

Executive Order on Ionising Radiation and Radiation Protection¹

Pursuant to Section 1(4) and (5); Section 2(2); Section 4(2); Section 5(2); Section 6(2); Section 7(2); Section 8(2); Section 9(2); Section 10(2); Section 11(1) and (2); Section 12(1); Section 13; Section 14(3); and Section 26(3) of Act No. 23 of 15 January 2018 on Ionising Radiation and Radiation Protection (the Radiation Protection Act), the following shall apply:

Chapter 1

Scope etc.

§ 1. The Radiation Protection Act, this Executive Order and the other rules laid down pursuant to the Act are applicable to the use of radiation sources and exposure in planned and existing exposure situations and in emergency exposure situations, with the exception of the following:

- 1) Radioactive substances naturally occurring in the human body; cf. Section 1(2) of the Radiation Protection Act.
- 2) Radiation generators operating with a voltage less than or equal to 5 kV.
- 3) Exposure to natural radiation; cf. the Radiation Protection Act, Section 1(3), however cf. (2) and Section 8.

(2) In case of exposure of air and space crews to cosmic radiation in flight or in space, the Radiation Protection Act and the provisions of this Executive Order are applicable to the extent prescribed by Section 101.

§ 2. The radiation protection requirements specified in the Radiation Protection Act, the provisions of this Executive Order and the other rules laid down pursuant to the Act are not applicable to:

- 1) radioactive substances in solid form, the activity concentration of which is less than or equal to the value specified in Annex 4 of Executive Order no. 670 of 1 July 2019 on Use of Radioactive Substances; cf. however (2) and (3) as well as Section 8;
- 2) cathode-ray tubes and other electrical apparatus that generate radiation as a by-product, operate with a voltage less than or equal to 30 kV and where the dose rate in normal operation is less than or equal to 1 µSv/h at a distance of 10 cm from any accessible surface of the apparatus; see, however, (4) and Section 8, and

3) electron microscopes; cf., however, (4) and Section 8.

(2) The exemption in (1), No. 1 is not applicable to building materials containing naturally-occurring radioactive material.

(3) The exemption in (1), No. 1 is likewise not applicable to:

- 1) the manufacture of radionuclides;
- 2) the deliberate administration of radionuclides for the purpose of medical exposure;
- 3) the deliberate administration of radionuclides for the purpose of veterinary medical use;
- 4) the manufacture of consumer products and other products, including pharmaceuticals, the manufacture of which entails the activation or deliberate addition of radionuclides;
- 5) the import of consumer products and other products, including pharmaceuticals, the manufacture of which entails the activation or deliberate addition of radionuclides.

(4) The exemptions in (1) Nos. 2 and 3 are not applicable to the manufacture and modification of the apparatus concerned.

§ 3. Any use of radiation sources that is justified and exempt from the licensing and notification requirements in accordance with the provisions of the Executive Order on Use of Radioactive Substances and Executive Order No. 671 of 1 July 2019 on Use of Radiation Generators shall not be subject to the other radiation protection requirements of the Radiation Protective Act, the provisions of this Executive Order and the other rules laid down pursuant to the Act; cf., however, (2).

(2) Notwithstanding (1), the following rules shall apply:

- 1) Section 21(2), according to which the Danish Health Authority may, in case of the use of radiation sources or exposure by multiple undertakings at the same geographical location, for each of those undertakings stipulate a dose constraint on the effective dose to members of the public of less than 0.1 mSv/year.
- 2) Section 5(3) in the Executive Order on Use of Radioactive Substances, according to which the Danish Health Authority may increase the level of regulatory control.

§ 4. For the transport of radioactive substances, Chapter 10 of this Executive Order concerning radiological monitoring and the provisions of Executive Order No. 993

¹ This Executive Order contains provisions implementing parts of Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom, Official Journal of the European Union 2014, No. L 13, page 1, and parts of Council Directive 2011/70/Euratom of 19 July 2011 establishing a Community framework for the responsible and safe management of spent fuel and radioactive waste, Official Journal of the European Union 2011, No. L 199, page 48.

of 5 December 2001 on Transport of Radioactive Substances shall apply. Further, Sections 11-13 of this Executive Order concerning responsibility shall likewise apply.

§ 5. For import and export of radioactive material except for radioactive waste; cf. Section 6, Section 19(1), Nos. 2 and 3, and (2) of the Executive Order on Use of Radioactive Substances and the provisions of Council Regulation No. 1493/93/Euratom of 8 June 1993 on transfers of radioactive substances between Member States shall apply.

(2) For import or export of consumer products, the manufacture of which entails the activation or intentional addition of radionuclides, the prohibitions of Sections 3 and 4 of the Executive Order on Use of Radioactive Substances must also be complied with. In addition, the licensing requirements of Section 6(3) in the Executive Order on Use of Radioactive Substances shall apply to the import of consumer products and other products, including pharmaceutical products, the manufacture of which entails the activation or deliberate addition of radionuclides.

§ 6. For the import, export and transit of radioactive waste, the provisions of Executive Order No. 672 of 1 July 2019 on Executive Order on Transboundary Shipments of Radioactive Waste and Spent Nuclear Fuel, and Section 19 of the Executive Order on Use of Radioactive Substances shall apply.

§ 7. For transfer of radioactive materials, Section 19(1), No. 1 and (2), and Sections 20 and 21 of the Executive Order on Use of Radioactive Substances shall apply. In addition, the following provisions of the same Executive Order must be complied with:

- 1) Section 16 on records of transfer of radioactive material;
- 2) Section 18 on documentation of transfer of radioactive waste; and
- 3) Section 23 on conclusion of an agreement with the manufacturer of a high-activity sealed source regarding the final transfer of the radiation source to that manufacturer.

(2) For transfer of consumer products, the manufacture of which entails the activation or intentional addition of radionuclides, the prohibitions of Sections 3 and 4 of the Executive Order on Use of Radioactive Substances must additionally be complied with. Furthermore, the provisions of the same Executive Order in Section 5(1) and Section 8(2) apply at the level of regulatory control.

§ 8. The Danish Health Authority may determine that provisions of the Radiation Protection Act in this Executive Order and in the other rules laid down pursuant to the Act shall be applicable in whole or in part to exposure to natural radiation in controllable situations or

to the use of radiation sources that are exempt pursuant to Section 1(1), No. 3 or Section 2, respectively, if the Danish Health Authority deems that such exposure cannot be disregarded or if such use is not justified from the point of view of radiation protection.

§ 9. The Danish Health Authority may determine that use of radiation sources or exposure shall be exempted in whole or in part from the provisions of the Radiation Protection Act in this Executive Order and in the other rules laid down pursuant to the Act, if it deems that such use is justified or if such exposure may be disregarded from a radiation protection point of view.

Chapter 2

Definitions

§ 10. In this Executive Order, the following definitions shall apply:

- 1) Facility: Interiors, including laboratories, radiography rooms and storage and refuse rooms and their associated structural elements constructed and fitted out to provide radiation protection from the use of radiation sources, and vehicles constructed and fitted to provide radiation protection from the use of radiation sources.
- 2) Employer: A natural or legal person who allows its workers to engage in the use of radiation sources or allows its workers to be exposed to ionising radiation; cf. Section 2(1), No. 3 of the Radiation Protection Act.
- 3) Worker: Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like situation; cf. Section 3(1) of the Radiation Protection Act.
- 4) Public exposure: The exposure of individuals, excluding any occupational or medical exposure.
- 5) Treatment: Medical exposure, the purpose of which is the cell-killing effect of ionising radiation for both curative and palliative purposes.
- 6) Exposure of individuals for non-medical imaging purposes: Any intentional exposure of individuals for imaging purposes in which the primary purpose of the exposure is not to benefit the health of the subject exposed, e.g. for forensic, insurance or security purposes.
- 7) Use:
 - a) Manufacture, processing, holding, import, export, transfer, handling, application, control, third-party inspection, storage, disposal, recycling, reuse, discharge and transport of radioactive substances; cf. Section 3, No. 2, Letter a of the Radiation Protection Act.
 - b) The manufacture of radiation generators where the process generates ionising radiation, the modification of radiation generators which may

- affect matters related to radiation protection, and the installation, application, control and third-party inspection of radiation generators; cf. Section 3, No. 2, Letter b of the Radiation Protection Act.
- 8) Building material: A construction product which will be or is incorporated permanently in a building or parts thereof, and where the performance of this product affects the performance of the building with regard to exposure of its occupants to ionising radiation.
 - 9) Diagnostic reference levels: Dose levels in medical radiodiagnostic or interventional radiology practices, or levels of activity for radiopharmaceuticals in typical examinations for groups of standard-sized patients for broadly defined types of radiation sources and equipment.
 - 10) Dosimetry service: A body or an individual with the competence to calibrate, read or interpret personal dosimeters and to make a dose determination based on a personal dosimeter or to measure radioactivity in the human body or in biological samples, or to assess doses.
 - 11) Dose constraint: An upper value of individual dose delivered by a radiation source in a planned exposure situation and which provides a basis for optimisation of radiation protection.
 - 12) Dose limit: The value of the effective dose or the equivalent dose in a specified period which may not be exceeded for an individual.
 - 13) Radiological monitoring programme: Individual radiological monitoring that is not based on the use of a personal dosimeter, including measurement of biological specimens from the individual, measurement of the individual in a whole body counter or for assessment of doses based on an estimate made on the basis of individual measurements obtained from other exposed workers, based on the results of workplace monitoring or on the basis of calculation methods.
 - 14) Operational limits and conditions: A specification of an acceptable range for critical parameters in order to thereby indicate when corrective action is required.
 - 15) Effective dose: The sum of the weighted equivalent doses in all the tissues and organs of the body from internal or external exposure; cf. Annex 4.
 - 16) Technical safety inspection: Regular inspection to ensure that radiation generators and sealed sources and facilities and equipment are in a satisfactory technical state from a safety perspective.
 - 17) Existing exposure situation: An exposure situation that already exists when a decision on its control has to be taken and which does not call or no longer calls for urgent measures to be taken.
 - 18) Export: The shipment of radioactive material from Denmark to another country.
 - 19) Outside worker: An exposed or other worker who performs work for an undertaking, cf. No. 63, that is not that worker's employer.
 - 20) External exposure: Exposure of the body to radiation sources outside the body.
 - 21) Member of the public: An individual who may be subject to public exposure.
 - 22) Occupational exposure: The exposure incurred by a worker from the use of radiation sources or from exposure in the undertaking that worker performs work for. For an individual pursuing a programme of vocational education of at least two years' duration which is governed by or pursuant to legislation and in which the use of radiation sources or exposure is an essential component of that programme, the exposure which that individual incurs from the use of radiation sources or exposure during the education is regarded as occupational exposure.
 - 23) Emergency occupational exposure: The exposure incurred by emergency workers in the event of an emergency exposure situation.
 - 24) Consumer product: A device or manufactured item into which one or more radionuclides have intentionally been incorporated or produced by intentional activation, or which generates ionising radiation, and which is manufactured for the purpose of making the device or item available to, or marketing the device or item to, consumers.
 - 25) Import: The shipment of radioactive material to Denmark from another country.
 - 26) Individual radiological monitoring: Determination of the effective dose or equivalent dose incurred by an individual, by means of a personal dosimeter or based on a radiological monitoring programme.
 - 27) Emergency workers: Any individual having a defined role in an emergency and who might be exposed to radiation as a result of taking action in response to the emergency, including volunteers who have been instructed on their role in advance.
 - 28) Internal exposure: Exposure of the body to radiation sources within the body.
 - 29) Ionising radiation: Particles, including photons, capable of causing ionisation in substances directly or indirectly, but in the case of electromagnetic radiation, only radiation with a wavelength of 100 nm or less; cf. Section 3, No. 3 of the Radiation Protection Act.
 - 30) Clinically responsible practitioner: An individual with medical education who possesses the requisite qualifications for assuming clinical responsibility for a medical exposure.
 - 31) Constancy testing: Regular testing performed during medical use of radiation sources to ensure that

- selected parameters for the radiation source and equipment constantly remain within the predetermined range.
- 32) Quality assurance: All planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, a facility, equipment, a system or component or a procedure will perform satisfactorily in compliance with agreed standards; cf. Section 3, No. 4 of the Radiation Protection Act.
- 33) Medical exposure: Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment which is intended to benefit their health, exposure incurred by carers and comforters in connection with this as well as the exposure incurred by volunteers in connection with medical or biomedical research; cf. Section 3, No. 5 of the Radiation Protection Act.
- 34) Acceptance testing: Testing carried out for the purposes of medical use of radiation sources at the time of commissioning and after any modifications and repairs, to ensure that the radiation source and equipment conform to the pre-defined specifications and applicable operational limits and conditions.
- 35) Natural radiation: Cosmic radiation and ionising radiation from naturally-occurring radioactive materials which have not been affected by human activity; cf. Section 3, No. 6 of the Radiation Protection Act.
- 36) Emergency exposure situation: A situation of exposure due to an emergency.
- 37) Emergency: A non-routine situation involving a radiation source and necessitating prompt action primarily to mitigate:
- serious adverse consequences for human health and safety, quality of life, property or the environment, or
 - a hazard that could give rise to such serious adverse consequences.
- 38) Carers and comforters: Individuals who, other than in the course of their occupation, knowingly and voluntarily incur an exposure to ionising radiation by attending to and comforting individuals undergoing or having undergone medical exposure. This includes the next of kin, including children, of individuals undergoing or having undergone medical exposure.
- 39) Transfer: Any reassignment of responsibility for radioactive material between undertakings, including between manufacturers and distributors.
- 40) Shipment: All measures necessary for the physical relocation of radioactive material from one country to another country.
- 41) Personal dosimeter: A device worn by an individual worker for determination of the effective dose or equivalent dose incurred by that individual.
- 42) Planned exposure situation: An exposure situation that arises from the planned use of a radiation source or the planned exposure to ionising radiation in an existing exposure situation. A planned exposure situation may include both normal and potential exposures.
- 43) Radioactive waste: Radioactive material for which no further use is foreseen.
- 44) Radioactive material: A radioactive substance with activity or activity concentration that cannot be disregarded from a radiation protection point of view.
- 45) Radioactive substance: A substance containing one or more radionuclides; cf. Section 3, No. 7 of the Radiation Protection Act.
- 46) Radiological monitoring: Continual or periodic determination and assessment of:
- the dose rate, radiation type or radiation quality in relation to facilities and areas, etc., or
 - volume, mass or surface-specific activity or the activity concentration of radionuclides in relation to individuals, the environment, areas, interiors, objects, raw materials, products, points of discharge, etc.
- 47) Radon: The radionuclide Rn-222 and, as appropriate, its progeny.
- 48) Reference level: The level of effective dose or equivalent dose or activity concentration above which, in an emergency exposure situation or in an existing exposure situation, it is judged inappropriate to allow exposures to occur as a result of that exposure situation, even though it is not a limit that may not be exceeded.
- 49) Safety assessment: An assessment of all aspects of an undertaking's specific use of radiation sources or exposure of relevance for safety and radiation protection.
- 50) Performance testing: Regular testing carried out for the purposes of medical use of radiation sources to ensure that the radiation source and equipment continue to conform to the pre-defined specifications and applicable operational limits and conditions.
- 51) Radiation protection: Arrangements for protection against ionising radiation, including prevention of emergencies, accidents and incidents as well as remediation of the consequences thereof.
- 52) Radiation source: A radioactive substance or a radiation generator; cf. Section 3, No. 8 of the Radiation Protection Act.
- 53) Exposed worker: A worker in an undertaking that uses radiation sources, where the worker is directly involved in, or performs, work necessary for that use, or a worker who is subjected to planned exposure to ionising radiation in an existing exposure situation and whose presence is necessary.

- 54) Exposure: Exposure to ionising radiation; cf. Section 3, No. 9 of the Radiation Protection Act.
- 55) Radiation: Ionising radiation; cf. No. 29.
- 56) Radiation generator: A device capable of generating ionising radiation; cf. Section 3, No. 10 of the Radiation Protection Act.
- 57) Transit: The shipment via Denmark of radioactive material from a country outside the European Union to another country outside the European Union.
- 58) Transport: The transportation and any operation involving loading, unloading, transit storage and handling on Danish territory. Transport therefore includes transportation to and from Danish consignors and consignees and transportation transiting via Danish territory.
- 59) Equipment: The supplementary material necessitated by the use of radiation sources or exposure, including containers, measurement instruments and other measuring equipment, imaging systems and material for radiation protection, including personal protective equipment.
- 60) Accidental exposure: An exposure of individuals as a result of an emergency, accident or incident, excluding the exposure of emergency workers providing emergency response.
- 61) Examination: Medical exposure arising from screening, diagnostics, intervention as well as planning, guiding and verification procedures.
- 62) Unintended exposure: Exposure that significantly exceeds that incurred by persons and the environment through correct use of radiation sources, and medical exposure that is significantly different from the medical exposure intended for a given purpose; cf. Section 3, No. 11 of the Radiation Protection Act.
- 63) Undertaking: A natural or legal person who owns, rents, leases, borrows or otherwise holds right of use of a radioactive substance or is responsible for an area exposed to ionising radiation, cf. Section 2(1), No. 1 of the Radiation Protection Act, or who is responsible for the use of a radiation source, cf. Section 2(1), No. 2 of the Radiation Protection Act.
- 64) Equivalent dose: The average absorbed dose in any tissue or organ weighted for the type and quality of ionising radiation; cf. Annex 4.
- 65) Other worker: A worker who is not an exposed worker in an undertaking that uses radiation sources or is responsible for exposure; cf. No. 53.

Chapter 3

Responsibility

§ 11. The responsibility for compliance with the requirements pursuant to the Radiation Protection Act, this Executive Order and other rules established pursuant to the Act rests with the undertaking, including where the

undertaking is responsible as an employer; cf. however Sections 12-14.

(2) In cases where multiple undertakings bear a responsibility, they must each be independently responsible.

§ 12. In relation to an outside worker, that worker's employer is responsible for compliance with:

- 1) the requirements for providing the worker with information and obtaining their consent in case of special occupational exposure; cf. Section 26(2),
- 2) the requirements regarding the worker's instruction concerning the necessity of early notification of pregnancy and breast-feeding; cf. Section 45(1), No. 6,
- 3) the requirement to disclose the results of radiological monitoring, etc. to the worker; cf. Section 84;
- 4) the requirement for notification of the Danish Health Authority in case of elevated doses; cf. Section 85;
- 5) the requirement for documentation of doses, etc.; cf. Section 86; and
- 6) the requirement for notification of individual radiological monitoring results to the Danish Health Authority's Personal Dose Registry ("SRP"); cf. Section 87.

(2) In relation to an outside worker, that worker's employer also has the responsibility for categorisation of that worker; cf. Sections 38-41, and the worker's employment in accordance with Sections 42 and 43, but the undertaking must verify that the categorisation is commensurate with the doses the outside worker is likely to receive within the undertaking and that the worker's employment is compliant with Sections 42 and 43.

§ 13. In relation to an outside worker, that worker's employer and the undertaking are each independently responsible for compliance with:

- 1) the requirements regarding justification, optimisation and dose limitation; cf. Chapter 2 of the Radiation Protection Act, the relevant provisions of Chapter 4-6 of this Executive Order, and relevant provisions in the Executive Order on Use of Radioactive Substances and the Executive Order on Use of Radiation Generators;
- 2) the requirements regarding provision of information to workers and their training, instruction, knowledge, skills, competences and so forth; cf. Section 45(1), Nos. 1-4 and (2), and Section 46 of this Executive Order and relevant provisions in the Executive Order on Use of Radioactive Substances and the Executive Order on Use of Radiation Generators;
- 3) the requirements regarding radiological monitoring in compliance with Sections 78, 79 and 81, and relevant provisions of the Executive Order on Use of Radioactive Substances and the Executive Order on Use of Radiation Generators.

(2) The undertaking's responsibility pursuant to (1) comprises the aspects of outside worker radiation protection directly associated with such workers' specific work within the undertaking.

§ 14. In relation to emergency workers, responsibility for compliance with the provisions of the Radiation Protection Act and of rules laid down pursuant to that Act for the purposes of worker protection rests with the respective employer.

§ 15. Responsibility for compliance with the provisions of the Radiation Protection Act and of Section 101 regarding the exposure of air and space crews to cosmic radiation in flight or in space rests with the employer concerned.

Chapter 4

Justification

§ 16. The use of radiation sources and exposure must take place solely if the health, financial, societal or other benefits of that use or exposure outweigh any detriment (justification); cf. Section 4(1) of the Radiation Protection Act.

(2) In advance of the introduction of radiation sources or practices differing significantly from existing ones, their justification must be sufficiently assessed.

(3) Assessment of the justification must include consideration of the options for using alternative techniques either not based on radiation or based on exposure from radiation generators as opposed to radioactive material.

(4) Assessment of the justification for use of radioactive material must include consideration of the radionuclide, the activity, whether the source is sealed or not, the sensitivity of any detection systems and the possibility for radiological monitoring.

(5) Assessment of the justification for medical exposure must consider the age and state of health of the patient or individual as well as the anticipated benefit. If it cannot be ruled out that a patient or individual is pregnant, the risk to the foetus must be included in the deliberations on justification.

(6) Any medical exposure of an asymptomatic individual to be performed for the early detection of disease may be carried out solely under a health screening programme or after specific documented individual justification.

(7) The justification must be reviewed when new evidence concerning the efficacy or detriments of radiation sources or techniques becomes available or when new evidence becomes available on techniques that are not based on radiation or are associated with reduced detriments.

§ 17. The Danish Health Authority may assess and

determine whether use of radiation sources or exposure are justified.

Chapter 5

Optimisation, etc.

§ 18. The use of radiation sources and exposure must take place solely if the likelihood and magnitude of exposure, including the number of individuals exposed, are as low as reasonably achievable taking into account the current state of technical knowledge and economic and societal factors (optimisation); cf. Section 5(1) of the Radiation Protection Act.

(2) In the case of examinations, doses must be kept as low as reasonably achievable taking into account the intended diagnostic benefits.

(3) The target volume in radiotherapy and the therapeutic dose and the activity administered in nuclear medical treatment must be determined individually, and exposure of tissue, including non-target-volume organs at risk must be as low as reasonably achievable and consistent with the intended purpose of the treatment.

(4) If, in connection with a medical exposure, it cannot be ruled out that a patient or individual is pregnant, the risk to the foetus must be included in the deliberations on optimisation.

§ 19. The Danish Health Authority may assess and determine whether use of radiation sources or exposure are optimised.

§ 20. In advance of any use of radiation sources or exposure subject to licensing under the provisions of rules laid down pursuant to the Radiation Protection Act, the undertaking must compile a safety assessment commensurate with the nature, scale and complexity of the undertaking's use of radiation sources or exposure.

(2) The assessment must be updated continuously to ensure that it reflects the undertaking's current use of radiation sources or exposure at any given time.

§ 21. An undertaking's use of radiation sources or exposure at the same geographical location must be subject to a dose constraint on the effective dose to members of the public not exceeding 0.1 mSv/year; cf. however, (2).

(2) Where the use of radiation sources or exposure by multiple undertakings may affect the same member of the public at the same geographical location, the Danish Health Authority may, for each of those undertakings, stipulate a lower dose constraint than that defined in (1).

§ 22. An undertaking's use of radiation sources or exposure must be subject to a dose constraint on the effective dose to other workers within the undertaking not exceeding 0.3 mSv/year.

Chapter 6

Dose limitation

Dose limits, etc. for occupational exposure

§ 23. Occupational exposure must be subject to the dose limits for the effective dose and equivalent dose set out in Annex 1.

(2) In special circumstances, the Danish Health Authority may authorise an effective dose of up to 50 mSv/year for an exposed worker aged 18 years or over, provided that the average annual dose over any five consecutive years does not exceed 20 mSv/year.

(3) In special circumstances, the Danish Health Authority may authorise an equivalent dose of up to 50 mSv/year to the lens of the eye for an exposed worker aged 18 years or over, provided that the average annual dose over any five consecutive years does not exceed 20 mSv/year.

§ 24. The equivalent dose to a foetus from maternal occupational exposure must be kept as low as reasonably achievable and, following notification of the pregnancy to the employer, must not exceed 1 mSv.

§ 25. If occupational exposure causes one of the dose limits in Annex 1 to be exceeded, the worker concerned must not perform further work involving the use of radiation sources or exposure without the Danish Health Authority's authorisation.

Dose limits, etc. for special occupational exposure

§ 26. For specific time-limited work, the Danish Health Authority may, in special circumstances, authorise doses to exposed category A workers; cf. Section 39, which exceed the dose limits for occupational exposure pursuant to Section 23.

(2) The exercise of (1) is conditional on the affected workers being informed in advance of the attendant risks of the work and the precautions to be taken during its performance and on having consented to participating in the work.

(3) Workers for whom special dose limits have been authorised pursuant to (1) are not excluded from their usual occupation.

Dose limits and reference levels, etc. for emergency occupational exposure

§ 27. Doses to emergency workers must be kept as low as reasonably achievable and should, as far as possible, not exceed the dose limits for occupational exposure; cf. Section 23.

§ 28. In cases where it is not feasible to remain within the dose limit for the effective dose for occupational exposure, a reference level for the effective dose of 100 mSv applies.

§ 29. In exceptional situations, in order to save life, prevent severe radiation-induced health effects, or prevent the development of catastrophic conditions, the Danish Health Authority may authorise a higher reference level for the effective dose, though not exceeding 500 mSv.

(2) In circumstances comprised by (1), emergency workers must be specifically instructed concerning the work and clearly and comprehensively informed of the health risks associated with the entailed actions, the protective measures available, and that their participation in the actions is voluntary.

§ 30. An exposed worker who has incurred emergency occupational exposure exceeding the dose limits in Section 23 may continue in their usual occupation, but the Danish Health Authority must authorise the conditions for their occupational exposure.

(2) Emergency workers who in the course of actions have incurred effective doses exceeding 100 mSv may not participate in further actions unless authorised to do so by the Danish Health Authority.

Dose limits and reference levels, etc. for public exposure

§ 31. Public exposure from undertakings' use of radiation sources and exposure must be subject to the dose limits for the effective dose and equivalent dose set out in Annex 1.

§ 32. Emergency exposure situations and subsequent existing exposure situations must be subject to the reference levels set by the Danish Health Authority as necessary in the specific circumstances.

Chapter 7

Designated expert individuals

Radiation Protection Officers, Radiation Protection Experts and Medical Physics Experts

§ 33. An undertaking subject to the licensing or notification requirement or which is the registrant of a facility in accordance with rules laid down pursuant to the Radiation Protection Act must, commensurate with the nature, scale and complexity of its use or exposure, have at its disposal one or more Radiation Protection Officers. The Radiation Protection Officer must, within their field of expertise, monitor and assist in maintaining the radiation protection of workers and members of the public entailed by the undertaking's use of radiation sources or exposures. The Radiation Protection Officer's tasks comprise, as a minimum, the areas set out in Annex 2.

(2) An undertaking with an obligation pursuant to Section 20 for compiling a safety assessment must, commensurate with the nature, scale and complexity of the undertaking's use of radiation sources or exposure consult a radiation protection expert concerning radiation protection arrangements of relevance to the undertaking.

The Radiation Protection Expert must, within the field of competence, advise the undertaking on facilitating the planned use of the undertaking's radiation sources or exposure and on issues from a radiation protection point of view associated with emergencies, accidents and incidents, with regard for workers and members of the public. The Radiation Protection Expert's tasks comprise as a minimum the areas set out in Annex 2.

(3) For the purposes of medical exposures, an undertaking subject to the licensing requirements, must in addition to the foregoing have one or more medical physics experts at its disposal at any time. The medical physics expert must, within the field of competence, advise on medical radiation physics and radiation sources, etc., and ensure the performance of dosimetry, including measurements for evaluation of doses incurred by patients and individuals subject to medical exposure.

(4) An undertaking may retain multiple radiation protection officers, radiation protection experts or medical physics experts who collectively possess the expertise needed for the undertaking's use of radiation sources or exposure.

Approval of designated expert individuals

§ 34. Radiation protection officers, radiation protection experts and medical physics experts must be authorised by the Danish Health Authority.

(2) Authorisation entails that the radiation protection officer, radiation protection expert and medical physics expert satisfy the requirements for knowledge, skills and competences laid down in the Executive Order on Use of Radioactive Substances and the Executive Order on Use of Radiation Generators. For types of practices for which no requirements have been established for the designated expert individuals' knowledge, skills and competences in these Executive Orders or for exposure, the Danish Health Authority authorises such expert individuals on a case-by-case basis. (2) is likewise applicable to the knowledge, skills and competences required for a radiation protection officer retained by an undertaking that is the registrant of a facility pursuant to Section 51(3).

(3) An authorisation to practice as a radiation protection expert or a medical physics expert is granted for a period of 5 years.

(4) The radiation protection officer's knowledge, skills and competences must be updated as required. Where high-activity sealed sources are used, and where unsealed sources and radiation generators posing equivalent risks are used, this updating must be completed at intervals of no more than five years.

The personal obligations, etc. of designated expert individuals

§ 35. A radiation protection officer and a medical physics expert must confirm fulfilment of their designated

remit vis-à-vis the Danish Health Authority as expert individuals for the undertaking they serve.

(2) Any radiation protection officer and a medical physics expert who in performance of their tasks discovers that the undertaking is failing to take the necessary actions for compliance with the provisions of the Radiation Protection Act and of the rules laid down pursuant to that Act and any terms and conditions established by the Danish Health Authority must ensure that this is duly reported to the Danish Health Authority.

(3) A radiation protection officer or a medical physics expert who no longer performs their function as a designated expert individual within a given undertaking or who is absent from work beyond the norm must immediately notify this to the Danish Health Authority.

§ 36. A radiation protection expert must document their advice to an undertaking and issue a copy of the signed documentation to the undertaking.

§ 37. The designated expert individuals must cooperate to the relevant extent in performance of their respective tasks.

Chapter 8

Requirements for use of radiation sources and exposure

Categorisation and employment of workers

§ 38. An exposed worker must be categorised according to the rules in Section 39, Section 40 or Section 41 before that worker commences using radiation sources or is exposed. The categorisation of each worker must be regularly reviewed.

§ 39. An exposed worker who, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose greater than 6 mSv/year or an equivalent dose greater than 15 mSv/year to the lens of the eye or an equivalent dose greater than 150 mSv/year to skin or extremities, must be classified as a category A exposed worker.

(2) Only individuals aged 18 years or over may be classified as category A exposed workers.

§ 40. An exposed worker who, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose greater than 1 mSv/year, but no greater than 6 mSv/year, or an equivalent dose greater than 50 mSv/year, but no greater than 150 mSv/year to skin or extremities, must be classified as a category B exposed worker.

§ 41. An exposed worker who, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose no greater than 1 mSv/year or an equivalent dose no greater than 50 mSv/year to skin or extremities must be classified as a

category C exposed worker.

§ 42. Only individuals aged 18 years or over or individuals aged between 16 and 18 years pursuing a programme of vocational education of at least two years' duration which is governed by or pursuant to legislation and in which the use of radiation sources or exposure are essential components may be employed as exposed workers of category B or C.

(2) An individual aged between 16 and 18 years who has completed an education as described in (1) may continue to be employed as an exposed worker of category B or C within their profession if this is necessary for their employment.

§ 43. An exposed worker who is breastfeeding must not be employed under conditions posing a significant risk of internal or external bodily contamination with radioactive material.

§ 44. An exposed outside worker of category A must not commence any work before the undertaking has received documentation from the worker's employer of the worker's relevant dose history and information stating that the worker has been informed and instructed by the employer, as required in Section 45. The documentation must contain the data specified in Annex 3.

Requirements for informing, training and instructing workers

§ 45. Exposed workers must:

- 1) be informed of the risks associated with the use of radiation sources or exposure;
- 2) be instructed on the safety arrangements to be made to prevent the risks mentioned in (1);
- 3) be trained to and instructed in use of radiation sources or exposure and in measures for limiting the consequences of any emergencies, accidents or incidents.
- 4) have attained sufficient knowledge, skills and competences before they may work independently with radiation sources;
- 5) be informed of the name and contact details of the relevant radiation protection officer and;
- 6) be instructed on the necessity of early notification of pregnancy and intention to breastfeed with a view to putting in place the necessary measures to ensure that the dose to the unborn or nursing infant is as low as reasonably achievable.

(2) The exposed workers' knowledge, skills, competences, information, training and instruction must be maintained and updated, as a minimum, when new or updated technologies and techniques are introduced.

(3) The undertaking must maintain a listing of exposed workers, recording each individual's knowledge, skills, competences, information, training and instruction. The

listing must be available to all relevant workers within the undertaking.

§ 46. Other workers must be informed on the use of radiation sources or exposure within the undertaking and concerning the precautions they are to take.

§ 47. Emergency workers must, at all times, be appropriately instructed in radiation protection and the health risks in emergency situations and informed of the preventive measures that may be of relevance.

§ 48. For any use of radiation sources and exposure, a worker is subject, from a radiation protection point of view, to the instructions issued by the undertaking responsible for the radiation source or exposure.

Supervised and controlled areas

§ 49. An area must be classified as supervised if any worker present in that area during normal operation or in the event of an incident or accident would be liable to receive an effective dose greater than 1 mSv/year, but no greater than 6 mSv/year, or an equivalent dose greater than 50 mSv/year, but no greater than 150 mSv/year, to skin or extremities.

(2) A supervised area must, where relevant in relation to the nature and extent of the radiological risk, be clearly and durably delineated with information stating, on the one hand, that it is a supervised area and, on the other hand, the type of radiation source and the risk associated with this type of radiation source.

§ 50. An area must be classified as controlled:

- 1) if a worker present in the area during normal operation or in the event of incidents or accidents is liable to receive an effective dose greater than 6 mSv/year or an equivalent dose greater than 15 mSv/year to the lens of the eye or an equivalent dose greater than 150 mSv/year to skin or extremities, or
- 2) if there is a significant risk of contamination with radioactive material of adjacent areas.

(2) A controlled area must meet the following requirements:

- 1) The area must be physically delimited or, if this is not feasible, secured or delineated in such a way that delimitation of the area is clearly apparent at all times.
- 2) If there is a risk of contamination of adjacent areas, arrangement must be made to minimise this risk.
- 3) Only individuals whose presence in the area is necessary for the use of radiation sources or exposure may be granted access to the area.
- 4) The area must be clearly and durably delineated with information stating, on the one hand, that it is a controlled area and, on the other hand, the type of radiation source and the risk associated with this type of radiation source.

Registration of radiation sources and facilities

§ 51. Pursuant to the provisions of the Executive Order on Use of Radioactive Substances or the Executive Order on Use of Radiation Generators, radiation sources and facilities must be registered in the Danish Health Authority's Registry of Radiation Sources and Facilities.

(2) The registration duty for radiation sources and facilities rests with the user of the radiation source and associated facilities; cf. however (3).

(3) The entity that is responsible for a facility without actually using the radiation sources in the facility has an independent duty to register the facility.

(4) Notwithstanding Section 11(2), a radiation source or facility must only be registered once.

(5) If use of a radiation source subject to the registration requirement is also subject to a licensing requirement, use of the radiation source and, as applicable, utilisation of the facility for use of such radiation sources may not be commenced until the Danish Health Authority has confirmed the registration of the radiation source and, as applicable, the facility. If use of a radiation source subject to the registration requirement is also subject to a notification requirement, use of the radiation source and, as applicable, utilisation of the facility for use of such radiation sources may not be commenced until the Danish Health Authority has acknowledged receipt of the application to register the radiation source and, as applicable, the facility.

(6) Any change pertaining to data included in the Danish Health Authority's Registry of Radiation Sources and Facilities, including changes to registered radiation sources and facilities must be notified to the Danish Health Authority.

(7) In case of a change to a registered radiation source, the use of which is subject to a licensing requirement, or in case of a change to a registered facility for use of such radiation sources, continued use of the radiation source and, as applicable, utilisation of the facility for use of such radiation sources is conditional on the Danish Health Authority having confirmed the registration of the changed radiation source or changed facility. If use of a radiation source is subject to the notification requirement, continued use of the radiation source and, where applicable, utilisation of the facility for use of such radiation sources is conditional on the Danish Health Authority having acknowledged receipt of the application to register the changed radiation source or the changed facility.

(8) Any registration and notification in accordance with (1) and (6) must be undertaken in accordance with the procedures and comprise the data stipulated by the Danish Health Authority.

Requirements for radiation sources and work performance

§ 52. Use of radiation sources must take place in facilities, unless otherwise stipulated in the Executive Order on Use of Radioactive Substances or the Executive Order on Use of Radiation Generators.

(2) The construction and design of the facility must be adapted to the type of radiation source and the risk associated with this type of radiation source, taking into account the dose constraints for occupational and public exposure.

§ 53. Use of radiation sources and exposure must be planned and performed utilising suitable equipment to ensure appropriate optimisation.

§ 54. Radiation sources, facilities and equipment must conform to national and international technical standards in force at any time that pertain to aspects of the undertaking's use of radiation sources or exposure from the point of view of radiation protection.

§ 55. Radiation sources, facilities and equipment must at all times be in a sound, orderly and technically satisfactory state and comply with all the safety provisions of this Executive Order and other rules established pursuant to the Radiation Protection Act and terms and conditions laid down by the Danish Health Authority.

(2) Any defect or deficiency discovered in any radiation source, facility or equipment must be notified to the undertaking immediately.

(3) Observed defects and deficiencies that might result in unintended exposure must be remedied before any further use of radiation sources or exposure.

§ 56. Measuring instruments must be tested at suitable intervals to ensure correct display of values, and the testing must, as applicable, be traceable.

§ 57. Readily comprehensible written instructions must be available for workers on use of radiation sources or exposure, including precautions to be taken in the event of an emergency, accident or incident. The instructions must be readily available during work.

§ 58. The Danish Health Authority must be notified as soon as possible concerning any circumstances that are systematic in nature which might result in unintended exposure or significant contamination with radioactive substances; cf. Section 14(2) of the Radiation Protection Act. Notification must be submitted of all instances in which the risk of unintended exposure or the significant contamination with radioactive substances is due to flawed design of the radiation source, reiterated defects or malfunctions or an erroneous manual or the like.

(2) Separate notification in accordance with (1) is not necessary if the circumstance was the cause of an incident that might have resulted in unintended exposure, which has

been notified to the Danish Health Authority pursuant to the provisions of Section 92.

§ 59. In case of accidental exposure and emergency occupational exposure, the undertaking must ensure that an adequate analysis is performed of the circumstances and consequences of the exposure, including determination of relevant doses and their distribution in the body.

Supplementary requirements for medical exposure

§ 60. Any undertaking that carries out examinations or treatment procedures must have established guidelines for referral and clinical assessment for examinations and treatment. For each type of examination and treatment, the guidelines must contain information about the typical doses to patients. The incorporation of data on prior, relevant examinations and treatment procedures must be part of the procedure for clinical assessment.

(2) The undertaking must have procedures for assessing the justification for and optimisation of the specific examination or treatment.

§ 61. A referral must contain the following information:

- 1) The referring entity and the identity and occupational role of the referrer.
- 2) The clinical condition justifying the examination or treatment.
- 3) Pregnancy status if applicable.
- 4) Previous relevant examinations or treatments which the referrer knows of or could reasonably be expected to know of.

§ 62. Every medical exposure must be carried out under the responsibility of a clinically responsible practitioner who possesses up-to-date knowledge, skills and competences in the field of radiation protection as laid down in the Executive Order on Use of Radioactive Substances and the Executive Order on Use of Radiation Generators. For types of practices for which no requirements have been established for the clinically responsible practitioner's knowledge, skills and competences in these Executive Orders, the practitioner's knowledge, skills and competences must be commensurate with the nature, scale and complexity of the medical exposure.

§ 63. For medical exposures, a medical physics expert must be involved to a suitable extent, in that the level of involvement must be commensurate with the radiological risk posed by the exposure.

§ 64. Instructions must be available for all types of examinations and treatment procedures. The instructions must be readily available during the examination or the treatment.

§ 65. For any examination, except for intraoral

examinations by a dentist, patient dosimetry must be carried out.

(2) Where radiation generators are used, directly measurable dose values must be utilised, and for administration of radioactive material, the administered activity must be utilised.

(3) The measured doses or activities, respectively, must be analysed in view of optimisation with reference to the diagnostic reference levels set by the Danish Health Authority, if such exist. The first comparison must be carried out within 6 months of the commissioning of a new radiation source or new equipment. The measurements and analysis must be repeated annually for nuclear medicine and intervention and every second year for other medical exposures

(4) If, based on the comparison described in (3), it is realised that the diagnostic reference levels are consistently being exceeded, a clinically responsible practitioner in consultation with the medical physics expert must ensure that the cause of this is identified and that corrective actions are duly taken.

§ 66. For treatment procedures, calculations must be performed of the dose distribution in accordance with the prescribed dose. In addition, an independent verification must be performed to ensure that the dose delivered corresponds with the planned dose within the established tolerances.

§ 67. For medical exposures, individuals performing paediatric examinations or treatment procedures, health screenings and examinations involving high doses to patients must be specially educated to do so.

§ 68. Precautionary measures must be established to limit the exposure of other patients and next of kin. For that purpose, special emphasis must be placed on precautionary measures for the protection of children.

§ 69. Operational limits and conditions must, where feasible, be determined in conformance with national and international guidelines or standards applicable to the specific practice.

§ 70. Acceptance testing must be performed for radiation sources and, where relevant, for equipment.

(2) Such tests must be completed and approved before use in connection with medical exposure.

(3) The results of the tests must be documented in a systematic manner.

(4) The documentation of the acceptance testing must contain the measurement results and criteria for assessment of those results as well as the outcome of the assessment of measurement results in relation to criteria.

(5) The undertaking must retain documentation of the results of all acceptance tests. The name of the undertaking and of the individual who conducted the test must be stated in the documentation.

§ 71. Where relevant, regular performance and constancy testing must be performed to verify that radiation sources and equipment constantly maintain a satisfactory quality.

(2) Radiation sources and equipment that fail to conform with the operational limits and conditions must not be used for medical exposure until the defects have been remedied.

(3) For radiation sources and equipment that only just meets the operational limits and conditions, it must be ensured that a satisfactory standard of quality in examinations and treatment can be attained based on an overall assessment.

(4) The results of the tests must be documented in a systematic manner.

(5) The documentation of the performance and constancy testing must contain the measurement results and criteria for assessment of those results as well as the outcome of the assessment of measurement results in relation to criteria.

(6) The undertaking must retain documentation of the results of the last five performance tests and the last five years' constancy tests. The name of the undertaking and of the individual who conducted the tests must be stated in the documentation.

§ 72. Biomedical research projects involving the exposure of human trial subjects must not be conducted until they have been authorised by a biomedical research ethics committee.

(2) Healthy trial subjects must not be irradiated in trials with curative or palliative intent.

§ 73. For biomedical research projects involving the exposure of human trial subjects, a determination of the dose and the risk of radiation-induced cancer entailed by the determined dose must be obtained in advance. Both the dose and the risk must be stated in the trial protocol.

§ 74. Biomedical research projects studying exposure of human trial subjects who cannot expect to benefit directly from the trial exposures must be subject to the dose constraints established in guidelines issued by the National Committee on Health Research Ethics.

Chapter 9

Requirements for the use of radiation sources for exposure of individuals for non-medical imaging purposes

§ 75. The exposure of individuals for non-medical imaging purposes entailing the use of medical radiological radiation sources and equipment must meet all the relevant requirements for medical exposure.

§ 76. The exposure of individuals for non-medical imaging purposes not entailing the use of medical radiological radiation sources and equipment is subject to

the requirements laid down by the Danish Health Authority.

§ 77. Individuals may only be exposed for non-medical imaging purposes if they have been informed of the health risk associated with the exposure and have given their consent in writing.

Chapter 10

Radiological monitoring, etc.

Radiological monitoring

§ 78. Exposed workers of category A and exposed workers of category B must be subject to individual radiological monitoring in accordance with (2)-(7).

(2) If a worker, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose greater than 6 mSv/year from external exposure, the effective dose must be determined by the use of a personal dosimeter for a measuring period of no longer than one month.

(3) If a worker, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose greater than 1 mSv/year, but less than or equal to 6 mSv/year, from external exposure, the effective dose must be determined by the use of a personal dosimeter for a measuring period of no longer than 3 months.

(4) If a worker, under normal circumstances or in the event of incidents or accidents, is liable to receive an equivalent dose greater than 15 mSv/year to the lens of the eye from external exposure, the equivalent dose to the lens of the eye must be determined by the use of a personal dosimeter.

(5) If a worker, under normal circumstances or in the event of incidents or accidents, is liable to receive an equivalent dose greater than 150 mSv/year to skin or extremities from external exposure, the equivalent dose to these organs must be determined by the use of a personal dosimeter.

(6) If radiological monitoring by means of a personal dosimeter is not expedient or feasible, then individual radiological monitoring must be carried out in accordance with a radiological monitoring programme approved by the Danish Health Authority.

(7) If a worker, under normal circumstances or in the event of incidents or accidents, is liable to receive an effective dose greater than 1 mSv/year from internal exposure, individual radiological monitoring must be carried out in accordance with a radiological monitoring programme approved by the Danish Health Authority.

§ 79. A pregnant exposed worker must be individually radiologically monitored if it cannot be ruled out with certainty that the effective dose to the foetus, after pregnancy has been notified to the employer, is liable to

exceed 1 mSv.

(2) In case of external exposure, radiological monitoring must, where possible be carried out by the use of a personal dosimeter and, if necessary, for a measuring period of one month.

(3) Where the risk exists of internal exposure, individual radiological monitoring must be carried out in accordance with a radiological monitoring programme approved by the Danish Health Authority.

§ 80. Radiological monitoring of emergency workers in a specific emergency situation is subject to such requirements as the Danish Health Authority might lay down, as necessary, in the specific circumstances.

Dose determination, etc.

§ 81. Determination of the dose from individual radiological monitoring must be carried out through a dosimetry service approved by the Danish Health Authority; cf. Section 89.

(2) Dose determination from individual radiological monitoring must be completed as soon as possible after the basis for the determination becomes available, in the form of, e.g., a personal dosimeter, urine sample, etc.

(3) Upon suspicion of an unusually large personal dose, the dose must be determined without undue delay.

§ 82. For the purpose of dose determination, the dosimetry service must employ techniques conforming to internationally recognised standards and relevant standard values and relationships, as recommended by the International Commission on Radiological Protection (ICRP); cf. Annex 4.

(2) The Danish Health Authority may approve other techniques.

§ 83. An undertaking must disclose the results of radiological monitoring of an outside worker to that worker's employer as soon as possible.

§ 84. A worker who has undergone radiological monitoring must be informed of the result of the radiological monitoring as soon as possible after the result becomes available.

(2) If the dose is determined on a basis other than by a personal dosimeter, the worker who underwent radiological monitoring must have access to all the factors upon which the dose determination was based.

§ 85. If a dose exceeds the dose value shown in Annex 5, the employer must notify the Danish Health Authority immediately.

§ 86. A any time, the employer must be able to document doses for its dose-monitored workers for the last five calendar years, including the current year if the worker has worked for the employer in that period.

(2) If doses are determined on a basis other than by a

personal dosimeter, all the factors upon which the dose determination was based must be stated in the record.

(3) In case of accidental exposure, including occupational exposure and emergency occupational exposure, a record must also be retained of the circumstances of such exposures and of the countermeasures taken.

The Danish Health Authority's Personal Dose Registry ("SRP")

§ 87. The results of individual radiological monitoring, including data on irregularities in the radiological monitoring, must within 4 weeks of the results becoming available, be notified to the Danish Health Authority's Personal Dose Registry (SRP). The notification duty resides with the employer.

(2) The notification must contain the relevant data specified in Annex 3.

(3) Data must be notified in the manner and in the format stipulated by SRP.

§ 88. SRP is required to retain the data for the duration of the work period in which that worker is exposed to radiation, and afterwards until they have or would have attained the age of 75 years, but in any case not less than 30 years after termination of the work involving exposure.

Chapter 11

Dosimetry services

§ 89. Dosimetry services must be approved by the Danish Health Authority.

(2) Dosimetry services performing individual radiological monitoring based on the use of personal dosimeters must document that the method conforms to the requirements of ISO 17025 or equivalent standards.

(3) Dosimetry services performing individual radiological monitoring not based on the use of personal dosimeters must obtain the Danish Health Authority's approval of the method employed.

§ 90. Other dosimetry services supplying dosimetric data required pursuant to the provisions of the Radiation Protection Act and rules laid down pursuant to that Act must conform to the requirements of ISO 17025 or equivalent standards.

Chapter 12

Emergencies, accidents and incidents

§ 91. In the event of an emergency, accident or incident involving a radiation source, the undertaking must promptly make all the relevant arrangements to respond to an emergency exposure situation or other significant unintended exposure and to limit the ensuing consequences.

§ 92. The Danish Health Authority must be notified

immediately of emergencies, accidents or incidents that have resulted in, and of incidents that could have resulted in, unintended exposure to any type of radiation source or resulted in significant contamination with radioactive substances and of any discovery, theft, loss, fire, flooding, or the like of significance for radiation protection; cf. Section 14(1) of the Radiation Protection Act.

(2) If any of the situations referred to in (1) has been notified to the Danish Medicines Agency pursuant to the legislation on medical equipment or to the reporting system for unintended incidents, pursuant to "Bekendtgørelse om rapportering af utilsigtede hændelser i sundhedsvæsenet m.v." (Executive Order on Reporting of Unintended Incidents within the Health Service, etc.), the Danish Health Authority must solely be notified separately if the emergency, accident or incident has resulted in or could have resulted in acute radiation injury in a patient or if it has resulted in unintended exposure of workers.

(3) Such notification to the Danish Health Authority must be submitted by calling the Danish Health Authority's 24-hour hotline (telephone no. 44 94 37 73).

Chapter 13

Quality assurance

General requirements

§ 93. The use of radiation sources and exposure must be carried out in accordance with an effective quality management system commensurate with the nature and scale of the undertaking's use of radiation sources or exposure.

§ 94. All radiation protection measures, including safety and emergency procedures, must be tested at suitable intervals.

(2) Written instructions must be available for the performance of all such tests.

(3) The results of the tests must be documented in a systematic manner.

Supplementary requirements for medical exposure

§ 95. The quality management systems for examinations or treatment procedures must, as a minimum, comprise procedures for:

- 1) all sub-procedures entailed by the use of radiation sources, including preparatory, planning-related and concluding sub-procedures;
- 2) supervision by a clinically responsible practitioner;
- 3) registration and analysis of non-conformities;
- 4) implementation of corrective actions;
- 5) dosimetry and other monitoring procedures; and
- 6) clinical audit.

(2) For treatment procedures, the quality management system must additionally comprise procedures for

ascertaining the risk of unintended exposure.

(3) Procedures pursuant to (1), No. 3 must comprise the forwarding of information concerning clinically significant incidents to the referrer and the practitioner with clinical responsibility for the specific medical exposure.

§ 96. An audit must be conducted at intervals no longer than 15 months to ascertain:

- 1) whether the quality assurance is performed effectively and as planned;
- 2) whether the results obtained are consistent with the planned targets; and
- 3) whether the quality assurance is otherwise adequate and fit-for-purpose.

(2) The audit must be conducted by one or more individuals representing all the relevant health-related and physics and technical areas of expertise.

(3) No-one should audit those components of the quality management system that comprise processes for which that individual is personally responsible.

Chapter 14

Special provisions for certain existing exposure situations

Exposure of workers to radon at workplaces

§ 97. At workplaces where the radon concentration exceeds a reference level corresponding to an annual average activity concentration of 100 Bq/m³, optimising measures must be taken to reduce the exposure as much as is reasonably achievable.

§ 98. Occupational exposure to radon that is liable to result in an effective dose greater than 6 mSv/year is subject to authorisation from the Danish Health Authority.

(2) Occupational exposure to radon, where the radon concentration at the workplace exceeds the reference level; cf. Section 97, but is not liable to give rise to an effective dose greater than 6 mSv/year is subject to notification to the Danish Health Authority.

(3) Authorisation must be obtained or notification must be submitted before the exposure commences. An application for authorisation or a notification must be made in accordance with the procedures, and it must comprise the information stipulated by the Danish Health Authority.

§ 99. Any occupational exposure to radon, where the radon level at the workplace, despite optimising measures, exceeds the reference level in Section 97, and which is subject to the authorisation requirement, cf. Section 98(1), is subject to the requirements laid down by the Danish Health Authority in the authorisation.

§ 100. Workplaces where the radon level, despite optimising measures, exceeds the reference level in Section 97, and which is subject to the notification requirement; cf. Section 98(2), must be subject to a radiological monitoring system approved by the Danish

Health Authority. In addition, Section 49 applies.

Exposure of air and space crews to cosmic radiation

§ 101. If air and space crews are liable to receive an effective dose greater than 1 mSv/year from exposure to cosmic radiation in flight or in space, the requirements for justification, optimisation, dose limitation and radiological monitoring shall be applicable; cf. Chapters 2 and 5 of the Radiation Protection Act and the applicable provisions of this Executive Order, including requirements for provision of information and instruction to workers pursuant to Section 45(1), Nos. 1 and 6, and for continuous radiological monitoring of crews.

(2) The exposure of air and space crews must be optimised by the implementation of duty rosters designed to reduce the doses.

(3) Radiological monitoring pursuant to (1) must be carried out in accordance with a radiological monitoring programme approved by the Danish Health Authority. Section 81(1), Sections 84-86 and Section 89(3) shall be applicable.

(4) The relevant data on radiological monitoring, as specified in Annex 6, must be filed by the employer by 1 March of the following year with the Danish Health Authority's Personal Dose Registry. Section 87(3) and Section 88 shall be applicable.

Exposure to external gamma radiation from building materials

§ 102. The reference level for indoor exposure to external gamma radiation from building materials containing naturally occurring radioactive material is 1 mSv/year.

(2) At workplaces where indoor exposure to external gamma radiation from building materials exceeds the reference level in (1), optimising measures must be taken to reduce the exposure as much as is reasonably achievable.

§ 103. In advance of the marketing of building materials emitting gamma radiation, which may cause doses exceeding the reference level in Section 102, the undertaking must determine the activity concentration of the radionuclides concerned and make the measurement results and the corresponding activity concentration index, cf. Annex 7, available to the Danish Health Authority.

Chapter 15

Appeals and penalties

§ 104. Appeals against decisions made by the Danish Health Authority pursuant to this Executive Order may be lodged solely with the Minister for Health if the appeal pertains to legal matters; cf. Section 25 of the Radiation Protection Act.

§ 105. Except where other legislation carries a higher penalty, any undertaking is liable for a fine or imprisonment for up to one year for:

- 1) contravention of Section 16(2)-(7), Section 18(2)-(4) and Section 45(1); Nos. 3-5, (2) or (3), Section 49, Section 50, Section 51(5)-(7), Section 52(1), Section 55(1) or (3), Section 57, Section 60, Sections 64-66, Section 68, Section 70(3)-(5), Section 71(3)-(5), Section 72, Section 73, Section 77 or Sections 93-96,
- 2) use of a radiation source or exposure of others to radiation in spite of the Danish Health Authority having assessed the use or exposure as non-justified; cf. Section 16(1), with reference to Section 17;
- 3) failing to optimise use of a radiation source or exposure in accordance with an assessment from the Danish Health Authority to that effect, cf. Section 18(1), with reference to Section 19, or failing to optimise a radiation source or exposure in accordance with a dose constraint as stated in Section 21, Section 22 and Section 74;
- 4) use of a radiation source or exposure of others to radiation in the absence of an updated safety assessment; cf. Section 20;
- 5) use of a radiation source or exposure of others to radiation without having an approved radiation protection officer or medical physics expert at its disposal or without having consulted an approved radiation protection expert; cf. Section 33(1)-(3), with reference to Section 34(1), or without ensuring that the radiation protection officer has the updated knowledge, skills or competences required by Section 34(4), second sentence;
- 6) failing to test or have tested measuring instruments for correct display of values; cf. Section 56, or failure to perform or have performed acceptance testing, as required by Section 70(1) and (2), or failing to conduct regular performance and constancy testing; cf. Section 71(1);
- 7) allowing medical exposures to be performed without a clinically responsible practitioner having responsibility for them; cf. § 62;
- 8) allowing examinations or paediatric treatment procedures, health screenings and examinations involving high doses to patients to be performed without those performing the examination or treatment procedure being specially trained to do so; cf. Section 67;
- 9) subjecting individuals to non-medical imaging exposure without complying with the requirements referred to by Section 75 and Section 77 or to the requirements laid down by the Danish Health Authority pursuant to Section 76;
- 10) in relation to an outside worker, contravention of Section 44, Section 45(1), No. 1 or 2, Section 46, Section 78, Sections 79-81 or Section 83;

- 11) subjecting an outside worker to occupational exposure with the result that the dose limits are exceeded, pursuant to Section 23(1), with reference to Annex 1; doses set by the Danish Health Authority pursuant to Section 23(2) or (3); the dose limit of 1 mSv mentioned in Section 24; or doses established by the Danish Health Authority pursuant to Section 26(1);
 - 12) in situations mentioned in Section 25, allowing an outside worker to perform further work involving the use of radiation sources or exposure without the Danish Health Authority's authorisation, or failing to observe the terms and conditions laid down by the Danish Health Authority in such an authorisation, or
 - 13) failing to check that an outside worker's categorisation pursuant to the provisions of Sections 39-41 are appropriate in relation to the doses which the outside worker is liable to incur at the undertaking, or that an outside worker's employment is in compliance with Section 42 or Section 43.
- (2) Except where other legislation carries a higher penalty, any employer is liable for a fine or imprisonment for up to one year for:
- 1) contravention of Section 29(2), Section 45(1) No. 1, 2 or 6, Section 46, Section 47, Section 78, Section 79, Section 81, Sections 84-87 or Section 101(2)-(4);
 - 2) assigning a worker to use radiation sources or to exposure in spite of the Danish Health Authority having assessed that use or exposure as non-justified; cf. Section 16(1), with reference to Section 17;
 - 3) assigning a worker to use radiation sources or to exposure in spite of the Danish Health Authority having assessed that use or exposure as non-optimised; cf. Section 18(1), with reference to Section 19;
 - 4) subjecting a worker to occupational exposure with the result that the dose limits are exceeded, pursuant to Section 23(1), with reference to Annex 1; doses set by the Danish Health Authority pursuant to Section 23(2) or (3); the dose limit of 1 mSv mentioned in Section 24; or doses established by the Danish Health Authority pursuant to Section 26(1);
 - 5) in situations mentioned in Section 25 and Section 30, allowing a worker to perform further work involving the use of radiation sources or exposure without the Danish Health Authority's authorisation, or failing to observe the terms and conditions laid down by the Danish Health Authority in such an authorisation;
 - 6) failing to inform a worker or obtain a worker's consent pursuant to Section 26(2);
 - 7) failing to classify a worker pursuant to Section 38 or making a classification pursuant to Sections 39-41 that is not appropriate;
 - 8) allowing a worker to perform work that is not in compliance with Section 42 or Section 43;
 - 9) allowing a worker to commence work as an outside worker without having procured documentation of the worker's relevant dose history and information about the worker's instruction in compliance with Section 44;
 - 10) contravening requirements concerning radiological monitoring of emergency workers as stipulated by the Danish Health Authority pursuant to Section 80;
 - 11) allowing a worker to work at workplaces where no optimising measures have been taken, as required in accordance with Section 97 or Section 102(2), or where the workplace is not subject to radiological monitoring, as required in accordance with Section 100(1), or where Section 49 has not been complied with; cf. Section 100(2);
 - 12) exposing workers to radon without authorisation from or without notification to the Danish Health Authority, as required pursuant to Section 98, or failure to observe the terms and conditions laid down by the Danish Health Authority in an authorisation or subsequent to a notification in accordance with Section 98.
- (3) Except where other legislation carries a higher penalty, any contravention of Article 4 or Article 6 of Council Regulation No. 1493/93/Euratom of 8 June 1993 on transfer of radioactive substances between Member States is punishable by a fine or by imprisonment for up to one year
- (4) In particularly aggravating circumstances, the penalty may be increased to imprisonment up to two years.
- (5) In sentencing pursuant to (4), the following is considered particularly aggravating circumstances:
- 1) that the offending party gained or intended to gain a financial advantage, either for itself or for others, by the contravention, or
 - 2) that the contravention was committed intentionally or due to gross negligence.
- (6) Companies etc. (legal persons) may be held criminally liable according to the rules of Chapter 5 of the Danish Criminal Code.

Chapter 16

Entry into force and transitional provisions

§ 106. This Executive Order enters into force on 1 July 2019.

(2) Executive Order No. 84 of 2 February 2018 on ionising radiation and radiation protection is hereby repealed.

§ 107. Exposure to radon at workplaces which commenced before 6 February 2018 is, however, permitted to continue provisionally without authorisation or notification; cf. Section 98, but the application for authorisation must be submitted or notification must be made by September 2019. The Danish Health Authority

may, in such cases, in the intervening period until an application for authorisation has been decided on or a notification has been received, set such requirements as the Danish Health Authority deems necessary for the purpose of radiation protection.

§ 108. An undertaking which, according to the provision in Section 33(1), is required to have at its disposal one or more radiation protection officers, may permit a responsible manager, radiation safety officer, medical doctor, senior radiologist, physicist or radiation physicist who, in compliance with the rules in force until 6 February 2018, supervised the undertaking's use of radiation sources, within that individual's field of expertise, to serve as the radiation protection officer for the same type of use of radiation sources until the Danish Health Authority determines otherwise. The individual concerned must perform all the tasks and fulfil all the duties incumbent upon a radiation protection officer in accordance with this Executive Order.

§ 109. An undertaking which, according to the provision in Section 33(3), is required to have at its disposal one or more medical physics experts may permit a responsible physicist or radiation physicist who, in compliance with the rules in force until 6 February 2018, supervised the undertaking's specific medical exposures, within that individual's field of expertise, to serve as the medical physics expert for the same type of exposure until

the Danish Health Authority determines otherwise. The individual concerned must perform all the tasks and fulfil all the duties incumbent upon a medical physics expert in accordance with this Executive Order.

§ 110. A dosimetry service performing individual radiological monitoring based on the use of personal dosimeters and which, according to the rules in force until 6 February 2018, were approved by the Danish Health Authority may provisionally continue its undertaking until the Danish Health Authority has decided on its application for approval. Undertakings required to perform individual radiological monitoring of workers may retain the services of the dosimetry service concerned pending the Danish Health Authority's decision.

(2) Dosimetry services performing individual radiological monitoring exclusively by other means than use of personal dosimeters, including in the form of a radiological monitoring programme, may continue their undertaking where this has been approved by the Danish Health Authority before 1 July 2019, until the Danish Health Authority determines otherwise. Undertakings with a duty to workers to perform individual radiological monitoring and that have been granted the Danish Health Authority's approval to do so by means other than use of personal dosimeters may continue to use the dosimetry services in question until the Danish Health Authority determines otherwise.

Danish Health Authority, 1 July 2019

SØREN BROSTRØM

/ Mette Øhlenschläger

Annex 1

Dose limits

The dose limits for occupational and public exposure from the use of radiation sources and exposure by undertakings are shown in the table below:

Category of individual	Effective dose limit [mSv/year]	Equivalent dose limit [mSv/year]		
		Lens of the eye	Skin ¹⁾	Extremities ²⁾
Exposed worker, aged 18 years or over	20	20	500	500
Individual aged between 16 and 18 years, pursuing a programme of vocational education of at least two years' duration which is governed by or pursuant to legislation and in which the use of radiation sources or exposure are necessary components of that programme	6	15	150	150
Member of the public	1	15	50	-

1) The dose limit for the skin applies to any surface of 1 cm².

2) Extremities means the hands, forearms, feet and ankles.

The dose limits for occupational exposure apply to the total over a calendar year of:

- all doses incurred from all use of radiation sources which a worker is employed in using;
- the contribution from occupational radon exposure in cases where the radon level, despite implementation of optimising and compensatory measures, make the worker liable to incur an effective dose greater than 6 mSv/year, and
- occupational exposure from existing exposure situations.

The dose limits for public exposure apply to the total over a calendar year of dose contributions from all undertakings' use of radiation sources or exposure.

Doses incurred from natural radiation or from medical exposure are not to be included in the determination of the total dose to a single individual.

Tasks of the designated expert individuals

1. Radiation protection officer

The radiation protection officer must assist the undertaking in the performance, as a minimum, of the following tasks, where appropriate:

- a) Ensuring that the use of radiation sources and any exposure are compliant with the undertaking's instructions.
- b) Supervision of the implementation of the programme for radiological monitoring of workplaces.
- c) Maintaining records of the undertaking's radiation sources and facilities.
- d) Carrying out regular assessments of the condition of the relevant safety and warning systems.
- e) Supervision of the performance of individual radiological monitoring.
- f) Supervision of the performance of medical surveillance pursuant to rules laid down by the Danish Working Environment Authority.
- g) Providing workers with information, instruction and training concerning the use of radiation sources and exposure.
- h) Reporting to local management.
- i) Implementation of the arrangements for prevention of, emergency preparedness for and response in emergency exposure situations.

2. Radiation protection expert

The radiation protection expert's advice must, as a minimum, comprise the following aspects, where relevant:

- a) Optimisation and the establishment of dose constraints.
- b) Compilation of documentation such as safety assessments and written instructions.
- c) Plans for new or modified facilities and the acceptance into service of new or modified radiation sources with consideration for any engineering controls, design features, safety features and warning devices of relevance to radiation protection.
- d) Classification of controlled and supervised areas.
- e) Training and further education programmes for exposed workers.
- f) Categorisation of workers.
- g) Employment conditions for pregnant and breastfeeding workers.
- h) Individual radiological monitoring.
- i) Radiological monitoring of workplaces.
- j) Equipment for monitoring radiation intensity and contamination with radioactive substances.
- k) Environmental monitoring programme.
- l) Arrangements for handling, storage, disposal and discharge of radioactive waste.
- m) Arrangements for the prevention of emergencies, accidents and incidents.
- n) Preparedness and response in emergency exposure situations.
- o) Investigation and analysis of emergencies, accidents and incidents.
- p) Quality management systems applicable to the use of radiation sources and to exposure.

3. Medical physics expert

The medical physics expert must assist the undertaking, as a minimum, in performance of the following tasks, where relevant:

- a) Performance of dosimetry, including physical measurements for evaluation of doses incurred by patients and other individuals subject to medical exposure.
- b) Advising on medical-radiological radiation sources, facilities and equipment.
- c) Optimisation of the radiation protection of patients and other individuals subject to medical exposure, including the application and use of diagnostic reference levels.

- d) Establishing methods and criteria for quality assurance of medical-radiological radiation sources and equipment, conducting acceptance and performance testing, and assessment of constancy testing.
- e) Preparation of technical specifications for medical-radiological radiation sources and equipment and facility design.
- f) Surveillance of the medical-radiological radiation sources, facilities and equipment.
- g) Analysis of incidents involving, or potentially involving, accidental or unintended medical exposures.
- h) Selection of equipment required to perform radiation protection measurements.
- i) Training of workers in relevant aspects of radiation protection.

Annex 3

Requirements for documentation of doses, etc.; cf. Section 44, and requirements for notification to SRP; cf. Section 87

Documentation and notification must contain the following information:

Documentation pursuant to Section 44	Notification to SRP pursuant to Section 87
<i>Employer</i>	<i>Employer</i>
Employer's name	Employer's name
Employer's address	Employer's address
Employer's business registration number ("CVR-nummer")	Employer's business registration number ("CVR-nummer")
Employer's manufacturing unit registration number ("P-nummer")	Employer's manufacturing unit registration number ("P-nummer")
Employer's SST-ID or health service registration number ("SOR-nummer")	Employer's SST-ID or health service registration number ("SOR-nummer")
<i>Worker</i>	<i>Worker</i>
Name	Name
Civil registration number ("CPR-nummer")	Civil registration number ("CPR-nummer")
	Health Authority's Personal Dose Registry Professional ID code ("SRP-profession")
Last medical examination	
<i>Information on doses, etc.</i>	<i>Per individual dose determination</i>
Total of recorded effective doses and, as applicable, equivalent doses for the last five calendar years, including the current year	Commencement date of individual radiological monitoring
	End date of individual radiological monitoring
	Whether any personal dosimeter was submitted on time, submitted too late or not submitted/read
Date of latest update of knowledge, skills, competences, information, training and instruction; cf. Section 45.	Effective dose and equivalent doses, respectively to the lens of the eye, skin and extremities in mSv, as applicable
	In the event of intake of radioactive material, the accumulated effective dose in mSv
	Separate registration of doses received from: a) accidental exposure b) special occupational exposure c) emergency occupational exposure d) radon

Determination of effective and equivalent doses

The dose limits are expressed in the radiation protection quantities *effective dose* and *equivalent dose*, as defined by the International Commission on Radiological Protection (ICRP).

Definitions

Basic physical quantities

Absorbed dose (D)

Absorbed dose (D) is given by the energy absorbed per unit mass:

$$D = \frac{d\varepsilon}{dm} \quad (1)$$

where $d\varepsilon$ is the energy from ionising radiation which is deposited in an infinitesimal volume of mass dm . Below, the absorbed dose denotes the average dose deposited in a tissue or an organ.

The unit for absorbed dose is gray [Gy], where one gray is equivalent to one joule per kilogram:

$$1 \text{ Gy} = 1 \text{ J kg}^{-1}.$$

Radiation protection quantities

Equivalent dose (H_T)

The biological effect of ionising radiation in a tissue or an organ depends on the absorbed dose and the type and energy of the radiation. Use of the quantity equivalent dose takes this factor into account.

Equivalent dose (H_T) is given by:

$$H_T = \sum_R w_R D_{T,R} \quad (2)$$

where $D_{T,R}$ is the average absorbed dose deposited in the organ or tissue T as a result of the radiation R , and w_R is the radiation weighting factor (Table 1).

The unit for equivalent dose is sievert [Sv].

Effective dose (E)

The body's organs and tissues have different levels of sensitivity to radiation. Use of the quantity effective dose takes this factor into account in cases where only part of the body is irradiated or where the body is subjected to an inhomogeneous exposure.

Effective dose (E) is determined as the sum of the weighted equivalent doses in all tissues and organs:

$$E = \sum_T w_T H_T = \sum_T w_T \sum_R w_R D_{T,R} \quad (3)$$

where H_T is the equivalent dose received by the tissue or organ T , and w_T is the tissue weighting factor for the tissue or organ T (Table 2).

The unit for effective dose is sievert [Sv].

Table 1. Radiation weighting factors w_R

Radiation type	w_R
Photons	1
Electrons and myons	1
Protons and charged pions	2
Alpha particles, fission fragments, heavy ions	20
Neutrons, $E_n < 1$ MeV	$2.5 + 18.2 \cdot \exp(-[\ln(E_n)]^2/6)$
Neutrons, $1 \text{ MeV} \leq E_n \leq 50 \text{ MeV}$	$5.0 + 17.0 \cdot \exp(-[\ln(2 \cdot E_n)]^2/6)$
Neutrons, $E_n > 50 \text{ MeV}$	$2.5 + 3.25 \cdot \exp(-[\ln(0.04 \cdot E_n)]^2/6)$

*The unit for E_n (neutron energy) is MeV

Table 2. Tissue weighting factors w_T

Organ or tissue	w_T
Bone marrow	0.12
Colon	0.12
Lung	0.12
Stomach	0.12
Breast	0.12
Remaining tissues (*)	0.12
Gonads	0.08
Bladder	0.04
Oesophagus	0.04
Liver	0.04
Thyroid	0.04
Bone surface	0.01

Brain	0.01
Salivary glands	0.01
Skin	0.01
(*) w_T for remaining tissue (0.12) is applied to the arithmetic mean dose of the 13 organs and tissue types below, for each of the sexes. Remaining tissues: adrenals, extrathoracic region, gall bladder, heart, kidneys, lymphatic nodes, muscle, oral mucosa, pancreas, prostate, small intestine, spleen, thymus and uterus/cervix.	

Determination of effective dose and equivalent doses from external exposure

Individual radiological monitoring of an exposed worker for external exposure is normally performed by means of a personal dosimeter worn on the body. The personal dosimeter must be calibrated to measure the operational quantities recommended by ICRP and the International Commission on Radiation Units and Measurements (ICRU).

When measuring in a radiation field, e.g. for measurements at a workplace, use may be made of a measuring instrument calibrated to measure the operational quantities recommended by ICRP and ICRU.

Determination of effective dose from internal exposure

The doses from intake of radioactive substances to be compared with the annual dose limits comprise the doses accumulated over a period of 50 years from intake of radioactive substances in the year in question. For intake in children, the doses must, however, be accumulated up to 70 years of age.

For determination of the effective dose following intake of radioactive substances, ICRP has calculated so-called dose coefficients for radionuclides for different categories of individuals and age-groups. The dose coefficients indicate the accumulated effective dose per unit intake from ingestion or inhalation of a given radionuclide.

The unit for the dose coefficients is sievert per becquerel [Sv/Bq].

If the intake of radioactive substances is not limited to a single mode of exposure (ingestion or inhalation) or to a single radionuclide, the total effective dose, E_{Internal} , from intake of radioactive substances is determined as follows:

$$E_{\text{Internal}} = \sum_j e(\tau)_{j,\text{ing}} A_{j,\text{ing}} + \sum_j e(\tau)_{j,\text{inh}} A_{j,\text{inh}} \quad (4)$$

where $e(\tau)_{j,\text{ing}}$ and $e(\tau)_{j,\text{inh}}$ are the dose coefficient for radionuclide j from ingestion (ing) and inhalation (inh) for the relevant category of individual and age-group. $A_{j,\text{ing}}$ and $A_{j,\text{inh}}$ are the activity of the associated intake of radionuclide j [Bq] from ingestion and inhalation, respectively.

The quantity of any intake will usually need to be assessed by means of a measurement or an estimate of the concentration of the radionuclide in question in inhaled air from excreta, e.g. urine, or of content in the body.

Determination of effective dose from radon at workplaces

For a general assessment of potential doses to workers, the generalised conversion factor of $6.7 \cdot 10^{-6} \text{ mSv} \cdot \text{h}^{-1}/(\text{Bq}/\text{m}^3)$ may be used.

For a detailed calculation of effective dose from radon, please refer to the ICRP recommendations currently in force.

Determination of the total effective dose

The dose limits for the effective dose apply to the sum of doses received from all relevant radiation sources and exposure. Thus, if an individual is subjected simultaneously to external and internal exposure and possible contribution from radon at their workplace, the effective and equivalent doses from each type of exposure must first be measured or estimated as described above before the total effective dose can be determined:

$$E_{\text{Total}} = E_{\text{External}} + E_{\text{Internal}} + E_{\text{Radon}} \quad (5)$$

Annex 5

Dose values for immediate notification of the Danish Health Authority pursuant to Section 85

Type of dose	Dose value for immediate notification of external exposure [mSv]
Effective dose	5
Equivalent dose to lens of eye	5
Equivalent dose to skin and/or extremities	50
For doses from internal exposure, the dose values for immediate notification of the Danish Health Authority are determined on a case-by-case basis.	

Annex 6

Requirement for notification to SRP concerning radiological monitoring of air and space crews; cf. Section 101

The following data concerning radiological monitoring of air and space crews must be reported to SRP by 1 March of the following year:

1. The number of crew members who, in the preceding calendar year, were measured or estimated to have incurred a total effective dose from cosmic radiation in flight greater than 1 mSv distributed in the intervals:
 - Greater than 1 mSv but less than or equal to 2 mSv.
 - Greater than 2 mSv but less than or equal to 3 mSv.
 - Greater than 3 mSv but less than or equal to 4 mSv.
 - Greater than 4 mSv but less than or equal to 5 mSv.
 - Greater than 5 mSv but less than or equal to 6 mSv.

2. For crews who in the preceding calendar year were measured or estimated to have incurred a total effective dose from cosmic radiation in flight greater than 6 mSv, the following data: Name, civil registration no. ("CPR-nummer") and individual annual effective dose.

Annex 7

Definition and use of the activity concentration index for the gamma radiation emitted by building materials; cf. Section 103

For identified types of building materials, the activity concentrations are set for the primordial radionuclides Ra-226, Th-232 (or its decay product Ra-228) and K-40.

The activity concentration index (I) is calculated by means of the following formula:

$$I = C_{\text{Ra-226}}/300 \text{ Bq/kg} + C_{\text{Th-232}}/200 \text{ Bq/kg} + C_{\text{K-40}}/3,000 \text{ Bq/kg}$$

where $C_{\text{Ra-226}}$, $C_{\text{Th-232}}$ and $C_{\text{K-40}}$ are the activity concentrations [Bq/kg] of the radionuclides concerned in the building material.

The index is related to the dose from gamma radiation from a specified building material. The index applies to the building material, not to its constituents, except when those constituents are building materials themselves and are separately assessed as such. For application of the index to such constituents, appropriate distribution coefficients must be used in particular for residues from industries processing naturally occurring radioactive material recycled into building materials.

An activity concentration index value equal to one ($I = 1$) may be used as a conservative screening tool for identifying materials that may cause the reference level, established in Section 102(1) to be exceeded. The calculation of dose needs to take into account other factors such as density, thickness of the material as well as factors relating to the type of building and the intended use of the material (bulk or superficial).