsection (1) nos. 1 to 4 and 6(a) are sat-

isfied, and

2. it is guaranteed that persons employed in the installations and facilities must comply with the orders that the radiation protection executives and radiation protection supervisor of said installations or facilities may issue in order to meet their obligations in accordance with this Act and with the statutory ordinances issued on the basis this Act.

The licence shall be valid for no more than five years.

Section 26

Notifiable employment in connection with the operation of third-party X-ray equipment or stray radiation emitters

(1) Anyone who employs people under his or her supervision in connection with the operation of third-party X-ray equipment or of an external stray radiation emitter, or who undertakes such tasks himself or herself, must notify the competent authority accordingly in writing prior to the commencement of the practice where said practice may give rise to an effective dose for those employees or for himself or herself exceeding 1 mSv per calendar year. Holders of a licence in accordance with section 25 for the practice in accordance with the first sentence shall be exempt from this obligation to notify.

(2) The following documents shall be enclosed with the notification

1. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not necessary, that the person required to notify, that person'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 possesses the requisite specialist knowledge in radiation protection,
2. proof that the other persons involved in the operation of the X-ray equipment possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented, and
3. proof that those employed in connection with the operation of the third-party X-ray equipment or the third-party stray radiation emitter must comply with the orders that the local radiation protection executives and radiation protection supervisors may issue in order to meet their obligations under this Act and any statutory ordinances issued on the basis of this Act.

(3) The competent authority may prohibit practices in accordance with the first sentence of subsection (1), where

1. one of the requirements in accordance with subsection (2) above is not satisfied or is no longer satisfied,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, 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, or the radiation protection supervisor.

Division 4

Carriage of radioactive substances; cross-border transportation

Section 27

Carriage requiring a licence

(1) Anyone who transports other radioactive substances via public traffic routes, or traffic routes that are accessible to the public, shall require a licence. Such licence may be granted to the consignor or the carrier within the meaning of the regulations concerning the transport of dangerous goods, to the deliverer or to the person who undertakes the consignment or carriage. The licence shall be granted for each individual transport operation; it may however be granted on a general basis to an applicant for a maximum of three years for several shipments. Licences shall also cover stretches of a transport operation that do not take place via public traffic routes or traffic routes accessible to the public insofar as no licence for handling radioactive substances has been issued for these parts of the route.

(2) A licence in accordance with subsection (1) above shall not be required insofar as a licence in accordance with section 4 subsection (1) of the Atomic Energy Act has been obtained and covers the transportation of radioactive substances requiring a licence in accordance with section 10a subsection (3) of the Atomic Energy Act.

(3) An authenticated or officially-certified copy of the licence shall be enclosed with each shipment. On request, the authenticated or other copy of the licence certificate shall be presented to the authority competent for supervision or to any party acting on its behalf.

(4) The stipulations contained in the licence certificate shall be observed during transport, including by any carrier that is not itself the holder of the licence.

(5) The statutory provisions governing the carriage of dangerous goods and applying to the respective modes of transport concerned shall remain unaffected thereby.

Section 28

Carriage not requiring a licence

(1) No licence in accordance with section 4 subsection (1) of the Atomic Energy Act or with section 27 subsection (1) of that Act shall be required for anyone who transports

1. substances the handling of which is not subject to a licence in accordance with a statutory ordinance issued in accordance with section 24, first sentence, no. 1,
2. substances that have been exempted from the application of the provisions governing the carriage of dangerous goods applying to radioactive substances,
3. other radioactive substances
 - a) under the conditions for exempted packages in accordance with the provisions governing the carriage of dangerous goods,
 - b) in accordance with the provisions contained in the German Ordinance on the Transport of Dangerous Goods by Sea (*Gefahrgutverordnung See*), or

- c) using aircraft and the permit required in accordance with section 27 of the Civil Aviation Act (*Luftverkehrsgesetz*).

The first sentence shall not apply to the transport of large sources within the meaning of section 186 subsection (1), second sentence. The first sentence no. 3(a) shall not apply to the transport of high-activity radioactive sources.

(2) Anyone who transports radioactive products or waste that constitute nuclear materials within the meaning of Annex 1 subsection (1) no. 5 of the Atomic Energy Act without requiring a licence therefor in accordance with section 27 subsection (1), first sentence, may accept said nuclear materials for transport or forwarding only where, at the same time, written confirmation is provided to him or her from the competent authority to the effect that the financial provision made by the party passing on nuclear materials to him or her also covers the satisfaction of statutory liabilities for damages in connection with the transport or forwarding. Such written confirmation need not be presented where he or she is responsible himself or herself for furnishing proof of the necessary financial provision to satisfy statutory liabilities for damages in accordance with section 4b subsection (1) of the Atomic Energy Act.

Section 29

Conditions for granting a licence

(1) The competent authority shall grant a licence in accordance with section 27 subsection (1) where

1. there are no facts giving rise to reservations regarding the reliability of the transferor, the consignor, the carrier and the persons carrying out the dispatch and transportation, their legal representatives or, in the case of legal persons or associations of persons without legal capacity, the parties entitled by law, articles or memorandum of association to effect representation or to manage the business, and, where a radiation protection supervisor is not necessary, one of said natural persons possesses the requisite specialist knowledge in radiation protection,
2. there are no facts giving rise to reservations regarding the reliability of the radiation protection supervisors, and the latter possesses the requisite specialist knowledge in radiation protection,
3. the number of radiation protection supervisors necessary for the safe execution of the transportation has been appointed and they have been granted the powers necessary to perform their tasks,
4. it is guaranteed that the transportation is performed by persons who possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented for the intended method of transportation,
5. it is guaranteed that the radioactive substances are transported in observance of the statutory provisions governing the carriage of dangerous goods applicable to the respective mode of transport or, insofar as no such provisions exist, the necessary financial provision to cover damages caused by the carriage of the radioactive substances is in place by other means in accordance with the scientific and technical state-of-the-art,

6. the necessary financial provision has been made to satisfy statutory liabilities for damages during the transport
 - a) of other radioactive substances in accordance with section 3 subsection (1), the activity of which per package exceeds 10^9 times the exemption levels for activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, or 10^{15} becquerels (Bq), or
 - b) of nuclear fuels in accordance with section 3 subsection (3), the activity of which per package exceeds 10^5 times the exemption levels for activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, or 10^{15} Bq,
7. the requisite protection against disruptive action or other interference by third parties is guaranteed,
8. it is ensured that, in the carriage of other radioactive substances the activity of which exceeds 10^{10} times the exemption levels for activity laid down in a statutory ordinance issued in accordance with section 24, first sentence, no. 10, in accordance with a statutory ordinance issued in accordance with section 82 subsection (1) no. 1, the requisite personnel and the requisite tools are at hand to contain and eliminate dangers that could arise in connection with transport due to hazardous incidents or emergencies,
9. the selection of the nature, the time and the method of transport do not run counter to the protection of the public against the harmful effects of ionising radiation.

(2) The documents required for verification shall be enclosed with the licence application.

(3) Insofar as liability may be incurred under the Paris Convention in conjunction with section 25 of the Atomic Energy Act, the provision contained in Annex 2 of the Atomic Energy Act shall apply to nuclear materials in place of the provision contained in subsection (1) no. 6.

Section 30

Empowerment to issue ordinances for the cross-border transportation of radioactive substances

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing that the cross-border transportation of radioactive substances requires a licence, notification or registration. In particular, the statutory ordinance may stipulate

1. the conditions for granting a licence,
2. the nature, content and scope of the documents to be submitted or proof to be furnished,
3. the nature and method of the submission of said documents and proof, and
4. the requirements pertaining to the person who first acquires the imported radioactive substances.

The statutory ordinance may also regulate under what conditions cross-border transportation

is exempt from such licence.

Division 5
Medical research

Section 31

Use requiring a licence of radioactive substances or ionising radiation on people for the purpose of medical research

(1) Anyone who uses radioactive substances or ionising radiation on people for the purpose of medical research shall require a licence insofar as the use of radioactive substances or ionising radiation on people for the purpose of medical research is not notifiable in accordance with section 32 subsection (1). Furthermore, anyone who significantly deviates from a use licensed in accordance with this provision shall require a licence.

(2) The documents required for verification shall be enclosed with the licence application.

(3) The competent authority is to check the documents necessary for verification for completeness within 21 calendar days of receiving the licence application. Should the documentation be incomplete, the competent authority is to call on the applicant to rectify the deficiencies which it has specified within 21 calendar days of receiving the request to do so. The competent authority shall decide on the licence application within 90 calendar days of receiving the complete application documentation. The competent authority may extend the period by 90 calendar days if the level of difficulty of the verification so requires. The extension of the period shall be justified and notified in good time. The licence shall be deemed to have been granted if the competent authority has not taken a decision on the licence application within the extended period.

(4) The competent authority may only grant a licence where

1. the radiation-related risks ensuing from the use to the person involved in the research project are medically justified, as measured by the anticipated significance of the results for the advancement of medical examination methods, treatment procedures or medical science, taking into consideration any medical benefit accruing to the person in question,
2. the radioactive substances or methods of using ionising radiation envisaged for the medical research are suited to the purpose of the research project, and cannot be substituted by other kinds of examination or treatment not involving any radiation exposure, or involving a lower radiation exposure, of the person in question,
3. the exposure occurring during the use and the activity of the radioactive substances to be used cannot, in accordance with the scientific and technical state-of-the-art, be further reduced without jeopardising the fulfilment of the purpose of the research project,
4. the number of persons involved in the research project is kept to the minimum required to fulfil the purpose of the research project,
5. a favourable opinion on the research project has been given by an ethics committee in accordance with section 36,
6. the uses will be directed by a medical doctor who possesses the requisite specialist knowledge in radiation protection and at least two years' experience in the use of radioactive substances or ionising radiation on people,

7. the necessary financial provision has been made to satisfy statutory liabilities for damages, and
8. a licence in accordance with section 12 subsection (1) nos. 1 to 4 for use on people has been granted or the operation of X-ray equipment notified for use on people in accordance with section 19 subsection (1) is permissible.

(5) The financial provision to satisfy statutory liabilities for damages within the meaning of subsection (4) no. 7 above shall be in place for the period from the commencement of the use until ten years have passed after the end of the research project. Subsection (4) no. 7 shall not apply insofar as the stipulations of the German Nuclear Financial Security Ordinance (*Atomrechtliche Deckungsvorsorge-Verordnung*) have been satisfied on the merits and in terms of their amount by the financial provision that has been made to satisfy statutory liabilities for damages in accordance with the relevant provisions of the Medicinal Products Act or of the Medical Devices Act.

(6) Where the application envisages the use of radioactive substances or ionising radiation in several facilities (a multi-centre study), the competent authority shall issue an overall licence for all the facilities for which the conditions under subsection (4) nos. 6 and 8 are satisfied.

(7) The competent authority shall send a copy of the licence certificate to the supervisory authority responsible for the research project.

Section 32

Notifiable use of radioactive substances or ionising radiation on people for the purpose of medical research

(1) Anyone who intends to use radioactive substances or ionising radiation on people for the purpose of medical research must inform the competent authority thereof in writing or electronically where

1. the object of the research project is to test the safety or efficacy of a procedure to treat sick adult human beings, and
2. the use of radioactive substances or ionising radiation is not itself the object of the research project.

Furthermore, anyone who intends to deviate significantly from a use notified in accordance with this provision shall be required to notify.

(2) It shall be clearly demonstrated as part of the notification that

1. the nature of the use corresponds to recognised standard processes for the examination of people,
2. the purpose of the research project justifies the nature and frequency of the use,
3. it is ensured that only adults with a disease the treatment of which is to be tested in the course of the research project are involved in the research project, and
4. a licence in accordance with section 12 subsection (1) nos. 1 to 4 for use on people has been granted or the operation of X-ray equipment notified for use on people in accord-

ance with section 19 subsection (1) is permissible.

(3) Proof must be enclosed with the notification that the necessary financial provision has been made to satisfy all statutory liabilities for damages in accordance with section 35. Federal and *Land* facilities are not obliged to furnish such proof insofar as the principle of self-insurance is applied to the body in question.

(4) Where the research project is intended to be a multi-centre study, the use of radioactive substances or ionising radiation on people for the purposes of medical research may be notified jointly for all the facilities involved. In such cases, the notifying party must demonstrate that the conditions under subsection (2) no. 4 have been satisfied in respect of each participating facility.

Section 33

Verification of the notification by the competent authority

(1) If the notification in accordance with section 32 is complete, the competent authority shall confirm this to the notifying party within 14 calendar days of receiving the notification, stating the date of receipt of the notification. Should the notification be incomplete, the competent authority shall invite the notifying party once, within 14 calendar days of receiving the notification, to rectify the deficiencies identified within 10 calendar days of receiving the request to do so. Within 12 calendar days of receiving the missing details or documents, the competent authority in accordance with the second sentence shall conclude the completeness check and inform the notifying party of the result of said check and of the date of receipt of the missing details or documents.

(2) The competent authority shall complete the verification of the content of the notification within 28 calendar days of the confirmation in accordance with subsection (1), first sentence, above or of the informing of the notifying party in accordance with subsection (1), third sentence. Should the competent authority have objections to the notified use, it shall inform the notifying party once, within the period referred to in the first sentence, of its objections and of the reasoning underlying them, and shall invite the latter to make the necessary changes to its notification within 21 calendar days of receiving this request. Where the second sentence applies, the competent authority shall complete the verification of the content of the notification within 21 calendar days of receiving the changed or missing notification documents.

(3) The notified use of radioactive substances or ionising radiation on people for the purposes of medical research may commence where

1. the allotted period for verifying the content of the notification in accordance with subsection (2) has elapsed or the competent authority has informed the notifying party that it will be waiving the remainder of said period,
2. the competent authority has confirmed the receipt of a favourable opinion on the research project from an ethics committee in accordance with section 36 subsections (1) to (3), and
3. the use in question has not been prohibited under section 34 subsection (1).

The competent authority must confirm to the notifying party the receipt of a favourable opinion on the research project from an ethics committee in accordance with section 36 without undue delay.

(4) Once use has commenced in accordance with subsection (3), the authority competent for the notification shall inform the competent supervisory authority of the main content of the notification without undue delay.

Section 34

Prohibition of notifiable use of radioactive substances or of ionising radiation on people for the purpose of medical research

(1) The competent authority may prohibit the notified use within the period allotted for verifying the content of the notification in accordance with section 33 subsection (2), first sentence, also in conjunction with the second and third sentences, where one of the conditions referred to in section 32 subsections (2) to (4) is not satisfied.

(2) The competent authority may prohibit the notified use after the expiry of the allotted period for verifying the content of the notification where

1. one of the requirements referred to in section 32 subsections (2) to (4) is not satisfied, or is no longer satisfied, and rectification is not effected within a reasonable period of time,
2. after the expiry of a reasonable deadline of which the notifying party has been informed, no favourable opinion on the research project from an ethics committee in accordance with section 36 subsection (1), first sentence, has been submitted to the competent authority, or
3. the provisions of this Act or of the statutory ordinances issued on the basis of this Act, or of the orders and instructions from the supervisory authorities based hereon, are seriously or repeatedly violated and rectification is not effected within a reasonable period of time.

Section 35

Financial security for notifiable use of radioactive substances or ionising radiation on people for the purpose of medical research

(1) Proof of the required financial security shall be furnished in the notification procedure by submitting a confirmation of insurance cover that grants benefits in the event that a person is killed or the body or health of a person is injured or impaired during the use of radioactive substances or ionising radiation on people for the purpose of medical research, even where no other party is liable for the damages. The insurance cover must be taken out on behalf of the persons on whom the radioactive substances or ionising radiation are used, with an insurer licensed to operate in a Member State of the European Union or in a Signatory State to the Agreement on the European Economic Area.

(2) The level of the insurance cover must be proportionate to the risks associated with the uses in question. It must also be set up, based on the risk assessment, in such a way that at least EUR 500,000 is available in the event of the death or permanent incapacity for work of any person on whom the radioactive substances or ionising radiation are used.

(3) By way of derogation from subsection (1) above, proof of the requisite financial security may be furnished by proving the existence of insurance cover with the beneficiary being the persons affected by the clinical trial in accordance with the Medicinal Products Act or the Medical Devices Act.

Section 36

Ethics committee

(1) An ethics committee operating within the scope of this Act must be an independent, interdisciplinary body formed in accordance with *Land* law and registered with the competent authority. The ethics committee must be composed of both medical experts and non-medical members who possess the necessary expertise. Registration shall only take place where the members, the procedure and the address of the ethics committee are listed in published rules of procedure. Changes to the composition of the committee, to the procedures or to the other provisions contained in the code of procedure shall be communicated to the authority competent for registration without undue delay.

(2) The ethics committee shall be tasked with offering verbal advice to the research project, involving at least five members, at the request of the applicant or of the notifying party, on ethical and legal matters, and with issuing a written opinion thereon within 60 calendar days of receiving the necessary documents. Only one ethics committee need issue an opinion for multi-centre studies. Where the research project is assessed by an ethics committee under both the law on medicinal products or on medical devices and under this Act, the opinion is to contain the evaluation in accordance with both the law on medicinal products or on medical devices, and with this Act.

(3) The ethics committee shall assess and evaluate whether the research project is ethically defensible. It shall provide an opinion as to whether

1. the research project is suitable to deliver a gain in scientific knowledge, given the current scientific state-of-the-art,
2. the research project, including the number of persons involved in the research project, is suited to answering the scientific questions posed,
3. the risk to the individual is defensible in consideration of the potential benefit to society,
4. inclusion is defensible insofar as the research project is intended to involve a particularly vulnerable group, and
5. the written information regarding the research project received by those involved in the research project, their legal or authorised representative sufficiently explains the benefits and risks, thus facilitating informed consent.

(4) Appeals against opinions from the ethics committee may only be asserted at the same time as the admissible appeals against a decision on substance.

Section 37

Empowerment to issue ordinances

(1) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what special requirements are to be satisfied in the use of radioactive substances or ionising radiation for the purpose of medical research in order to ensure the proper execution of a research project and the protection of the persons involved in the research project. In particular, the statutory ordinance may contain regulations concerning

1. obligations to inform and consent requirements,

2. prohibitions and restrictions on use on individual groups of people,
3. medical or dental examinations of the persons involved in the research project prior to the commencement of the use,
4. the empowerment of the competent authority, in the event of exceeding licensed or notified dose levels for the use, to order medical or dental examinations of the persons involved in the research project,
5. limits and measures to ensure compliance with the limits,
6. measures to limit and monitor the exposure of the persons involved in the research project,
7. obligations to make and retain records,
8. obligations to inform and report.

The statutory ordinance may also stipulate the provisions of the statutory ordinance with which the radiation protection executive is to ensure compliance.

(2) The fundamental right to physical integrity (Article 2 para. 2, first sentence, of the German Basic Law [*Grundgesetz*]) shall be restricted in accordance with subsection (1) nos. 3 and 4.

Division 6

Protection of consumers in the case of the addition of radioactive substances and activation; type-approved devices

Sub-division 1

Justification

Section 38

Justification of types of practice involving consumer products or type-approved devices; empowerment to issue ordinances

(1) The Federal Office for Radiation Protection shall verify the justification of the type of practice within the meaning of section 6 subsection (1) within 12 months of receiving an application passed on by the competent authority in accordance with section 41 subsection (5), section 43 subsection (2) or section 46 subsection (3), and shall publish an opinion. The opinion shall include an appraisal of the justification of the type of practice. Trade and business secrets and personal data shall be rendered unrecognisable in said opinion.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, laying down

1. what documents the applicant must submit to the Federal Office for Radiation Protection,
2. stipulations for the verification procedure in accordance with subsection (1), including the involvement of the authorities,
3. to what assessment criteria the Federal Office for Radiation Protection must pay particular attention in the procedure in accordance with subsection (1),
4. that the competent authorities must pass on to the Federal Office for Radiation Protection information about licences granted for consumer products under section 40 or section 42 and type approvals in accordance with section 45 subsection (1) no. 1 or 3 to 6, and by what means the Federal Office for Radiation Protection is to publish a list detailing the types of practice for which such licences or type approvals have already been granted,
5. rules governing by what means the Federal Office for Radiation Protection is to publish its opinion on the justification of the type of practice, and
6. by what means the Federal Office for Radiation Protection is to pass on said opinion to the competent authorities of other Member States of the European Atomic Energy Community and to third countries.

Sub-division 2

Protection of consumers in the case of the addition of radioactive substances and activation

Section 39

Impermissible addition of radioactive substances and impermissible activation

(1) The addition of radioactive substances in the manufacture of the following products shall be impermissible

1. toys within the meaning of section 2 subsection (6) no. 5 of the Food and Feed Code,
2. jewellery,
3. foodstuffs, including drinking water and food additives, within the meaning of the Food and Feed Code,
4. feed within the meaning of the Food and Feed Code,
5. products within the meaning of section 2 subsection (1) of the Tobacco Products Act (*Tabakerzeugnisgesetz*),
6. tattooing products, including comparable substances and mixtures of substances that are designed to be applied on or under human skin in order to affect the appearance and to remain there, including temporarily,
7. cosmetic products,
8. incandescent gas mantles, unless these are intended to be used to illuminate public streets,
9. lightning protection systems, and
10. food contact materials and articles within the meaning of section 2 subsection (6) no. 1 of the Food and Feed Code.

The cross-border transportation in accordance with section 42 subsection (1) of products in accordance with the first sentence to which radioactive substances have been added and the placing on the market of such products shall also be impermissible. The first and second sentences shall not apply to the addition of radionuclides for which no exemption levels have been laid down.

(2) Subsection (1), first and second sentences, shall apply *mutatis mutandis* to the activation of products of the relevant nature where this gives rise to a specific activity in the product exceeding 500 µBq/g or where, in the case of jewellery, the exemption levels laid down for the specific activity in a statutory ordinance in accordance with section 24, first sentence, no. 10 are exceeded.

(3) The statutory provisions governing the products referred to in subsection (1), first sentence, nos. 1 to 10 shall remain unaffected in all other respects.

Section 40

Addition of radioactive substances requiring a licence and activation requiring a licence

(1) Anyone who adds radioactive substances in the manufacture of consumer products, medicinal products within the meaning of section 2 of the Medicinal Products Act, of pesticides, of plant protection products within the meaning of section 2 of the Plant Protection Act or of substances in accordance with section 2, first sentence, nos. 1-8, of the Fertiliser Act purchased within the scope of this Act, or intended to be delivered to others, shall require a licence. The first sentence shall apply *mutatis mutandis* to the activation of the products referred to therein. Section 39 shall remain unaffected thereby.

(2) The licence in accordance with subsection (1) shall not be deemed to replace a licence in accordance with section 12 subsection (1) no. 1 or 3.

(3) No licence in accordance with subsection (1) shall be required for the addition of

1. noble gases extracted from the air, where the isotopic ratio in the additive corresponds to that of the air, or
2. radionuclides for which no exemption levels have been laid down in accordance with the statutory ordinance in accordance with section 24, first sentence, no. 10.

(4) The documents required for verification, in particular the documents referred to in Annex 2, Part B, and, in the case of the manufacture of consumer products, the documents referred to in Annex 2, Part F, shall be enclosed with the licence application.

Section 41

Conditions for granting a licence for the addition of radioactive substances or activation

(1) The competent authority shall grant a licence in accordance with section 40 for the manufacture of consumer products where

1. the activity of the added radioactive substances is as low as permitted by the technical state-of-the-art,
2. it is demonstrated that
 - a) the exemption levels for activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10 are not exceeded in the consumer product, or
 - b) only an effective dose in the range of 10 μSv in a given calendar year can occur for members of the public,
3. it is laid down in a take-back plan that the consumer product may be returned free of charge after use to the applicant or to a body specified by the latter where
 - a) the specific activity of the artificial radioactive substances added to the consumer product exceeds the exemption levels for specific activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, or
 - b) the specific activity of the natural radioactive substances added to the consumer

product exceeds 0.5 Bq/g,

4. the material containing the radioactive substances is covered so as to prevent contact, or the radioactive substance is solidly incorporated into the consumer product and the ambient dose rate at a distance of 0.1 m from the accessible surface of the consumer product does not exceed 1 mSv per hour of use under normal conditions,
5. it is guaranteed that information is enclosed with the consumer product that
 - a) explains the radioactive additive,
 - b) describes the intended use, and
 - c) points out the return obligation in accordance with section 44 and indicates the body obliged to take back the product

if the specific activity of the artificial radioactive substances added to the consumer product exceeds the exemption levels for the specific activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10 or the specific activity of the natural radioactive substances added to the consumer product exceeds 0.5 Bq/g,

6. the addition involves other radioactive substances in accordance with section 3 subsection (1),
7. in the case of addition, the conditions for a licence for handling in accordance with section 13 subsections (1) to (3) are satisfied,
8. the use of the consumer product does not involve an unjustified type of practice in accordance with a statutory ordinance in accordance with section 6 subsection (3), and
9. the Federal Office for Radiation Protection has not stated in an opinion in accordance with section 38 subsection (1) that the intended use or storage of the consumer product represents an unjustified type of practice.

(2) In the case of consumer products primarily used for occupational rather than household purposes, the competent authority may permit deviations from subsection (1) no. 2(a) and no. 4, insofar as the exemption level laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, is not exceeded by a factor of 10 in a single consumer product.

(3) The competent authority shall grant a licence in accordance with section 40 for the manufacture of medicinal products within the meaning of section 2 of the Medicinal Products Act, of pesticides, of plant protection products within the meaning of section 2 of the Plant Protection Act and of substances in accordance with section 2, first sentence, nos. 1-8 of the Fertiliser Act, where

1. the addition involves other radioactive substances in accordance with section 3 subsection (1),
2. it is demonstrated that the exemption levels for activity or specific activity laid down in a statutory ordinance in accordance with section 24, first sentence, no. 10, are not exceeded in the medicinal product within the meaning of section 2 of the Medicinal Products Act, the pesticide, the plant protection product within the meaning of section 2 of the Plant Protection Act, or the substance in accordance with section 2, first sentence, nos. 1-8 of the Fertiliser Act, and

3. in the case of addition, the conditions in accordance with section 13 subsections (1) to (3) for a handling licence are satisfied.

(4) Subsections (1) to (3) shall apply *mutatis mutandis* to the activation of the products referred to in these subsections.

(5) The competent authority shall pass on the licence application to the Federal Office for Radiation Protection insofar as the proposed use or storage of the consumer product for the manufacture of which the addition of radioactive substances or their activation an application has been made constitutes a new type of practice. The procedure in accordance with section 38 shall be applied; the competent authority shall suspend the licensing procedure until the former procedure has been completed.

Section 42

Cross-border transportation of consumer products, requiring a licence

(1) Anyone who transports consumer products to which radioactive substances have been added or that have been activated

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

shall require a licence.

(2) Subsection (1) shall not apply to

1. the transportation of goods in tourism not intended for trade or commercial use,
2. transit subject to customs supervision,
3. consumer products the manufacture of which is licensed in accordance with section 40 where it has been demonstrated in accordance with section 41 subsection (1) no. 2(b) that only an effective dose in the range of 10 μSv in a given calendar year can occur for members of the public,
4. products into which consumer products are integrated, where the manufacture of the consumer products is licensed in accordance with section 40 or their transportation is licensed in accordance with subsection (1),
5. Consumer products to which
 - a) noble gases extracted from the air are added, where the isotopic ratio in the additive corresponds to that of the air, or
 - b) radionuclides are added for which no exemption levels have been laid down in accordance with the statutory ordinance in accordance with section 24, first sentence, no. 10.

(3) The documents required for verification, in the case of transportation into the territorial scope of this Act in particular those documents referred to in Annex 2, Part F, shall be enclosed with the licence application.

Section 43

Conditions for granting a licence for the cross-border transportation of consumer products

(1) The competent authority shall grant a licence in accordance with section 42 where the conditions for a licence for the cross-border transportation of radioactive substances in accordance with the statutory ordinance in accordance with section 30 are satisfied. In the case of transportation into the territorial scope of this Act, the conditions of section 41 subsection (1) nos. 1-6, 8 and 9 must also be satisfied. Section 41 subsection (2) and section 44, first sentence, shall apply *mutatis mutandis*, in connection with which the transporting party shall take the place of the manufacturer within the meaning of section 44, first sentence.

(2) The competent authority shall pass on to the Federal Office for Radiation Protection a licence application for transportation into the territorial scope of this Act insofar as the proposed use or storage of the consumer product to which radioactive substances have been added or that has been activated, and for the cross-border transportation of which the application has been made, constitutes a new type of practice. The procedure in accordance with section 38 shall be applied; the competent authority shall suspend the licensing procedure until the former procedure has been completed.

Section 44

Return of consumer products

Anyone who requires a licence as the manufacturer of a consumer product under section 40 and must establish a take-back plan in accordance with section 41 subsection (1) no. 3 shall ensure that the consumer product in question is taken back free of charge. After finishing its use, the final consumer must return the consumer product to the body indicated in the information in accordance with section 41 subsection (1) no. 5 without undue delay.

Sub-division 3

Type approval

Section 45

Type-approved devices

(1) Type approval may be granted for the following devices at the request of the manufacturer or transporting party (type-approved devices)

1. a device type containing other radioactive substances in accordance with section 3 subsection (1), or an installation type for the generation of ionising radiation or a stray radiation emitter type, where the radiation protection and safety of the device in question mean that it may be used without a licence or notification in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2),
2. an X-ray tube assembly type where the radiation protection properties of the X-ray equipment including said X-ray tube assembly permit it to be operated without a licence in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2),

3. an X-ray equipment type as a basic-protection device where the high level of protection of the device type, including any openings in the protective housing for the introduction or removal of articles, means that the X-ray equipment may be operated without a licence in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2),
4. an X-ray equipment type as a high-protection device where the high level of protection of the device type means that the X-ray equipment may be operated without a licence in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2),
5. an X-ray equipment type as a full-protection device where the particularly high level of protection of the device type means that the X-ray equipment may be operated without a licence and without supervision by a person in possession of the requisite specialist knowledge in radiation protection in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2),
6. an X-ray equipment type as school X-ray equipment where the radiation protection of the device type means that the X-ray equipment may be operated in connection with teaching in schools in accordance with the statutory ordinance in accordance with section 49 subsections (1) and (2).

(2) Subsection (1) shall not apply to medical devices or accessories within the meaning of the Medical Devices Act. Subsection (1) no. 1 shall not apply to devices containing high-activity radioactive sources.

Section 46

Type approval procedure

(1) The documents required for verification, in particular those documents referred to in Annex 2, Part G, shall be enclosed with the application for type approval.

(2) The applicant must, on request, supply the authority competent for type approval with the design necessary for verification. In the case of a device type containing radioactive substances, the competent authority shall consult the Federal Institute for Materials Research and Testing (*Bundesanstalt für Materialforschung und -prüfung*) on issues relating to leakage, materials selection and construction of the equipment or devices, and relating to quality assurance, before taking its decision.

(3) The authority competent for type approval shall pass on the application in accordance with section 45 subsection (1) nos. 1, 3, 4, 5 or 6 to the Federal Office for Radiation Protection insofar as the intended use or the intended operation of devices, installations, X-ray equipment or stray radiation emitters for which type approval has been applied constitutes a new type of practice. The procedure in accordance with section 38 shall be applied; the authority competent for type approval shall suspend the type approval procedure until the former procedure has been completed.

(4) The competent authority may grant only a type approval where

1. the device satisfies the requirements in accordance with the statutory ordinance in accordance with section 49 nos. 1 and 2,
2. there are no facts giving rise to reservations regarding
 - a) the reliability of the manufacturer or transporting party or of the party responsible

for managing the manufacture, or

- b) the technical experience necessary for the manufacture on the part of the party responsible for managing the manufacture,
3. no overriding public interests preclude the granting of type approval,
4. the use or operation of the device to be type-approved does not involve an unjustified type of practice in accordance with the statutory ordinance in accordance with section 6 subsection (3), and
5. the Federal Office for Radiation Protection has not laid down in an opinion in accordance with section 38 subsection (1) that the intended use or operation of the device to be type-approved in accordance with section 45 subsection (1) no. 1 or 3 to 6, of the installation for the generation of ionising radiation, of the X-ray equipment or of the stray radiation emitter constitutes an unjustified type of practice.

(5) Such type approval shall be valid for no more than ten years. It may be extended by a maximum of ten further years on application.

(6) The competent authority is to decide on the application for authorisation within 12 months of receiving the complete application documentation. If the applicant has provided the competent authority, at its request, with the designs necessary for verification, the competent authority is to take a decision on the application within 12 months of receiving the complete application documentation and the design necessary for verification.

Section 47

Approval certificate

Where a device type is approved in accordance with section 45, the authority competent for the type approval shall issue an approval certificate. The approval certificate shall contain the following information

1. the essential radiation protection characteristics of the type-approved device,
2. the approved use of the type-approved device,
3. identification of the apparatus serving to provide radiation protection for the type-approved device,
4. restrictions, additional conditions and time restrictions of the type approval with regard to content,
5. the type approval marking and other information to be marked on the type-approved device,
6. a reference to the obligations incumbent on the holder of the type-approved device in accordance with the statutory ordinance in accordance with section 49 subsection (5), and
7. in the case of a device containing radioactive substances, requirements pertaining to the return of the device to the holder of the type approval or pertaining to the disposal of the device in accordance with the statutory ordinance in accordance with section 49

subsections (4) and (5).

Section 48

Use or operation of type-approved devices

A type-approved device may,

1. in the case of a type in accordance with section 45 subsection (1) no. 1, be operated without a licence or notification in accordance with the conditions laid down in the statutory ordinance in accordance with section 24, first sentence, no. 1, or
2. in the case of a type in accordance with section 45 subsection (1) nos. 2, 3, 4, 5 or 6, be operated in accordance with the conditions applicable for the notifiable operation of X-ray equipment in accordance with section 19.

Where the type-approved device has entered into circulation prior to the expiry of the deadline for type approval, it may continue to be used or operated after the expiry of said deadline. The second sentence shall not apply where the authority competent for the type approval has made it known that the device may no longer be operated given that sufficient protection against the harmful effects of radiation is not guaranteed.

Section 49

Empowerment to issue ordinances

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. the technical requirements for the type approval of devices permitting a type-approved device to be used without a licence or notification, or to be operated without a licence,
2. under what conditions the authority competent for the type approval may approve exceptions to the technical requirements in accordance with no. 1 above,
3. that, and by what means,
 - a) details of a type approval are to be made known, and
 - b) the stipulation that a type-approved device must not continue to be operated is to be made known,
4. the obligations incumbent on the holder of a type approval, including the obligation to take back a type-approved device containing radioactive substances after its use has finished, and
5. the obligations incumbent on the holder of a type-approved device, including the obligation to return the type-approved device to the holder after its use has finished or to dispose thereof.

Division 7

Practices relating to cosmic radiation

Section 50

Notifiable operation of aircraft

(1) Anyone who intends to operate an aircraft registered in the German Aircraft Register in accordance with section 3 subsection (1) of the Civil Aviation Act of 10 May 2007, as amended, must notify the competent authority thereof four weeks prior to the intended commencement of operation, where the effective dose received by the air crew as a result of cosmic radiation may exceed 1 mSv over a calendar year. The first sentence shall apply *mutatis mutandis* to the operation of aircraft registered in another country where the operator is a German national or a legal person or partnership with its registered head office in the territorial scope of this Act and deploys air crew who are in an employment relationship in accordance with German labour law.

(2) Subsection (1) shall apply *mutatis mutandis* where the operation of an aircraft not previously subject to a notification requirement is changed in such a way that the effective dose received by the air crew as a result of cosmic radiation may exceed 1 mSv over a calendar year.

(3) The following documents shall be enclosed with the notification

1. proof that the number of radiation protection supervisors necessary for the safe execution of the practice has been appointed and that they have been granted the powers necessary to perform their tasks,
2. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not necessary, that the person required to notify, 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 possesses the requisite specialist knowledge in radiation protection,
3. proof that the other people involved in the execution of the practice possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented,
4. designation of a computer program recognised by the competent authority, or proof that suitable measuring instruments are used, in either case these being used to determine the body dose, that satisfy the requirements set out in the statutory ordinance issued on the basis of section 76 subsection (1), second sentence, no. 11.

(4) The obligation to notify shall also apply to aircraft operated within the area of operations of the Federal Ministry of Defence.

Section 51

Verification of the notified operation of aircraft

(1) The competent authority shall verify the documents within four weeks of receiving

notification. Should the authority inform the notifying party in writing before the expiry of this deadline that all the proof required under section 50 subsection (3) has been received, the notifying party may commence the practice as soon as it receives the communication.

(2) The competent authority may prohibit the notified operation where

1. one of the requirements to be proven is not satisfied or is no longer satisfied; after the expiry of the deadline in accordance with subsection (1), this shall only apply where rectification is not effected within a reasonable period of time,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, their 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, or the radiation protection supervisor, or
3. the provisions of this Act or of any statutory ordinances issued on the basis of this Act, or of the orders and instructions from the supervisory authorities based thereon, are seriously or repeatedly violated and rectification is not effected within a reasonable period of time.

Section 52

Notifiable operation of spacecraft

(1) Anyone with a registered head office in the territorial scope of this Act who intends to operate spacecraft and to deploy space crew in that connection who are in an employment relationship in accordance with German labour law shall notify the competent authority thereof two months prior to the intended commencement of the practice where the effective dose received by the space crew as a result of cosmic radiation during operation of the spacecraft may exceed 1 mSv over a calendar year.

(2) The following documents shall be enclosed with the notification

1. proof that the number of radiation protection supervisors necessary for the safe execution of the practice has been appointed and that they have been granted the powers necessary to perform their tasks,
2. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where no radiation protection supervisor is necessary, that the person required to notify, their 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 possesses the requisite specialist knowledge in radiation protection,
3. proof that the other persons involved in the execution of the practice possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented, and
4. a plausible explanation of the intended procedure for determining the body dose in accordance with the requirements set out in the statutory ordinance issued on the basis of section 76 subsection (1), second sentence, no. 11.

(3) Where it is to be expected that the exposure of the space crew will exceed the dose limit in accordance with section 78 subsection (1), first sentence, a separate notification shall also be required in respect of the increased exposure level at least two months

prior to the deployment of the space crew. The limits in accordance with sections 77 and 78 for the occupational exposure of space crew as a result of cosmic radiation shall not apply in such cases.

(4) The following documents shall be enclosed with the separate notification

1. a statement that the increased exposure is justified,
2. proof that the increased exposure has been discussed with the space crew to be deployed and with the authorised doctor,
3. proof that the space crew to be deployed have been informed of the expected doses, of the risks associated with the increased exposure, and of the precautionary measures to be implemented,
4. the consent of the space crew to be deployed to the increased exposure.

Section 53

Verification of the notified operation of spacecraft

(1) The competent authority shall verify the documents within two months of receiving notification. Should the authority inform the notifying party in writing before the expiry of this deadline that all the proof required in accordance with section 52 subsection (2) or (4) has been provided, the notifying party may commence the practice as soon as it receives the communication.

(2) In the event of a notification in accordance with section 52 subsection (1), the competent authority may prohibit the deployment of crew where

1. one of the requirements to be proven in accordance with section 52 subsection (2) is not satisfied or is no longer satisfied; after the expiry of the deadline in accordance with subsection (1) above, this shall only apply where rectification is not effected within a reasonable period of time,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, their 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, or the radiation protection supervisor, or
3. the provisions of this Act or of the statutory ordinances issued on the basis of this Act or the orders and instructions from the supervisory authorities based thereon are seriously or repeatedly violated and rectification is not effected within a reasonable period of time.

(3) In the event of a separate notification in accordance with section 52 subsection (3), first sentence, the competent authority may also prohibit the deployment of space crew where one of the requirements to be proven in accordance with section 52 subsection (4) is not satisfied.

Section 54

Cessation of the notified practice

Anyone who ceases a practice notified in accordance with section 50 subsection (1) or section 52 subsection (1), or changes it in such a way that the effective dose received by the air or space crew as a result of cosmic radiation will no longer be able to exceed 1 mSv over a calendar year, must notify the competent authority thereof without undue delay.

Division 8

Practices relating to naturally-occurring radioactivity

Sub-division 1

Workplaces with exposure resulting from naturally-occurring radioactivity

Section 55

Estimation of the exposure

(1) Anyone who performs a practice in accordance with section 4 subsection (1), first sentence, no. 10 (or has such practice performed) in his or her place of operation that belongs in one of the categories of practice referred to in Annex 3 must perform an estimation of the body dose in relation to the workplace before the practice commences. That estimation shall be repeated without undue delay if the workplace is modified such that higher exposure may occur.

(2) Where there are indications that exposures corresponding to those of the categories of practice referred to in Annex 3 may occur in connection with a practice in accordance with section 4 subsection (1), first sentence, no. 10 that does not belong in one of the categories of practice referred to in Annex 3, the competent authority may order an estimation in accordance with subsection (1), first sentence, to be carried out without undue delay. Where the workplace in question is modified in such a way that higher exposure may occur, the competent authority may order the estimation to be repeated without undue delay.

Section 56

Notification

(1) Where the result of the estimation is that the body dose may exceed one of the levels for categorisation as an occupationally-exposed person, the party obliged to carry out the estimation must notify the competent authority of the practice in writing. The notification on the basis of an estimation in accordance with section 55 subsection (1), first sentence, must be made by no later than four weeks prior to the intended commencement of the practice; once this period has passed, the notifying party may commence the practice unless the competent authority has suspended the procedure in accordance with section 57 subsection (2) or prohibited the practice. Notification based on an estimation in accordance with section 55 subsection (1), second sentence, or in accordance with section 55 subsection (2), shall be effected without undue delay following the estimation.

(2) The following documents shall be enclosed with the notification

1. A test report from an officially-appointed authorised expert in the field in accordance with section 172, in which

- a) the notified practice and the planned radiation protection measures are described,
- b) the potential body dose for the occupationally-exposed persons is established, and
- c) it is proven that such equipment is available and such measures have been implemented in connection with the practice as are necessary in accordance with the

technical state-of-the-art to ensure that regulations governing protection are complied with,

2. proof that the number of radiation protection supervisors necessary for the safe execution of the practice has been appointed and that they have been granted the powers necessary to perform their tasks,
3. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not necessary, that the notifying party, 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, possesses the requisite specialist knowledge in radiation protection, and
4. proof that the other persons involved in the execution of the practice possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented.

Where the notification is made on the basis of an estimation in accordance with section 55 subsection (1), second sentence, or section 55 subsection (2), the competent authority may lay down a later deadline for the submission of all documents, or of individual documents, in an individual case.

(3) Subsections (1) and (2) shall apply *mutatis mutandis* in the event of significant changes to the notified practice.

Section 57

Verification of the notified practice

(1) The competent authority shall verify the notification within four weeks of receiving the documents. Should the authority inform the notifying party in the case of an estimation in accordance with section 55 subsection (1), first sentence, in writing before the expiry of this deadline that all the proof required has been provided, the notifying party may commence the practice as soon as it receives the communication.

(2) Where the competent authority instigates a procedure to verify justification in accordance with section 7 within the deadline set out in subsection (1), first sentence, above, it shall suspend the procedure to verify the notification for the duration of the procedure to verify justification.

(3) The competent authority may prohibit the practice where

1. one of the requirements to be proven in accordance with section 56 subsection (2), first sentence, is not satisfied or is no longer satisfied; after the expiry of the deadline in accordance with subsection (1) above; this shall only apply where rectification is not effected within a reasonable period of time,
2. there are facts giving rise to reservations regarding the reliability of the person required to notify, their 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, or the radiation protection supervisor,
3. there are facts giving rise to reservations regarding whether the necessary personnel

are available for the safe execution of the practice,

4. the practice in question is an unjustified type of practice in accordance with a statutory ordinance in accordance with section 6 subsection (3) or where, in consideration of a report published in accordance with section 7 subsection (2), there are serious doubts about the justification of the type of practice,
5. the provisions of this Act or of the statutory ordinances issued on the basis of this Act, or of the orders and instructions from the supervisory authorities based thereon, are seriously or repeatedly violated and rectification is not effected within a reasonable period of time, or
6. so required due to a serious danger to employees, third parties or the general public.

(4) Where the party obliged to perform an estimation on the basis of section 55 subsection (2) fails to comply with the enforceable administrative order, the competent authority may prohibit the practice in full or in part until said order has been complied with.

Section 58

Cessation of the notified practice

Anyone who ceases a practice notified in accordance with section 56 subsection (1), first sentence, or changes it in such a way that an estimation in accordance with section 55 subsection (1), second sentence, indicates that the body dose will no longer be able to exceed the levels for categorisation as an occupationally-exposed person shall notify the competent authority thereof without undue delay.

Section 59

External practice

(1) The obligation to estimate the body dose in accordance with section 55 subsection (1) shall apply *mutatis mutandis* to anyone who carries out the practices referred to therein on his or her own account, or who has such practices carried out by persons under his or her supervision, in an external place of operation. Where a workplace-related estimation already exists for the external place of operation, the operator of the place of operation must hand over a copy of the records concerning the estimation to the party under an obligation in accordance with the first sentence without undue delay. Section 55 subsection (2) shall apply *mutatis mutandis*.

(2) Where the result of the estimation in accordance with subsection (1), first or third sentence, is that the body dose may exceed one of the levels for categorisation as an occupationally-exposed person, the party under an obligation in accordance with subsection (1), first or third sentence, must notify the competent authority in accordance with section 56 subsection (1) of the practice.

(3) The result of the estimation in accordance with section 55 subsection (1), as well as the following documents, shall be enclosed with the notification in accordance with subsection (2)

1. proof that every radiation protection supervisor possesses the requisite specialist knowledge in radiation protection or, where a radiation protection supervisor is not nec-

essary, that the notifying party, 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 the requisite specialist knowledge in radiation protection,

2. proof that the other persons involved in the execution of the practice possess the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented,
3. proof that those employed are obliged to comply with such orders as the radiation protection executives and radiation protection supervisors of those places of operation in which a practice notified in accordance with section 56 subsection (1) is performed may issue as a result of their obligations under this Act and under the statutory ordinances issued on the basis of this Act, and
4. proof that such equipment is available and such measures have been implemented for employment in places of operation for which no notification in accordance with section 56 subsection (1) has been filed as are necessary in accordance with the technical state-of-the-art in order to ensure that regulations governing protection are complied with.

(4) Section 56 subsection (3) and sections 57 and 58 shall apply *mutatis mutandis* to the practice notified in accordance with subsection (2).

Sub-division 2

Practices involving residues; materials

Section 60

Accumulation, recovery or disposal of residues

(1) Anyone who carries out industrial and mining processes, or has them carried out, at his or her place of operation, in the course of which a total exceeding 2,000 tonnes of residues will be produced and are to be recovered or disposed of, shall declare this to the competent authority, and to the competent authority in accordance with section 47 subsection (1), first sentence, of the Circular Economy Act at the beginning of each calendar year. This obligation to declare shall also apply *mutatis mutandis* to anyone who recovers residues requiring monitoring (or accepts them for recovery) that have accumulated abroad and have been brought to Germany.

(2) The party obliged to declare in accordance with subsection (1) shall draw up a plan for the recovery and disposal of the residues (residues plan), and to submit same to the competent authority on request. The residues plan must include the following

1. details of the nature, mass, specific activity and fate of the residues, including estimates of the residues that will accumulate over the next five years, and
2. an account of the disposal or recovery measures in place or planned for the next five years.

(3) The residues plan must be updated every five years or at the earlier request of the competent authority.

(4) The party obliged to declare in accordance with subsection (1) must draw up an annual statement for the preceding year concerning the nature, mass, specific activity and fate of the residues to be recovered and disposed of (residues statement), which it must retain for five years and submit to the competent authority on request. In addition, the competent authority may require the submission of corresponding documentary proof in accordance with section 21 of the Circular Economy Act.

(5) The competent authority may require that the residues plan and the residues statement satisfy certain requirements in terms of form and content and may verify their veracity.

Section 61

Accumulation and storage of residues requiring monitoring; empowerment to issue ordinances

(1) Anyone who carries out industrial or mining processes on his or her own account (or has them carried out) that cause the accumulation of residues requiring a monitoring, as a result of the storage, recovery or disposal of which the constraint for the effective dose of 1 mSv in a given calendar year may be exceeded for members of the public, shall take steps to protect the public in order to ensure that the constraint is not exceeded, and must seek advice from a person in possession of the requisite specialist knowledge in radiation protection. The first sentence shall also apply *mutatis mutandis* to anyone who recovers residues requiring a monitoring (or accepts them for recovery) that have accumulated abroad and have been brought to Germany.

(2) Residues require a monitoring where it is not ensured that the monitoring limits and methods of recovery and disposal laid down by a statutory ordinance in accordance with the second sentence are complied with in their disposal or recovery. The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing the monitoring limits and methods of recovery and disposal to apply to residues.

(3) Residues accumulated may not be mixed or diluted prior to their intended disposal or recovery in order to satisfy the monitoring limits in accordance with subsection (2). The first sentence shall also apply to residues accumulated abroad and brought into Germany for recovery.

(4) If the residues requiring monitoring are stored on the operating premises of the party subject to an obligation in accordance with subsection (1), the latter must declare said storage to the competent authority. The competent authority shall be informed without undue delay if such storage ceases.

(5) For those residues that are not subject to a monitoring requirement, the competent authority may require that compliance be proven with the monitoring limits and methods of recovery and disposal in accordance with a statutory ordinance in accordance with the second sentence of subsection (2). To this end, the competent authority may lay down technical procedures, suitable measurement procedures and other requirements, in particular those covering the ascertainment of representative measurement values for the specific activity.

(6) The party subject to an obligation in accordance with subsection (1) shall secure residues against loss and against access by unauthorised parties prior to their disposal or recovery. They may only be passed on to other party for the purpose of the disposal or recovery.

(7) The cross-border transportation of residues into Germany for their disposal is here-

with prohibited.

Section 62

Release of residues from monitoring; empowerment to issue ordinances

(1) The party under an obligation in accordance with section 61 subsection (1), first sentence, must declare the intended recovery or disposal of the residues to the competent authority without undue delay, stating their nature, mass and specific activity, as soon as he or she has established that said residues require monitoring in accordance with section 61 subsection (2). A declaration in accordance with the first sentence above may be dispensed with where notification is made in accordance with section 63 subsection (1) due to the nature and specific activity of the residues requiring monitoring.

(2) At the request of the party under an obligation in accordance with section 61 subsection (1), first sentence, the competent authority shall release residues requiring monitoring from that monitoring for the purpose of a particular recovery or disposal, where

1. the requisite protection of the population against exposure is ensured by means of the measures put in place for recovery or disposal,
2. the body dose of occupational workers in the course of disposal or recovery cannot exceed the levels for categorisation as an occupationally-exposed person, and
3. there are no reservations under the law on waste as to the permissibility of the envisaged method of recovery or disposal and as to whether it will be complied with.

Release from the monitoring obligation shall be effected by means of notice in writing.

(3) The criteria for the protection of the public shall be that, as the constraint for the exposure of members of the public caused by disposal or recovery, even without additional measures an effective dose of 1 mSv in a given calendar year is not exceeded, once recovery or disposal has been completed. Where the residues requiring monitoring are to be recovered as a construction product, the criteria for the protection of the public shall be the satisfaction of the requirements of sections 133 to 135.

(4) The exposure in connection with residues shall be determined in application of the principles of the statutory ordinance in accordance with subsection (6) no. 1. Residues requiring monitoring may not be recovered or disposed of under the law on waste without being released from the monitoring requirement.

(5) Subsections (1) to (4) shall apply *mutatis mutandis* to the cross-border transport of residues requiring monitoring that accumulated abroad. Anyone who intends to transport residues accumulated abroad to Germany for recovery must demonstrate to the competent authority in advance that

1. the monitoring limits and methods of recovery laid down by means of a statutory ordinance in accordance with section 61 subsection (2), second sentence, are adhered to, or
2. the conditions for release from monitoring for a specific recovery are satisfied.

(6) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. principles for determining exposures in connection with residues,

2. under what conditions the competent authority may assume, when residues are released from monitoring to be jointly landfilled with other residues and waste, that for the exposure of members of the public caused by disposal or recovery, an effective dose in the region of 1 mSv over a calendar year will not be exceeded, even without further measures, once the landfilling has finished, and
3. by means of what procedure residues requiring monitoring are released from monitoring, in particular where residues requiring monitoring are to be recovered as a construction product, or where recovery or disposal in another Federal *Land* is envisaged.

(7) Insofar as the release from monitoring of residues requiring monitoring, that takes place in accordance with this Act, the Atomic Energy Act, or with a statutory ordinance issued on the basis of this Act, or with the Atomic Energy Act, envisages disposal in accordance with the provisions of the Circular Economy Act or of the statutory ordinances issued on the basis thereof, or on the basis of the Closed Substance Cycle and Waste Management Act (*Kreislaufwirtschafts- und Abfallgesetz*) that was in force until 1 June 2012, such residues may not be re-used or recovered in accordance with said provisions.

Section 63

Residues that remain subject to monitoring; empowerment to issue ordinances

(1) Where release from monitoring in accordance with section 62 subsection (2) is not possible, the party subject to an obligation under section 61 subsection (1), first sentence, shall notify the competent authority of the nature, mass and specific activity of those residues that remain subject to monitoring, as well as of the planned disposal or recovery of these residues or of their relinquishment to that end within the deadline set out in the second sentence. Following the rejection of an application in accordance with section 62 subsection (2), the notification must take place within one month — or else without undue delay — of the party subject to an obligation establishing the need for monitoring in accordance with section 61 subsection (2).

(2) The competent authority may order that, and what, protective measures are to be taken, and how those residues that remain subject to monitoring are to be further processed or stored at a location to be determined by it.

(3) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing by what means residues that remain subject to monitoring are to be disposed of.

Section 64

Decontamination of land

(1) Anyone who terminates industrial or mining processes, in the course of which residues requiring monitoring have accumulated, shall remove any contamination with residues requiring monitoring before the use of the land by third parties, but no later than five years after the termination of use, in such a way that the residues do not give rise to any restrictions on use. The criteria for finding that there are no restrictions on the use of the land shall be that the exposure to which members of the public are exposed as a result of residues that have not been removed does not exceed the constraint of an effective dose of 1 mSv in a given calendar year.

(2) The party subject to an obligation in accordance with subsection (1), first sentence,

shall inform the competent authority of the completion of the removal of contamination, enclosing therewith suitable proof in accordance with the second sentence, within three months. The proof in accordance with the first sentence shall be furnished in application of the principles laid down in a statutory ordinance in accordance with section 62 subsection (6) no. 1. The authority may require that the fate of the removed contaminants be proven.

(3) The competent authority may grant full or partial exemption from the obligation in accordance with subsection (1) in individual cases where the intended use of the land or protective measures prevent exposure with an effective dose exceeding 1 mSv in a given calendar year for members of the public, even without the removal of the contaminants. It may also permit the obligation in accordance with subsection (1) to be fulfilled at a later date where industrial or mining processes in accordance with section 61 subsection (1) are to continue to be performed on the land in question.

Section 65

Monitoring of other materials; empowerment to issue ordinances

(1) Where practices in accordance with section 4 subsection (1), first sentence, no. 10, involving materials accumulated either in Germany or abroad which do not constitute residues, or the performance of industrial or mining process in which such materials accumulate, may increase the exposure of members of the public so significantly that radiation protection measures are necessary, the competent authority may issue orders. In particular, the authority may order

1. that, and what, protective measures are to be implemented,
2. that, and by what means, the materials are to be further processed or stored at a location to be determined by it, or
3. that the party that accepted materials that were accumulated abroad and brought to Germany must return them to the original holder in the State from which they were sent.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing by what means materials are to be disposed of.

Section 66

Operating organisations' information obligations

Where the body entitled to represent legal persons consists of several members or where, in the case of associations of persons with partial or no legal capacity, there are several persons entitled to act as representatives, the competent authority shall be informed which of them is to satisfy the obligations in accordance with this subsection. The joint liability of all members of the body, or of all members of the association of persons who are entitled to represent it, shall remain unaffected thereby.

Division 9
Exemption

Section 67

Exemption from the licence and notification requirement

Anyone who is employed as an employee or otherwise under supervision in connection with a practice requiring a licence or notification under this Act shall neither require a licence nor be obliged to give notification.

Chapter 3

Clearance

Section 68

Empowerment to issue ordinances; prohibition of use and recovery

(1) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. under what conditions and subject to what supplementary provisions, and via what procedure, the clearance of radioactive substances for the purposes of release from the monitoring obligation in accordance with this Act or with a statutory ordinance issued on the basis of this Act is to take place,
2. who may request clearance, and
3. what obligations are to be observed in connection with the clearance, in particular that and by what means such substances are to be kept account of and the competent authority is to be informed.

The statutory ordinance may also regulate the procedure and the information obligations in respect of cases in which the conditions for clearance are no longer satisfied.

(2) Insofar as the clearance of radioactive substances in accordance with a statutory ordinance issued on the basis of this Act envisages disposal in accordance with the provisions of the Circular Economy Act or of the statutory ordinances issued on the basis thereof or on the basis of the Closed Substance Cycle and Waste Management Act that was in force until 1 June 2012, such substances may not be re-used or recovered in accordance with said provisions.

Chapter 4

Operational organisation of radiation protection

Section 69

Radiation protection executive

(1) Anyone who satisfies one of the following conditions shall be deemed a radiation protection executive

1. anyone who requires a licence in accordance with sections 10 or 12 subsection (1) or sections 25 or 27, a licence in accordance with sections 4, 6, 7 or 9 of the Atomic Energy Act, plan approval in accordance with section 9b of the Atomic Energy Act, or a licence in accordance with section 9b subsection (1a) of the Atomic Energy Act,
2. anyone who performs a practice in accordance with section 5 of the Atomic Energy Act,
3. anyone who has to file a notification in accordance with sections 17, 19, 22, 26, 50, 52, 56 or 59, or
4. anyone who, in accordance with section 12 subsection (4), does not require a licence in accordance with section 12 subsection (1) no. 3.

(2) Where the radiation protection executive is a legal person or an association of persons with legal capacity, the tasks of the radiation protection executive shall be performed by the party entitled by law, articles or memorandum of association to effect representation. Where the body entitled to represent it consists of several members or where, in the case of associations of persons without legal capacity, there are several persons entitled to act as representatives, the competent authority shall be informed which of these persons perform the tasks of the radiation protection executive. The joint liability of all members of the body, or of all members of the association of persons, shall remain unaffected thereby.

Section 70

Radiation protection supervisor

(1) The radiation protection executive shall be responsible for appointing in writing and without undue delay the requisite number of radiation protection supervisors for the management or supervision of a practice insofar as necessary in order to ensure radiation protection in a practice. In the event of making the appointment(s) referred to in the previous sentence, the radiation protection executive shall still remain responsible for compliance with the responsibilities incumbent on him or her under this Act and the statutory ordinances issued on the basis hereof.

(2) On appointing a radiation protection supervisor, the radiation protection executive must lay down in writing the former's tasks, operational decision-making responsibilities and the powers necessary to perform his or her tasks. The obligations imposed on the radiation protection supervisor by this Act and by the statutory ordinances issued on the basis hereof shall only be incumbent on him or her in connection with the powers bestowed on him or her.

(3) Persons may only be appointed as radiation protection supervisors where there are

no facts giving rise to reservations regarding their reliability and where they possess the requisite specialist knowledge in radiation protection.

(4) On appointing a radiation protection supervisor, the radiation protection executive must inform the competent authority thereof in writing and without undue delay, stating the tasks and powers stipulated. The certificate documenting the requisite specialist knowledge in radiation protection shall be enclosed with the communication. The radiation protection supervisor and the works council or the staff committee shall each be provided with a copy of the communication. The first and third sentences shall apply *mutatis mutandis* in the event of a change to the tasks or powers of a radiation protection supervisor, and in the event of a radiation protection supervisor leaving the role. The second sentence shall apply *mutatis mutandis* in the event of an expansion of the tasks or powers of a radiation protection supervisor.

(5) The competent authority may stipulate to the radiation protection executive that a person may not be appointed as a radiation protection supervisor where he or she lacks adequate powers, adequate specialist knowledge in radiation protection, is not reliable or is, for other reasons, unable to perform the duties of a radiation protection supervisor satisfactorily.

(6) The radiation protection supervisor may not be obstructed in the satisfaction of his or her duties, nor may he or she be disadvantaged as a result of performing them. Where the radiation protection supervisor is in an employment relationship with the radiation protection executive tasked with making appointments, the termination of the working relationship shall be impermissible unless there are circumstances that entitle the radiation protection executive to terminate for cause without observing a notice period. Where a radiation protection supervisor is relieved of his or her post, termination shall not be permissible within one year of the ending of that post, unless the radiation protection executive is entitled to terminate for cause without observing a notice period.

(7) Radiation protection supervisors to be appointed for exploration, extraction or treatment of radioactive mineral resources must be appointed as the responsible person for managing or supervising the operation, or a part of an operation, in accordance with section 58 subsection (1) no. 2 of the Federal Mining Act where the provisions of the Federal Mining Act apply to the practices in question.

Section 71

Operational collaboration in radiation protection

(1) The radiation protection executive shall inform the radiation protection supervisor without undue delay of all administrative acts and measures that have an impact on the tasks or powers of the radiation protection supervisor.

(2) The radiation protection supervisor shall inform the radiation protection executive without undue delay of all deficiencies that have a deleterious impact on radiation protection. Where the radiation protection supervisor is unable to reach agreement with the radiation protection executive about a measure that the former has proposed to remedy deficiencies that have arisen, the radiation protection executive must inform the radiation protection supervisor of the rejection of the proposal in writing, including providing reasoning; the radiation protection executive shall provide the works council or the staff committee and the competent authority with a copy of this communication each, including the explanation. Should the communication or its submission to the competent authority fail to occur, the radiation protection supervisor may contact the competent authority directly.

(3) The radiation protection executive and the radiation protection supervisor shall collaborate with the works council or the staff committee, the occupational health and safety specialists and the authorised doctor in accordance with section 79 subsection (1), second sentence, no. 9(a) in the performance of their tasks, and shall inform them of important radiation protection matters. The radiation protection supervisor shall advise the works council or the staff committee on radiation protection matters on request.

Section 72

Further duties of the radiation protection executive and of the radiation protection supervisor; empowerment to issue ordinances

(1) The radiation protection executive must ensure, taking account of the scientific and technical state-of-the-art in the case of practices in accordance with section 4 subsection (1), first sentence, nos. 1-7 and 9, taking account of the technical state-of-the-art in practices in accordance with section 4 subsection (1), first sentence, nos. 8, 10 and 11 for the protection of people and the environment against the harmful effects of ionising radiation, in particular by means of the preparation of suitable rooms, equipment and devices, by means of suitable regulation of how the operation is performed and by means of the provision of sufficient and suitable personnel, that

1. within the meaning of section 8 subsection (1), all unnecessary exposure or contamination of people and of the environment is prevented and, within the meaning of section 8 subsection (2), that all exposure or contamination of people and the environment even below the limits is minimised as far as possible, taking into consideration all the circumstances of the individual case,
2. the following provisions are complied with
 - a) section 27 subsection (3), section 77, first sentence; section 78 subsections (1) to (4); section 80 subsections (1) and (2), section 83 subsections (1) and (3) first, fourth and fifth sentences and section 166; as well as, in accordance with section 115 subsection (1) no. 1 and section 115 subsection (2) no. 1, the provisions of sections 113, 114 and 116, and
 - b) sections 76 subsection (2), 85 subsections (1) to (3), 90 subsection (2), 167 and 168,
3. the provisions and the regulations governing protection of a statutory ordinance issued on the basis of sections 24 and 37 subsection (1), of section 68 subsection (1), of sections 73, 76 subsection (1), 79 subsection (1), 81, 82 and 85 subsection (4), of sections 86, 87, 89, 90 subsection (2), of section 170 subsection (10), and of section 171, are complied with, insofar as said statutory ordinance so decrees, and
4. the necessary measures are in place to prevent nuclear fuels from unintentionally going critical.

The first sentence shall apply *mutatis mutandis* to practices in accordance with section 4 subsection (1), second sentence.

(2) The radiation protection supervisor shall ensure that

1. in connection with the tasks and powers assigned to him or her in accordance with section 70 subsection (2),

- a) the provisions referred to in subsection (1), first sentence, nos. 1 and 2 are complied with,
- b) the provisions and the regulations governing protection referred to in subsection (1), first sentence, no. 3 are complied with,

except where the statutory ordinance in accordance with the second sentence dictates that the radiation protection executive alone is to be responsible for ensuring compliance in this regard, and that

- 2. the provisions of the notice on the licence, clearance or type approval, and the orders and special conditions imposed by the competent authority, are complied with, insofar as the implementation and satisfaction thereof have been assigned to him or her in accordance with section 70 subsection (2).

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that the radiation protection executive alone is to be responsible for ensuring compliance with specific provisions and specific regulations governing protection referred to in subsection (1), first sentence, no. 3. The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating how the powers of the radiation protection supervisor required in accordance with section 29 subsection (1), first sentence, no. 3, are to be structured.

(3) The radiation protection executive and the radiation protection supervisor shall ensure that, where there is a danger to people or the environment, suitable steps are taken without undue delay to avert said danger.

Section 73

Empowerment to issue a radiation protection order

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing that the radiation protection executive may issue a radiation protection order and what content such a radiation protection order must have.

Section 74

Requisite specialist and general knowledge in radiation protection; empowerments to issue ordinances

(1) As a rule, the requisite specialist knowledge in radiation protection is acquired by means of training suited to the relevant area of application, through practical experience and by successfully completing courses recognised by the competent authority.

(2) As a rule, the requisite general knowledge in radiation protection shall be acquired by means of instruction suited to the relevant area of application, and by means of practical experience. As a rule, the persons referred to in a statutory ordinance in accordance with subsection (4) no. 5 shall acquire the requisite knowledge in radiation protection by means of suitable training, practical experience and successfully completing courses recognised by the competent authority.

(3) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing details regarding the requisite specialist and requisite general knowledge in radiation protection in dependence on the area of application

and the tasks of the person required to possess the requisite specialist or requisite general knowledge in radiation protection.

(4) The Federal Government is herewith also empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. what proof is to be furnished in respect of the requisite specialist knowledge in radiation protection or requisite general knowledge in radiation protection,
2. that, and in what way, the presence of the requisite specialist knowledge in radiation protection or requisite general knowledge in radiation protection is to be verified and certified,
3. what requirements are to be laid down with regard to the recognition of courses for the acquisition of the requisite specialist knowledge in radiation protection or the requisite general knowledge in radiation protection, to the recognition of vocational training that includes the acquisition of the requisite specialist knowledge in radiation protection or the requisite general knowledge in radiation protection and to refresher courses,
4. what content is to be disseminated in the courses to acquire the requisite specialist knowledge in radiation protection or the requisite general knowledge in radiation protection and in refresher training,
5. who is required to acquire the requisite general knowledge in radiation protection in accordance with subsection (2), second sentence,
6. that, at what intervals, and by what means, the requisite specialist knowledge or requisite general knowledge in radiation protection is to be refreshed,
7. under what conditions comparable specialist knowledge in radiation protection or comparable general knowledge in radiation protection acquired outside the scope of this Act, or attendance at a course that took place outside the scope of this Act, may be recognised, and
8. under what conditions the competent authority may revoke certification in respect of the requisite specialist knowledge in radiation protection or requisite general knowledge in radiation protection, may impose additional conditions on the continued validity of such certification, or may order a verification of the specialist or general knowledge.

Section 75

Verification of reliability

Section 12b of the Nuclear Reliability Verification Ordinance (*Atomrechtliche Zuverlässigkeitsüberprüfungs-Verordnung*) shall apply to the verification of the reliability of persons in order to protect against unauthorised actions that could lead to the misappropriation or release of other radioactive substances.

Chapter 5

Requirements pertaining to the performance of practices

Section 76

Empowerments to issue ordinances for physical radiation protection surveillance and radiation protection areas; obligations to keep and pass on records of the body dose data

(1) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, laying down requirements governing physical radiation protection surveillance and stipulations for supervised areas, controlled areas and exclusion areas as part of the controlled area (radiation protection areas), and the protection of persons spending time in radiation protection areas. In particular, the statutory ordinance may stipulate

1. when radiation protection areas are to be established and what characteristics they must fulfil,
2. how radiation protection areas are to be delimited, secured and identified,
3. under what conditions individuals are to be allowed entry into radiation protection areas,
4. that persons must receive training prior to entering radiation protection areas, prior to deployment as flight or space crew, or prior to handling radioactive substances or operating installations for the generation of ionising radiation, X-ray equipment or stray radiation emitters, or prior to the transportation of radioactive substances, what content this training must have, and at what intervals it must take place,
5. that a record is to be made of who has attended training in accordance with no. 4 above, how long that record is to be retained, and under what conditions it must be submitted to the competent authority,
6. that personal protective equipment must be used and what such equipment must be used,
7. that and how metrological control is to take place, including the use of specific radiation measurement equipment,
8. how persons who spend time in or have spent time in radiation protection areas are to be monitored, including the obligation incumbent on such persons to wear dosimeters,
9. that a record must be made of who has spent time in radiation protection areas and what the results of the surveillance are, that and how long such records are to be retained, that and under what conditions they are to be submitted to the competent authority, and under what conditions the results of the surveillance are to be passed on to authorised doctors and employers,
10. that and to what extent persons who could be subject to occupational exposure, or who spend time in or have spent time in a radiation protection area, are obliged to undergo measurements to determine their body dose, medical examination and, where necessary to protect others and the public at large, medical treatment, and that the examina-

tion or treatment in question is to be performed by authorised doctors,

11. that, by what means and by whom the body dose is to be determined,
12. what technical and organisational requirements are to apply to the required making, retention and handing on of records of the body dose data ascertained in accordance with subsection (2), section 85 subsection (1) no. 3(b) and sections 167 and 168,
13. what dosimeters may be used to measure occupational exposure, and that these must be made available to the person to be monitored,
14. what requirements are to be applied to the recognition of a computer program to ascertain the body dose of air crew,
15. what protective measures are to be implemented in and when leaving radiation protection areas in order to detect and eliminate the contamination of persons and objects, and to detect the activation of objects, what levels are to be used for the surface-specific and specific activity in this regard, and what requirements are to be laid down for people tasked with decontamination,
16. what arrangements are to be put in place in order to protect firefighters against the harmful effects of ionising radiation when fighting fires, and
17. what additional obligations to make, retain, pass on and submit records exist in connection with the obligations under nos. 1 to 16 above.

The statutory ordinance may also stipulate the provisions of the statutory ordinance with regard to which the radiation protection executive is responsible for ensuring compliance.

(2) The radiation protection executive shall ensure that the results of the body dose data ascertained in accordance with the statutory ordinance in accordance with subsection (1), second sentence, no. 11 for individuals who are subject to physical radiation protection surveillance, or have spent time in radiation protection areas, and are neither subject to occupational exposure nor are carers and comforters, must be recorded without undue delay. The records shall be retained for ten years from the date of their creation, and shall be submitted to the competent authority on request.

(3) The fundamental right to physical integrity (Article 2 para. 2, first sentence, of the Basic Law) shall be restricted in accordance with subsection (1), second sentence, no. 10.

Section 77

Limits for the working life dose

The limit for the sum of the effective doses calculated in all calendar years for occupationally-exposed persons shall be 400 mSv. In consultation with an authorised doctor, the competent authority may authorise additional occupational exposure provided that this will not result in the effective dose per calendar year of 10 mSv being exceeded, and provided that the exposed worker consents thereto. Consent must be given in writing.

Section 78

Limits for occupationally-exposed persons

(1) The limit for the effective dose for occupationally-exposed persons shall be 20 mSv per calendar year. In individual cases, the competent authority may permit an effective dose of 50 mSv for a particular calendar year, provided that a total of 100 mSv is not exceeded over the period of five consecutive years including the year in question.

(2) The limit for the equivalent dose for occupationally-exposed persons shall be

1. 20 mSv in a given calendar year for the lens of the eye,
2. 500 mSv in a given calendar year for the skin, averaged over any area of 1 cm², regardless of the area exposed (local skin dose), and
3. 500 mSv in a given calendar year in each case for the hands, the forearms, the feet and the ankles.

Subsection (1), second sentence, shall apply *mutatis mutandis* to the equivalent dose for the lens of the eye.

(3) The limit for the effective dose for occupationally-exposed persons under 18 years of age shall be 1 mSv per calendar year. The limit for the equivalent dose shall be

1. 15 mSv in a given calendar year for the lens of the eye,
2. 50 mSv in a given calendar year for the local skin dose,
3. 50 mSv in a given calendar year in each case for the hands, the forearms, the feet and the ankles.

By way of derogation from the above, the competent authority may permit a limit of 6 mSv per calendar year for the effective dose, and a limit of 150 mSv per calendar year for the equivalent dose, in each case for the skin, the hands, the forearms, the feet and the ankles for apprentices and students aged between 16 and 18 where this is necessary in order to achieve the training objective.

(4) In the case of women of child-bearing age, the limit for the equivalent dose for the uterus shall be 2 mSv per calendar month. For an unborn child exposed to radiation in connection with maternal employment, the limit for the effective dose from the time when pregnancy is confirmed until the end of pregnancy shall be 1 mSv.

(5) The empowerment of the authority competent in accordance with the statutory or-

dinance in accordance with section 79 subsection (1), second sentence, no. 1 to permit exposures that deviate from the limits values laid down in subsections (1) and (2) and subsection (4), first sentence, in exceptional circumstances evaluated case by case in order to carry out necessary specific operations shall remain unaffected thereby.

Section 79

Empowerment to issue ordinances for occupational exposure; keeping of medical records

(1) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what precautionary and monitoring measures are to be put in place in order to protect workers who are subject to occupational exposure. The statutory ordinance may stipulate in particular

1. under what conditions continued employment as an occupationally-exposed person is permissible in the event of a limit being exceeded, and under what conditions exposures may be permitted deviating from the limits,
2. in what cases, by what means and by whom dose constraints may be laid down for occupational exposure, and who must take these dose constraints into account when implementing radiation protection measures,
3. that and how radiation protection arrangements are to be made for external or internal exposure, what prohibitions and restrictions on employment are to apply to those aged under 18, as well as exceptions from such prohibitions and restrictions,
4. what special protective measures are to be put in place for a pregnant or breastfeeding woman and her child,
5. that persons are to be allocated to categories for the purposes of monitoring and medical surveillance,
6. under what circumstances persons may only be so employed that they will be subject to occupational exposure if they submit certification by authorised doctors, and that, in the event of health concerns in respect of employment of this kind, the competent authority is to decide, after obtaining an opinion from a medical expert, that the medical examination is to be repeated at regular intervals and may also be ordered at shorter intervals and after the working relationship has come to an end,
7. what documents, including the medical records in accordance with no. 10, an authorised doctor is to consult in order to issue the certification in accordance with no. 6, what details the certification must include, and what procedure is to be followed in issuing the certificate,
8. under what circumstances special medical surveillance of a person is to take place and who is to perform it,
9. that and under what conditions
 - (a) the competent authority may authorise doctors to perform the medical surveillance of exposed persons (authorised doctors),
 - (b) the authorisation can be time-limited,

10. what tasks and responsibilities the authorised doctors have, including the obligation to keep medical records,
11. that and under what conditions an authorised doctor
 - a) must submit the certification in accordance with no. 6 to the radiation protection executive, to the person examined, to another authorised doctor and to the competent authority,
 - b) must submit the medical records to another authorised doctor, and when the authorisation ends, to a body nominated by the competent authority,
12. that the working rotas for air crew must take into account the exposure identified with a view to reducing doses,
13. what additional obligations to make, retain, pass on and submit records exist in connection with the obligations under nos. 1 to 11 above.

The statutory ordinance may also stipulate the provisions of the statutory ordinance with regard to which the radiation protection executive is responsible for ensuring compliance.

(2) The medical records in accordance with the statutory ordinance in accordance with subsection (1), second sentence, no. 10 shall contain the following information

1. details of the working conditions,
2. details of the results of the medical surveillance,
3. the medical certification in accordance with subsection (1), second sentence, no. 6,
4. details of the results of the special medical surveillance in accordance with subsection (1), first sentence, no. 8,
5. details of the competent authority's decision based on the statutory ordinance in accordance with subsection (1), second sentence, no. 6,
 - a) that medical surveillance is to be carried out for a shorter period than that laid down in the statutory ordinance,
 - b) in the event of health concerns regarding the employment, including the opinion of the medical expert, and
6. details of the body dose received.

(3) While the occupationally-exposed person is performing the practice in question, his or her medical records must be kept fully up to date. They shall be retained until such time as the person concerned has reached, or would have reached, 75 years of age, and for a minimum of 30 years after the cessation of his or her tasks as an occupationally-exposed person. They shall be destroyed by no later than 100 years after the birth of the monitored person.

(4) At the competent authority's request, the authorised doctor in accordance with subsection (1), second sentence, no. 9(a), must provide the medical records to a body nominated by the competent authority for perusal and, when the authorisation ends, must submit the medical records to such body. Appropriate measures shall be taken to ensure that the protection of patient confidentiality by the nominated body is guaranteed. The authorised doctor

shall grant the examinee access to his or her medical records on request.

(5) The fundamental right to physical integrity (Article 2 para. 2, first sentence, of the Basic Law) shall be restricted in accordance with subsection (1), second sentence, nos. 6 and 8.

Section 80

Limits for public exposure

(1) The limit for the sum of effective doses for members of the public shall be 1 mSv per calendar year as a result of exposure from

1. practices requiring a licence or notification under this Act or the Atomic Energy Act,
2. the government custody of nuclear fuels in accordance with section 5 subsection (3), first sentence, of the Atomic Energy Act,
3. the construction requiring plan approval, the operation requiring plan approval or the decommissioning requiring plan approval of the installations of the Federation referred to in section 9a subsection (3) of the Atomic Energy Act, and
4. the exploration, extraction or treatment of radioactive mineral resources, where such practices are subject to an operating plan requirement in accordance with section 51 of the Federal Mining Act.

(2) The limit for the sum of the equivalent doses for members of the public shall be

1. 15 mSv in a given calendar year for the lens of the eye, and
2. 50 mSv in a given calendar year for the local skin dose.

(3) Exposures resulting from non-medical use in accordance with section 83 subsection (1) no. 2 shall not be taken into account for the limits for members of the public.

(4) The competent authority shall endeavour to ensure that, where several practices requiring a licence or notification are to be taken into account, the limits referred to in subsections (1) and (2) are adhered to overall.

Section 81

Empowerment to issue ordinances for the protection of the public and of the environment

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what precautionary and monitoring measures are to be put in place in order to protect members of the public in connection with planned exposure situations in order to ensure that specific body doses and concentrations of radioactive substances in the air and water are not exceeded. The statutory ordinance may stipulate in particular

1. in the planning or performance of what practices the anticipated exposure of members of the public is to be ascertained, and what exposures from other practices are to be

taken into account when ascertaining the exposure, as well as what information is to be submitted to the competent authority in order to perform its task in accordance with section 80 subsection (4),

2. for what licensed or notified practices the exposure received by members of the public is to be ascertained, and what information the radiation protection executive is to pass on to the authority competent in this connection,
3. that and by what means the ascertainment of the exposure received is to be documented,
4. by what means and under what assumptions the exposure of members of the public is to be ascertained, and what contributions are to be taken into account in the composition of the sum of body doses in accordance with section 80 subsections (1) and (2),
5. what dose limits for discharges into the air or water are to apply to the planning, construction, operation, decommissioning, safe enclosure and dismantling of nuclear installations, installations within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act, installations for the generation of ionising radiation, and facilities,
6. that and by what means the competent authority is to identify permissible discharges of radioactive substances into the air and water in connection with nuclear installations, installations within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act, installations for the generation of ionising radiation and facilities, and under what conditions the competent authority may assume that the dose limits in accordance with no. 5 are being complied with,
7. what stipulations are to be satisfied for emissions and immissions monitoring, which includes the monitoring of exposure via direct radiation, of nuclear installations, installations within the meaning of the second half of the first sentence of section 9a subsection (3) of the Atomic Energy Act, of installations for the generation of ionising radiation, and of facilities,
8. for what practices a general investigation into compliance with environmental criteria is to be carried out for the long-term protection of human health, and what procedures are to be applied in so doing,
9. in what cases, by what means and by whom dose constraints may be laid down, and who must take these dose constraints into account when implementing radiation protection measures, and
10. in planning what activities structural and other technical protective measures are to be put in place in order to limit exposure as a result of hazardous incidents, and what principles and what maximum levels are to be observed in relation to exposures.

The statutory ordinance may delegate tasks relating to quality assurance, to process development for sampling, analysis and measurement, and to data-handling, to administrative authorities of the Federation. The statutory ordinance may also stipulate the provisions of the statutory ordinance with regard to which the radiation protection executive is responsible for ensuring compliance.

Section 82

Empowerment to issue ordinances for duties of the radiation protection executive in connection with hazardous incidents and emergencies

(1) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what obligations the radiation protection executive must satisfy in connection with preparing appropriate responses to hazardous incidents, potential emergencies and in the event of an emergency, in particular

1. that the requisite personnel and tools are to be kept available in order to contain and eliminate dangers that have arisen in connection with the practice of the radiation protection executive as a result of hazardous incidents or emergencies, and what requirements are to be laid down in respect of the requisite specialist or requisite general knowledge in radiation protection and the tools,
2. that and by what means the public is to be informed about the protective measures and the recommended action to take in the case of any emergencies,
3. that, in an emergency, all appropriate measures must be taken without undue delay in order to avert dangers to people and the environment, or to limit their deleterious impact,
4. that and by what means specific authorities are to be informed without undue delay on the occurrence of an emergency, that the latter must be sent an interim initial assessment of the circumstances and estimation of the consequences of the emergency without undue delay, and that assistance must be given to the competent authorities and aid organisations in their decision-making and protective measures, in particular in terms of information needed and necessary advice.

(2) The obligations incumbent on the radiation protection executive, on the basis of other legal provisions at Federal or *Land* level, to avert dangers to human health, the environment or public safety, or on the basis of directly-applicable European Union or European Atomic Community legislation, shall remain unaffected to the extent that such provisions and legal acts also apply to radiological hazards.

Section 83

Use of ionising radiation or radioactive substances on people

(1) Ionising radiation or radioactive substances may only be applied on people

1. in connection with medical exposure, or
2. in connection with the exposure of the public in order to examine a person in cases envisaged or permitted by the law or in accordance with general occupational health and safety regulations, or in accordance with other countries' provisions on immigration (non-medical use).

(2) The use must deliver a sufficient benefit. When evaluating whether the use in question delivers a sufficient benefit, its overall potential diagnostic or therapeutic benefit, including the direct health benefit for the individual and the benefit for society, must be weighed against the potential harm to the individual from the exposure.

(3) The use may only take place after a medical doctor or dentist who possesses the requisite specialist knowledge in radiation protection has decided that and by what means the use is to be effected (justifying indication). In uses in connection with medical exposure, the justifying indication shall require it to be established that the health benefit of the individual use outweighs the radiation risk. In the case of non-medical uses, the justifying indication shall require it to be established that the benefit associated with the specific examination outweighs the radiation risk. The justifying indication may only be issued where the medical doctor issuing it is able to examine the person on whom the ionising radiation or radioactive substances are being applied in person and in situ, except in a case of teleradiology in accordance with section 14 subsection (2).

(4) Subsection (3) shall not apply to examinations involving X-radiation under the Infection Protection Act (*Infektionsschutzgesetz*), or to uses on people for the purpose of medical research in accordance with section 31 subsection (1) or section 32 subsection (1).

(5) The exposure resulting from an examination using ionising radiation or radioactive substances shall be limited to the extent that this is compatible with the requirements of medical science. In the use of ionising radiation or radioactive substances to treat people, the dose beyond the target volume shall be kept as low as is possible, taking into account the objective of the treatment. The first sentence shall apply *mutatis mutandis* in the case of non-medical uses.

Section 84

Screening; empowerment to issue ordinances

(1) Screening to detect non-communicable diseases shall only be permitted where provided for in accordance with the statutory ordinance in accordance with subsection (2) below.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, without the consent of the Bundesrat, laying down what forms of screening are permissible for a particularly affected group of individuals in order to detect a non-communicable disease, and under what conditions. Said statutory ordinance may only regulate the permissibility of screening that makes it possible to detect a serious disease at an early stage by means of a scientifically-recognised screening procedure, and thus facilitates more effective treatment of a sick person. The results of the scientific evaluation in accordance with subsection (3) must be taken into account.

(3) Screening to detect non-communicable diseases shall be scientifically evaluated by the Federal Office for Radiation Protection, with the involvement of specialists in the field, with the risks and benefits of the screening being weighed up against one another. The scientific evaluation shall be published. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall regulate the further procedure in respect of the scientific evaluation and its publication by means of general administrative provisions in agreement with the Federal Ministry of Health.

(4) Screening in order to detect communicable diseases in parts of the country or for population groups with above-average incidence of disease shall only be permissible where the *Land's* highest competent health authority, in agreement with that *Land's* highest radiation protection authority, has authorised screening for public health reasons.

(5) Where the screening takes place as part of a screening programme, the statutory

ordinance in accordance with subsection (2), or the authorisation in accordance with subsection (4), may permit exceptions to the obligation to obtain a justifying indication insofar as the nature and scope of the inclusion criteria for the screening programme render unnecessary a decision on whether or by what means the use is to be carried out.

Section 85

Obligations to make, retain and pass on records to the authorities in respect of data and image documents in the case of use on people; empowerment to issue ordinances

(1) The radiation protection executive must ensure that records are made of the use of ionising radiation or radioactive substances on people. The records shall include the following

1. details of the justifying indication,
2. the time and nature of the use,
3. information regarding the exposure
 - a) of the person examined or treated, or to determine said exposure, including reasons in the event of exceeding diagnostic reference levels, and
 - b) of carers and comforters insofar as their body dose is to be determined in accordance with the statutory ordinance in accordance with section 86, second sentence, no. 3,
4. the collected findings of an examination,
5. the radiation treatment plan and the radiation treatment records of a treatment.

The records shall be secured against unauthorised access and unauthorised alteration.

(2) The radiation protection supervisor shall retain these records, as well as X-ray images, digital image data and other examination data, as follows

1. in the case of treatment, for 30 years,
2. in the case of examinations
 - a) in the case of adults, for 10 years,
 - b) in the case of minors, until they reach the age of 29.

The competent authority may require that, in the event of the cessation of a medical practice or other discontinuation of the operation, the records together with the X-ray images, the digital image data, and the other examination data, be deposited with a body nominated by it without undue delay; appropriate measures shall be taken to ensure that the protection of patient confidentiality by the nominated body is guaranteed.

(3) The radiation protection manager shall

1. submit said records to the competent authority on request; this shall not apply to medical findings,

2. submit to the medical or dental authority on request the records and the X-ray images, the digital image data and the other examination data required to perform its tasks in accordance with the statutory ordinance in accordance with section 86, second sentence, no. 9,
3. provide a doctor or dentist performing further examination(s) or treatment with information regarding the records, and hand over to said doctor or dentist on a temporary basis the records and the X-ray images, the digital image data and the other examination data.

When passing on records, suitable steps must be taken to ensure that medical confidentiality is maintained. The person examined or treated shall be provided with a copy of the notes on request.

(4) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. that a person who has been examined using X-rays or radioactive substances is to be offered information on the examination that has been carried out, what content this information must have, and in what form this information is to be made available,
2. what requirements are to be laid down in respect of the retention of records, X-ray images, digital image data and other examination data, in particular in order to ensure their availability and to prevent data losses,
3. what requirements are to be laid down in respect of the passing on of records, X-ray images, digital image data and other examination data.

The statutory ordinance may also stipulate the provisions of the statutory ordinance with which the radiation protection executive is responsible for ensuring compliance.

Section 86

Empowerments to issue ordinances for the protection of persons in the case of the use of ionising radiation or radioactive substances on people

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing what measures, including precautionary and monitoring measures, are to be put in place in order to protect persons on whom ionising radiation and radioactive substances are applied, and for the protection of members of the public during or following the use of ionising radiation or radioactive substances on people. The statutory ordinance may stipulate in particular

1. by what means each individual exposure is to be justified,
2. by what means, during use, the medical exposure and the exposure of the people on whom ionising radiation or radioactive substances is/are being applied in connection with a non-medical use are to be limited,
3. that and by what means, during use, the medical exposure and the exposure of the persons being examined in connection with non-medical uses are to be ascertained and assessed,
4. what steps are to be taken before, during and after use in order to ensure adherence to

the quality necessary for radiation protection, in consideration of the requirements of medical science,

5. by what means teleradiology is to be carried out, and what requirements are to be laid down in relation to the quality of teleradiology systems,
6. what persons are entitled to use radioactive substances and ionising radiation on people or to practice the technical implementation of such use, and which criteria are to be used as a basis for determining the sufficient number of necessary personnel in accordance with section 14 subsection (1) no. 4,
7. that and by what means diagnostic reference levels are to be ascertained, compiled and published,
8. that and by what means the medical exposure for the public is to be ascertained and inquiries are to be carried out in that connection,
9. that and by what means medical and dental bodies are to be involved in order to safeguard quality in the use of radioactive substances or ionising radiation on people, and that the competent authorities are to appoint medical and dental bodies for this purpose,
10. that and to what extent a medical physics expert is to be called in in accordance with the radiological risk of the use of radiation, and what examinations using radioactive substances or ionising radiation could be associated with significant exposure of the person being examined,
11. that and by what means it is to be guaranteed that the public is protected from exposure via a person on whom radioactive substances have been applied,
12. what requirements are to be imposed on the equipment, apparatus and devices in use, in particular in connection with the quality objective under section 14 subsection (1) no. 5,
13. that, by whom and by what means quality assurance measures are to be put in place in connection with the equipment, apparatus and devices in use, in particular checks on the metrological parameters via acceptance and constancy tests, in view of the quality objective under section 14 subsection (1) no. 5,
14. that and by what means the procedures utilised in connection with the treatment of people are to be investigated for risks in terms of unintended exposures, and how the results of such investigations are to be taken into account in the performance of the practice,
15. that the success of the treatment is to be examined after treatment, and at what intervals it is to be examined,
16. that and by what means a person on whom ionising radiation or radioactive substances is/are being applied and his or her carer or comforter are to have the risks explained to them before and after the use,
17. that and by what means records of the use of radioactive substances or ionising radiation are to be made and retained, including the equipment, apparatus and devices used and a list of equipment, apparatus and devices used,
18. that and by what means information and records concerning the use of radioactive substances and ionising radiation are to be made available to the competent body, and

19. by what means screening is to be carried out and what special requirements are required in terms of the equipment, apparatus and devices and in respect of the necessary knowledge and skills in relation to the potential radiation hazard and the protective measures to be implemented in respect of personnel and quality assurance measures.

The statutory ordinance may also establish what information and personal data the radiation protection executive must make available to the medical or dental authority in order to perform its task in accordance with the second sentence, no. 9, and whether and under what conditions the medical or dental authority may process and store said information and personal data and pass it on to the competent authority. It may also be laid down in the statutory ordinance that and by what means the medical or dental authority may pass on the results of its checks, including the name and address of the radiation protection executive, to the body responsible for quality assurance in accordance with Book V, Chapter 4, Division 9 of the Social Code (*Sozialgesetzbuch*); the personal data of persons being examined or treated may not be passed on. The statutory ordinance may also stipulate the provisions of the statutory ordinance with which the radiation protection executive is responsible for ensuring compliance.

Section 87

Empowerments to issue ordinances for the protection of persons in the case of the use of radioactive substances or ionising radiation on animals in veterinary medicine

In order to protect those persons present during the use of radioactive substances or ionising radiation in veterinary medicine, the Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing

1. who is entitled to apply radioactive substances or ionising radiation in veterinary medicine or to execute the technical implementation of such use, and
2. that and by what means the exposure of persons accompanying animals is to be limited.

The statutory ordinance may also stipulate the provisions of the statutory ordinance the radiation protection executive with which is responsible for ensuring compliance.

Section 88

Register of high-activity radioactive sources; empowerments to issue ordinances

(1) The data regarding high-activity radioactive sources collected on the basis of this Act or of a statutory ordinance in accordance with section 89, first sentence, no. 1, shall be included in a register established by the Federal Office for Radiation Protection for the purpose of the safety and monitoring of radioactive sources in order to protect life and health.

(2) The register shall include, in particular, the following details relating to the high-activity radioactive source, its monitoring, and to licences issued in accordance with this Act, with the Atomic Energy Act, or with a statutory ordinance in accordance with section 30 of this Act or with section 11 subsection (1) no. 6 of the Atomic Energy Act,

1. the holder, date of issue and expiry date of the licence,
2. the identity number of the high-activity radioactive source,

3. the characteristics, monitoring and use of the high-activity radioactive source,
4. the place of handling or storage of the high-activity radioactive source,
5. the acquisition or relinquishment of possession of the high-activity radioactive source,
6. the loss, theft or discovery of the high-activity radioactive source.

(3) The authorities competent in accordance with sections 184, 185, 188, 190 and 191 shall have read-only access to the register, along with the authorities competent in accordance with section 24 of the Atomic Energy Act, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, and the Federal Office of Civil Protection and Disaster Assistance (*Bundesamt für Bevölkerungsschutz und Katastrophenhilfe — BBK*). For the purpose of the immediate establishment of the holder and of the characteristics of a high-activity radioactive source as a result of its discovery, loss or the risk of misuse, and in the case of evidence and investigations in connection with combating nuclear terrorism, nuclear criminality and nuclear smuggling, or with other illegal cross-border transportation of high-activity radioactive sources, the Federal Criminal Police Office (*Bundeskriminalamt*) and the *Länder* Criminal Police Offices, the Federal Police authority nominated in the statutory ordinance in accordance with section 58 subsection (1) of the Act on the Federal Police (*Bundespolizeigesetz*), the Central Customs Authority (*Zollkriminalamt*), and the Federal and *Länder* Offices for the Protection of the Constitution, in accordance with their statutory respective competences, shall also have read-only access.

(4) Information from the register may be provided to

1. the other police authorities in the *Länder*, the customs authorities, the Military Counterintelligence Service (*Militärischer Abschirmdienst*) and the Federal Intelligence Service (*Bundesnachrichtendienst*), to the extent required to perform their respective tasks,
2. authorities in other countries with comparable tasks, and international organisations, to the extent necessary to perform their respective tasks and insofar as this is provided for by binding decisions of the European Union or is required under other international agreements.

(5) The data stored in the register shall be retained for 30 years after the last updating of the details for a high-activity radioactive source.

(6) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing details in respect of

1. the content and form of data collection and entry in respect of access rights and the procedure for sharing information,
2. access rights for the licence-holder in respect of the data concerning him or her, and
3. the transmission, correction, blocking and deletion of data.

Section 89

Empowerments to issue ordinances in respect of the security of radioactive sources

In order to protect people against the harmful effects of ionising radiation, and in order

to ensure the monitoring and security of radioactive substances, the Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating

1. that and by what means account is to be taken of the generation, extraction, acquisition, possession, location, relinquishment and other disposition of radioactive substances, and in respect of measurements of doses and dose rates, that communications are to be drawn up and documents retained, deposited and submitted, and by what means the competent authority is to verify the data submitted,
2. what requirements are to be laid down in respect of the security and storage of radioactive substances,
3. what requirements are to be laid down in respect of the maintenance and inspection of equipment, apparatus and other devices, and who is to perform the maintenance and inspections,
4. what requirements are to be laid down in respect of the leakage test of sealed radioactive substances, and who is to perform the leakage test ,
5. what radiation measurement equipment is to be used, and what requirements are to be applied to it,
6. what areas, rooms, equipment, devices, containers, casings, installations for the generation of ionising radiation and type-approved devices are to be marked, by what means and under what conditions marking is to take place, and under what circumstances markings are to be removed,
7. what requirements are to be laid down in respect of the surrender of radioactive substances,
8. what requirements are to be laid down in respect of the take-back of high-activity radioactive sources,
9. in what cases of practices involving radioactive sources X-ray rooms or exposure rooms are to be used, and what requirements are to be laid down in respect of X-ray rooms and exposure rooms,
10. what persons may use radiation, or perform the technical execution of a use, in connection with practices involving radioactive sources, that and how persons are to be instructed in connection with practices involving radioactive sources, and what documents must be available when such practices are carried out, that records are to be made of such instruction, and that these are to be submitted to the authority on demand,
11. that additional precautionary and monitoring measures are to be put in place for the control of radioactive substances in order to protect individuals and the public, and which such measures are to be put in place,
12. what additional obligations to make, retain, pass on, submit and deposit records exist in connection with the obligations under nos. 1 to 10 above.

The statutory ordinance may also stipulate the provisions of the statutory ordinance with which the radiation protection executive is responsible for ensuring compliance.

Chapter 6

Reporting and information obligations

Section 90

Empowerments to issue ordinances for obligations, tasks and powers for incidents; recording, notification and retention obligations

(1) With regard to incidents in planned exposure situations, the Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating obligations for the radiation protection executive, as well as official tasks and powers. The statutory ordinance may stipulate in particular

1. that and in what manner the radiation protection executive is to initiate measures in order to minimise exposure in the event of such an incident,
2. that and in what manner the radiation protection executive is to take measures in order to avoid such incidents in future,
3. that and by what means the radiation protection executive is to record and to investigate an incident, and for how long he or she is to retain such records,
4. that and by what means, with regard to the supervisory authorities, the radiation protection executive is to
 - a) report an incident,
 - b) report information and findings regarding the causes and effects of the incident and measures to resolve and limit the effects of the incident, and
 - c) report measures taken to avoid incidents,
5. that and by what means the supervisory authority is to create, review and evaluate reports in accordance with no. 4;
6. that and by what means a central agency for recording, processing and evaluating information and findings about incidents arising from the use of radioactive substances or ionising radiation on human beings is to be established at the Federal Office for Radiation Protection (BfS), which tasks the central agency performs in detail, and how it performs these tasks;
7. that and by what means the supervisory authorities provide the central agency with information and findings regarding incidents arising from the use of radioactive substances or ionising radiation on human beings, and their assessment in this regard;
8. under what circumstances and by what means the supervisory authorities and the central agency publish information and findings about incidents.

(2) In the event of an incident subject to the statutory ordinance in accordance with subsection (1), the radiation protection executive shall ensure prompt recording of the surname, first names, date and place of birth, gender and address of an individual exposed by the incident, as well as details of the exposure and the health consequences of the exposure. Insofar as the radiation protection executive is required to report the incident in accordance with the statutory ordinance in accordance with subsection (1), and measures to

protect the exposed individual are required, he or she shall report this data to the competent authorities without undue delay. The data shall be safeguarded against unauthorised access through technical and organisational measures. In instances other than those specified in the second sentence, the data shall be provided to the competent authorities on request. The data shall be retained for 30 years and erased without undue delay once this period has expired.

Section 91

Empowerments to issue ordinances for information obligations of the manufacturer or supplier of devices

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing that the manufacturers or suppliers of installations for the generation of ionising radiation, X-ray equipment, stray radiation emitters, irradiation facilities and other equipment, devices and tools used in relation to practices, must provide information about these devices to the radiation protection executive. The statutory ordinance may stipulate in particular

1. when the manufacturer or supplier must provide the radiation protection executive with information for which of the aforementioned devices,
2. what details and documents must be made available,
3. for what purpose the documents must be suitable and what requirements they must satisfy,
4. that the information must also be made available to persons who intend to become radiation protection executives.

Part 3

Radiation protection in emergency exposure situations

Chapter 1

Emergency management system of the Federation and the *Länder*

Division 1

General principles of emergency preparedness and response

Section 92

General principles of emergency preparedness and response

(1) The provisions of the following subsections (general principles of emergency preparedness and response) shall be considered as stipulations in the evaluation of dangers which may arise in emergencies due to ionising radiation

1. when adopting, reviewing and amending emergency response plans and statutory ordinances in accordance with this Chapter and in accordance with section 117,
2. for the competent authorities when responding to emergencies, and for authorities and organisations involved in emergency response on the basis of this Act, of the statutory ordinances referred to in no. 1, as well as to the legal provisions of the Federation and the *Länder* to avert dangers to human health, the environment or public safety, insofar as they are also applicable to radiological risks, and of directly-applicable legal acts of the European Union and of the European Atomic Energy Community, insofar as these do not make conclusive stipulations for the Member States in respect of radiological risks.

(2) Actual levels are where possible to fall short of the reference levels defined in this Act, and in the statutory ordinances issued on the basis of this Act for the protection of the public and of emergency workers.

(3) In accordance with the scientific state-of-the-art, and taking all the circumstances of the respective emergency into account, appropriate measures shall be taken to keep the exposure levels of the public and emergency workers in emergency situations, as well as contamination of the environment, as low as possible, even where they fall short of the reference levels.

Division 2

Reference, dose and contamination levels; waste and installations

Section 93

Reference levels for the protection of the public; empowerments to issue ordinances

(1) When planning protective measures, and when making decisions on their implementation in an emergency, in the interest of the protection of the public, a reference level of 100 mSv shall apply to the effective dose that an exposed individual would receive within one year as a result of the emergency, if the envisaged protective measures had been taken. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating procedures and assumptions to assess the extent to which actual values have fallen short of, maintained or exceeded this reference level.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing additional appropriate reference levels for equivalent organ doses for potential emergencies or for an emergency that has already occurred. This shall apply especially to facilitating cooperation with other Member States of the European Union and of the European Atomic Energy Community, or with third countries, for the protection of the public.

(3) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing a lower reference level for the effective dose relating to one year or to a single exposure for an emergency that has already occurred.

Section 94

Dose levels and contamination levels for protection of the public; empowerments to issue ordinances

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall issue a statutory ordinance, with the consent of the Bundesrat, establishing dose levels for potential emergencies, which shall serve as a radiological criterion for the appropriateness of the following protective measures

1. instruction to remain indoors,
2. distribution of iodine tablets or instruction to take iodine tablets, and
3. evacuation.

These levels shall relate to the dose that exposed individuals would receive without protective measures in a defined period once the emergency had occurred.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing dose limits for emergency-related contamination or dose rates for

potential emergencies, for an emergency that has already occurred, and for an existing exposure situation after an emergency,

1. for members of the public,
2. for drinking water,
3. for foodstuffs, animal feed, consumer goods, cosmetics and products within the meaning of section 2 subsection (1) of the Tobacco Products Act (*Tabakerzeugnisgesetz*),
4. for medicinal products and their precursor materials, and for medical devices,
5. for other products, objects and substances,
6. for vehicles, goods or luggage, and
7. for contaminated areas, especially for contaminated land and bodies of water

where it is to be presumed that members of the public will be at risk from ionising radiation if these dose limits are exceeded. These limits shall be used to implement optimised protection strategies in accordance with section 98 subsection (3), first sentence, no. 1.

(3) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, without the consent of the Bundesrat, repealing statutory ordinances in accordance with subsection (2), declaring said ordinances temporarily invalid, or adjusting their wording to a remaining scope, insofar as they have become permanently or temporarily inapplicable by virtue of the handing down of corresponding provisions contained in directly-applicable acts of law of the European Atomic Energy Community or of the European Union.

(4) The statutory ordinances in accordance with subsections (1) and (2) may also lay down

1. procedures and assumptions for the measurement, calculation or estimation of the dose levels, contamination levels or dose rate levels, or
2. conditions under which these levels apply.

(5) Statutory ordinances in accordance with subsection (2) shall be handed down in consultation with the Federal Ministry of Health, with the Federal Ministry of Food and Agriculture, with the Federal Ministry for Economic Affairs and Energy, with the Federal Ministry of Labour and Social Affairs, with the Federal Ministry of Transport and Digital Infrastructure, with the Federal Ministry of the Interior and the Federal Ministry of Finance.

Section 95

Managing waste that may be contaminated as the result of an emergency, establishing and operating installations, empowerments to issue ordinances

(1) The Federal Government shall issue a statutory ordinance, with the consent of the Bundesrat, for potential emergencies, for an emergency that has already occurred, and for an existing exposure situation after an emergency, establishing contamination levels for waste and other objects or substances that have been or may be contaminated because of an emergency. If actual levels fall short of these contamination levels, it shall be assumed that the requisite protection is in place for human beings and the environment against the

harmful effects of ionising radiation, without additional special protective measures, for managing this waste and establishing and operating or using the installations referred to below in accordance with the Circular Economy Act and with other Federal legislation applicable to waste and to the installations, and the statutory ordinances based on this legislation

1. installations in which this waste is disposed of,
2. waste water plants that take waste water that has been or may have been contaminated by an emergency,
3. installations in which this waste or these other objects or substances have been, or may be, stored, used or treated, especially as fuel, raw materials, materials, precursors, lubricants, solvents or other tool.

(2) In order to ensure protection for human beings and the environment against the harmful effects of ionising radiation, the Federal Government shall issue a statutory ordinance, with the consent of the Bundesrat, introducing regulations to avoid, use, dispose of or otherwise manage waste which has been or may be radioactively contaminated because of an emergency, to establish and operate the installations referred to in subsection (1), second sentence, and to introduce the supplementary requirements and exceptions to the following legal provisions for water supervision, or permit the competent authorities to grant exceptions to these legal provisions,

1. to the Circular Economy Act and to the other Federal legislation applicable to waste and to the statutory ordinances based on this legislation, and
2. to Federal legislation that applies to establishing and operating the installations referred to in subsection (1), second sentence, and to the statutory ordinances based on this legislation.

Exceptions may only be regulated, permitted or granted if no danger to human health is expected as a result, and if such are not precluded by legal acts of the European Union or of the European Atomic Energy Community. Such exceptions shall minimise or not lead to significant disadvantages for the general public or the local area, insofar as this is feasible and reasonable, taking into account the radiological situation and the other significant circumstances of the exception for the emergency in question. With regard to the exceptions and supplementary rules, requirements shall be taken into account to prevent harmful environmental effects and other dangers, and to prevent significant disadvantages and significant nuisances, especially in terms of suitable measures being taken in accordance with the state of the art.

(3) The rules in accordance with subsection (2) shall particularly apply to

1. the ranking of the measures to avoid and manage waste,
2. requirements as to the harmlessness of recovery,
3. the arrangement and execution of waste disposal,
4. requirements relating to the establishment and operation of landfill sites and their approval, including the approval procedure,
5. requirements relating to monitoring waste management,
6. requirements for collectors, carriers, dealers and brokers of waste and their approval,

including the approval procedure,

7. requirements relating to the establishment, characteristics, operation and substantial alterations to the installations referred to in subsection (1), second sentence, requirements as to the approval of such installations, including the approval procedure, as well as to the condition of the installations and the site after operation has ceased,
8. requirements relating to the use of the waste water plants referred to in subsection (1), second sentence, no. 2,
9. requirements relating to the use of bodies of water, with particular regard to the introduction and discharge of substances into a body of water; the requirements may also be defined for the location of the waste water release, or before it mixes,
10. requirements relating to the fulfilment of the waste water disposal obligation,
11. requirements relating to the monitoring of the characteristics of a body of water,
12. measuring methods and procedures, especially as part of waste water disposal and monitoring of the characteristics of a body of water,
13. obligations of the operator of the installations referred to in subsection (1), second sentence,
14. the conditions under which the competent authorities may grant exceptions on the basis of a statutory ordinance in accordance with subsection (2), and
15. the requirements that must be met in order to fulfil the obligations arising from subsection (2), second and third sentences.

(4) The *Länder* shall define which legal persons are obliged as public disposal providers within the meaning of section 17 of the Circular Economy Act to dispose of such waste from private households and from other sources as is not or may not be treated, stored or deposited in the installations or facilities designated for the disposal of other waste, due to its contamination as the result of an emergency.

(5) Section 94 subsections (3) and (4) shall apply *mutatis mutandis* to statutory ordinances in accordance with subsections (1) to (3).

Section 96

Fast-track legislation

- (1) In the event of urgent necessity once an emergency has occurred,
 1. the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety may adopt regulations in accordance with sections 93, 94 and 95 subsection (1), and
 2. the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, or the Federal Ministry with responsibility for waste management regulations outside the scope of the Circular Economy Act, or for regulations on the establishment and operation of the installations referred to in section 95 subsection (1), second sentence, no. 2, may adopt regulations in accordance with section 95 subsections (2) and (3),

by statutory ordinance without the consent of the Bundesrat and without the agreement of the Federal Ministries involved (fast-track legislation), insofar as no corresponding regulations already exist, or insofar as the existing regulations are insufficient.

(2) Fast-track legislation shall lapse at the latest six months after coming into force. Its period of validity may only be extended by statutory ordinance with the consent of the Bundesrat and in agreement with the Federal Ministries that must be involved. Fast-track legislation that amends existing regulations shall be repealed without undue delay if the Bundesrat so requests.

Division 3

Emergency preparedness

Section 97

Collective regulations for emergency response plans

(1) The Federation and the *Länder* shall prepare emergency response plans in accordance with sections 98, 99, 100 and 101. These emergency response plans shall illustrate the planned adequate responses to potential emergencies using specific reference scenarios. The emergency responses to be illustrated shall cover

1. the protective measures, which shall include the following
 - a) measures to avoid or reduce exposure and contamination of human beings or the environment, and
 - b) measures for medical treatment or care after exposure,
2. other measures that shall be taken in an emergency by the authorities involved, and by other organisations, in order to prevent or minimise harmful effects of the emergency for human health or the environment, especially measures to review, prepare, implement, monitor, amend or cancel protective measures and to cooperate and coordinate in the event of emergencies.

(2) The emergency response plans are to enable the authorities and organisations involved in emergency response to make coordinated decisions without undue delay, and to take the appropriate action in a timely manner in the event of an emergency.

(3) The authorities responsible for developing the emergency response plans shall

1. coordinate their emergency response plans with one another, insofar as this is required for the preparation of a coordinated emergency response, and
2. strive within the framework of their responsibilities to appropriately coordinate their emergency response plans with other Member States of the European Union and of the European Atomic Energy Community, and in accordance with the principles of reciprocity and equivalence with third countries.

(4) A group of representatives to be selected in each instance from Academia, the affected industries, environmental associations, local authorities and municipal associations, organisations involved in emergency preparedness and response, and from other stakeholders and from the supreme *Land* authority competent for the area in question, is to be heard with regard to the draft emergency response plans of the Federation, the draft statutory ordinances in accordance with sections 93 to 95 and section 117 subsection (1), and the drafts of substantial changes to these emergency response plans and statutory ordinances. The first sentence shall not apply to the enactment of fast-track legislation in accordance with sections 93 to 95 and section 117 subsection (2), or to the enactment, amendment and supplementation of statutory ordinances and emergency response plans for an emergency that has occurred in accordance with sections 94 and 111. A group of stakeholders to be selected by the *Land* is to be consulted on the drafts of the general and special emergency response plans of the *Länder*, and on substantial changes to these emergency response plans. The *Länder* may restrict the hearing to relevant *Land*- or area-specific substantiation or supplementation of the optimised protection strategies and measures described in the

emergency response plans of the Federation.

(5) Until the Federation enacts emergency response plans or statutory ordinances in accordance with sections 93 to 95, the corresponding definitions and illustrations contained in the documents referred to in Annex 4 shall apply on a provisional basis as the emergency response plans of the Federation. Until the *Länder* issue emergency response plans in accordance with section 100, the corresponding definitions and illustrations in *Länder* plans, concepts and decrees, in relation to disaster response or other defences against dangers for human health, the environment or public safety, shall apply on a provisional basis as the general and specific emergency response plans of the *Länder*.

Section 98

General emergency response plan of the Federation

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall evaluate potential emergency exposure situations. The Federal Government shall create a general emergency response plan of the Federation, based on the Ministry's proposal. The general emergency response plan of the Federation shall be passed as a general administrative regulation with the consent of the Bundesrat.

(2) The general emergency response plan of the Federation shall include

1. defined reference scenarios which the Federation and the *Länder* shall use as the basis of their planning for emergency responses, and
2. the following general planning for potential emergencies within or outside the scope of this Act
 - a) planning of the Federation,
 - b) planning of the European Union and the European Atomic Energy Community, their Member States and third countries, as well as
 - c) planning by international organisations and planning within the framework of international treaties.

(3) The general emergency response plan of the Federation shall cover, in particular

1. coordinated strategies for the protection of the public and workers, optimised for the reference scenario in question, which shall also take into account particularly-vulnerable persons (optimised protection strategies), and
2. the other elements referred to in Annex 5.

The general emergency response plan of the Federation may also include references to the emergency response plans of the *Länder*, local authorities and municipal associations, and of other organisations involved in emergency preparedness and response, or may provide summaries of such emergency response plans.

Section 99

Special emergency response plans of the Federation

(1) The Federal Government shall supplement and substantiate the special emergency response plan of the Federation with specific emergency response plans at the proposal of the Federal Ministries responsible for the respective specialist areas. The special emergency response plan of the Federation emergency response plan shall be adopted as general administrative provisions with the consent of the Bundesrat.

(2) The special emergency response plan of the Federation emergency response plan shall present planning for the following areas of application in particular

1. for disaster response, general security and relief, as well as for medical treatment and care after the exposure of the public and workers,
2. for drinking water production and supply,
3. for the production of plant and animal products, for food, feed, consumer goods, cosmetics, and for products within the meaning of section 2 subsection (1) of the Tobacco Products Act,
4. for medicinal products and their precursor materials, as well as for medical devices,
5. for other products, objects and substances,
6. for the transportation of goods,
7. for cross-border transportation of people, vehicles, goods and baggage,
8. for contaminated areas, especially for contaminated land and bodies of water,
9. for the of waste and for the disposal of waste water, as well as for the establishment and operation of the installations referred to in section 95 subsection (1), second sentence.

(3) The special emergency response plans shall cover the elements referred to in Annex 6 in particular. Section 98 subsection (3), second sentence, shall apply *mutatis mutandis*.

Section 100

General and specific emergency response plans of the *Länder*

The *Länder* shall prepare general and specific emergency response plans. These *Länder* emergency response plans shall supplement and substantiate the general emergency response plan of the Federation and the special emergency response plans of the Federation emergency response plan, insofar as the *Länder* are responsible for planning or for taking protective measures.

Section 101

External emergency response plans for fixed installations or facilities with particular risk potential

(1) The authorities responsible for disaster response or public safety shall prepare special protection plans (external emergency response plans) in accordance with their *Land* law provisions for the area surrounding nuclear installations, installations within the meaning of the second half of section 9a subsection (3), first sentence, of the Atomic Energy Act, installations for the production of ionising radiation, or installations within the meaning of section 5 subsection (12) of this Act, insofar as emergencies in the facility or installation may lead to serious health problems for a substantial number of people in the area surrounding the facility or installation.

(2) The external emergency response plans shall supplement and substantiate the planning included in the general and specific emergency response plans of the Federation Government and the *Länder*. They shall incorporate the local characteristics, as well as the provisions made by the radiation protection executives for on-site emergency response.

Section 102

Emergency exercises

(1) The authorities and organisations who are involved in emergency response in accordance with the emergency response plans of the Federation and the *Länder*, as well as the managers responsible for the basic and further training of workers in accordance with section 115 subsection (1), shall regularly conduct emergency exercises.

(2) The emergency exercises shall vary in terms of the type of exercise, scope, emergency scenarios and parties involved. The following shall be tested and exercised, in particular

1. organisational provisions for emergency response, and
2. information exchange and the cooperation of the authorities, organisations and radiation protection executives involved in the emergency response in accordance with the emergency response plans for
 - a) collecting information on and evaluating the situation,
 - b) coordinating the decisions taken by the competent authorities, and
 - c) executing appropriate protective measures.

Section 103

Reviewing and amending the emergency response plans

(1) The emergency response plans of the Federation and the *Länder* shall be regularly reviewed, and where necessary amended, taking into account the experiences of the emergency exercises, findings from emergencies in Germany and abroad, and changes in the scientific state-of-the-art and the legal situation.

(2) The information supplementing the emergency response plans, such as contact details for the competent authorities and organisations involved, or the lists of applicable legal provisions, shall be updated in the event of changes, and shall be regularly reviewed. The deadlines for the reviews shall be defined in the emergency response plans.

Section 104

Procuring protective materials

(1) The authority competent in accordance with section 192 subsection (1) shall procure protective materials to the extent necessary to supply the public in Germany in the event of potential emergencies. It shall provide these protective materials to the *Länder* for disaster response for stockpiling, distribution and issue to the public.

(2) Protective materials shall include medicinal products

1. which are suitable to prevent the absorption of radioactive iodine into the human thyroid, or
2. which are suitable to prevent the absorption of radionuclides into the human body or to remove radionuclides from the human body.

Section 105

Informing the public about protective measures and recommendations for steps to be taken in the event of potential emergencies

(1) The competent agencies of the Federation shall publish the emergency response plans of the Federation in accordance with section 10 of the Environmental Information Act (*Umweltinformationsgesetz*).

(2) The competent agencies of the Federation

1. shall inform the public in accordance with section 10 of the Environmental Information Act in a suitable manner
 - a) regarding the basic concepts of radioactivity and the effects of radioactivity on human beings and the environment,
 - b) regarding the emergencies considered in the emergency response plans and their consequences for the population and the environment,
 - c) regarding planned measures to warn and protect the population in the event of potential emergencies,
2. shall provide the public with recommendations for steps to be taken in the event of potential emergencies.

(3) The *Länder* shall inform the public regarding the matters referred to in subsection (2) no. 1 in accordance with the *Land* law provisions, and shall provide the public with recommendations for steps to be taken in the event of potential emergencies, which shall supplement and substantiate the recommendations made in subsection (2) no. 2.

(4) The information and recommendations for steps to be taken shall be updated regularly and in the event of major amendments, and the updated version shall be published without request. They must always be available to the public.

Division 4

Radiological situation, emergency response

Section 106

Radiological Situation Centre of the Federation

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall establish a Radiological Situation Centre of the Federation.

(2) The Radiological Situation Centre of the Federation shall have the following tasks

1. collecting, evaluating and documenting data about regional and supra-regional emergencies,
2. creating the radiological situation report in accordance with section 108 subsection (2), first and third sentences,
3. providing or sending this radiological situation report to the *Länder* and to the joint reporting and situation centre of the Federation and the *Länder* in the Federal Office of Civil Protection and Disaster Assistance (BBK),
4. providing or sending this radiological situation report to the supreme *Land* authority stipulated in the general emergency response plan of the Federation,
5. exchanging information on the radiological situation and on its evaluation within the Federal Government and with the *Länder*, as well as with other Member States, with bodies and institutions of the European Union and of the European Atomic Energy Community, with third countries and with international organisations, insofar as no other competence has been stipulated by an Act or on the basis of an Act,
6. coordinating the protective measures and the measures for informing the public and relief efforts in the event of emergencies within the Federal Government and with the *Länder*, as well as with other Member States, with bodies and institutions of the European Union and of the European Atomic Energy Community, with third countries and with international organisations, insofar as no other competence has been stipulated by an Act or on the basis of an Act,
7. informing the public and recommending steps to be taken in the event of emergencies in accordance with section 112 subsection (3),
8. coordinating the measurements taken by the Federation and by the *Länder* and other organisations involved in managing the emergency in order to complete the radiological situation report and the database for dose estimation.

(3) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall be supported in the performance of its tasks by the Federal Office for Radiation Protection (BfS), by the Federal Office for the Safety of Nuclear Waste Management (BfKEG), by the German Organisation for Reactor Safety (GRS), and by the Federal Office of Civil Protection and Disaster Assistance (BBK).

Section 107

Tasks of the *Länder* in terms of investigating and evaluating the radiological situation

The *Länder* shall, without undue delay, provide the Radiological Situation Centre of the Federation with

1. data that are sent to the Federal Centre for the Monitoring of Environmental Radioactivity (ZdB) in accordance with section 162 subsection (2),
2. communications from the radiation protection executive regarding a supra-regional or regional emergency on their *Land* territory, or an event occurring in their *Land* territory, which may lead to such an emergency, or
3. other findings relating to a supra-regional or regional emergency occurring on their *Land* territory,
4. the relevant data, in the event of a supra-regional or regional emergency occurring on their *Land* territory, for the radiological situation relating to the installation or source of the radiation, to the radiological inventory and to releases and release estimates and forecasts,
5. the facility-based measurement data, in the event of a supra-regional or regional emergency occurring in Germany or in other countries close to its borders, which come from installation-based measurement programmes for emissions monitoring or from other emissions measurements taken on a situation-dependent basis,
6. communications, in the event of supra-regional or regional emergencies, regarding the protective measures taken by the competent *Land* authorities, as well as regarding information for the population and recommended steps to be taken in accordance with section 112 subsection (2), and
7. communications regarding the effectiveness of these protective measures and recommended steps to be taken.

Section 108

Radiological situation report

(1) A radiological situation report shall be created once a supra-regional or regional emergency has occurred. The radiological situation report shall include, describe and assess the information in accordance with sections 106, 107 and 161 to 163 and other relevant information regarding the manner, scope and anticipated development of the radiological situation. The radiological situation report shall be updated as the emergency and the relevant information develop. Insofar as a dose estimate exists in accordance with section 111 subsection (1), this shall also be included in the radiological situation report.

(2) In the event of a supra-regional emergency, the radiological situation report shall be prepared by the Federal Radiological Situation Centre. In the event of a regional emergency, the radiological situation report shall be prepared by the *Land* in which the emergency has occurred. The *Land* may pass this task on to the Federal Radiological Situation Centre in general or on a case-by-case basis in agreement with the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety; the Federal Radiological Situation Centre may undertake this task in consultation with the *Land* on a case-by-case basis. If the Federal Radiological Situation Centre is responsible for preparing the radiological situation

report, it may pass the task of updating the radiological situation report, in agreement with the competent supreme *Land* authority, to the *Land* in which the emergency has occurred, where the further effects of this emergency are likely to be restricted primarily to this *Land*.

(3) The Federal Government may define in the general emergency response plan of the Federation when an emergency is to be considered supra-regional, regional or local emergency response plan, with the consent of the Bundesrat, particularly by means of the reference scenarios described therein.

(4) In the event of an emergency in a nuclear installation or facility which requires a licence in accordance with section 6, 7 or 9 of the Atomic Energy Act or plan approval in accordance with section 9b of the Atomic Energy Act, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety may stipulate, by administrative arrangement with the competent supreme *Land* authority, that the *Land* in which the nuclear installation or facility is situated shall present its regional data to the Federal Radiological Situation Centre, in addition to the data in accordance with section 107, namely up to the distance from the nuclear installation or facility that is allowed from a diagnostic and prognostic perspective within the parameters of the *Land's* procedures and technical equipment.

Section 109

Decisions relating to protective measures by the competent authorities

(1) The competent authorities shall decide whether protective measures are to be taken in the event of an emergency, and which protective measures are appropriate for this emergency, in accordance with the statutory ordinances on the basis of sections 94 to 96 and, unless stipulated otherwise therein, on the basis of

1. the legal provisions of the Federation and the *Länder* that are applicable to such measures in order to avert dangers to human health, the environment or public safety, and
2. directly-applicable legal acts of the European Union and of the European Atomic Energy Community,

insofar as such legal provisions and legal acts are also applicable to radiological dangers. The emergency response plans shall be followed when making such decisions, and the radiological situation as well as such other circumstances of the respective emergency as are relevant to the decision, shall be taken into account.

(2) In the event of supra-regional and regional emergencies, the radiological situation report in accordance with section 108 shall be material to the evaluation of the radiological situation.

(3) As the emergency progresses, the competent authorities shall review whether the protective measures need to be modified, supplemented or terminated. They shall take account thereby of the effectiveness of the protective measures taken, as well as of any changes to the radiological situation, and to the other circumstances related to the emergency.

Section 110

Cooperation and coordination in emergencies

The authorities and organisations that are involved in making decisions regarding protective measures or their implementation shall work together in accordance with the emergency response plans. The decisions and protective measures shall be coordinated to the extent necessary, insofar as this does not hinder or unreasonably delay the prompt implementation of appropriate protective measures.

Section 111

Estimating doses, assessing the effectiveness of the protective measures, modifying emergency response planning in the event of supra-regional and regional emergencies

(1) In the event of a supra-regional or regional emergency, the authority or agency responsible for preparing the radiological situation report shall estimate the dose that affected groups of the population have already absorbed as a result of the emergency, and which they are likely to still absorb (dose estimate).

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall, in the event of a supra-regional or regional emergency, compare the results of the dose estimate with the reference level, and shall assess the effectiveness of the protective measures, of the recommended steps to be taken, and of the protection strategies that have been applied. It shall review whether the reference levels for the protection of the public, the dose levels and the limits for emergency-related contamination, or dose rates, need to be adjusted because of the radiological situation and of the other relevant circumstances of the respective emergency, or due to changes in these circumstances that have occurred or are expected to occur. It shall take into account thereby the emergency response principles, the results of the dose estimate, as well as the information regarding the protective measures that have been taken and which are planned, and recommended steps to be taken, which have been prepared by the competent Federal and *Land* authorities in accordance with sections 106 and 107.

(3) In the event of a supra-regional or regional emergency, the competent Federal Ministries shall review, within the scope of their competences referred to in section 98, section 99 and section 96 subsection (1), whether the protection strategies, the protective measures, the recommended steps to be taken and other provisions that are defined in the emergency response plans of the Federation and in statutory ordinances in accordance with section 95 need to be adjusted because of the radiological situation and of the other relevant circumstances of the respective emergency, or due to changes in these circumstances that have occurred or are expected to occur. They shall take into account thereby the results of the assessment of the effectiveness of the protective measures, the recommended steps to be taken and applied protection strategies.

(4) If necessary for coordinated and appropriate decisions on the necessary protective measures, or their implementation, in the event of a supra-regional or regional emergency, the Federal Government shall amend or supplement the Federal emergency response plans for this emergency by means of general administrative provisions with the consent of the Bundesrat, at the proposal of the competent Federal Ministries.

(5) When there is an urgent necessity in the event of a supra-regional or regional emergency, the Federal Government is hereby empowered to issue individual instructions in accordance with section 84 subsection (5) of the Basic Law for this emergency

1. to specify which of the optimised protection strategies defined in the emergency response plans for specific reference scenarios are to be applied fully or partially, if this emergency may potentially deviate considerably from the reference scenarios, or if the findings with regard to this emergency are still insufficient to assign it to a specific reference scenario, or
2. to define guideline values for emergency-related contamination or dose rates.
 - (6) Urgent necessity shall be deemed to exist where
 1. the optimised protection strategies defined in the emergency response plans of the Federation, or the protection strategies defined in these emergency response plans, and in statutory ordinances issued in accordance with this Chapter, taking into account the estimates in accordance with subsections (1) and (2), as well as international collaboration and coordination, are inadequate or insufficient, and
 2. it is likely not to be feasible to enact or modify statutory ordinances in accordance with this Chapter or emergency response plans of the Federation in time for this emergency.

Section 112

Information for the affected public and recommended steps to be taken in the event of an emergency

(1) If a local emergency occurs, the authorities competent in accordance with *Land* law shall inform the potentially-affected public without undue delay regarding the emergency, and shall provide it with suitable recommendations on the steps to be taken in this emergency.

(2) In the event of supra-regional and regional emergencies which have caused or may cause a disaster within their area of competence, the authorities responsible for disaster response shall inform the potentially-affected public within their area of competence regarding the emergency that has occurred without undue delay, and shall provide it with suitable recommendations on the steps to be taken in this emergency.

(3) In the event of supra-regional and regional emergencies, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall inform the potentially-affected public without undue delay, and shall provide it with suitable recommendations on the steps to be taken in this emergency, unless the authorities responsible for disaster response in accordance with subsection (2) are responsible for informing the population and recommending steps to be taken.

(4) The information, instructions and recommended steps to be taken shall cover the points listed in Annex 7 that are applicable to the emergency in question.

Chapter 2

Protection of emergency workers

Section 113

Information, basic and further training of emergency workers as an element of emergency preparedness

(1) Persons who are identified in the emergency response plans of the Federation or of the *Länder*, or in the internal planning of the radiation protection executives,

1. as emergency workers,
2. as specialists involved in making decisions about tasks and measures to be undertaken by emergency workers, or
3. as persons responsible for instructing emergency workers in the event of an emergency

shall be given adequate information, on the health risks their intervention in an emergency might involve, and on the protective and monitoring measures to be taken in such an intervention and shall as well receive congruous basic and further training regarding.

(2) The information, as well as the basic and further training shall take into account the range of emergencies covered in the emergency response plans and the corresponding different types of interventions, involvements in decision making and/or instructions. The content of the information, basic and further training, as well as the teaching and learning resources, shall be updated regularly. Where appropriate, the basic and further training shall also include participation in emergency exercises.

Section 114

Protection of emergency workers during emergency response actions

(1) Protective and monitoring measures that are appropriate to the purpose of the deployment shall be taken during emergency response actions with the objective that emergency workers' exposure in this emergency exposure situation remains below the levels stipulated as dose limits for planned exposure situations in section 78 of this Act. Exposure of emergency workers shall be deemed to constitute occupational radiation exposure within the meaning of section 3 subsection (2) no. 31 of the Radiation Protection Ordinance.¹

(2) Provided that it is not possible to comply with one of the values referred to in subsection (1), even by taking adequate protective and monitoring measures during intervention in order to protect life or human health, efforts shall be made to ensure that emergency workers' exposure does not exceed the reference level for the effective dose of 100 mSv. Emergency workers must be adequately informed, prior to the respective emergency response action, about the associated health risks and the protective and monitoring

¹ Translation of section 114 subsection (1), as amended by Article 2 no. 3 (a) of the Act of 27 June 2017 to Reform the Legislation on Protection against the Harmful Effects of Ionising Radiation (Federal Law Gazette, Part I 1966, p. 2058), which entered into force on 31 December 2018 in accordance with Article 32 para. 2, second sentence, of that Act.

measures to be taken. Emergency workers who have already received general information (on health risks and protective and monitoring measures) in the course of emergency preparedness shall be given supplementary information and instructions appropriate to the circumstances of the emergency in question. Pregnant women and persons under the age of 18 may not be deployed in situations referred to in the first sentence.

(3) Provided that, even when adequate protective and monitoring measures are taken, an effective dose of 100 mSv may be exceeded during intervention in order to save life, to prevent serious radiation-induced health effects, or to prevent or respond to a disaster, efforts shall be made to ensure that emergency workers' exposure does not exceed the reference level for the effective dose of 250 mSv. In exceptional cases in which it is possible that the effective dose may exceed the level of 250 mSv even when appropriate protective and monitoring measures are taken, the command and control post may stipulate an increased reference level of 500 mSv. Intervention in accordance with the first and second sentences may only be undertaken by volunteers who have been informed of the possibility of such exposure prior to the intervention in question. Subsection (2), second and fourth sentences, shall apply *mutatis mutandis*.

(4) Efforts shall be made to ensure that workers who have already been exposed in an emergency to an effective dose of more than 250 mSv, or for whom the limit of the occupational life dose stipulated in section 77² has been reached, are not deployed during further emergencies in situations referred to in subsection (3).

(5) When determining or estimating a worker's exposure in an emergency exposure situation, the determined or estimated body doses of all interventions undertaken by the emergency worker in this emergency exposure situation shall be added. The exposure which an emergency worker received during his or her interventions in an emergency exposure situation shall be taken into account in regard of the limit for the occupational life dose stipulated in section 77.

Section 115

Responsibility for the protection of emergency workers

(1) Responsibility for providing information, as well as basic and further training of own workers shall lie with

1. the radiation protection executives,
2. the authorities competent for or involved in emergency response measures in accordance with the emergency response plans of the Federation and the *Länder*, and
3. the organisations involved in emergency response.

(2) Responsibility for the protection of emergency workers deployed in emergency response actions shall lie with

1. the radiation protection executives with regard to their own emergency workers and

² Translation of section 114 subsections (4) and (5), as amended by Article 2 no. 3 (b) of the Act of 27 June 2017 to Reform the Legislation on Protection against the Harmful Effects of Ionising Radiation (Federal Law Gazette Part I 1966, 2058), which entered into force on 31 December 2018 in accordance with Article 32 para. 2, second sentence, of that Act.

emergency workers deployed on their behalf,

2. with regard to other emergency workers, this shall lie with
 - a) the authority in command of the emergency response actions of several authorities or organisations involved in the emergency response, or
 - b) the authorities and organisations competent for or involved in the emergency response measures, insofar as the emergency workers are not under the control of an authority in command of the emergency response.

Section 116

Protection of workers deployed in other hazardous situations

Sections 113 to 115 shall apply *mutatis mutandis* to preparing for and implementing actions that do not serve to combat an emergency within the meaning of this Act, but which do serve to combat another hazardous situation in which the deployed workers may be exposed to ionising radiation.

Section 117

Empowerments to issue ordinances for the protection of emergency workers

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance

1. regulating the main content of the information, basic and further training prescribed in section 113,
2. regulating the type and content of the information prescribed in section 114 subsections (2) and (3),
3. stipulating the other regulations described in section 76 subsection (1) and section 79 on physical radiation protection controls, protection areas, precautionary, protective, and monitoring measures with a view to protect the emergency workers,
4. specifying which persons, authorities or organisations shall be responsible for the measures for the protection of emergency workers provided for in no. 3.

Statutory ordinances in accordance with the first sentence, nos. 2 to 4, shall require the consent of the Bundesrat.

In the event of urgent necessity once an emergency has occurred, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety may adopt provisions in accordance with subsection (1), first sentence, nos. 2 to 4, by statutory ordinance without the consent of the Bundesrat (fast-track legislation), insofar as no corresponding provisions yet exist. Fast-track legislation shall lapse at the latest six months after coming into force. Its period of validity may only be extended by statutory ordinance with the consent of the Bundesrat and in agreement with the Federal Ministries that must be involved. Fast-track legislation that amends existing regulations shall be repealed without undue delay if the Bundesrat so requests.

(2) *Land* legislation shall regulate whether and to what extent statutory ordinances in accordance with subsection (1), first sentence, no. 1, shall also apply to the employees of competent *Land* or local authorities and those of other corporate bodies, institutions and foundations under public law of the *Länder*, and those of private relief organisations which are involved in disaster response or in the execution of other provisions of *Land* legislation for danger aversion hazard/danger control and aid and assistance.

(3) The basic right of physical integrity (Article 2 para. 2, first sentence, of the Basic Law) shall be restricted in accordance with subsection (1), first sentence, no. 3.

Part 4

Radiation protection in existing exposure situations

Chapter 1

Exposure situations existing following an emergency

Section 118

Transition to an existing exposure situation; empowerments to issue ordinances

(1) Where the radiological situation in the event of a supra-regional or regional emergency has essentially stabilised, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (BMUB) shall also estimate, in the course of assessing effectiveness in accordance with section 111 subsection (2), whether the effective dose in the exposed population is likely to exceed the level of 1 mSv per year in the following year in Germany or parts thereof as a result of the emergency. If the level of 1 mSv is likely to still be exceeded in the following year in Germany or parts thereof, the reviews to be conducted by the competent Federal Ministries in accordance with section 111 subsections (3) and (4) shall also be extended to

1. whether and how long appropriate protective measures and other measures in accordance with Part 3 are still required in Germany or parts thereof, with a view to ensuring that the effective dose in the exposed population is brought below the level of 20 mSv as soon as possible, and
2. whether and from what date, in applying the legal provisions on existing exposure situations through appropriate protective, remedial or other measures, the effective dose can be reduced further and can be brought as far below the reference level set out in subsection (4) as possible.

(2) If a reduction in the effective dose is possible, the Federal Government shall, at the proposal of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, issue a plan of the Federation for the protection of the public in the exposure situation existing after an emergency, in compliance with sections 92 and 97 subsections (1) to (4), first to third sentences, as well as section 98. This plan shall be adopted as a general administrative regulation with the consent of the Bundesrat.

(3) At the proposal of the Federal Ministries responsible for the respective areas, the Federal Government may where necessary supplement and substantiate the plan of the Federation in accordance with subsection (2) with specific plans of the Federation, which shall outline the special planning for measures in accordance with subsection (1), second sentence, no. 2, for specific applications as referred to in section 99 subsection (2). These specific plans of the Federation shall be adopted as general administrative regulations with the consent of the Bundesrat.

(4) After a supra-regional or regional emergency in accordance with subsection (1), second sentence, no. 2, the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall issue a statutory ordinance, with the consent of the Bundesrat, establishing a reference level for the effective dose for an existing exposure situation which exposed individuals receive via all pathways of exposure if the stipulated protective

measures have been taken. The reference level may not exceed 20 mSv per year. The statutory ordinance shall furthermore establish the areas in which, and the date from which, the reference levels, sections 119, 120 and 152, as well as plans in accordance with subsections (2) and (3), are to be applied.

(5) Insofar as is required for the adequate protection of the population, the *Länder* shall set out *Land* plans, which shall supplement and substantiate the plans of the Federation in accordance with subsections (2) and (3), for this existing exposure situation, insofar as the *Länder* are responsible for the planning or execution of measures in accordance with subsection (1), second sentence, no. 2.

(6) Where the radiological situation in the event of a local emergency has essentially stabilised, but the effective dose in the exposed population due to the emergency still exceeds the level of 1 mSv per year, the competent authority shall define by means of a general order a reference level for the effective dose which exposed individuals receive because of the emergency via all pathways of exposure, if the stipulated protective measures have been taken. The reference level may not exceed 20 mSv per year. The competent authority may additionally define appropriate reference levels for equivalent organ doses.

Section 119

Radiological situation, measures, collaboration and coordination in an exposure situation existing after an emergency

Sections 92 and 106 to 111 shall be applied accordingly in the event of an existing exposure situation after an emergency. The reference levels in accordance with section 118 subsection (4) or (6) shall apply to the protection of the public in place of the reference levels in accordance with section 93; the emergency response plans in accordance with sections 98 to 100 shall apply in place of the plans in accordance with section 118 subsections (2), (3) and (5).

Section 120

Information for the population and recommended steps to be taken

(1) Plans of the Federation in accordance with section 118 subsections (2) and (3) shall be published by the competent agencies of the Federation in accordance with section 10 of the Environmental Information Act (*Umweltinformationsgesetz*).

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall inform the affected population regarding an existing supra-local exposure situation existing after a supra-regional or regional emergency. Section 105 subsection (2) shall apply *mutatis mutandis*.

(3) The competent *Land* authorities shall supplement and substantiate the information provided and steps to be taken recommended by the Federal Government in the event of a supra-regional or regional emergency. Section 105 subsection (3) shall apply *mutatis mutandis*.

(4) The competent authorities in accordance with *Land* law shall inform the affected population of an existing exposure situation after a local emergency, of the reference levels in accordance with section 118 subsection (6) and of protective, remedial and other measures that have been taken and which are stipulated. They shall make appropriate rec-

ommendations to the affected population for steps to be taken in this exposure situation.

(5) Section 105 subsection (4) shall apply *mutatis mutandis*.

Chapter 2

Protection against radon

Division 1

Common provisions

Section 121

Identification of areas; empowerments to issue ordinances

(1) Within two years of a statutory ordinance in accordance with subsection (2) coming into force, the competent authority shall identify by means of a general order the areas for which it is expected that the averaged Rn-222 activity concentration in the air in a significant number of buildings with recreation rooms or workplaces is in excess of the reference level in accordance with section 124 or section 126. It shall publish the area identification. The area identification shall be reviewed every ten years.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating the circumstances under which the competent authority may assume that the reference levels in accordance with section 124 or section 126 are exceeded in an area in a significant number of buildings with recreation rooms or workplaces, and which procedures and criteria are to be used in the identification of areas.

Section 122

Radon action plan

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall draw up a radon action plan. The radon action plan shall be drawn up with the participation of the *Länder*. It shall define the measures in accordance with this Act, and shall include targets for combating the long-term risks ensuing from radon exposure in recreation rooms and indoor workplaces with regard to all sources from which radon is released, whether from the ground, from construction products or from water.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall announce the radon action plan in the Federal Gazette (*Bundesanzeiger*).

(3) The radon action plan shall be updated regularly by the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety with the participation of the *Länder*, but at least every ten years.

(4) The competent authority shall develop strategies adapted to the respective conditions for its area of competence in order to manage the long-term risks from radon exposure. It shall take the radon action plan into account thereby. It shall collect the necessary data. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall coordinate development of the strategies.

Section 123

Measures in buildings; empowerment to issue ordinances

(1) Anyone constructing a building with recreation rooms or workplaces shall take suitable measures to prevent or severely restrict the entry of radon from the subsoil. This duty shall be deemed to have been performed where

1. the necessary measures for humidity protection have been heeded in accordance with generally-accepted practice, and
2. the specific measures in the statutory ordinance in accordance with subsection (2) are additionally adhered to in the areas identified in accordance with section 121 subsection (1), first sentence.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating other radon protection measures for buildings to be constructed within the areas identified in accordance with section 121 subsection (1), first sentence.

(3) The competent authority may grant an exemption on request from the duty in accordance with subsection (1), first sentence, insofar as the requirements would constitute undue hardship due to a disproportionate burden or otherwise. Undue hardship may arise in particular if it is unlikely that the reference level in the building will be exceeded even if no measures are taken.

(4) Anyone who, in the course of making structural changes to a building with recreation rooms or workplaces, takes measures that lead to a substantial reduction in the air exchange rate is to consider taking measures to protect against radon, insofar as such measures are necessary and reasonable.

Division 2

Protection against radon in recreation rooms

Section 124

Reference level; empowerment to issue ordinances

The reference level for the averaged annual Rn-222 activity concentration in the air in recreation rooms shall be 300 Bq/m³. The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall submit a report on the development of protective measures for the general population against radon exposure, on their effectiveness and costs at Federal and *Länder* level no later than ten years after this Act enters into force. The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating how the Rn-222 activity concentration in the air in recreation rooms is to be measured.

Section 125

Information for the population; reducing the radon concentration

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, as well as the competent *Land* authorities, shall inform the population in a suitable manner regarding radon exposure in recreation rooms and the associated health risks, regarding the importance of radon measurements, and regarding the technical possibilities that are available for reducing existing Rn-222 activity concentrations in the air.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, as well as the competent *Land* authorities, shall encourage measures to identify recreation rooms in which the averaged annual Rn-222 activity concentration in the air exceeds the reference level in accordance with section 124, and shall recommend technical or other means to reduce radon exposure.

Division 3

Protection against radon in indoor workplaces

Section 126

Reference level

The reference level for the averaged annual Rn-222 activity concentration in the air in workplaces shall be 300 Bq/m³.

Section 127

Measuring radon concentration

(1) Anyone responsible for an indoor workplace shall measure the Rn-222 activity concentration in the air within the period set by the second sentence where

1. the workplace is located on the ground floor or basement level of a building which lies within an area identified in accordance with section 121 subsection (1), first sentence, or
2. the type of workplace is classified as one of the fields of work in accordance with Annex 8.

In cases falling under the first sentence, no. 1, the measurement must be effected within 18 months of the area being identified and the occupational activity commencing at the workplace and, in cases falling under the first sentence, no. 2, within 18 months of the occupational activity commencing at the workplace. The competent authority may order that the party responsible for the workplace is also to measure Rn-222 activity concentration in the air at other indoor workplaces if there are indications that the Rn-222 activity concentration in the air is above the reference level in accordance with section 126.

(2) Responsibility for a workplace shall lie with anyone

1. engaged in or permitting occupational activity on their premises, or
2. on whose premises a third party engages in occupational activity on their own responsibility, or permits other persons to engage in occupational activity under their supervision.

(3) The party responsible for the workplace shall, without undue delay, record the results of the measurements in accordance with subsection (1), first and third sentences, shall retain them for five years from the date of recording, and shall present them to the competent authority on request.

(4) In the case of responsibility in accordance with subsection (2) no. 1, the party responsible for the workplace shall inform the affected workers, as well as the works council or the staff council, without undue delay of the results of the measurements. In the case of responsibility in accordance with subsection (2) no. 2, the party responsible for the workplace shall inform the third party without undue delay; the duty under the first sentence shall apply *mutatis mutandis* to the third party.

Section 128

Reducing radon concentration

(1) If the Rn-222 activity concentration in the air at a workplace exceeds the reference level in accordance with section 126, the party responsible for the workplace shall take action without undue delay to reduce the Rn-222 activity concentration in the air.

(2) The party responsible for the workplace shall review the success of the action that it has taken by measuring the Rn-222 activity concentration in the air; the measurement must be effected within 24 months after the exceeded reference level has been detected by the measurement in accordance with section 127 subsection (1). The party responsible shall record the measurement without undue delay, shall retain these records for five years from

the date of recording, and shall provide them to the competent authority on request.

(3) In the case of responsibility in accordance with section 127 subsection (2) no. 1, the party responsible for the workplace shall inform the affected workers, as well as the works council or the staff council, without undue delay of the results of the measurements. In the case of responsibility in accordance with section 127 subsection (2) no. 2, the party responsible for the workplace shall inform the third party without undue delay; the duty under the first sentence shall apply *mutatis mutandis* to the third party.

(4) The party responsible for the workplace shall not be required to take measures to reduce Rn-222 activity concentration in the air if the measures are not feasible, or are only feasible with a disproportionate burden, this being because of special circumstances that may arise due to

1. the prevailing interests of occupational safety or health protection, or
2. the nature of the workplace.

In the case of responsibility in accordance with section 127 subsection (2) no. 2, the party responsible for the workplace shall inform the third party without undue delay once the reasons have come to light.

Section 129

Registration

(1) The party responsible in accordance with section 128 subsection (1) shall register the workplace with the competent authority without undue delay if a measurement taken in accordance with section 128 subsection (2), first sentence, does not fall below the reference level stipulated in section 126. The following shall be enclosed with the registration

1. information regarding the type of workplace and the number of affected workers,
2. the results of the measurements in accordance with section 127 subsection (1),
3. information regarding the measures taken to reduce the Rn-222 activity concentration, and the results of the measurements in accordance with section 128 subsection (2), and
4. the additional measures envisaged to reduce exposure.

(2) If the party responsible for the workplace takes no action on the basis of section 128 subsection (4), he or she shall register the workplace with the competent authority without undue delay once the special reasons have come to light. The documents in accordance with subsection (1), second sentence, shall be enclosed with the registration; in derogation from subsection (1), second sentence, no. 3, reasons must be given as to why no reduction measures have been taken. Insofar as the reasons presented do not justify the failure to take action, the competent authority may order action to be taken to reduce Rn-222 activity concentration in the air at this workplace.

(3) A third party engaging in or permitting occupational activity on their own responsibility on third-party premises shall register this activity without undue delay, as soon as it occurs at several workplaces that require registration in accordance with subsection (1), first sentence. Documents in accordance with subsection (1), second sentence shall be enclosed with the registration; the parties responsible for the workplaces shall provide the third party

with the information necessary therefor.

(4) The duty of operational cooperation in accordance with section 71 subsection (3) shall apply *mutatis mutandis* to party obliged to register.

Section 130

Estimation of exposure

(1) The party obliged to register shall conduct a workplace-related estimate of Rn-222 exposure, of the potential alpha energy exposure, or of the body dose from radon exposure, within six months of registration; in the case of registration by the third party in accordance with section 129 subsection (3), first sentence, the estimate shall be conducted in relation to all activity. The estimate shall be repeated without undue delay as soon as the workplace is modified in a way that may give rise to higher exposure. The results of the estimate shall be recorded and presented to the competent authority without undue delay. The results of the estimate shall be retained for five years.

(2) If the estimate shows that the effective dose is lower than 6 mSv per calendar year, the party obliged to conduct the estimate shall review radon exposure regularly. He or she shall minimise exposure through suitable radiation protection measures based on the general provisions of occupational safety, and taking into account all the circumstances of the individual case. The competent authority may request the presentation of corresponding documentary evidence.

(3) If the estimate shows that the effective dose may be higher than 6 mSv per calendar year, the requirements of occupational radiation protection, in accordance with section 131 and with the statutory ordinance in accordance with section 132, second sentence, no. 6, shall be fulfilled.

Section 131

Occupational radiation protection

(1) If the result of the estimate in accordance with section 130 subsection (3) necessitates compliance with the requirements of occupational radiation protection, the party obliged to conduct the estimate shall

1. take suitable measures to minimise radon exposure, taking into account all the circumstances of the individual case in question,
2. determine, in a suitable manner, the Rn-222 exposure, the potential alpha energy exposure or the body dose of the workers employed at the workplaces subject to registration,
3. ensure that the dose limits are not exceeded, and that the body doses are determined in accordance with section 166; the provisions and limit values in accordance with section 77 and section 78 subsections (1) and (3), first and third sentences, shall apply *mutatis mutandis* in this regard,
4. ensure compliance with the requirements of occupational radiation protection in accordance with the statutory ordinance issued in accordance with section 132, second sentence, no. 6.

(2) If the party obliged to conduct the estimate is a legal person or a partnership with legal capacity, section 69 subsection (2) shall apply *mutatis mutandis*.

Section 132

Empowerment to issue ordinances

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating requirements for protection against radon in workplaces. The statutory ordinance may stipulate in particular

1. in which instances and in what manner several places of work are to be considered a workplace within the meaning of this Division
2. how the Rn-222 activity concentration at workplaces is to be averaged over the calendar year,
3. how the measurement of the Rn-222 activity concentration in the air at workplaces in accordance with sections 127 and 128 is to be effected, that it is to be conducted by a recognised body, and which requirements is to be imposed on the measurement and on the body conducting the measurement, and on the procedure for recognising this body,
4. how the Rn-222 activity concentration in the air and the time spent exposed, or the potential alpha energy exposure, is to be converted into an effective dose that a worker receives,
5. how the workplace-related estimate of Rn-222 exposure, of the potential alpha energy exposure or of the body dose from radon exposure is to be conducted in accordance with section 130 subsection (1), and which requirements are to be imposed on the procedure for estimates and on the person conducting the estimate,
6. that the measures and requirements of occupational radiation protection for the protection of workers, which are applicable to Part 2 of this Act and which are detailed in section 76 subsection (1) and section 79, are to also be applied in the case of section 130 subsection (3),
7. how the Rn-222 exposure, the potential alpha energy exposure, or the body dose, is to be determined in cases falling under section 131 subsection (1) no. 2, and which requirements are to be imposed on the calculation procedure,
8. that the calculation in accordance with section 131 subsection (1) no. 2 is to be effected by an officially-appointed measuring body in accordance with section 169, and what information is to be made available to the measuring body for the calculation, and
9. what obligations of recording, retention, communication and submission arise in connection with the obligations in accordance with section 131 and nos. 1 to 8.

Chapter 3

Protection against radon in construction products

Section 133

Reference level

The reference level for the effective dose for individual members of the public from external exposure in recreation rooms due to gamma radiation from construction products shall be set at 1 mSv per calendar year, in addition to the effective dose from external exposure outdoors.

Section 134

Determination of specific activity

(1) Anyone producing or bringing construction products into Germany which contain the primary mineral raw materials or residues referred to in Annex 9 must determine the specific activity of the radionuclides Rn-226, Th-232 or its decay product Ra-228, and K-40 before the construction products are placed on the market.

(2) The results of the determination of specific practices in accordance with subsection (1) shall be recorded and retained for five years.

(3) The competent authority may require to be informed by the parties responsible for determining specific activity of the results of the determination and the activity index created in accordance with the statutory ordinance in accordance with section 135 subsection (1), third sentence, as well as of other values used to calculate the activity index that are referred to in the statutory ordinance.

Section 135

Measures; empowerment to issue ordinances

(1) The party responsible for determining specific activity may only bring construction products which contain the primary mineral raw materials or residues referred to in Annex 9 into circulation without restriction if it can demonstrate that the likely exposure to the radiation emitted from the construction product does not exceed the reference level. Compliance with the reference level shall be assumed if the activity index created in accordance with the statutory ordinance in accordance with the third sentence does not exceed the levels set therein. The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating how the activity index is to be calculated and which levels the activity index may not exceed.

(2) If the probable effective dose emitted by a construction product which contains the primary mineral raw materials or residues referred to in Annex 9 exceeds the reference level, the party responsible for producing or bringing the construction product into Germany shall inform the competent authority without undue delay.

(3) The competent authority may, within one month of receiving the information,

1. order the necessary measures for compliance with the reference level when using the construction product to construct buildings with recreation rooms, or
2. prohibit the use of the construction product in the construction of buildings with recreation rooms if compliance with the reference level is not feasible.

The construction product may only be placed on the market once the period of one month has expired, or in accordance with the official decision.

(4) The obliged parties shall inform the client, the architect and the contractor within the meaning of the respectively-applicable *Land* building regulations with regard to the restrictions imposed. If these persons are unknown, the construction product shall be issued with accompanying documents highlighting the usage restrictions.

Chapter 4

Radioactively-contaminated areas

Division 1

Radioactively-contaminated sites

Section 136

The term 'radioactively-contaminated site'; empowerment to issue ordinances

(1) 'Radioactively-contaminated sites' means land, sections of land, buildings or water bodies contaminated by human activity, where exposure is or may be caused by the contamination which exceeds the reference level for the effective dose of 1 mSv per calendar year for individual members of the public.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating the requirements for determining exposure and the test levels below which a site is not to be considered radioactively contaminated.

(3) When determining exposure to identify a radioactively-contaminated site, the usage for the land and its surroundings as permitted under planning law shall be taken into account, as shall the resulting need for protection. If there are no planning specifications, the character of the area shall be used as a basis, taking the foreseeable development into account. Any usage in some areas that diverges from the usage in accordance with the first or second sentence, and which may lead to higher exposures, shall be taken into account.

(4) By way of derogation from subsection (3), if there is a concern that a radioactively-contaminated site is affecting an aquifer, usage of the groundwater shall be assumed to have occurred as a matter of principle.

Section 137

Responsibility for radioactively-contaminated sites

(1) Responsibility for radioactively-contaminated sites shall lie with anyone who

1. has caused the contamination,
2. follows a person in accordance with no. 1 in universal succession,
3. owns the radioactively-contaminated site;
4. exercises actual physical control over the radioactively-contaminated site, or
5. relinquishes ownership of the radioactively-contaminated site.

(2) Responsibility shall also lie with anyone who, under commercial or company law, has to vouch for a legal person to whom a radioactively-contaminated site belongs.

(3) The former owner of a radioactively-contaminated site shall also be responsible if they were aware, or should have been aware, of the contamination, and ownership was

transferred after 31 December 2018. This shall not apply to those who trusted that there was no contamination when the land was acquired, if said trust was legitimate under the circumstances of the individual case.

Section 138

Suspected radioactively-contaminated sites

(1) If a person referred to in section 137 has indications that a site may be radioactively contaminated, he or she must report this to the competent authority without undue delay.

(2) If the competent authority has indications that a site may be radioactively contaminated, it is to take suitable measures to determine the facts.

(3) If there is sufficient suspicion that a site is radioactively contaminated, the competent authority may require the persons referred to in section 137 to conduct the necessary investigations, particularly as regards the type, level and spread of the contamination and the exposure. Sufficient suspicion shall generally be deemed to exist if investigations have revealed, or are expected to reveal, that the test values stipulated in the statutory ordinance in accordance with section 136 subsection (2) have been exceeded, or if it is highly probable on the basis of other findings that a site is radioactively contaminated.

Section 139

Official jurisdiction for measures; empowerment to issue ordinances

(1) If a site is radioactively contaminated, the competent authority may require a party responsible for the radioactively-contaminated site to

1. investigate the type and spread of the radioactive contamination and the exposure, and to investigate potential remedial and other measures to prevent or reduce the exposure,
2. notify the competent authority of the result of these investigations,
3. ensure that the test values fall below the reference level in accordance with section 136 subsection (1) by taking specific remedial measures, other measures to prevent or reduce the exposure, or aftercare measures,
4. monitor public exposure caused by the remediation work,
5. take other measures, including after taking the measures in accordance with no. 3, insofar as this is necessary to achieve the goal of remedial or other measures to prevent or reduce the exposure, or
6. monitor the emissions and immissions containing radionuclides emanating from the radioactively-contaminated site, including direct radiation.

Section 13 subsection (2) and section 18, first sentence, of the Federal Soil Protection Act (*Bundesbodenschutzgesetz*) shall apply *mutatis mutandis*.

(2) The measures to be taken in accordance with subsection (1), first sentence, nos. 3 and 5, are to be based on scientifically-justified, technically- and economically-feasible processes which have been tried out and proven in practical use, or the practical suitability of

which appears assured. The type, scope and duration of measures shall be optimised.

(3) If exposure is temporarily increased during the remedial measures, this is not to exceed a guide value for an individual member of the public for the effective dose of 6 mSv per calendar year. The guide value for an individual member of the public for the effective dose of 1 mSv per calendar year should not be exceeded thereby due to discharge into surface waters.

(4) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat,

1. laying down stipulations for emissions and immissions monitoring in accordance with subsection (1), first sentence, no. 6, and
2. stipulating requirements for the optimisation of the measures in accordance with subsection (2), second sentence.

Section 140

Other obligations relating to the implementation of measures

(1) The party responsible for the radioactively-contaminated site shall notify the competent authority without undue delay of the start and completion of the measures, and shall submit suitable documentary evidence of the effectiveness of the measures taken.

(2) Anyone intending to make changes to the affected land following measures taken in accordance with section 139 subsection (1), first sentence, nos. 3 and 5, particularly modifying use or introducing or removing substances, shall notify the competent authority thereof four weeks before the intended start, and shall provide documentary evidence that exposure will not be increased due to the change.

Section 141

Application of the provisions on practices with residues

By way of derogation from sections 138 to 140, the provisions contained in Part 2, Chapter 2, Division 8, Sub-division 2 of this Act shall apply *mutatis mutandis* where residues or other materials are removed from the contaminated land, including for the purpose of cleaning up the land, unless the residues or materials are used in the cleaning up of other radioactively-contaminated sites.

Section 142

Public information; collection

(1) The competent authority shall inform the affected public of the radioactively-contaminated site and of the exposure emanating therefrom, as well as of the remedial measures and other measures to prevent or reduce exposure and aftercare measures that have been taken.

(2) The competent authorities shall record the radioactively-contaminated sites and areas suspected of being radioactively contaminated.

Section 143

Remediation planning; empowerment to issue ordinances

(1) With regard to radioactively-contaminated sites for which a coordinated approach is required because of the diversity of the necessary measures, or from which a notable risk to individuals or the general public emanates due to the type or spread of contamination, the competent authority may oblige a party responsible for the radioactively-contaminated site to present a remediation plan. The remediation plan shall include the following in particular

1. a representation of the results of the investigations performed, of the type and extent of the radioactively-contaminated site, and a summary of the estimated exposure,
2. details of the previous and future use of the land that requires remediation, and
3. a representation of the intended remedial measures, other measures to prevent or reduce exposure, and aftercare measures.

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, regulating the content of remediation plans.

(2) Section 136 subsections (3) and (4) and section 139 subsection (2) of this Act, as well as section 13 subsections (2) and (4) and section 18, first sentence, of the Federal Soil Protection Act shall apply *mutatis mutandis*. The competent authority may decree that the remediation plan, including with modifications or incidental provisions, is binding.

Section 144

Official remediation planning

(1) The competent authority may itself create or expand the remediation plan in accordance with section 143 subsection (1), or may have this plan drawn up or expanded by an authorised expert where

1. the plan has not been drawn up, or not within the period set by the authority, or the plan is functionally inadequate,
2. a party responsible for the radioactively-contaminated site cannot be consulted, or cannot be consulted in good time, or
3. a coordinated approach is required due to the complexity of the contaminated site situation, especially due to widespread contamination or the number of responsible parties involved.

Section 18, first sentence, of the Federal Soil Protection Act shall apply to the authorised expert *mutatis mutandis*.

(2) The competent authority may decree that the remediation plan, including with modifications or incidental provisions, is binding.

(3) The remediation plan may include the draft of a remediation agreement on the execution of the plan. The remediation agreement may allow for the involvement of third parties.

Section 145

Protection of workers; empowerment to issue ordinances

(1) Where remedial and other measures are carried out in order to prevent or reduce exposure from radioactively-contaminated sites, the party who carries out said measures personally in a professional capacity, or who has said measures carried out by workers under his or her supervision, shall conduct an estimation of the body dose for workers. The estimate shall be repeated without undue delay as soon as the work situation is modified in such a way that may give rise to higher exposure. The results of the estimate shall be recorded, retained for five years, and presented to the competent authority on request. For other practices in connection with radioactively-contaminated sites, the competent authority may demand that an estimation of the body dose for workers be conducted by the party carrying out said practices personally in a professional capacity, or having said practices carried out by workers under his or her supervision.

(2) If the estimate shows that the body dose may exceed one of the levels for classification as an occupationally-exposed person, the party obliged to conduct the estimate shall notify the competent authority of the implementation of measures before starting to implement them. The following shall be enclosed with the registration

1. information regarding the measures to be taken,
2. the estimated body dose,
3. the number of affected workers, and
4. information on the precautions and measures to reduce occupational exposure when implementing the measures.

(3) The party obliged to register shall

1. take suitable measures to minimise occupational exposure, taking into account all the circumstances of the individual case in question,
2. ensure that the dose limits are not exceeded, and that the body doses are determined in accordance with section 166, for those workers with regard to whom the estimate has revealed that the body dose may exceed the level for grading as an occupationally-exposed person; the regulations and limits of sections 77 and 78 shall apply *mutatis mutandis*,
3. ensure compliance with the requirements of occupational radiation protection in accordance with the statutory ordinance issued in accordance with subsection (5).

(4) The duty of operational cooperation in accordance with section 71 subsection (3) shall apply *mutatis mutandis* to parties obliged to register. Section 69 subsection (2) shall apply *mutatis mutandis* if the party obliged to conduct the estimate is a legal person or a partnership with legal capacity.

(5) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that

1. the measures and requirements of occupational radiation protection for the protection of workers in accordance with subsection (1), which are detailed in section 73, section 76 subsection (1) and sections 79 and 89, are also to be applied, and

2. the party obliged to register is to seek advice from persons with the necessary expertise or knowledge of radiation protection when taking the measures.

Section 146

Costs; claim for compensation

(1) The costs of the measures ordered in accordance with section 138 subsection (3), section 139 subsection (1), as well as with section 143 and 144 subsection (1) no. 1, shall be met by the parties obliged to carry them out. If the investigations in the case of section 138 subsection (3) do not confirm the suspicion, the parties called on to conduct the investigation shall be reimbursed for the costs if they are not responsible for the circumstances that gave rise to the suspicion. In cases falling under section 144 subsection (1) no. 2 and 3, the costs shall be met by the party that could have been required to draw up a remediation plan.

(2) Several responsible parties shall have a claim for compensation regardless of their relationship *inter se*. Unless otherwise agreed, the extent of the compensation to be paid shall be governed by the degree to which the situation giving rise to the remediation obligation can be attributed to the individual obliged parties; section 426 subsection (1), second sentence, of the Civil Code (*Bürgerliches Gesetzbuch*) shall apply *mutatis mutandis*. The compensation claim shall lapse in three years; sections 438, 548 and 606 of the Civil Code shall not apply. The limitation period shall start after the recovery of costs if an authority carries out measures itself, otherwise after the measures are completed by the party responsible, as per the date on which the party becomes aware of the person from whom compensation is owed. The compensation claim shall lapse 30 years after completion of the measures, regardless of this knowledge. Recourse to the courts of ordinary jurisdiction shall be available should any disputes arise.

Section 147

Compensation of equal value; empowerment to issue ordinances

(1) Where the use of public funds for measures in fulfilment of obligations in accordance with section 139 or section 143 significantly increases the market value of the land, and the owner has not met or has not fully met the costs in this regard, the owner shall pay compensation of equal value to the public funding agencies in the amount of the value increase caused by the measures, which shall be determined by the competent authority. The amount of compensation shall be limited by the amount of public funds that have been expended. The obligation to pay compensation of equal value shall not arise insofar as an exemption has been granted from the responsibility or the costs obligation with regard to existing radioactively-contaminated sites on a piece of land in accordance with Article 1 section 4 subsection (3), first sentence, of the Environmental Framework Act (*Umweltrahmengesetz*) of 29 June 1990 (Law Gazette I, p. 649), most recently amended by Article 12 of the Act of 22 March 1991 (Federal Law Gazette I, p. 766), in the respectively applicable version. Insofar as measures within the meaning of the first sentence are taken as regulatory measures by the local authority in formally defined remediation areas or development areas, the resulting increase in market value shall be satisfied within the scope of the financial settlement in accordance with section 154 of the Federal Building Code (*Baugesetzbuch*).

(2) The increase in the market value of a piece of land due to remedial measures shall be the difference between the amount that the land would have been worth if the measures had not been taken (initial value), and the market value of the land once the exploratory and

remedial measures have been taken (final value).

(3) The financial settlement shall become due when the remedial measures or other measures to prevent or reduce exposure are completed and the amount has been determined by the competent authority. The obligation to pay compensation of equal value shall lapse if the amount has not been determined by the end of the fourth year following completion of the measures referred to in the first sentence.

(4) The competent authority shall deduct from the financial settlement in accordance with subsection (1) the expenses that the owner has incurred for his or her own remedial measures or other measures to prevent or reduce exposure, or for the purchase of the land in legitimate faith that there were no radioactively-contaminated sites thereon. If the owner is able to demand compensation from third parties, this shall be taken into account in the decision in accordance with the first sentence.

(5) Determination of a financial settlement may be waived, in full or in part, in individual cases where this is required in the public interest or in order to avoid undue hardship. If costs of remedial measures or of other measures to prevent or reduce exposure are reimbursed to the public funding agency, the determination of a fixed financial settlement must be waived in this respect, a financial settlement that has been determined must be rescinded, or a financial settlement that has already been paid must be reimbursed.

(6) The financial settlement shall constitute a public encumbrance on the land. The Federal Ministry of Justice and Consumer Protection is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, regulating the manner in which the public encumbrance shall be referenced in the land registry.

Section 148

Other mining and industrial legacies

Sections 136 to 147 shall apply *mutatis mutandis* to mine workings and other legacies from completed mining and industrial activities not covered by section 136 which give rise, or could give rise, to exposure which cannot be disregarded, insofar as the contamination is due to completed human activity. The first sentence shall not apply to the Asse II mine, which is subject to section 57b of the Atomic Energy Act.

Section 149

Decommissioning and remediation of the operational installations and sites of uranium ore mining; empowerment to issue ordinances

(1) **Authorisation** shall be required for decommissioning and remediation of operational installations and sites of uranium ore mining on the basis of the Act on the Agreement between the Government of the Federal Republic of Germany and the Government of the Union of Soviet Socialist Republics of 16 May 1991 regarding the termination of the activities of the Soviet-German Public Limited Company Wismut of 12 December 1991 (Federal Law Gazette 1991 II, p. 1138).

(2) The competent authority shall grant **authorisation** in accordance with subsection (1) where

1. exposure may fall below the reference level in accordance with section 136 subsec-

tion (1) due to the planned remedial measures, other measures to prevent or reduce exposure, and aftercare measures, insofar as this is proportionate taking all the circumstances of the individual case into account,

2. the conditions in accordance with section 145 subsections (2) and (3) have been met,
3. measures have been taken to monitor the emissions and immissions containing radionuclides emanating from the operational installations and sites, including direct radiation, and to monitor public exposure due to the decommissioning and remediation works, and
4. the equipment is provided for and measures are planned which are required in accordance with the technical and scientific state-of-the-art in order to guarantee the protection of workers from occupational exposure in accordance with subsection (5) and section 145 subsection (3) and in accordance with the statutory ordinance in accordance with section 145 subsection (5).

(3) The necessary documents for review shall be enclosed with the application for **authorisation**.

(4) Section 136 subsections (3) and (4) and sections 140 to 142 shall apply *mutatis mutandis* in other respects.

(5) With regard to occupational radiation protection

1. sections 8 and 9 shall apply *mutatis mutandis*,
2. anyone who requires **authorisation** in accordance with subsection (1) shall be equivalent to the radiation protection executive in accordance with section 69, and
3. section 70 subsections (1) to (6), section 71 and section 72 subsection (2) shall apply *mutatis mutandis*.

(6) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat,

1. establishing test values, compliance with which shall negate the need for **authorisation** in accordance with subsection (1),
2. laying down stipulations for determining exposure and for emissions and immissions monitoring.

Section 150

Relationship with other provisions

(1) Sections 136 to 144 and 146 to 148 shall not apply insofar as provisions of the Federal Mining Act and of the statutory ordinances issued on the basis of the Federal Mining Act require the termination of an operation.

(2) Orders for investigations to be performed in accordance with section 139 subsection (1), a remediation plan that has been declared as binding in accordance with section 143 subsection (2), second sentence, official remediation planning in accordance with section 144, orders for the taking of remedial measures, other measures to prevent or re-

duce exposure, and aftercare measures in accordance with section 139 subsections (1) no. 3 and 5, as well as authorisations in accordance with section 149, shall include other decisions relating to the radioactively-contaminated site, insofar as they are made in agreement with the respectively competent authority, and with the decisions that are included are detailed in the orders. The first sentence shall not apply to decisions which are taken regarding the radioactively-contaminated site in accordance with the Federal Soil Protection Act and to other decisions relating to the radioactively-contaminated site, where they are included in remediation planning officially declared as binding in accordance with section 13 or section 14 of the Federal Soil Protection Act, or in an order for remediation in accordance with section 16 of the Federal Soil Protection Act. The authorities competent in accordance with this Act and the Federal Soil Protection Act shall establish agreement in cases in accordance with the second sentence.

Division 2

Areas contaminated as a result of an emergency

Section 151

Contaminated areas in an emergency exposure situation; empowerments to issue ordinances

Sections 136 to 138, section 139 subsections (1), (2) and (4), as well as sections 140 to 144, 146, 147 and 150, shall apply *mutatis mutandis* in an emergency exposure situation to land, sections of land, buildings and water bodies contaminated as a result of an emergency. In place of the reference level in accordance with section 136 subsection (1), the reference level in accordance with section 93 subsection (1), or the reference levels defined in accordance with section 93 subsections (2) or (3), shall apply to public protection.

Section 152

Contaminated areas in an exposure situation existing after an emergency; empowerments to issue ordinances

Sections 136 to 138, section 139 subsections (1), (2) and (4), as well as sections 140 to 147 and 150, shall apply *mutatis mutandis* in an existing exposure situation to land, sections of land, buildings and water bodies contaminated as a result of an emergency. In place of the reference level in accordance with section 136 subsection (1), the reference levels defined in accordance with section 118 subsection (4) or (6) shall apply to public protection.

Chapter 5

Other existing exposure situations

Section 153

Responsibility for other existing exposure situations

(1) Responsibility for other existing exposure situations shall lie with the manufacturer, supplier, transferor or owner of the radiation source that has caused the other existing exposure situation, or anyone who has actual physical control of this radiation source.

(2) Responsibility for another existing exposure situation shall not lie with anyone who,

1. as a manufacturer, supplier or transferor, has passed actual physical control of the radiation source to a third party in accordance with the provisions of this Act or in accordance with statutory ordinances issued on the basis thereof, if this third party was aware of the radiation source properties when acquiring physical control,
2. as an end consumer, is the owner of consumer goods or other products originating from the economy that contain a radiation source which causes the other existing exposure situation, or who has actual physical control over such consumer goods or other products,
3. as a tenant or leaseholder has actual physical control over a radiation source which causes the other existing exposure situation, or
4. has found or unwillingly acquired actual physical control over a radiation source which causes the other existing exposure situation, or has acquired actual physical control over the radiation source which causes the other existing exposure situation, without knowing that it is a radiation source.

Section 154

Determination and evaluation of another existing exposure situation

(1) In the event of indications of another existing exposure situation, or of another proven existing exposure situation, which in each case cannot be disregarded from a radiation protection perspective, the competent authority shall take the necessary measures with a view to

1. determining the cause, detailed circumstances and magnitude of the other existing exposure situation,
2. determining the associated occupational exposure as well as public exposure, and
3. evaluating the collected findings as a whole.

Section 53 of the Atomic Energy Act shall remain unaffected thereby.

(2) Insofar as the other existing exposure situation relates to contaminated consumer goods or to other products on the market, the exposure situation cannot be disregarded where these consumer goods or other products

1. contain artificially-produced radionuclides the activity and specific activity of which ex-

ceeds the exemption levels stipulated in a statutory ordinance in accordance with section 24, first sentence, no. 10, or

2. contain naturally-occurring radionuclides which may cause an effective dose for an individual member of the public of more than 1 mSv per calendar year.

(3) The competent authority may oblige one or more of the parties responsible for the other existing exposure situation to take measures in accordance with subsection (1), and to notify the authority of the outcomes.

Section 155

Empowerment to issue ordinances for determination of reference levels

The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, establishing reference levels for types of other existing exposure situations which facilitate appropriate treatment, corresponding to the risks and effectiveness of the measures to be taken.

Section 156

Measures

(1) Based on the calculation and evaluation of the other existing exposure situation, the competent authority may stipulate the type, scope, duration and goal of the remedial and other measures to be taken to prevent or reduce exposure. Measures that are taken on the basis of other legal regulations shall take precedence.

(2) The following principles shall be observed when establishing measures in accordance with subsection (1)

1. all unnecessary exposure or contamination of human beings and the environment is to be avoided,
2. exposure should fall below the reference levels defined in accordance with section 155 wherever possible,
3. all exposure or contamination of human beings and of the environment, including below the reference levels, should also be kept as low as possible.

(3) The competent authority may compel one or more parties responsible for the exposure situation

1. to take the stipulated measures and other measures to prevent or reduce exposure, and
2. to determine, once the measures are complete, the effective dose for workers who have been subjected to occupational exposure, and for individual members of the public.

The competent authority shall coordinate the measures in accordance with the first sentence.

- (4) The competent authority shall evaluate the measures that have been taken at regu-

lar intervals. It may demand the submission of documents required for the evaluation from one or more of the parties responsible for the exposure situation.

Section 157

Costs; claim for compensation

The costs of the measures ordered in accordance with section 154 subsection (3) and section 156 subsection (3) shall be borne by the parties responsible for taking the measures. section 146 subsection (2) shall apply *mutatis mutandis*.

Section 158

Information

(1) The competent authority shall

1. regularly inform the exposed and potentially exposed population of potential risks caused by the other existing exposure situation, and of the available measures to reduce their exposure, and
2. publish recommendations for individual steps to be taken or measures at the local level, and shall update these as required.

(2) The competent authority may compel one or more of the parties responsible for the exposure situation to make the preceding information available.

Section 159

Registration; application of the provisions on planned exposure situations; empowerment to issue ordinances

(1) The provisions of the following subsections shall be applied where

1. the other existing exposure situation is significant in terms of radiation protection, especially if the reference level in accordance with section 155 may be exceeded or, if no reference level has been defined, if an effective dose of 1 mSv per calendar year may be exceeded, and
2. a party responsible for the exposure situation is also the cause of the other existing exposure situation.

(2) The party responsible shall register the other existing exposure situation with the competent authority without undue delay. Registration shall include documentary evidence of how the obligations in accordance with subsection (3) no. 1 and 2, and with the statutory ordinance in accordance with subsection (5), have been fulfilled.

(3) The party responsible shall

1. ensure that all exposure or contamination of human beings and of the environment is minimised, taking all the circumstances of the individual case into account,

2. ensure that the dose limits are not exceeded, and that the body doses in accordance with section 166 are determined, for the workers implementing measures in accordance with section 156 subsection (1); the provisions and limits contained in sections 77 and 78 shall apply *mutatis mutandis*, and
3. ensure compliance with the requirements of the statutory ordinance issue in accordance with subsection (5).

(4) The duty of operational cooperation in accordance with section 71 subsection (3) shall apply *mutatis mutandis* to the party responsible. If the party responsible is a legal person or a partnership with legal capacity, section 69 subsection (2) shall apply *mutatis mutandis*.

(5) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that

1. the measures and requirements of occupational radiation protection for other existing exposure situations requiring registration, which are detailed in section 73, section 76 subsection (1) and sections 79 and 89, are applied, and
2. the party responsible seeks advice from persons with the necessary expertise or knowledge of radiation protection when performing his or her duties.

Section 160

Relationship with Chapters 1 to 4

The provisions of this Chapter shall not apply to existing exposure situations after an emergency, to radon in recreation rooms and in the workplace, to radioactively-contaminated areas, and to radioactivity in construction products.

Part 5

General provisions on exposure situations

Chapter 1

Monitoring environmental radioactivity

Section 161

Tasks of the Federation

(1) The tasks of the Federation shall be

1. the large-scale determination of
 - a) radioactivity in the air,
 - b) radioactivity in rainfall,
 - c) radioactivity in Federal waterways and in the North Sea and Baltic Sea beyond the federal waterways and in marine organisms,
 - d) radioactivity in the soil surface, and
 - e) the gamma local dose rate,
2. the development and establishment of sampling, analysis, measuring and calculation procedures in order to determine environmental radioactivity and to conduct comparative measurements and comparative analyses,
3. the summary, documentation and preparation of the data on environmental radioactivity determined by the Federation, and the data provided by the *Länder* and bodies outside the scope of this Act,
4. the drafting of dispersion forecasts,
5. the development and operation of decision support systems,
6. the evaluation of data on environmental radioactivity, insofar as they have been determined by the Federation, or by the *Länder* on behalf of the Federation, and
7. the preparation of data and documents in accordance with nos. 1, 3, 4 and 5 for the *Länder*, and the provision of information for the *Länder* regarding the results of the data evaluation.

(2) The competent authorities of the Federation shall provide the Federal Centre for the Monitoring of Environmental Radioactivity (section 163) with the data that they have determined in accordance with subsection (1) no. 1.

(3) The *Länder* may conduct additional determinations of radioactivity in the areas referred to in subsection (1) no. 1.

(4) The Federation shall stipulate the measuring bodies for the determination of radioactivity in accordance with subsection (1) no. 1 in consultation with the competent *Land* authorities.

Section 162

The tasks of the *Länder*

(1) The *Länder* shall determine radioactivity more specifically

1. in food, feed and consumer goods, insofar as these serve as indicators for environmental radioactivity,
2. in medicinal products and their precursor materials,
3. in drinking water, in groundwater and in surface waters except the Federal waterways,
4. in waste water, in sewage sludge and in waste, and
5. in the ground and in plants.

(2) The *Länder* shall provide the Federal Centre for the Monitoring of Environmental Radioactivity (section 163) with the data that they have determined in accordance with subsection (1).

Section 163

Federal integrated measuring and information system

(1) As the central agency of the Federation for monitoring environmental radioactivity, the Federal Office for Radiation Protection shall operate an integrated measuring and information system for monitoring environmental radioactivity. The data determined in accordance with section 161 subsection (1) and section 162 subsection (1) shall be incorporated into this measuring and information system.

(2) The data in the integrated measuring and information system shall be made directly available to the competent *Land* authorities.

Section 164

Evaluation of the data, informing the Bundestag and the Bundesrat

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall evaluate the data on environmental radioactivity. The central agency of the Federation for monitoring environmental radioactivity shall support the Ministry in the performance of this task.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety shall submit a report on the development of radioactivity in the environment to the Deutscher Bundestag and to the Bundesrat on an annual basis.

Section 165

The right to enter and take samples

The agents of the competent authorities are herewith empowered to enter land as well as operating and commercial premises during operating and working hours in order to determine radioactivity and to take samples.

Chapter 2

Other provisions

Section 166

Rules for the determination of occupational exposure

(1) The body doses for one person from occupational exposure shall be added together if they are to be determined in accordance with this Act, or with a statutory ordinance based on this Act, in several of the following areas

1. when working as an occupationally-exposed person,
2. in connection with radon in the workplace,
3. in the case of remedial and other measures to prevent and reduce exposure on radioactively-contaminated sites and other practices in connection with radioactively-contaminated sites, and
4. in the case of other existing exposure situations requiring registration.

The total shall be decisive with regard to documentary evidence that the applicable respective limit values have not been exceeded.

(2) Exposures occurring outside the scope of this Act which correspond to exposures in accordance with subsection (1) shall be taken into account when determining occupational exposure.

Section 167

Obligations of recording, retention and official communication for the determined body dose for occupational exposure

(1) For persons subject to occupational exposure and for whom a measurement, calculation or estimate of the body dose has been performed, the radiation protection executive, the party obliged in accordance with section 131 subsection (1) or section 145 subsection (1), first sentence, and the responsible party in accordance with section 115 subsection (2) or section 153 subsection (1) or section 115 subsection (2), shall record without undue delay

1. the results of these measurements, calculations or estimates, as well as data that were used for this measurement, calculation or estimate,
2. the surname, first names, date and place of birth, gender and nationality (personal data),
3. the personal identification number in accordance with section 170 subsection (3), first sentence,
4. for radiation passport holders, the registration number of the radiation passport, and
5. the employment characteristics and exposure ratios.

(2) The parties subject to the recording obligation shall retain the records until the monitored person has or would have reached the age of 75, but for at least 30 years after the employment relationship in question has terminated.

(3) The parties subject to the recording obligation shall present the records to the competent authority on request, or shall deposit them with a body to be appointed by the competent authority. Section 168 subsection (2) shall remain unaffected thereby. The parties subject to the recording obligation shall inform any new employer, on request, of the results of the calculation in the event of a change in their employment relationship, if they continue to be subject to occupational exposure. The third sentence shall apply *mutatis mutandis* to air crew working in an aircraft for another radiation protection executive. The parties subject to the recording obligation must present the records to the competent body stipulated by *Land* law if they are no longer required due to termination of the employment relationship.

(4) The parties subject to the recording obligation shall inform the competent authority without undue delay of the following

1. the body dose limits being exceeded, and
2. the body doses incurred in specially-permitted exposures in accordance with the statutory ordinance in accordance with section 79 subsection (1), second sentence, no. 1.

The competent authority shall also be provided with the personal data of the persons affected and with the calculated body dose, as well as with the reason for the body dose limits being exceeded. The parties subject to the recording obligation shall be informed to inform the affected persons of the body dose without undue delay.

Section 168

Transfer of the body dose calculation results

(1) The radiation protection executive, the party obliged in accordance with section 131 subsection (1) or section 145 subsection (1), first sentence, and the responsible party in accordance with section 115 subsection (2) or section 153 subsection (1), insofar as they employ a measuring body in accordance with section 169 subsection (1) to determine occupational exposure, must provide this measuring body with the data in accordance with section 170 subsection (2) nos. 1 to 7 with regard to the persons for whom the body dose is to be calculated. The competent authority shall be presented with the details in accordance with the first sentence and the calculated body dose on request.

(2) If the parties obliged to determine the occupational exposure in accordance with subsection (1) do not employ a measuring body in accordance with section 169 subsection (1), they shall present the competent authority with the data in accordance with section 170 subsection (2), including the calculated body dose.

Section 169

Appointment of measuring bodies; empowerment to issue ordinances

(1) The competent authority shall appoint measuring bodies to determine the occupational exposure

1. from external exposure whilst working,
2. from internal exposure whilst working,
3. of workers intervening in an emergency exposure situation or other hazardous situation,
4. from radon in the workplace,
5. in relation to measures for radioactively-contaminated sites, and
6. in other existing exposure situations.

(2) A measuring body may only be appointed where

1. it has sufficient personnel to perform its tasks and its personnel, especially the management of the measuring body and the other expert managerial staff, possess the necessary qualifications, aptitude and experience,
2. it has the required procedures to determine the exposure,
3. it has the necessary space and technical conditions and equipment, particularly the necessary measuring devices, for the performance of its tasks,
4. it operates an adequate quality management system, and
5. there are no facts giving rise to reservations regarding the reliability of the head of the measuring body or its other expert managerial staff, and the measuring body has the necessary independence.

(3) The measuring body must record the results of the occupational exposure calculation and inform the respective person in accordance with section 168 subsection (1) who has arranged the measurement. The measuring body shall retain the records for five years following the calculation. It shall present these results, including the data in accordance with section 168 subsection (1), to the competent authority on request, or if it believes this to be necessary based on the results of its calculations.

(4) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating

1. how the requirements in accordance with subsection (2) are to be specified in greater detail, taking the different exposures in accordance with subsection (1) into account,
2. which tasks are to be performed by the officially-appointed measuring bodies in relation to determining exposure,
3. that the officially-appointed measuring bodies are to be subject to quality assurance, which bodies are to carry this out, and how this is to be carried out,
4. which information, in addition to the information in accordance with section 168 subsec-

tion (1), is to be made available to the measuring bodies for the purpose of determining the exposure and for monitoring the dose limits of the respective person being monitored, and for compliance with the radiation protection principles for preparedness and monitoring measures,

5. to which other recording, retention, communication and submission obligations the measuring bodies are to be subject in relation to the performance of their tasks, and
6. that and under which circumstances a measuring body's appointment may be time-limited, and under what conditions the appointment may be withdrawn.

Section 170

Radiation protection register; empowerment to issue ordinances

(1) Data on occupational exposure which are collected on the basis of this Act, or of a statutory ordinance on the basis of this Act, shall be recorded in a register (radiation protection register) established by the Federal Office for Radiation Protection, for the purpose of monitoring dose limits and compliance with the radiation protection principles, to verify the validity of a claim against a statutory accident insurance institution, and for the purpose of scientific research in radiation protection.

(2) The following data shall be entered in the radiation protection register

1. the personal identification number in accordance with subsection (3),
2. the relevant personal data,
3. employment characteristics and exposure conditions,
4. the operating number of the employment company,
5. the name and address of the radiation protection executive, of the parties obliged in accordance with section 131 subsection (1) and section 145 subsection (1), first sentence, and of the responsible parties in accordance with section 115 subsection (2) and section 153 subsection (1),
6. information on a registered radiation passport in accordance with a statutory ordinance on the basis of this Act,
7. information on the competent authority, and
8. the body dose from occupational exposure calculated in accordance with this Act or with a statutory ordinance on the basis of this Act, the exposure conditions and the findings of the competent authority with regard to this body dose and the exposure conditions.

(3) The Federal Office for Radiation Protection shall issue a personal identification number for each person for whom entries are made for clear allocation of entries in accordance with subsection (2). The personal identification number shall be derived by means of untraceable encryption from the insurance number in accordance with section 147 of Book VI of the Social Code which is allocated to the person in question. The insurance number shall be deleted once the identification number has been derived. If a person has already been allocated a different identity number which a competent body has issued outside the scope of this Act, and if this identity number is suitable for use in the radiation protection register, the Federal Office for Radiation Protection may use this identity number as the per-

sonal identification number. For persons to whom neither an insurance number nor an identity number has been issued, the Federal Office for Radiation Protection shall issue a personal identification number based on their personal data.

(4) The data in accordance with subsection (2) shall be forwarded to the radiation protection register by

1. the measuring bodies in accordance with section 169,
2. the Federal Aviation Office,
3. the competent authorities, or
4. the radiation protection executive, the parties obliged in accordance with section 131 subsection (1) and section 145 subsection (1), first sentence, or the responsible parties in accordance with section 115 subsection (2) or section 153 subsection (1).

The persons in accordance with no. 4 shall forward the insurance number or identity number in accordance with subsection (3) to the radiation protection register for creation of the personal identification number, in addition to the data required for allocation in accordance with subsection (2).

(5) Information from the radiation protection register shall be provided insofar as this is necessary for the recipient to perform their tasks

1. to a competent authority,
2. to a measuring body in accordance with section 169,
3. on request to a radiation protection executive, party obliged in accordance with section 131 subsection (1) and section 145 subsection (1), first sentence, or to the responsible party in accordance with section 153 subsection (1), regarding data concerning persons who are in their employ,
4. on request to a responsible party in accordance with section 115 subsection (2) regarding data concerning persons for whom they are responsible, and
5. on request to a statutory accident insurance institution regarding data concerning persons who are insured with said institution.

The competent authority may forward information from the radiation protection register to a radiation protection executive, to obliged or responsible parties, to their radiation protection supervisors, and to authorised doctors in accordance with section 79 subsection (1), second sentence, no. 9(a), insofar as this is necessary for them to perform their tasks.

(6) The affected persons shall be informed of the storage of data concerning them. Information from the radiation protection register on these data shall be provided to them on request.

(7) The personal data stored in the radiation protection register may be used for the purpose of scientific research (research purposes) in the circumstances stipulated by section 14 subsection (5), first sentence, no. 2, and the second sentence, of the Federal Data Protection Act (*Bundesdatenschutzgesetz*). The data may only be passed to third parties for research purposes subject to the conditions contained in subsections (8) and (9). Research findings may only be published on an anonymised basis. The provisions of the Federal Data Protection Act, and of Regulation (EU) 2016/679 of the European Parliament and of the

Council of 27 April 2016 for the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (OJ L 119 of 4 May 2016, p. 1), shall continue to apply even after the death of the affected persons.

(8) Personal data from the radiation protection register may be forwarded to third parties with the consent of the affected persons for research purposes in the field of radiation protection. In the absence of such consent, the data may be forwarded if such forwarding, or the intended use of the data, is not precluded by the affected persons' legitimate interests, or if the public interest in the research work substantially outweighs the affected persons' interest in maintaining the confidentiality of the data. Personal data shall not be forwarded for research purposes if the purpose of the research can be fulfilled with a reasonable amount of effort using anonymised data. Other data protection regulations concerning the processing and use of personal data for scientific research shall remain unaffected thereby.

(9) The written consent of the affected persons shall be enclosed with any application for disclosure of personal data for research purposes. If the disclosure is made without the consent of the affected persons, the details required to verify the conditions in accordance with subsection (8), second sentence, shall be provided; prima facie evidence shall be provided for subsection (8), third sentence, in order to show that the purpose of the research cannot be fulfilled with a reasonable amount of effort by using anonymised data. Personal data may only be used for the research work for which it has been forwarded; use for other research work, or passing on, shall comply with the second and third sentences, and shall require the consent of the Federal Office for Radiation Protection.

(10) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating

1. in what manner the personal identification number in accordance with subsection (3) is to be created, what form it is to take, and under which conditions an identity number which was issued outside the scope of this Act may be used,
2. which technical and organisational measures are to be taken by the bodies in accordance with subsection (4) in order to transfer information to the radiation protection register in accordance with subsection (2), and
3. under which conditions, and in what procedure, information from the radiation protection register may be disclosed and forwarded – to the necessary extent – to bodies and persons in accordance with subsection (5) for the purpose of monitoring dose limits, of compliance with the radiation protection principles, of verifying the validity of a disclosure request, or for quality assurance, thus transferring personal data.

Section 171

Empowerment to issue ordinances for stipulations in relation to a radiation passport

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating

1. when a radiation passport is to be made for the purpose of monitoring dose limits and compliance with the radiation protection principles, what data are to be entered in accordance with section 170 subsection (2), and what data are to be entered regarding the result of the medical screening test, what form the radiation passport is to take, how it is to be registered, and who may make entries and use the contents,

2. under what conditions radiation passports which were issued outside the scope of this Act are to be recognised.

Section 172

Appointment of authorised experts; empowerment to issue ordinances

(1) The competent authority shall appoint authorised experts for the following expert activities

1. verification of X-ray equipment, including issuing certificates, and verification of X-ray equipment or stray radiation emitters in accordance with the statutory ordinance in accordance with section 89, first sentence, no. 3,
2. verification of workplaces with exposure from naturally-occurring radioactivity,
3. verification of installations for the generation of ionising radiation, of irradiation facilities, and of devices for gamma radiography,
4. leakage test on sealed radioactive substances, and on type-approved devices that contain radioactive substances.

The officially-appointed authorised expert shall not require a licence in order to work as an authorised expert, nor must he or she present such licence.

(2) The officially-appointed authorised expert shall be independent of persons involved in the manufacture, sale or maintenance of installations for the generation of ionising radiation, stray radiation equipment, X-ray equipment, stray radiation emitters or sealed radioactive substances. The officially-appointed authorised expert or, in the case of legal persons or associations of individuals without legal capacity, the persons who perform tasks as officially-appointed authorised experts, must possess the necessary expertise in radiation protection. The officially-appointed authorised expert may not be subject to any specialist instructions with regard to the expert activity.

(3) The obligations incumbent on the radiation protection executive in accordance with section 72 subsection (1) shall apply *mutatis mutandis* to the expert activity of an officially-appointed authorised expert. If the officially-appointed authorised expert is a legal person or a partnership without legal capacity, section 70 shall also apply *mutatis mutandis* to this person. By way of derogation from the first and second sentences, if the officially-appointed authorised expert is performing the expert activity as an employee, section 70 and section 72 subsection (1) shall apply *mutatis mutandis* to the person with whom the employment relationship exists.

(4) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating

1. the requirements on training, professional expertise and skills, particularly with regard to occupational experience and aptitude, for the officially-appointed authorised experts or, in the case of legal persons or associations of individuals without legal capacity, on the persons who perform tasks as officially-appointed authorised experts,
2. which requirements are to be imposed on the reliability, independence and impartiality of the authorised experts and, in the case of legal persons or associations of individuals without legal capacity, on the persons who perform tasks as officially-appointed authorised experts,

3. the manner of instruction for the authorised expert's activity, the scope of the verification practice, how the verification criteria are to be defined, and what other conditions and obligations, including quality assurance, are to apply to officially-appointed authorised experts in relation to the verifications and cooperation with the competent authorities, and
4. which requirements are to be verified in the official appointment of an authorised expert, that and under which circumstances the appointment of an authorised expert may be time-limited, and under which conditions the appointment may be withdrawn.

Section 173

Empowerments to issue ordinances for communication obligations in cases of finding and acquisition

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that, in what manner and by whom the following is to be reported to the competent authority

1. the finding, the loss and the retrieval of substances, insofar as there is concern that their activity or specific activity may exceed the levels defined by a statutory ordinance in accordance with section 24, first sentence, no. 10,
2. the presence of water in a water supply system or in a sewage treatment plant which contains radionuclides the activity concentration of which exceeds the levels or limits stipulated in the statutory ordinance,
3. the presumption or knowledge that an orphan radiation source has been melted down or otherwise used in metallurgical operations.

Section 174

Empowerment to issue ordinances for official powers in case of contaminated metal

The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that contaminated metal may only be used, placed on the market or disposed of in accordance with the stipulations of the competent authority.

Section 175

Dose and measured values; empowerment to issue ordinances

(1) Unless otherwise specified, external and internal exposure shall be taken into account in the determination of the equivalent organ dose; exposure occurring outside the reference period, due to radionuclides absorbed during the reference period, shall also be taken into account for internal exposure in accordance with the statutory ordinance in accordance with subsection (2) no. 3. The first sentence shall apply *mutatis mutandis* to the effective dose.

(2) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety is herewith empowered to issue a statutory ordinance, without the consent of the Bundesrat,

1. stipulating detailed requirements as to the determination and calculation of the equivalent organ dose, especially the weighting factors to be used for different types of radiation and radiation energies, as well as details of averaging for the tissue or organ,
2. stipulating detailed requirements as to the determination and calculation of the effective dose, especially the tissue or organs to be taken into account and the weighting factors to be used, and to make specifications for the determination of the effective dose in an unborn child,
3. establishing in what manner and for what period the dose from absorbed radionuclides is to be taken into account for internal exposure,
4. stipulating which measured values are to be used when calculating external exposure, and how this calculation is to be effected,
5. stipulating the data that are to be used when calculating the body dose from the size of the radiation field or the activity, and
6. specifying what units are to be used for the values in radiation protection.

Section 176

Liability for damage caused by ionising radiation

Within the scope of this Act and of the statutory ordinances based on this Act, liability for damage caused by ionising radiation shall be in accordance with sections 25 to 40 of the Atomic Energy Act.

Section 177

Financial security to comply with the legal liability to pay compensation for damage

Within the scope of this Act and of the statutory ordinances based on this Act, the financial security necessary to comply with the legal liability to pay compensation for damage shall be in accordance with sections 13 to 15 of the Atomic Energy Act and with the Nuclear Financial Security Ordinance (*Atomrechtliche Deckungsvorsorge-Verordnung*). Section 35 shall remain unaffected thereby. By way of derogation from section 13 subsection (1), second sentence, of the Atomic Energy Act, the competent authority may, in the event of practices in accordance with section 12 subsection (1) no. 1, 2 or 3 and section 31 subsection (1), forego a new determination of financial security if the review has shown that the coverage level is still sufficient.

Part 6

Supervision under radiation protection law, administrative procedure

Section 178

Supervision under radiation protection law

Implementation of this Act, and of the statutory ordinances based on this Act, shall be subject to supervision by the competent authorities. This shall not apply to Part 3, Chapter 1 and Part 4, Chapter 1, with the exception of section 95 and of the fast-track legislation in accordance with section 96, insofar as they regulate the management of waste or the construction, operation or use of installations in accordance with section 95.

Section 179

Application of the Atomic Energy Act

(1) Within the scope of this Act, and of the statutory ordinances based on this Act, the respectively-applicable version of the following shall be applied *mutatis mutandis*

1. to licences and type approvals: section 17 subsection (1), second to fourth sentences, and section 17 subsections (2) to (6), of the Atomic Energy Act on substantive restrictions, obligations, time limits, withdrawal, revocation and designation as the owner of a nuclear installation,
2. section 19 subsection (1), second to fourth sentences, section 19 subsection (2), first to third sentences, and section 19 subsections (3) to (5) of the Atomic Energy Act on state supervision, and
3. section 20 of the Atomic Energy Act on authorised experts.

(2) The fundamental right contained in Article 13 of the Basic Law to the inviolability of the home shall be restricted insofar as it obstructs the powers in accordance with subsection (1) nos. 2 and 3.

Section 180

Supervisory programme; empowerment to issue ordinances

(1) Within the course of supervision under radiation protection law in the case of planned exposure situations, the competent authority shall establish a programme for supervisory inspections, taking account of the potential magnitude and type of the risks associated with the practices (supervisory programme). The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating requirements for the arrangement of the supervisory programme. The statutory ordinance may stipulate in particular

1. criteria for determining the magnitude and type of risk associated with a practice,
2. time intervals between inspections by the competent authority at the premises of a radiation protection executive.

(2) The competent authority shall record the results of each on-site inspection, and shall pass them to the radiation protection executive. In the cases defined in Part 2, Chapter 2, Division 8, Sub-division 2, the results shall be passed to the obliged party in accordance with the first sentence. If the results relate to an external worker, the radiation protection executive in accordance with the first sentence, or the obliged party in accordance with the second sentence, shall also disseminate these results, with the exception of business and trade secrets, to the party with whom the external worker has an employment relationship.

(3) The competent authority shall make an outline of the supervisory programme, and of the most important findings acquired whilst implementing it, available to the public. The information in accordance with the first sentence may not include any business and trade secrets. Federal and *Land* laws on environmental information shall remain unaffected thereby.

Section 181

Environmental impact assessment

(1) If an obligation to perform an environmental impact assessment exists in accordance with the Environmental Impact Assessment Act (*Gesetz über die Umweltverträglichkeitsprüfung - UVP*) for projects that require a licence in accordance with this Act (projects subject to environmental impact assessment), the environmental impact assessment shall constitute an integral component of the procedures for granting a licence required under this Act. The environmental impact assessment shall be conducted in accordance with the provisions contained in section 7 subsection (4), first and second sentences, of the Atomic Energy Act, and with the provisions contained in the Nuclear Licensing Procedure Ordinance (*Atomrechtliche Verfahrensverordnung*) on the object of the environmental impact assessment, the application documents, the disclosure of the project, and interpretation of application documents, the lodging of objections, the involvement of authorities, the substance of the approval decision, and the notification and public announcement of the decision. After expiry of the objection period, the licensing authority may discuss with the applicant, and with those who lodged the objections that were raised against the project, in good time. Section 2 subsection (1), fourth sentence, and section 14 of the Environmental Impact Assessment Act, shall remain unaffected thereby.

(2) No review in preliminary proceedings shall be required before an administrative

court action is brought, if this involves an administrative act undertaken after an environmental impact assessment is conducted.

Section 182

Written form, electronic communication

(1) Licences and type approvals in accordance with this Act or with a statutory ordinance based on this Act shall be issued in writing.

(2) If an administrative act for which the written form is ordered in this Act or in a statutory ordinance based on this Act is undertaken electronically, it shall include a permanently-verifiable eligible electronic signature in accordance with section 37 subsection (4) of the Administrative Procedure Act (*Verwaltungsverfahrensgesetz*).

(3) Notification and registration obligations, as well as reporting and communication obligations in accordance with this Act or a with statutory ordinance based on this Act, may be fulfilled electronically, if the recipient has established access for this purpose and specifies the procedure and the necessary requirements for the data transfer. Measures in accordance with the state-of-the-art must be taken in order to ensure data protection and data security, in particular data confidentiality and integrity; encryption processes shall be applied when using generally-accessible networks. If a document sent electronically is not suitable for processing by the recipient, they shall notify the sender accordingly without undue delay, stating details of the technical conditions relevant for receipt.

(4) If the application, notification, registration, reporting or communication are effected electronically, the competent authority shall be provided on request with paper copies of the documents that were submitted electronically.

Section 183

Costs; empowerment to issue ordinances

(1) Fees and charges (costs) shall be levied

1. for determinations in accordance with section 177 in conjunction with section 13 subsection (1), second sentence, of the Atomic Energy Act,
2. for decisions in accordance with section 179 subsection (1) no. 1 in conjunction with section 17 subsection (1), third sentence, and section 17 subsections (2) to (5) of the Atomic Energy Act, and for decisions in accordance with section 179 subsection (1) no. 2 in conjunction with section 19 subsection (3) of the Atomic Energy Act,
3. for the other supervisory measures in accordance with section 179 subsection (1) no. 2 in conjunction with section 19 of the Atomic Energy Act, defined in greater detail in the Cost Ordinance on the Atomic Energy Act and the Radiation Protection Act (*Kostenverordnung zum Atomgesetz und zum Strahlenschutzgesetz*),
4. for other official acts, including inspections and investigations by the Federal Office for Radiation Protection, insofar as the latter is competent in accordance with section 185 subsection (1) nos. 1 to 9,

5. for decisions by the Federal Office for the Safety of Nuclear Waste Management relating to applications in accordance with section 27 subsection (1), insofar as it is competent in accordance with section 186 subsection (1),
6. for other official acts, including inspections and investigations by the Federal Aviation Office, insofar as the latter is competent in accordance with section 189.

(2) The statutory ordinances in accordance with section 81 and section 185 subsection (2) nos. 5 and 6 may also define regulations on the levying of charges for official acts by the authorities deemed therein to be competent.

(3) Costs shall be levied in the case of the

1. revocation or withdrawal of an official act in accordance with subsection (1) or subsection (2), insofar as the affected party is responsible for this and costs are not already being levied in accordance with subsection (1) or (2),
2. rejection of an application for the performance of an official act in accordance with subsection (1) or (2) for reasons other than the authority's lack of competence,
3. withdrawal of an application for the performance of an official act or of a notice in accordance with subsection (1) or (2) after the official process has commenced, but before it has completed,
4. complete or partial rejection or withdrawal of an appeal against
 - a) an official act in accordance with subsection (1) or (2), or
 - b) a cost decision taken in accordance with subsection (1) or (2) in conjunction with the Cost Ordinance on the Atomic Energy Act and on the Radiation Protection Act.

The fee shall be set in cases falling under the first sentence, nos. 1, 2 and 4(a), up to the amount of the fee stipulated for an official act, in cases falling under the first sentence, no. 3, up to three-quarters of the amount of the fee stipulated for the official act, and in cases falling under the first sentence, no. 4(b), up to 10 % of the amount at issue.

(4) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, regulating the details in accordance with the principles of the Administrative Costs Act (*Verwaltungskostengesetz*) in the version applicable until 14 August 2013. The actions that incur fees shall be defined in more detail therein, and the fees shall be defined with fixed rates, with framework rates, or by the value of the object. The fee rates shall be calculated so as to cover the personnel and material expenses incurred by virtue of the official acts, inspections or investigations; in addition, the significance, the commercial value or other benefit for the party liable to pay the fees shall be suitably taken into account in the event of beneficial official acts. The ordinance may also regulate the exemption from costs of the Federal Office for Radiation Protection and the obligation to pay fees for the official acts of specific authorities by way of derogation from section 8 of the Administrative Costs Act, in the version applicable until 14 August 2013. The limitation period for the cost liability may be extended by way of derogation from section 20 of the Administrative Costs Act, in the version applicable until 14 August 2013. It may stipulate that the ordinance is also to be applied to administrative proceedings pending at the time the ordinance comes into force, insofar as the costs have not already been established at this point.

(5) Section 21 subsection (2) of the Atomic Energy Act, and the Cost Ordinance on the Atomic Energy Act and on the Radiation Protection Act shall be applied to the levying of

costs in accordance with this Act or to with statutory ordinances based on this Act; section 21 subsections (4) and (5) of the Atomic Energy Act shall apply *mutatis mutandis*.

Part 7

Administrative authorities

Section 184

Competence of the *Land* authorities

(1) The following shall be performed as autonomous matters by the *Länder*

1. Part 3, Chapter 1 with the exception of section 107,
2. Part 3, Chapter 2,
3. Part 4, Chapter 1 with the exception of the *mutatis mutandis* application of section 107 provided for in section 119,
4. Part 4, Chapter 2, Division 1, with the exception of section 121 and Division 2,
5. Part 4, Chapter 3,
6. Part 4, Chapter 4, with the exception of sections 145, 149 subsection (5) and the *mutatis mutandis* application of section 145 provided for in section 152, first sentence,
7. the statutory ordinances issued on the basis of empowerments contained in the regulations referred to under nos. 1 to 6,

insofar as the Federation is not responsible for execution in accordance with the provisions of this Act, or with the statutory ordinances respectively issued on the basis thereof.

(2) Subject to the proviso of section 81, third sentence, as well as of sections 185 to 192 and subsection (1), the administrative tasks in accordance with this Act and with the statutory ordinances issued on the basis thereof shall be executed by the *Länder* on behalf of the Federation.

Section 185

Competence of the Federal Office for Radiation Protection; empowerment to issue ordinances

(1) The Federal Office for Radiation Protection shall be responsible for

1. licences for the use of radioactive substances or ionising radiation on people for the purpose of medical research, and withdrawing or revoking said licence,
2. reviewing the notification of the use of radioactive substances or ionising radiation on people for the purpose of medical research, and for prohibiting said use,
3. reviewing the notification of the operation of spacecraft, and for prohibiting said operation,
4. type approving devices that contain radioactive substances and installations for the

generation of ionising radiation in accordance with section 45 subsection (1) no. 1,

5. taking quality assurance measures when determining the body dose of air crew,
6. monitoring compliance with requirements for protection against public exposure from cosmic radiation when operating spacecraft in accordance with this Act or with a statutory ordinance issued on the basis of this Act,
7. establishing and managing a register of ethics committees which evaluate research projects on the use of radioactive substances or ionising radiation on people for the purpose of medical research, registering the ethics committees, and revoking said registration,
8. establishing and managing the register of occupational exposures,
9. establishing and managing the register of highly active radiation sources,
10. reviewing the justification of types of practice and reporting on the justification in accordance with section 7,
11. reviewing the justification for types of practice with consumer goods or type-approved devices and responding to the justification in accordance with section 38.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, with the consent of the Bundesrat, stipulating that the Federal Office for Radiation Protection is to be responsible

1. for retrospectively determining exposure of individual members of the public through practices defined, authorised or notified in the statutory ordinance in accordance with section 81, second sentence, no. 2,
2. for calculating, creating and publishing diagnostic reference levels, calculating the medical exposure of individuals and determining the surveys required in each instance on the basis of a statutory ordinance in accordance with section 86, second sentence, nos. 7 and 8,
3. for administering and issuing identification numbers for highly active radiation sources,
4. as the central body, for establishing and operating a system to record, process and evaluate information on significant incidents, especially in relation to the use of radioactive substances or ionising radiation on people in accordance with the statutory ordinance in accordance with section 90 subsection (1), second sentence, nos. 6 to 8,
5. for recognising bodies involved in the measurement of Rn-222 activity concentration, and
6. for taking quality assurance measures for measuring bodies for internal exposure and exposure caused by radon.

Section 186

Competence of the Federal Office for the Safety of Nuclear Waste Management

(1) The Federal Office for the Safety of Nuclear Waste Management shall be competent for licensing the transport of major sources, as well as withdrawing and revoking said

authorisation. Major sources shall be deemed to be radioactive substances the activity of which exceeds the activity level of 1 000 TBq per transported or despatched unit.

(2) The Federal Office for the Safety of Nuclear Waste Management shall also perform the responsibilities designated in section 184 as

1. the licensing and supervisory authority within the course
 - a) of surface exploration in accordance with section 16 subsection (1) of the Repository Site Selection Act (*Standortauswahlgesetz*),
 - b) of subterranean exploration in accordance with section 18 subsection (1) of the Repository Site Selection Act,
 - c) of establishing, operating and decommissioning installations of the Federation in accordance with section 9a subsection (3), first sentence, of the Atomic Energy Act, and
2. the supervisory authority competent for the Asse II mine.

Section 187

Competence of the German National Meteorology Institute (PTB)

(1) The National Meteorology Institute (*Physikalisch-Technische Bundesanstalt*) shall be competent for

1. type approval of stray radiation emitters in accordance with section 45 subsection (1) no. 1 and type approval in accordance with section 45 subsection (1) nos. 2 to 6,
2. taking quality assurance measures for measuring bodies for external exposure in accordance with the statutory ordinance in accordance with section 169 subsection (4), and
3. providing radioactivity standards for comparative measurements in accordance with the statutory ordinance in accordance with section 81, second sentence, no. 7.

(2) In relation to the tasks in accordance with this Act, the National Meteorology Institute shall be subject to the legal and technical supervision of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety. Insofar as the Institute's technical or scientific matters or its strategic orientation or other framework conditions are affected as a result, agreement shall be sought from the Federal Ministry for Economic Affairs and Energy.

Section 188

Competences for cross-border shipments and their monitoring

(1) The Federal Office for Economic Affairs and Export Control shall be competent for granting a licence for the cross-border shipment of consumer goods, as well as for withdrawing and revoking said authorisation. The same shall apply insofar as the statutory ordinances in accordance with section 24, first sentence, no. 7, and section 30 provide for licence and approval requirements, as well as for the inspection of notifications or registrations for

cross-border shipments.

(2) The Federal Ministry of Finance, or the customs offices which it designates, shall be competent for monitoring cross-border shipments of radioactive substances, of consumer goods or of products in accordance with section 39 subsection (1), first sentence, nos. 1 to 10, in which radioactive substances have been added or activated, and of residues. The customs offices may

1. hold for monitoring any cross-border shipments which contain radioactive substances, residues or the consumer goods or products referred to in the first sentence, as well as their means of transport, containers, loading equipment and packaging material,
2. report to the competent authorities if, in the course of performing their tasks, factual indications give them cause to suspect infringements of the prohibitions and restrictions in accordance with this Act or with statutory ordinances issued on the basis of section 24, first sentence, no. 7 and section 30, and
3. order, in cases falling under no. 2, that shipments in accordance with no. 1 be presented to the competent authorities at the cost and risk of the party entitled to dispose of the items in question.

Privacy of correspondence and posts in accordance with Article 10 of the Basic Law shall be restricted in accordance with the first and second sentences.

(3) Subject to the proviso of deviating provisions in national or European legal provisions, subsection (2) shall apply *mutatis mutandis* to cross-border shipments of substances with regard to which there is concern that their activity or specific activity may exceed the levels defined in accordance with a statutory ordinance in accordance with section 24, first sentence, no. 10.

(4) Where the Federal Office for Economic Affairs and Export Control decides by virtue of subsection (1), it shall be bound by the technical instructions of the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety, irrespective of its subordination to the Federal Ministry for Economic Affairs and Energy, and of its empowerment to issue directives derived from other legal provisions.

Section 189

Competence of the Federal Aviation Office

The Federal Aviation Office shall be competent for

1. reviewing the notification of the operation of aircraft, and for prohibiting said operation,
2. recognising calculation tools to determine the body dose of air crew,
3. monitoring compliance with requirements for protection against exposure of humans from cosmic radiation when operating aircraft in accordance with this Act or with a statutory ordinance issued on the basis of this Act,
4. a certificate of specialist knowledge in radiation protection insofar as it is required in connection with the operation of aircraft, and
5. the recognition of courses insofar as they serve to acquire the necessary specialist knowledge in radiation protection in connection with the operation of aircraft.

Section 190

Competence of the Federal Railway Authority

Section 24 subsection (1), second and third sentences, of the Atomic Energy Act on the competence of the Federal Railway Authority shall apply *mutatis mutandis* to the supervision and licensing of the transport of other radioactive substances. Competence to license the transport of major sources shall be determined in accordance with section 186 subsection (1).

Section 191

Remit of the Federal Ministry of Defence

(1) By way of derogation from section 189, the tasks in accordance with section 189 subsections (1) and (3) shall fall to the Federal Ministry of Defence, or to offices that it designates, with regard to the operation of aircraft that are operated within the remit of said Federal Ministry.

(2) Within the remit of the Federal Ministry of Defence, the competences designated in section 184 shall be executed by said Federal Ministry, or by offices that it designates. In cases falling under section 184 subsection (2), this shall be effected in consultation with the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety. The first and second sentences shall also apply to civilian workers in military forces that are in the Federal Republic of Germany under international agreements, and their civilian components.

Section 192

Competences of administrative authorities of the Federation for tasks related to emergency response and environmental radioactivity monitoring; empowerment to issue ordinances

(1) The Federal Office for Radiation Protection shall have competence for procuring and making available protective materials in accordance with section 104, insofar as no other jurisdiction is stipulated by statute or on the basis of a statute.

(2) The Federal Government is herewith empowered to issue a statutory ordinance, without the consent of the Bundesrat, stipulating which Federal authorities, corporations under direct federal control, or public agencies, or other bodies, shall perform the tasks of the Federation referred to in sections 104, 105, 106 subsection (2) no. 5, in sections 113 to 116, in section 120 subsections (1) and (2), second sentence, and in section 161 subsection (1).

Section 193

Transmission of information

(1) The Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety may transmit the following information, which is included in legal radiation protection licences granted by the authorities competent in accordance with sections 184 to

191, to the supreme Federal authorities responsible for foreign trade for the performance of their tasks in relation to licences or monitoring foreign trade

1. the holder of the licence,
2. the legal grounds for the licence,
3. the substantial content of the licence.

If this information is insufficient in an individual case, more information may be transferred from the legal radiation protection licence.

(2) The recipients may only use the transmitted information for the purpose for which it was transmitted, unless otherwise provided for by law.

Part 8

Final Provisions

Chapter 1

Regulatory fining provisions

Section 194

Regulatory fining provisions

(1) Anyone shall be deemed to have committed a regulatory offence who, by intent or negligence

1. contravenes a statutory ordinance in accordance with

- a) section 6 subsection (3), section 24, first sentence, no. 3, 4, 7(a) or 8 or second sentence, section 37 subsection (1), first sentence, nos. 2 to 5 or no. 6 or third sentence, section 49 no. 4 or 5, section 61 subsection (2), second sentence, section 62 subsection (6) no. 3, section 63 subsection (3), section 65 subsection (2), section 68 subsection (1), first sentence, section 72 subsection (2), second sentence, section 76 subsection (1), first sentence, and subsection (2) no. 1, 2, 6, 7, 8, 10, 11, 13, 15 or 16 or third sentence, section 79 subsection (1), first sentence, nos. 1 to 3 or no. 4, 6 or 8 or third sentence, section 81, first sentence, and subsection (2) no. 5, 7, 8, 9 or 10 or fourth sentence, section 82 subsection (1) no. 1 or 3, section 84 subsection (2), section 86, first sentence, and second sentence no. 2, 4, 5, 6, 9 to 14 or 15 or 19 or fifth sentence, sections 87 and 89, first sentence, no. 2, 3, 4, 5, 7, 8, 9 or 11 or second sentence, section 90 subsection (1), first sentence, or no. 1 or 2, section 95 subsection (2), first sentence, or subsection (3), section 123 subsection (2), section 143 subsection (1), third sentence, section 169 subsection (4) no. 1, 2 or 3, section 174,
- b) section 24, first sentence, no. 1, 2, 5, 6 or 9, section 37 subsection (1), second sentence, no. 1, 7 or 8, section 38 subsection (2) no. 1, section 68 subsection (1), second sentence, section 73, section 74 subsection (3) or (4) no. 1, 2, 4, 5 or 6, section 76 subsection (1), second sentence, no. 3, 4, 5, 9, 12 or 17, section 79 subsection (1), second sentence, no. 5, 7, 10, 11 or 12, section 81, second sentence, no. 1, 2, 3 or 4, section 82 subsection (1) no. 2 or 4, section 85 subsection (4), section 86, second sentence, no. 1, 3, 7, 8, 16, 17 or 18 or third or fourth sentence, section 88 subsection (6), section 89, first sentence, nos. 1, 6, 10 or 12, section 90 subsection (1), second sentence, no. 3 or 4, section 91, section 124, third sentence, section 132, 135 subsection (1), third sentence, section 136 subsection (2), section 139 subsection (4), section 169 subsection (4) no. 4, 5 or 6, section 170 subsection (10) no. 2 or 3, section 171, 172 subsection (4), section 173 or section 175 subsection (2),
- c) section 24, first sentence, no. 7(b) or section 30, first or second sentence,

or who contravenes an enforceable order based on such a statutory ordinance, insofar as the statutory ordinance makes reference to this regulatory fining provision for a particular offence,

2. without a licence in accordance with
 - a) section 10, builds an installation referred to therein,
 - b) section 12 subsection (1) no. 1 clause 1, operates an installation referred to therein,
 - c) section 12 subsection (1) no. 2, uses ionising radiation from X-ray equipment referred to therein,
 - d) section 12 subsection (1) no. 3 clause 1, handles other radioactive materials,
 - e) section 12 subsection (1) no. 4 clause 1, operates an X-ray installation,
 - f) section 12 subsection (1) no. 5 clause 1, operates a stray radiation emitter
 - g) section 12 subsection (2) in conjunction with subsection (1) no. 1, 4 or 5, modifies a practice requiring authorisation,
 - h) section 25 subsection (1), first sentence, employs a person in an installation referred to therein, or undertakes a task himself or herself,
 - i) section 27 subsection (1), first sentence, transports other radioactive substances on public transport routes or on transport routes accessible to the public,
 - j) section 31 subsection (1), first sentence, also in conjunction with the second sentence, uses radioactive substances or ionising radiation on people,
 - k) section 40 subsection (1), first sentence, also in conjunction with the second sentence, adds radioactive substances,
 - l) section 42 subsection (1), moves a consumer good referred to therein,
3. in contravention of section 17 subsection (1), first sentence, section 19 subsection (1), first sentence, section 22 subsection (1), section 26 subsection (3), first sentence, section 32 subsection (1), first sentence, also in conjunction with the second sentence, section 50 subsection (1), also in conjunction with subsection (2), section 52 subsection (1), also in conjunction with subsection (3), first sentence, section 56 subsection (1) also in conjunction with subsection (3), section 59 subsection (2), also in conjunction with subsection (4), or section 63 subsection (1), first sentence, fails to submit a notification, or fails to do so correctly or completely or in good time,
4. contravenes an enforceable order in accordance with section 18 subsection (3), section 20 subsection (3), (4) or (5), section 22 subsection (3), section 26 subsection (3), section 34, section 51 subsection (2), section 53 subsection (2) or (3), section 55 subsection (2), section 57 subsection (3) or (4), in each case also in conjunction with section 59 subsection (4), section 61 subsection (5), first sentence, section 63 subsection (2), section 64 subsection (2), third sentence, section 65 subsection (1), section 127 subsection (1), third sentence, section 129 subsection (2), third sentence, section 130 subsection (2), third sentence, section 134 subsection (3), section 135 subsection (3), first sentence, section 139 subsection (1), first sentence, also in conjunction with section 148, first sentence, section 156 subsection (3), first sentence, or section 156 subsection (4), second sentence, or section 158 subsection (2),

5. in contravention of section 21, section 54, section 58, also in conjunction with section 59 subsection (4), section 61 subsection (4), second sentence, section 64 subsection (2), first sentence, section 70 subsection (4), first sentence, section 71 subsection (2), first sentence, or section 167 subsection (3), third sentence, also in conjunction with the fourth sentence, fails to submit a communication, or fails to do so correctly or completely or in good time,
6. in contravention of section 28 subsection (2), first sentence, accepts nuclear material for shipment or transshipment,
7. in contravention of section 39 subsection (1), first sentence, also in conjunction with subsection (2), adds radioactive substances,
8. in contravention of section 39 subsection (1), second sentence, also in conjunction with subsection (2), moves or places on the market a product referred to therein,
9. contravenes an enforceable condition in accordance with section 47, second sentence, no. 4,
10. in contravention of section 55 subsection (1), first sentence, also in conjunction with the second sentence, in each case also in conjunction with section 59 subsection (1), first sentence, section 130 subsection (1), first sentence, also in conjunction with the second sentence or section 145 subsection (1), first sentence, also in conjunction with the second sentence, in each case also in conjunction with section 148, first sentence, fails to carry out an estimate, or fails to do so correctly or in good time,
11. in contravention of section 59 subsection (1), second sentence, fails to provide an estimate, or fails to do so in good time,
12. in contravention of section 60 subsection (1), first sentence, also in conjunction with the second sentence, section 62 subsection (1), first sentence, also in conjunction with subsection (5), first sentence, section 129 subsection (1), first sentence, section 129 subsection (2), first sentence, section 129 subsection (3), first sentence, section 145 subsection (2), first sentence, also in conjunction with section 148, or section 159 subsection (2), first sentence, fails to register, or fails to do so correctly or completely or in good time,
13. in contravention of section 60 subsection (2), first sentence, or section 60 subsection (4), first sentence, fails to present a residue concept or a residue balance, or fails to do so correctly or completely or in good time,
14. in contravention of section 61 subsection (3), first sentence, also in conjunction with the second sentence, mixes or dilutes residues,
15. in contravention of section 61 subsection (6), first sentence, fails to secure residues, or fails to do so correctly or in good time,
16. in contravention of section 61 subsection (6), second sentence, hands over residues,
17. in contravention of section 61 subsection (7), brings residues into Germany,
18. in contravention of section 62 subsection (4), second sentence, also in conjunction with subsection (5), first sentence, uses or disposes of residues,
19. in contravention of section 64 subsection (1), first sentence, fails to clear up contamination, or fails to do so correctly or completely or in the prescribed manner or in good time,

20. in contravention of section 70 subsection (1), first sentence, fails to appoint a radiation protection supervisor, or fails to do so correctly or in the prescribed manner or in good time,
21. in contravention of section 72 subsection (1), first sentence, no. 1 or section 72 subsection (2) no. 1(a), in each case also in conjunction with subsection (1), second sentence, fails to ensure that an exposure or contamination referred to therein is avoided or kept as low as possible,
22. in contravention of section 72 subsection (1), first sentence, no. 2(a) or section 72 subsection (2) no. 1(a), in each case also in conjunction with subsection (1), second sentence, fails to ensure compliance with a provision referred to therein,
23. in contravention of section 72 subsection (1), first sentence, no. 4, also in conjunction with the second sentence, fails to ensure that the necessary measures are carried out to prevent nuclear fuels becoming critical,
24. in contravention of section 85 subsection (1), first sentence, fails to ensure that a record is produced,
25. in contravention of section 85 subsection (1), third sentence, fails to secure a record, or fails to do so correctly,
26. in contravention of section 85 subsection (3) no. 1(a) clause 1 or section 85 subsection (3) no. 1(b), fails to present a record, or fails to do so correctly or completely or in good time,
27. in contravention of section 127 subsection (1), first sentence, fails to arrange for a measurement, or fails to do so correctly or in good time,
28. in contravention of section 127 subsection (3), section 128 subsection (2), second sentence, section 130 subsection (1), third sentence, section 134 subsection (2) or section 145 subsection (1), third sentence, also in conjunction with section 148 subsection (1), fails to produce a record referred to therein, or fails to do so correctly or completely or in good time, or fails to store said record, or fails to do so for at least five years, or fails to present said record, or fails to do so correctly or completely or in good time,
29. in contravention of section 128 subsection (1), fails to take action, or fails to do so correctly or in good time,
30. in contravention of section 128 subsection (2), first sentence, fails to conduct a review, or fails to do so correctly or in good time,
31. in contravention of section 129 subsection (3), second sentence, clause 2, fails to provide information,
32. in contravention of section 131 subsection (1) no. 3 clause 1, also in conjunction with clause 2, section 145 subsection (3) no. 2 clause 1, also in conjunction with clause 2, or section 159 subsection (3) no. 2 clause 1, also in conjunction with clause 2, fails to ensure that a dose limit is not exceeded,
33. in contravention of section 134 subsection (1), fails to determine the specific activity, or fails to do so correctly or in good time,
34. in contravention of section 135 subsection (1), first sentence, or section 135 subsection

tion (3), second sentence, places a construction product on the market,

35. in contravention of section 135 subsection (2), fails to transfer information, or fails to do so correctly or completely or in good time,
36. in contravention of section 138 subsection (1), also in conjunction with section 148, first sentence, or section 167 subsection (4), first sentence, fails to provide a notification, or fails to do so correctly or completely or in good time,
37. in contravention of section 140, also in conjunction with section 148, first sentence, fails to provide a communication, or fails to do so correctly or completely or in good time, or fails to provide documentary evidence, or fails to do so correctly or completely or in good time,
38. in contravention of section 167 subsection (1), fails to produce a record, or fails to do so correctly or completely or in good time,
39. in contravention of section 167 subsection (3), first sentence, fails to present a record, or fails to do so correctly or completely or in good time, or fails to deposit a record, or fails to do so correctly or completely or in good time,
40. in contravention of section 168 subsection (1), first sentence, fails to make available the data referred to therein, or fails to do so correctly or completely or in good time,
41. in contravention of section 168 subsection (1), second sentence, or section 168 subsection (2), fails to provide information, or fails to do so correctly or completely or in good time, or
42. contravenes an enforceable condition in accordance with section 179 subsection (1) no. 1 of this Act in conjunction with section 17 subsection (1), the second or third sentence, of the Atomic Energy Act, or contravenes an enforceable order in accordance with section 179 subsection (2) no. 1 of this Act in conjunction with section 19 subsection (3) of the Atomic Energy Act.

(2) The regulatory offence may, in cases falling under subsection (1) nos. 1(a) and (c), 2 to 4, 6 to 9, 14 to 23, 29, 32, 34 and 42, be punished with a penalty of up to fifty thousand Euros and, in the other cases, with a penalty of up to ten thousand Euros.

(3) The administrative authority within the meaning of section 36 subsection (1) no. 1 of the Act on Regulatory Offences (*Gesetz über Ordnungswidrigkeiten*) shall be

1. in cases falling under subsection (1) nos. 1(a) and (b), 2, 5 to 41 or 42, the Federal Office for the Safety of Nuclear Waste Management for its area of responsibility as designated in section 186,
2. in cases falling under subsection (1) nos. 1(c) and 2(l), the Federal Office for Economic Affairs and Export Control,
3. in cases falling under subsection (1) nos. 3 and 4
 - a) the Federal Office for Radiation Protection in connection with the operation of spacecraft,
 - b) the Federal Aviation Office in connection with the operation of aircraft,
 - c) the Federal Office for the Safety of Nuclear Waste Management for its area of re-

sponsibility as designated in section 186.

Section 195

Confiscation

If a regulatory offence in accordance with section 194 subsection (1) is committed intentionally, items may be confiscated that

1. are connected to the regulatory offence, or
2. were used or were intended to be used in committing or preparing for the offence.

Chapter 2

Transitional provisions

Section 196

The establishment of installations requiring a licence (section 10)

A licence to establish installations for the generation of ionising radiation which is granted before 31 December 2018 shall continue to apply as a licence in accordance with section 10 with all incidental provisions.

Section 197

Practices requiring a licence (section 12)

(1) A licence to operate installations for the generation of ionising radiation which is granted before 31 December 2018 shall continue to apply as a licence in accordance with section 12 subsection (1) no. 1 with all incidental provisions. This shall apply to licences in connection with use on people for treatment with ionising radiation based on an individual radiation treatment plan, if it has been demonstrated to the competent authority by 31 December 2020 that the prerequisites in accordance with section 14 subsection (1) no. 2(a) and Nos. (3)(a) and (4) have been met.

(2) A licence for handling other radioactive substances which is granted before 31 December 2018 shall continue to apply as a licence in accordance with section 12 subsection (1) no. 3 with all incidental provisions. This shall apply to licences

1. for managing highly active radiation sources only if evidence is presented by 31 December 2020 that the condition contained in section 13 subsection (4) has been met,
2. in connection with human use for treatment with radioactive substances and ionising radiation, which is based on an individual radiation plan, if evidence is presented to the competent authority by 31 December 2020 that the conditions in accordance with section 14 subsection (1) no. 2(a), 3(a) and 4 have been met,
3. in connection with human use for standardised treatment with radioactive substances, and for examination with radioactive substances, which may involve significant exposure for the person undergoing the examination, if evidence is presented to the competent authority by 31 December 2022 that the conditions in accordance with section 14 subsection (1) no. 2(b), 3(b) and 4 have been met.

The competent authority may require a licence-holder in accordance with the first sentence to provide a security in accordance with section 13 subsection (7) within two years of the entry into force of this Act.

(3) If a licence in accordance with section 6, section 7 or section 9 of the Atomic Energy Act, or a plan approval decision in accordance with section 9b of the Atomic Energy Act which is granted before 31 December 2018 extends to the handling of radioactive substances requiring authorisation, such extension shall continue to apply as an extension to han-

ding requiring authorisation in accordance with section 12 subsection (1) no. 3 of this Act.

(4) Practices in accordance with section 4 subsection (1), first sentence, no. 1, which were undertaken without a licence prior to 31 December 2018, and which require authorisation from 31 December 2018 in accordance with section 12 subsection (1) no. 3, may be continued if the application for the licence was submitted by 31 December 2019.

Section 198

X-ray equipment and stray radiation emitter operation requiring a licence (section 12)

(1) A licence for the operation of X-ray equipment granted before 31 December 2018, with the exception of the X-ray equipment referred to in subsections (2) and (3), shall continue to apply as a licence in accordance with section 12 subsection (1) no. 4 with all incidental provisions. This shall apply to

1. licences in connection with human use for treatment with ionising radiation which is based on an individual radiation plan, if evidence is presented to the competent authority by 31 December 2020 that the conditions in accordance with section 14 subsection (1) nos. 2(a), 3(a) and 4 have been met,
2. licences in connection with human use for standardised treatment with ionising radiation and examination with ionising radiation which may involve significant exposure for the person undergoing the examination, if evidence is presented to the competent authority by 31 December 2022 that the conditions in accordance with section 14 subsection (1) nos. 2(b), 3(b) and 4 have been met;
3. indefinite licences for teleradiology if evidence is presented to the competent authority by 31 December 2022 that the condition set out in section 14 subsection (2) no. 4 and, if applicable, the conditions referred to in no. 2, have been met.

(2) A licence for the operation of X-ray equipment for teleradiology purposes, other than for overnight, weekend and public holiday services which is granted before 31 December 2018 in accordance with section 3 subsection (1) of the X-ray Ordinance (*Röntgenverordnung*), in the version applicable until 31 December 2018, and which has been restricted in accordance with section 3 subsection (4), fourth sentence, of the X-ray Ordinance, shall continue to apply with all incidental provisions until the period referred to in the licence expires.

(3) A licence for the operation of X-ray equipment for the examination of human beings within the framework of voluntary X-ray screening programmes which is granted before 31 December 2018 in accordance with section 3 subsection (1) of the X-ray Ordinance, in the version applicable until 31 December 2018, and which is restricted in accordance with section 3 subsection (4a), second sentence, of the X-ray Ordinance, shall continue to apply with all incidental provisions until the period referred to in the licence expires.

(4) A licence for the operation of stray radiation emitters granted before 31 December 2018 shall continue to apply as a licence in accordance with section 12 subsection (1) no. 5 with all incidental provisions.

Section 199

Notifiable operation of installations (section 17)

If the operation of an installation for the generation of ionising radiation was notified before 31 December 2018, this shall continue to apply as notification in accordance with section 17 subsection (1).

Section 200

Notifiable X-ray equipment and stray radiation emitter operation (section 19)

(1) If the operation of X-ray equipment was notified before 31 December 2018, this shall continue to apply as notification in accordance with section 19 subsection (1) no. 1. This shall apply to notifications in connection with use on human beings for examination with X-ray radiation which may involve significant exposure for the person being examined, if evidence has been presented to the competent authority by 31 December 2022 that the applicable conditions in accordance with section 19 subsection 3 no. 7, in conjunction with section 14 subsection (1) nos. 2(b) and 4, have been met.

(2) If the operation of a basic-, high- or full-protection device or X-ray equipment for training purposes is notified before 31 December 2018, this shall continue to apply as notification in accordance with section 19 subsection (1) no. 2.

Section 201

Notifiable verification, testing, maintenance and repair of X-ray equipment and stray radiation emitters (section 22)

If the verification, testing, maintenance and repair of X-ray equipment and stray radiation emitters was notified before 31 December 2018, this shall continue to apply as notification in accordance with section 22 subsection (1).

Section 202

Employment requiring a licence in third-party installations or facilities (section 25)

A licence for employment in third-party installations or facilities which was granted before 31 December 2018 shall continue to apply as a licence in accordance with section 25 subsection (1) with all incidental provisions, until the date specified in the licence notice, and at the latest until 31 December 2023.

Section 203

Employment requiring authorisation in connection with the operation of third-party X-ray equipment and stray radiation emitters (section 26)

If the performance of tasks in connection with the operation of third-party X-ray equipment or of third-party stray radiation emitters was notified before 31 December 2018, this shall continue to apply as notification in accordance with section 26 subsection (1).

Section 204

Transport of radioactive substances requiring a licence (section 27)

(1) A licence for transport that was granted before 31 December 2018 shall continue to apply as a licence in accordance with section 27 subsection (1) with all incidental provisions if evidence of the required expertise in accordance with section 29 subsection (1) no. 2 is presented to the competent authority by 31 December 2021.

(2) If a licence in accordance with section 4 subsection (1) of the Atomic Energy Act that was granted before 31 December 2018 extends to the transport – requiring authorisation – of radioactive substances, such extension shall continue to apply as an extension to transport requiring authorisation in accordance with section 27 subsection (1) of this Act, if evidence of the required expertise in accordance with section 29 subsection (1) no. 2 of this Act is presented to the competent authority before 31 December 2021.

Section 205

Medical research (sections 31 and 32)

(1) Authorisation for the use of radioactive substances or ionising radiation on human beings for the purpose of medical research that was granted in accordance with section 23 subsection (1), in conjunction with section 24 subsection (1) of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, or in accordance with section 28a subsection (1) in conjunction with section 28b subsection (1) of the X-ray Ordinance, in the version applicable until 31 December 2018, shall continue to apply as authorisation with all incidental provisions in accordance with section 31.

(2) Authorisation for the use of radioactive substances or ionising radiation on human beings for the purpose of medical research that was granted in accordance with section 23 subsection (1), in conjunction with section 24 subsection (2), of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, or in accordance with section 28a subsection (1), in conjunction with section 28b subsection (2), of the X-ray Ordinance, in the version applicable until 31 December 2018, shall continue to apply as notification in accordance with section 32.

(3) Authorisation procedures that were commenced before 31 December 2018 for the use of radioactive substances or ionising radiation on human beings for the purpose of medical research, in accordance with section 23 subsection (1), in conjunction with section 24 subsection (2), of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, or in accordance with section 28a subsection (1) in conjunction with section 28b subsection (2) of the X-ray Ordinance, in the version applicable until 31 December 2018, shall be completed in accordance with the provisions applicable before 31 December 2018. Subsection (2) shall apply *mutatis mutandis* to licences in accordance with the first sentence.

(4) Registrations of ethics committees in accordance with section 92 of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, or with section 28g of the X-ray Ordinance, in the version applicable until 31 December 2018, shall continue to apply as registrations in accordance with section 36 subsection (1) of this Act.

Section 206

Addition of radioactive substances requiring a licence and activation requiring a licence (section 40)

(1) A licence for the addition of radioactive substances and activation which was granted before 31 December 2018 shall continue to apply as a licence in accordance with section 40 subsection (1) with all incidental provisions. If a withdrawal concept in accordance with section 41 subsection (1) no. 3 which was not required prior to 31 December 2018, first sentence, is required after 31 December 2018 before a licence can be granted, the first sentence shall only apply if a withdrawal concept was created by 31 December 2019 for consumer goods produced from this date onwards.

(2) A licence shall still not be required for the use, storage and disposal of consumer goods that were produced prior to 1 August 2001, or for which authorisation was not required in accordance with section 117 subsection (6), first sentence, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018.

Section 207

Cross-border shipment of consumer goods requiring a licence (section 42)

A licence for the cross-border shipment of consumer goods which was granted before 31 December 2018 shall continue to apply as a licence in accordance with section 42 with all incidental provisions; section 206 subsection (1), second sentence, shall apply *mutatis mutandis*.

Section 208

Type approval (section 45)

(1) Type approvals for devices and other equipment to which other radioactive substances have been added in accordance with section 2 subsection (1) of the Atomic Energy Act for installations for the generation of ionising radiation and for X-ray tube assemblies, X-ray equipment for training purposes, basic-protection devices, high-protection devices, full-protection devices or stray radiation emitters which were valid on 31 December 2018 shall continue to apply until the period referred to on the type approval certificate expires; they may be extended on application in accordance with section 46 subsection (5), second sentence, as approvals in accordance with section 45 subsection (1).

(2) Equipment the type approval of which expired before 31 December 2018, and which has continued to be operated in accordance with section 25 subsection (5) of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, or in accordance with section 8 subsection (5) of the X-ray Ordinance, in the version applicable until 31 December 2018, may continue to be operated in accordance with section 48.

(3) The use and storage of equipment which contains radioactive substances and for which a type approval was granted before 1 August 2001 shall continue to be subject to the provisions contained in section 4 subsection (1) no. 2, second and fifth sentences, in conjunction with Annex II number 2 or 3 and Annex III, Part B, number 4, section 29 subsection (1), first sentence, sections 34 and 78 subsection (1) no. 1 of the Radiation Protection Ordinance of 30 June 1989; once this type approval has expired, the provision contained in section 23 subsection (2), third sentence, of the Radiation Protection Ordinance of 30 June

1989 shall also continue to apply; section 69 subsection (2), sections 70, 71 and 72 of this Act shall apply *mutatis mutandis*.

(4) Equipment the type approval of which expired before 1 August 2001, and which has continued to be operated on the basis of section 117 subsection (7), third sentence, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, in accordance with section 23 subsection (2), third sentence, in conjunction with section 4 of the Radiation Protection Ordinance of 30 June 1989, may continue to be operated without authorisation.

Section 209

Notifiable aircraft operation (section 50)

Activities within the meaning of section 4 subsection (1), first sentence, no. 11 which commenced before 31 December 2018 and require notification in accordance with section 50 in accordance with this Act may be continued if the notification is made by 31 December 2020.

Section 210

Notifiable practices (section 56)

(1) Notification of an activity within the meaning of section 4 subsection (1), first sentence, no. 10, which was made before 31 December 2018 shall continue to apply as notification in accordance with section 56 subsection (1), insofar as the documents required in accordance with section 56 subsection (2), first sentence, have been submitted to the competent authority by 31 December 2020.

(2) If an activity within the meaning of section 4 subsection (1), first sentence, no. 10, was commenced before 31 December 2018 without notification being required, an estimation shall be conducted in accordance with section 55 subsection (1), first sentence, by 31 December 2020; section 56 subsection (1), first sentence, shall apply *mutatis mutandis*. The estimation need not be repeated if a workplace-related estimation of body dose was conducted and recorded before 31 December 2018; in this case, notification as required in accordance with section 56 subsection (1), first sentence, must be effected without undue delay; section 56 subsection (2), second sentence, shall apply *mutatis mutandis*.

Section 211

Appointment of radiation protection supervisors (section 70)

The appointment of a radiation protection supervisor that was effected before 31 December 2018 shall continue to apply as an appointment in accordance with section 70 subsection (1).

Section 212

Limits for occupationally-exposed persons; determination of public exposure (sections 78 and 80)

(1) The limit in accordance with section 78 subsection (2) no. 1 shall be complied with from 1 January 2019 onwards.

(2) Section 80 shall apply to the determination of public exposure from 1 January 2019 onwards.

Section 213

Approval of early detection (section 84)

Approval of voluntary X-ray screening programmes to identify communicable diseases in regions or groups of the population with above-average morbidity in accordance with section 25 subsection (1), second sentence, of the X-ray Ordinance, in the version applicable until 31 December 2018, shall continue to apply in accordance with section 84 subsection (4).

Section 214

Registration of indoor workplaces (section 129)

(1) Registration of work effected before 31 December 2018 which was attributed to a field of work referred to in Annex XI, Part A, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, shall continue to apply as registration in accordance with section 129 subsection (1), providing that measures to reduce Rn-222 exposure, insofar as they are necessary in accordance with section 128 subsection (1), are taken by 31 December 2020.

(2) A measurement of the Rn-222 activity concentration, which is performed before 31 December 2018 as part of an estimation in accordance with section 95 subsection (1) in conjunction with Annex XI, Part A, of the Radiation Protection Ordinance, in the version applicable until 31 December 2018, shall be deemed to fulfil the measurement obligation in accordance with section 127 subsection (1).

Section 215

Radioactively-contaminated sites

(1) Permits which were granted before 31 December 2018 in the territory referred to in Article 3 of the Unification Treaty of 6 September 1990 (Federal Law Gazette 1990 II, p. 885) for remedial, protective or aftercare measures on the legacy of earlier human activities within the meaning of section 136 subsection (1), as well as for the decommissioning and remediation of the operational installations and sites of uranium ore mining on the basis of

1. the Nuclear Safety and Radiation Protection Ordinance (*Verordnung über die Gewährleistung von Atomsicherheit und Strahlenschutz*) of 11 October 1984 (Law Gazette I No 30, p. 341), along with implementing provisions of the Nuclear Safety and Radiation Protection Ordinance of 11 October 1984 (Law Gazette I No 30, p. 348, Law Gazette

1987 I No 18, p. 196), and

2. the Order for the Guarantee of Radiation Protection in Dumps and Industrial Sedimentation Installations and the Use of Materials Stored Therein (*Anordnung zur Gewährleistung des Strahlenschutzes bei Halden und industriellen Absetzanlagen und bei der Verwendung darin abgelagerter Materialien*) of 17 November 1980 (Law Gazette I No 34, p. 347),

shall continue to apply, insofar as they were granted after the Unification Treaty entered into force, or were granted prior to this date but continue to apply.

(2) The measures based on the permits may be terminated in accordance with the permit in question.

Section 216

Determinations by measuring bodies (section 169)

Official determinations of measuring bodies which were effected before 31 December 2018 shall continue to apply as determinations in accordance with section 169 subsection (1) if evidence is presented to the competent authority by 31 December 2020 that the conditions in accordance with section 169 subsection (2) are met.

Section 217

Determinations by authorised experts (section 172)

Official determinations by authorised experts which were effected before 31 December 2018 shall continue to apply as determinations in accordance with section 172 subsection (1) no. 1, 3 or 4 for five years at the most.

Section 218

Licence-exempt handling of devices, ceramic objects, porcelain and glassware or electronic components and other products

(1) Devices, ceramic objects, porcelain and glassware or electronic components that were procured before 1 April 1977 the handling of which was exempt from authorisation in accordance with section 11 of the First Radiation Protection Ordinance of 15 October 1965 may continue to be used and disposed of without a licence if these objects complied with the provision contained in section 11 of the First Radiation Protection Ordinance of 15 October 1965 at the time when they were procured.

(2) Other products which comply with the requirements of Annex III, Part A, no. 5, 6 or 7 of the Radiation Protection Ordinance in the version of 30 June 1989, and which were acquired before 1 August 2001, may continue to be used, stored or disposed of without authorisation.

Annex 1

(re section 5 subsection (32))

Residues in accordance with section 5 subsection (32)

Residues within the meaning of this Act shall include the following materials:

1. sludge and deposits from the extraction, processing and preparation of crude oil and natural gas from deep geothermics;
2. gravel, sand, resin and granular activated carbon from groundwater treatment;
3. untreated phosphogypsum, sludge from its treatment and dust and slag from the processing of rock phosphate (phosphorite);
4. leftover rock, sludge, sand, slag and dust
 - a) from the extraction and treatment of bauxite, columbite, pyrochlore, microlite, euxenite, copper shale, tin, rare earth and uranium ores,
 - b) from further processing or concentrates and residues that occur in the extraction and treatment of these ores and minerals;
5. materials that equate to the ores referred to in no. 4 and that occur in the extraction and treatment of other raw materials;
6. dust and sludge from flue gas purification for primary smelting in pig iron and non-ferrous metallurgy.

Residues within the meaning of this Act shall also include

1. materials in accordance with the first sentence if these materials have been produced deliberately;
2. shaped parts from the materials referred to in the first sentence, as well as
3. excavated or removed ground and rubble from the demolition of buildings or other structural installations, if this ground and rubble contains residues in accordance with the first sentence and is removed in accordance with section 64 after the cessation of activities, or from land in accordance with section 141.

Materials in accordance with the first sentence shall not constitute residues within the meaning of this Act

1. if their specific activity for each radionuclide of the nuclide chains U-238sec and Th-232sec is below 0.2 Bq/g and they are not used as construction products, or
2. they are introduced as raw materials in the technological processes referred to there.

Annex 2

(re section 16, section 25 subsection (2), section 40 subsection (4) and section 46 subsection (1))

Documents required to assess licence applications

Part A: Documents required to apply for licences in accordance with section 12 subsection (1) nos. 1 and 2

1. Safety report which
 - a) describes the installation and its operation and uses site plans and layout drawings to represent the same,
 - b) describes the effects and risks associated with the installation and its operation, and
 - c) details the equipment and measures to be arranged in accordance with section 13 subsection (1) no. 6(a),
2. Supplementary plans, drawings and descriptions of the installation and its parts
3. Information that makes it possible to check whether
 - a) the necessary number of radiation protection supervisors have been appointed for the safe execution of the activity and they have been granted the necessary powers for the performance of their duties,
 - b) it is guaranteed that the equipment is available and the measures have been taken which are necessary in accordance with the scientific and technical state-of-the-art in order to comply with the safety regulations,
 - c) the necessary protection is ensured against disturbances or other interventions by third parties, insofar as the installation requires a licence in accordance with section 10,
4. Information that makes it possible to check whether the radiation protection executive and the radiation protection supervisors are reliable and possess the necessary expertise in radiation protection,
5. Copy of radiation protection instructions in accordance with the statutory ordinance in accordance with section 73,
6. Documentary evidence of the required financial security to comply with the legal liability to pay compensation for damage;
7. In connection with
 - a) use on human beings: information that makes it possible to check whether the conditions of section 14 subsection (1) have been met,
 - b) use on animals in veterinary medicine: information that makes it possible to check whether the conditions of section 15 have been met,
 - c) the operation of installations for the generation of ionising radiation in medicine

within the meaning of the Medical Products Act: information on the intended purpose of the equipment that makes it possible to check whether the medical product is suitable for the intended use.

Part B: Documents required to apply for licences in accordance with section 12 subsection (1) no. 3 and section 40

1. Plans, drawings and descriptions that are required to verify compliance with the licensing conditions,
2. Information that makes it possible to verify whether
 - a) the necessary number of radiation protection supervisors have been appointed for the safe execution of the activity and they have been granted the necessary powers for the performance of their duties,
 - b) it is ensured that the equipment is available and that measures are taken which are necessary in accordance with the scientific and technical state-of-the-art in order to comply with the safety regulations,
 - c) the necessary protection is ensured against disturbances or other interventions by third parties,
3. Information that makes it possible to check whether the radiation protection executive and the radiation protection supervisors are reliable and possess the necessary expertise in radiation protection,
4. Copy of radiation protection instructions in accordance with the statutory ordinance in accordance with section 73,
5. documentary evidence of financial security to comply with the legal liability to pay compensation for damage,
6. In connection with
 - a) use on human beings: information that makes it possible to verify compliance with the conditions of section 14 subsection (1),
 - b) use on animals in veterinary medicine: information that makes it possible to verify compliance with the conditions of section 15,
 - c) the use of radioactive substances in medical irradiation facilities within the meaning of the Medical Products Act: information on the intended purpose of the installation that makes it possible to verify whether the medical product is suitable for the intended use,
 - d) the early detection of diseases: information that makes it possible to verify whether the conditions of section 14 subsection (3) no. 2 have been met.

Part C: Documents required to apply for licences in accordance with section 12 subsection (1) no. 4

1. Plans, drawings and descriptions that are required to verify compliance with the licensing conditions,

2. Information that makes it possible to verify whether
 - a) the necessary number of radiation protection supervisors have been appointed for the safe execution of the activity and they have been granted the necessary powers for the performance of their duties,
 - b) it is guaranteed that the equipment is available and that measures have been taken which are necessary in accordance with the state-of-the-art in order to comply with the safety regulations,
3. Information that makes it possible to verify whether the radiation protection executive and the radiation protection supervisors are reliable and possess the necessary expertise in radiation protection,
4. Copy of a radiation protection instruction in accordance with the statutory ordinance in accordance with section 73, if it is necessary that a radiation protection instruction be issued,
5. In connection with
 - a) use on human beings: information that makes it possible to verify whether the conditions of section 14 subsection (1) have been met,
 - b) use on animals in veterinary medicine: information that makes it possible to verify whether the conditions of section 15 have been met,
 - c) use of X-ray equipment in teleradiology: information that makes it possible to verify whether the conditions of section 14 subsection (2) have been met,
 - d) the early detection of diseases: information that makes it possible to check verify the conditions of section 14 subsection (3) no. 2 have been met.

Part D: Documents required to apply for licences in accordance with section 12 subsection (1) no. 5

Part C nos. 1 to 4 shall be applied *mutatis mutandis* to licences in accordance with section 12 subsection (1) no. 5.

Part E: Documents required to apply for licences in accordance with section 25

1. Information that makes it possible to verify whether
 - a) the necessary number of radiation protection supervisors have been appointed for the safe execution of the activity and they have been granted the necessary powers for the performance of their duties,
 - b) it is ensured that the equipment is available and measures taken which are necessary in accordance with the scientific and technical state-of-the-art in order to comply with the safety regulations,
2. Information that makes it possible to verify whether the radiation protection executive and the radiation protection supervisors are reliable and possess the necessary expertise in radiation protection,
3. Information that outlines the distribution of tasks between the licence holder's radiation protection supervisor and the radiation protection supervisor of the third-party installa-

tion or facility; this may be in the form of a draft delimitation agreement.

Part F: Documents required to apply for licences in accordance with section 40 subsection (1) and section 42 subsection (1)

1. Information on the intended use of the consumer good,
2. Information on the technical properties of the consumer good, including the necessary drawings, and on the type of insertion, attachment, embedding or enclosure of the radioactive substances,
3. Information on the added radioactive substances, including physical and chemical composition, and on the activity and the specific activity of each added radionuclide,
4. Information on dose rates at the distances relevant for the use of the consumer good, including the dose rates at a distance of 0.1 metres from any accessible surface,
5. Documentary evidence that the activity of the added radioactive substances is as low as possible in accordance with the state of the art,
6. In cases where the activity in a consumer good exceeds the exemption levels stipulated in a statutory ordinance in accordance with section 24, first sentence, no.10, information on the potential human exposure as the result of using the consumer good, and
7. In cases where the specific activity of the added artificial radioactive substances exceeds the exemption levels stipulated in a statutory ordinance in accordance with section 24, first sentence, no. 10, for the specific activity, or the specific activity of the added natural radioactive substances in the consumer good is in excess of 0.5 Bq/g, information on the withdrawal concept, as well as the information in accordance with section 41 subsection (1) no. 5.

Part G: Documents required to apply for approvals in accordance with section 45 subsection (1) no. 1

1. Drawings that are required for the type examination,
2. Descriptions of the design, operating method and purpose and, where necessary, references to the type of recurring leakage test in accordance with the statutory ordinance in accordance with section 89, first sentence, no. 3,
3. Information on quality assurance,
4. Information on the return of the device which contains radioactive substances to the approval holder or information on disposal of the device.

Annex 3

(re section 55 subsection (1))

Fields of activity in accordance with section 55 subsection (1)

1. Grinding of thoriated welding electrodes and AC welding with thoriated welding electrodes,
2. Handling and storage of thoriated incandescent gas mantles,
3. Handling and storage of optical components containing thorium,
4. Use of thorium or uranium in its natural isotopic composition, including the daughter nuclides arising in each case, if present, for analytical or preparative chemical purposes,
5. Handling of products made from thoriated alloys, especially the assembly, disassembly, processing and examination of such products,
6. Extraction, use and processing of pyrochlore ores,
7. Use and processing of slag from the smelting of copper shale ores,
8. Processing of niobium and tantalum ores,
9. Handling, especially maintenance or cleaning activities, of sludge and deposits from the extraction, processing and preparation of crude oil and natural gas from deep geothermics,
10. Processing of substances containing zirconium in the manufacture of refractory materials,
11. Maintenance of clinker furnaces in cement production and boilers in coal-fired power stations,
12. Storage of residues requiring monitoring and the removal of contamination from land in accordance with section 64.

Annex 4

(re section 97 subsection (5))

Documents applicable as provisional emergency response plans of the Federation

1. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety: Notice of a recommendation made by the Technical Committee for Radiation Protection (framework recommendation for disaster protection in the area surrounding nuclear installations of 19 February 2015), adopted at the 274th session of the Committee on 19/20 February 2015, approved by the General Committee of the *Länder* Committee for Nuclear Energy (LAA) on 25/26 June 2015, approved by the Standing Conference of Interior Ministers and Senators of the *Länder* at their 203rd session on 3/4 December 2015, published in the Federal Gazette (BAnz) AT 4 January 2016 B4;
2. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety: Notice of a joint recommendation made by the Reactor Safety Commission (RSK) and the Commission on Radiological Protection (Criteria for alerting the disaster protection authorities by the operators of nuclear installations of 28 February 2013), adopted at the 366th session of the Reactor Safety Commission (RSK) on 16 October 2003 and at the 453rd session of the Commission on 13 December 2012, as well as at the 186th session of the Commission on Radiological Protection (SSK) on 11/12 September 2003, and at the 260th session of the Commission on 28 February 2013, published in the Federal Gazette AT 9 October 2014 B1;
3. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety: Notice of a recommendation made by the Commission on Radiological Protection (Basic radiological principles for decisions on measures for the protection of the population against accidents involving releases of radionuclides), adopted at the 268th session of the SSK on 13/14 February 2014, published in the Federal Gazette AT 18 November 2014 B5;
4. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: Notice of a recommendation made by the Commission on Radiological Protection (Guidelines on informing the public in case of nuclear emergencies), adopted at the 220th session of the SSK on 5/6 December 2007, published in the Federal Gazette No 152a of 8 October 2008;
5. Reports of the Commission on Radiological Protection of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Issue 60, Parts 1 and 2 (Overview of measures to reduce radiation exposure following incidents with a significant radiological impact), published on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by the Secretariat of the Commission on Radiological Protection at the Federal Office for Radiation Protection in May 2010, ISBN 978-3-87344-163-7, adopted at the 220th session of the SSK on 5/6 December 2007;
6. General administrative regulation on the integrated measuring and information system for monitoring radioactivity in the environment (IMIS) in accordance with the Preventive Radiation Protection Act (*Strahlenschutzvorsorgegesetz*) (AVV-IMIS) of 13 December 2006, published in the Federal Gazette No 244a of 29 December 2006;
7. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: Notice of the Guideline on Emission and Immission Monitoring of Nuclear Installations (REI) of 7 December 2005, approved by the General Committee of the *Länder* Committee for

Nuclear Energy on 27 October 2005, published in the Joint Ministerial Gazette (GMBI.) 2006, Nos. 14-17, p. 254;

8. Reports of the Commission on Radiological Protection of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Issue 37 (Guidance for the expert adviser for radiation protection of disaster protection management in case of nuclear emergencies), published on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by the Secretariat of the Commission on Radiological Protection at the Federal Office for Radiation Protection in September 2003, ISBN 3-437-22178-7, adopted at the 182nd session on 4/6 December 2002;
9. Publications of the Commission on Radiological Protection of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Volume 4 (Medical measures in case of nuclear power plant accidents), published in 2007 on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by the Secretariat of the Commission on Radiological Protection at the Federal Office for Radiation Protection, ISBN 978-3-87344-131-6;
10. Publications of the Commission on Radiological Protection of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, Volume 32 (The radiation accident), published in 2008 on behalf of the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety by the Secretariat of the Commission on Radiological Protection at the Federal Office for Radiation Protection, ISBN 978-3-87344-139-2;
11. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: Notice of a recommendation made by the Commission on Radiological Protection (Use of iodine tablets for iodine blockage of the thyroid in case of nuclear accident), adopted at the 247th session of the SSK on 24/25 February 2011, published in the Federal Gazette p. 3144;
12. Federal Ministry for the Environment, Nature Conservation and Nuclear Safety: Notice of a recommendation made by the Commission on Radiological Protection (Guidelines on setting contamination limits for surfaces of vehicles crossing borders in accordance with the Preventive Radiation Protection Act), adopted at the 139th session of the SSK on 26-28 June 1996, published in the Federal Gazette 1997 p. 43;
13. Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety: Notice on the use of the German version of the International Nuclear and Radiological Event Scale (INES) User's Manual in nuclear installations and in radiation protection outside the nuclear technology area, published in the Federal Gazette AT 30 March 2015 B1;
14. Federal Office of Civil Protection and Disaster Assistance (BBK): Safety of drinking water supplies, Part 1: Risk analysis, basic principles and recommended actions for water supply agencies in local authorities in relation to unusual hazardous situations, *Praxis im Bevölkerungsschutz*. Vol. 15, version: January 2016, ISBN 978-3-93947-69-9;
15. DVGW Deutscher Verein des Gas- und Wasserfachs e.V. — Technisch-Wissenschaftlicher Verein: *Radioaktivitätsbedingte Notfallsituationen; Technische Mitteilung — Hinweis W 255*, December 2008, ISSN 0176-3504;
16. Federal Government: General administrative regulation on the implementation of the monitoring of foodstuffs in accordance with Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radi-

ological emergency (AVV-StrahLe) of 28 June 2000 (Joint Ministerial Gazette p. 490);

17. Federal Government: General administrative regulation on the monitoring of maximum levels in animal feeding stuffs in accordance with Council Regulation (Euratom) No 3954/87 of 22 December 1987 laying down maximum permitted levels of radioactive contamination of foodstuffs and of feeding stuffs following a nuclear accident or any other case of radiological emergency (FMStrVVwV) of 22 June 2000 (Federal Gazette p. 12 565).

Key elements of the general emergency response plan of the Federation

1. A general representation of the legal foundations, tasks and competences of the Federation and the *Länder*, of their competent authorities responsible for emergency response measures, of the authorities involved in emergency response, and of the organisations and persons under public law involved in emergency response;
2. A representation
 - a) of the procedures and arrangements for the exchange of information, cooperation, assistance and coordination of the emergency response at Federal level, between the Federation and the *Länder*, with bodies, offices, organisations and other Member States of the European Union, with third countries and with international organisations, and
 - b) of the bodies and organisations that are responsible for this exchange of information, cooperation, assistance and coordination;
3. The reference levels defined for public exposure in accordance with section 93;
4. The reference scenarios;
5. The exposure levels referred to in section 114 subsection (1) which workers' exposure should fall short of, and the reference levels in accordance with section 114 subsections (2) and (3);
6. Scenario-specific optimised protection strategies, which shall include the following in particular:
 - a) representation of the priority and other measures to be considered for the protection of the public and workers,
 - b) information on the dose levels that serve as the radiological criterion for the suitability of specific protective measures,
 - c) information on the criteria for triggering the alert system and for taking specific protective measures (trigger criteria), especially measured quantities or indicators of conditions at the location of the radiation source,
 - d) information on limits or guide values which relate to specific, directly-quantifiable consequences of the emergency, e.g. dose rates, contamination levels or activity concentrations,
 - e) information on calculation procedures and assumptions on which the optimised protection strategy in question is based;
7. Information on the determination and evaluation of the radiological situation, especially
 - a) on the exchange of information with the Federal Radiological Situation Centre,
 - b) on the tasks of the Federal Radiological Situation Centre,

- c) on the tasks, competences and monitoring measures of the Federation and the *Länder* in accordance with sections 107, 161 to 163 and 165, especially measuring strategies, in an emergency, and
 - d) on the radiological situation report in accordance with section 108;
8. Information on the application of the optimised protection strategy taking the actual situation into account, especially
- a) on the relationship of the radiation protection regulations, emergency response principles and protection strategies with the provisions and objectives
 - aa) of other legal provisions of the Federation and the *Länder* for measures of that kind to avert dangers to human health, the environment or public safety, as well as
 - bb) of directly-applicable acts of the European Union and of the European Atomic Energy Community,
 - b) on the selection and adaptation of the protection strategy for an actual situation that deviates from the reference scenarios,
 - c) on the verification of the suitability, feasibility, prioritisation, necessity and appropriateness of the protective measures, taking into account all relevant non-radiological decision-making criteria, especially the damage and other disadvantages which may arise due to the protective measures during the emergency in question;
9. Guidelines for the review and adaptation of the protection strategy and measures (section 111 and section 109 subsection (3)); this shall include stipulations
- a) on dose estimation,
 - b) on a comparison of the results of the dose estimation with the applicable reference level,
 - c) on the assessment of the effectiveness of the protection strategies and measures,
 - d) on the adaptation of the protection strategies and measures to the developing circumstances of the emergency in question, and to the results of the effectiveness assessment,
 - e) on the criteria and procedures for changing reference levels,
 - f) on the adaptation of the protection strategies and measures to a changed reference level or other changed or new legal provisions,
 - g) on the criteria and procedures for cancelling protective measures;
10. Stipulations on informing the population and recommending steps to be taken;
11. Stipulations on the transition to an existing exposure situation.

Key elements of the specific emergency response plans of the Federation

1. A representation of the legal foundations, tasks and competences applicable emergency response plan of the Federation and the *Länder*, of their competent authorities responsible for emergency response measures and of the authorities involved in emergency response, and of the organisations and persons under public law involved in emergency response within the scope of the specific emergency response plan;
2. A representation
 - a) of the procedures and arrangements applicable within the scope of the specific emergency response plan for the exchange of information, cooperation, assistance and coordination of the emergency response at Federal level, between the Federation and the *Länder*, with bodies, offices, organisations and other Member States of the European Union, with third countries and with international organisations, and
 - b) of the bodies and organisations that are responsible for this exchange of information, cooperation, assistance and coordination;
3. Information and an explanation of the interfaces to
 - a) other procedures and arrangements for the exchange of information, cooperation, assistance and coordination of the emergency response which are detailed in the other emergency response plans of the Federation and the *Länder*,
 - b) the other bodies and organisations that are also responsible for the exchange of information, cooperation, assistance and coordination of the emergency response;
4. On the substantiation, amendment and application of the optimised protection strategies defined in the general emergency response plan of the Federation, including a representation
 - a) of the prioritised and other measures for the protection of the public and workers considered within the scope of the specific emergency response plan, and
 - b) of the arrangements and criteria for the area-specific substantiation, application and adaptation of the trigger criteria and limits or guidelines detailed in the general emergency response plan, taking into account the legal provisions applicable to the respective protective measure and the actual characteristics of the emergency, insofar as such a representation is possible in advance within the course of emergency response planning.

Information for the public and recommended steps to be taken in the event of emergencies

1. Information and recommended action to be provided to the affected population in an emergency

On the basis of the emergency response plans applicable to the respective emergency, the affected population shall rapidly and repeatedly receive the following

- a) information on the emergency that has occurred, and where possible its characteristics, such as its origin, dispersion and probable development;
- b) recommended steps to be taken, which, depending on the circumstances of the respective emergency, may
 - aa) include the following points in particular: restrictions on the consumption of certain possibly contaminated foodstuffs and water, simple rules on hygiene and decontamination, recommendations to stay indoors, distribution and use of iodine tablets or other protective substances, arrangements for the event of an evacuation;
 - bb) be accompanied by special warnings for certain groups of the population;
- c) announcements recommending compliance with instructions or appeals from the competent authorities.

2. Information and recommendations in the pre-alarm phase

Insofar as the emergency is preceded by a pre-alarm phase, the population likely to be affected shall already receive information and recommendations during that phase, such as

- a) an invitation to tune in to relevant communication channels;
- b) preparatory recommendations to organisations with public tasks;
- c) recommendations to particularly affected occupational groups.

3. Supplementary information regarding the basic concepts of radioactivity and its effects on human beings and the environment

If time permits, the population likely to be affected shall be reminded of the basic facts regarding radioactivity and its effects on human beings and on the environment. Reference may also be made for this purpose to the information published in this regard in accordance with section 105.

Annex 8

(re section 127 subsection (1) no. 2)

Fields of work with increased radon exposure

1. Workplaces in subterranean mines, shafts and caves, including exhibition mines,
2. Workplaces in radon health spas and radon healing galleries,
3. Workplaces in facilities where water is extracted, treated and distributed.

Annex 9

(re section 134 subsection (1))

Radiologically-relevant primary mineral raw materials in the construction of buildings with recreation rooms

1. Acidic igneous rocks, and the resulting metamorphic and sedimentary rocks,
2. Sedimentary rock with a high organic content, such as oil, copper and alum shale,
3. Travertine.