Executive Order No. 670 of 01/07/2019
Ministry of Health, Danish Health Authority

Executive Order on Use of Radioactive Substances[1)]

Pursuant to Section 1(5); Section 2(2); Section 4(2); Section 5(2); Section 7(2); Section 8(2); Section 9(2); Section 10(2); Section 11(1); Section 15; Section 16 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 and definitions

§ 1. This Executive Order supplements the provisions of Executive Order No. 669 of 1 July 2019 on Ionising Radiation and Radiation Protection.

(2) This Executive Order is applicable to use of radioactive substances within the constraints set out in Sections 1-9 of the Executive Order on Ionising Radiation and Radiation Protection.

§ 2. Any application of the provisions of this Executive Order shall be based on the definitions in the Executive Order on Ionising Radiation and Radiation Protection and the following definitions:

1) Emergency response plan: Arrangements for planning an adequate reaction to an emergency exposure situation on the basis of hypothetical incidents and related scenarios.
2) Radiation safety cabinet: A cabinet providing protection during the use of radioactive material capable of causing external or internal exposure, e.g. a hot cell, glove box, fume cupboard or ducted laminar air flow bench.
3) Discharge and disposal: The discharge, injection into geological layers, or the disposal of radioactive waste.
4) Disposal: Emplacement without the intention of subsequent retrieval of radioactive waste in a natural or engineered barrier system, including in a facility, for the purpose of providing radiation protection.
5) Clearance: A change in regulatory status entailing that requirements from the point view of radiation protection in the Radiation Protection Act and the provisions in the rules laid down pursuant to the Act are no longer in force.
6) High-activity sealed source: A sealed source in which the activity exceeds or is equal to the lower activity limit for security category C in Annex 6.
7) Industrial radiography: Radiography for industrial or research purposes, e.g. for weld inspection, in which high-activity sealed sources are used inside or outside of facilities, and where the radiation source is moved outside the container.
8) Sealed source: Radioactive material that is permanently sealed in a capsule or incorporated in a solid form with the objective of preventing, under normal conditions, any dispersion of the radioactive material.
9) NORM: Naturally Occurring Radioactive Material.
10) Useful beam: The fraction of radiation from a sealed source contained within a device that is not permanently shielded and which is put to use when the device is operated.
11) Security measures: Arrangements or precautions for the purpose of preventing, detecting and responding to theft, unintended access to, or misuse of radioactive material.
12) Security category: A class of high-activity sealed sources, which based on their activity and the potential for radiation injury from theft, unintended access or misuse, are subject to the same requirements regarding security measures.
13) Security plan: Arrangements for planning precautions for the purpose of preventing, detecting and responding to theft, unintended access to, or misuse of high-activity sealed sources.
14) Demonstration source: An unsealed or sealed source approved by the Danish Health Authority for teaching purposes at lower and upper secondary educational institutions.
15) Vulnerability Assessment: The identification of threats and security weaknesses during the use of radioactive material.
16) Discharge: The dispersion of radioactive waste, for example via drains, chimneys or ventilation ducts into the external environment.
17) Point of discharge: The location at which discharged radioactive waste is dispersed freely in the external environment, for example via drains to public sewers, chimney emission or ventilation ducts into the atmosphere.
18) Veterinary medical use: The use of radioactive material for veterinary medical diagnostics, treatment

[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.

or research within these domains.

19) Unsealed source: Radioactive material in the form of a gas, aerosol, fluid or solid that is not sealed in a capsule, where contact with, or dispersion of, the material may arise during its use.

Chapter 2

Prohibition, licensing, notification, exemption and clearance Prohibition

§ 3. Use of toys, personal jewellery or adornments, cosmetics, foodstuffs and feedstuffs containing radioactive material is not justified and is hence prohibited.

§ 4. It is prohibited to market consumer products or make consumer products available to consumers unless the intended use of those products meets the criteria and requirements for exemption from the licensing and notification requirements; cf. Section 8(1).

Licensing, notification and exemption from these requirements

§ 5. Use of radioactive material is subject to licensing from or notification to the Danish Health Authority or is exempt from the licensing and notification requirements in accordance with the limits of activity and activity concentration specified in Annex 1; cf. however (2) and (3) and Sections 6-8.

(2) The Danish Health Authority may exempt use of radioactive material from the licensing or notification requirements if the criteria in Annex 2 are met.

*(3)*The Danish Health Authority may increase the level of regulatory control in Annex 1 governing use of radioactive material if deemed necessary based on the likelihood and impact of any exposure incurred from use.

§ 6. A licence from the Danish Health Authority is required in all and any instances of:

1) manufacture of radionuclides;
2) manufacture and processing of sealed sources;
3) manufacture and import of consumer products and other products, including pharmaceuticals, the manufacture of which entails the activation or intentional addition of radionuclides;
4) intentional administration of radionuclides to patients;
5) intentional administration of radionuclides to animals in veterinary medical applications;
6) acceptance and performance testing of equipment;
7) technical safety inspection of sealed sources and ancillary equipment;
8) servicing of sealed sources and ancillary equipment with implications from a radiation protection point of view;
9) recycling of radioactive material;
10) injection into geological layers of radioactive material; and
11) disposal.

§ 7. Application of demonstration sources for teaching purposes at lower and upper secondary educational institutions is subject to the requirement for notification to the Danish Health Authority.

(2) Any application of radioactive material, cf. (1), that is not a demonstration source and which is not subject to the licensing requirement pursuant to Annex 1 is subject to the requirement for notification to the Danish Health Authority.

§ 8. Use by consumers of consumer products is exempt from the licensing and notification requirements if that use is compliant with the accompanying user guide, cf. (5) below, and meets the criteria of Annex 2 and the following requirements:

1) The consumer product has been approved by an EU Member State.
2) The radiation source is a sealed source.
3) The dose rate at the time of marketing does not exceed 1 µSv/h at a distance of 10 cm from the consumer product's accessible surfaces.
4) The consumer product is marked with the symbol for ionising radiation and the legend in Danish: "Radioaktivitet" ("Radioactivity"), unless this is not feasible for practical reasons for that consumer product.
5) The consumer product is accompanied by a user guide on use of the consumer product and information on the content of radioactive material, including the radionuclide and its activity.

(2) In addition, the following uses of consumer products are exempt from the licensing and notification requirements:

1) Storage of consumer products meeting the criteria and requirements of (1) provided that the total activity is less than or equal to 1,000 times the value in Annex 3.
2) Transfer of a consumer product to a consumer if the consumer product meets the criteria and requirements of (1).

§ 9. A licence shall be obtained or notification shall be submitted before any use of radioactive material commences.

(2) An application for a licence or a notification shall be submitted in accordance with the procedures, and must comprise the data stipulated by the Danish Health Authority.

Clearance

§ 10. A radioactive material in solid form may be granted clearance if the activity concentration is less than

or equal to the value in Annex 4, and radioactive material in any physical form may be granted clearance if the criteria in Annex 2 are met.

(2) Clearance of radioactive material in accordance with the criteria in Annex 2 requires the Danish Health Authority's prior approval.

(3) In determination of activity concentrations for purposes of clearance pursuant to (1), the following shall apply:

1) For amounts less than or equal to 1,000 kg, the activity concentration may be obtained as the mean value.
2) For volumes greater than 1,000 kg, the Danish Health Authority may permit the activity concentration to be determined as the mean value subject to documentation that the deviation around the mean value is acceptable.
3) For determination of the mean value, parts of the material with identified activity concentrations greater than the value in Annex 4 shall be removed if this is reasonably achievable.

§ 11. Buildings, facilities and objects, including equipment, may be granted clearance if the surface-specific activity concentration is less than or equals the value in Annex 5. In the case of removable contamination, buildings, facilities and objects, including equipment, shall be cleaned before clearance. The cleaning shall continue for as long as effective activity reduction is achieved.

(2) Clearance pursuant to (1) requires the Danish Health Authority's prior approval except for:

1) clearance of facilities that are not required to register, and
2) clearance of objects, including equipment.

(3) In determination of surface-specific activity concentrations for purposes of clearance pursuant to (1), the following shall apply:

1) The surface-specific activity concentration shall be determined as the total non-removable activity on and below the surface divided by the surface area.
2) For areas up to 1 m^2, the surface-specific activity concentration may be obtained from the mean value.
3) For determination of the mean value, partial areas of the surface with identified surface-specific activity concentrations greater than the value in Annex 5 shall be removed if this is reasonably achievable.
4) For areas greater than 1 m^2, the Danish Health Authority may permit the surface-specific activity concentration to be determined as the mean value, subject to documentation that the deviation around the mean value is acceptable.

(4) Buildings and facilities may furthermore be granted clearance if the building's or facility's constituent materials may be granted clearance pursuant to the provisions of Section 10(1) and (3). Such clearance requires the Danish Health Authority's prior approval.

§ 12. The clearance of land is subject to a dose constraint on the effective dose of 10 µSv/year to members of the public.

(2) Clearance pursuant to (1) requires the Danish Health Authority's prior approval.

§ 13. The undertaking shall be able to document that the criteria for clearance have been met.

(2) The documentation shall be in reasonable proportion to the scale of what is granted clearance. For clearance of radioactive material with an activity greater than 10 times the value in Annex 3, the documentation shall be based on standardised test methods and standardised test method validation.

Chapter 3

Dilution and mixing

§ 14. Radioactive material must not be diluted in the interests of gaining:

1) exemption from the Radiation Protection Act's requirements from the point view of radiation protection or the provisions of this Executive Order and of other rules laid down pursuant to the Act; cf. Section 2(1) No. 1 of the Executive Order on Ionising Radiation and Radiation Protection;
2) exemption from licensing or notification requirements pursuant to Section 5(1) or (2);
3) exemption from the scope of Executive Order No. 672 of 1 July 2019 on Transboundary Shipments of Radioactive Waste and Spent Fuel; and
4) clearance; cf. Section 10.

(2) In special circumstances, the Danish Health Authority may approve the mixing of radioactive and non-radioactive material for the purpose of reuse.

Chapter 4

Registration and records

§ 15. The following shall be recorded in the Danish Health Authority's Registry of Radiation Sources and Facilities:

1) Sealed sources shall be registered if the activity of any single source is greater than 100 times the value in Annex 3.
2) Facilities utilised for use of radioactive material subject to the licensing requirement.

(2) If a registered sealed source is no longer held by the undertaking or a registered facility is no longer in use, the Danish Health Authority shall be duly notified.

§ 16. An undertaking holding radioactive material shall keep arecord of the following:

1) Sealed sources if the activity of any single radiation

source is greater than the value in Annex 3.

2) Unsealed sources if the activity concentration or activity of any single storage container is greater than the values in Annex 3.

(2) The record in compliance with (1) No. 1 shall contain the same information as that which, in accordance with the Danish Health Authority's instructions, shall be notified to the Danish Health Authority's Registry of Radiation Sources and Facilities.

(3) The record in compliance with (1), No. 2 shall comprise the last five years' reception, production and transfer of unsealed sources for other applications, and shall contain the following information for the individual storage container:

1) Radionuclide.
2) Chemical and physical form.
3) Date, activity at the time of reception or production, and when applicable, activity concentration.
4) In case of transfer: the date of the transfer, activity and, when applicable, the activity concentration and the name of the undertaking to which the transfer was made.
5) Storage location.
6) Relevant contact name.

§ 17. An undertaking responsible for a facility utilised for use of radioactive material subject to the licensing or notification requirement shall keep records containing the following information:

1) Information for unique identification of the facility.
2) Facility type.
3) A drawing of the facility with information on the design and the capacity of its features to provide radiation protection.
4) Any classification as a controlled or supervised area.
5) For facilities subject to requirements for technical safety inspection, the date of the last inspection and the latest date for the next one.

§ 18. An undertaking shall keep records of the last five years' discharge, storage and transfer of radioactive waste, containing the following information:

1) Storage of radionuclides with half-lives longer than 24 hours: Radionuclide, chemical and physical form, date, estimated activity and, where relevant, activity concentration at the time of storage as radioactive waste and the storage location and relevant contact name.
2) Discharge and transfer: Date, estimated activity and, when applicable, the activity concentration at the time of discharge or transfer, the method of discharge and, for transfer, the name of the undertaking to which the radioactive waste was transferred.

(2) For discharges from human or animal patients to which radionuclides have been administered internally, the documentation may be based on model calculations, which include a statistical estimate of discharges based on the number of human or animal patients.

Chapter 5

Approval and notification of transfer, import and export

§ 19. The Danish Health Authority's prior approval is required for:

1) transfer within Denmark of a high-activity sealed source;
2) export to a country outside of the European Union of a sealed source, the activity of which is greater than the value in Annex 3; and
3) import from a country outside of the European Union of radioactive material, the activity and activity concentration of which are greater than the values in Annex 3.

(2) An application for a licence pursuant to (1) shall be made according to the procedures and comprise the data stipulated by the Danish Health Authority.

§ 20. For transfer within Denmark of radioactive material, the activity and activity concentration of which are greater than the values in Annex 3, the transferring undertaking shall notify this to the Danish Health Authority.

(2) (1) is not applicable to

1) transfer of high-activity sealed sources subject to the requirement for prior approval pursuant to Section 19(1), No. 1;
2) transfer to a consumer of a consumer product if the intended use meets the criteria and requirements for exemption from the licensing and notification requirements; cf. Section 8(1).

(3) The notification shall be submitted within 21 days of the end of a quarter for transfers made within that same quarter, and shall contain the data stipulated by the Danish Health Authority.

§ 21. Prior to transfer to a country outside of the European Union of a sealed source with activity higher than the value in Annex 3, the undertaking shall ensure that the transferee is entitled to take receipt of the radiation source under the legislation of the recipient country.

Chapter 6

Transfer, discharge and disposal

Transfer of radioactive material no longer in application

§ 22. Radioactive material that is no longer to be applied by the undertaking shall be transferred as soon as reasonably achievable.

(2) Radioactive material scheduled for transfer may be stored for no more than 12 months.

(3) In special cases, the Danish Health Authority may

authorise later consignment.

§ 23. Sealed sources shall be transferred to the manufacturer or another undertaking; cf. however (2).

(2) High-activity sealed sources within security category A, cf. Annex 6, for which no further use is foreseen, shall as far as possible be transferred to the manufacturer. Prior to acquisition of the radioactive source, an agreement shall be concluded with the manufacturer concerning final transfer of the radiation source to that manufacturer.

Discharge and disposal of radioactive waste

§ 24. Radioactive waste shall be discharged or disposed of as soon as reasonably achievable.

(2) Radioactive waste may be stored for no more than 12 months with a view to its decay and subsequent clearance or discharge and disposal.

(3) In special cases, the Danish Health Authority may authorise storage for more than 12 months.

§ 25. Radioactive waste shall be discharged or disposed of by a suitable means for this purpose.

§ 26. For the discharge of radioactive waste subject to the notification requirement, cf. Annex 1, and with an activity less than in Annex 3, the activity concentration immediately after the point of discharge must not be greater than 10 times the value in Annex 3.

§ 27. Radioactive waste that is not discharged or injected into geological layers, shall be disposed of.

(2) In special cases, the Danish Health Authority may authorise another method of discharge or disposal.

Disposal

§ 28. Disposal of radioactive waste may be carried out only by a specially-appointed undertaking.

(2) The disposal of radioactive waste is subject to a dose constraint on the effective dose of 10 μSv/year to members of the public.

(3) In special cases, the Danish Health Authority may authorise another dose constraint for disposal.

Chapter 7

Requirements for the knowledge, skills and competences of designated expert individuals and clinically-responsible practitioners

§ 29. Requirements for the knowledge, skills and competences of radiation protection officers, medical physics experts and radiation protection experts are set out in Annexes 7, 8 and 9, respectively.

§ 30. Requirements for the knowledge, skills and competences of clinically-responsible practitioners are set out in Annex 10.

Chapter 8

Requirements for the knowledge, skills and competences of exposed workers

§ 31. Exposed workers employed for the specific types of use and practices specified in Annex 11 shall be specially trained for these. Requirements for their knowledge, skills and competences are set out in that Annex.

(2) The knowledge, skills and competences of exposed workers engaged in using high-activity sealed sources shall be updated at intervals of no more than five years.

Chapter 9

Requirements for use of radioactive material

Optimisation

§ 32. Manufacture of radionuclides and any holdings of radioactive material shall be kept to the minimum necessary for its use.

§ 33. The relocation of radioactive material on an undertaking's site shall be minimised and carried out in such a way that relocation does not cause needless exposure and that the risk of accidents during relocation is minimised.

§ 34. All use of radioactive material shall be facilitated in such a way that the production of radioactive waste is kept to the minimum necessary for that use.

Storage

§ 35. Radioactive material with a total activity greater than the value in Annex 3 shall be stored at specially-equipped storage locations within the facilities where the material is used or handled or in a special facility for storage of radioactive material.

(2) Radioactive material in the form of waste with a total activity as that mentioned in (1) shall be stored in facilities that may be used for no other purposes. The Danish Health Authority may, however, authorise storage of other than that of radioactive waste inside the facility if radiation exposure from the radioactive waste is negligible. In such cases, the radioactive waste shall be stored inside a locked unit within the facility.

(3) To the extent necessary for application or handling, short-term storage is permitted outside of the specially-equipped storage locations or special facilities for storage. The storage shall only give rise to negligible radiation exposure.

(4) Radioactive material shall be stored in suitable containers or packing that secure the contents against unintended dispersion.

(5) Radioactive material at risk of forming airborne material shall be stored in airtight containers or inside

facilities with adapted air exchange; cf. Annex 13, Subsection 1.1.9.

(6) Storage of radioactive material shall be well organised so as to permit easy identification of individual storage units.

§ 36. Radioactive material with a total activity greater than the value in Annex 3 shall be stored so as to be secured against theft and vandalism as well as fire, flooding and similar environmental impacts.

(2) Radioactive material such as that mentioned in (1) must not be stored together with explosive, corrosive or highly flammable substances or other substances that might compromise safety during storage.

Signage

§ 37. All locations for storing radioactive material with a total activity greater than the value in Annex 3 shall display warning signs for ionising radiation in compliance with the applicable standard supplemented by the legend in Danish: "Radioaktivt materiale" ("Radioactive material"). The warning sign shall be clearly legible and durable.

§ 38. Entrances to facilities or areas using radioactive material with a total activity greater than 100 times the value in Annex 3 shall display warning signs for ionising radiation in compliance with the applicable standard supplemented by the legend in Danish: "Radioaktivt materiale" ("Radioactive material").

(2) If a facility or area is classified as a supervised area, cf. Section 49 of the Executive Order on Ionising Radiation and Radiation Protection, the signage shall, as mentioned in (1) and commensurately with the nature and magnitude of the radiological risk, be supplemented by the legend in Danish: "OVERVÅGET OMRÅDE" ("SUPERVISED AREA"), and for sealed sources, the legend in Danish: "Risiko for extern bestråling" ("Risk of external exposure"), and for unsealed sources, the legend in Danish: "Risiko for intern og ekstern bestråling" ("Risk of internal and external exposure").

(3) If a facility or area is classified as a controlled area, cf. Section 50 of the Executive Order on Ionising Radiation and Radiation Protection, the signage shall, as mentioned in (1), be supplemented by the legend in Danish: "KONTROLLERET OMRÅDE" ("CONTROLLED AREA"), and for sealed sources, the legend in Danish: "Risiko for extern bestråling" ("Risk of external exposure"), and for unsealed sources, the legend in Danish: "Risiko for intern og ekstern bestråling" ("Risk of internal and external exposure").

(4) Warning signs in accordance with (1)-(3) shall be clearly visible and durable.

Supplementary requirements for use of radioactive material for teaching purposes at lower and upper secondary educational institutions

§ 39. Use of radioactive material for teaching purposes at lower and upper secondary educational institutions shall take place under the constant guidance and supervision of a teacher appointed by the school's management. Requirements for the teacher's knowledge, skills and competences are set out in Annex 11.

Supplementary requirements for medical use

§ 40. Patients administered radioactive material shall be advised of the radiation safety precautions to be taken during and after their examination or treatment.

(2) In the case of treatment, the advice provided shall be supplemented by written information.

§ 41. Where radioactive material is administered to a patient, precautionary measures for radiation protection shall be planned with the following dose constraints:

1) For examinations: 1 mSv for the effective dose to any carer or comforter.
2) For treatment: 1 mSv for the effective dose to a carer or comforter under 18 years of age; 3 mSv for the effective dose to carers or comforters who are over 18 years of age but under 60 years of age; and 15 mSv for the effective dose to carers or comforters who are at least 60 years of age.

(2) For examination or treatment of children, higher dose constraints for carers or comforters may be justified. Where this is the case, these shall be determined by the medical physics expert. Justification for higher dose constraints must be documentable.

§ 42. Patients administered radioactive material must not be discharged from hospital to home until such time as they are not expected to cause an effective dose greater than 0.1 mSv to members of the public.

Supplementary requirements for veterinary medical use

§ 43. Individuals responsible for animals to which radioactive material has been administered shall receive written advice on precautions for radiation protection purposes.

§ 44. Animals administered radioactive material must not be discharged from the place of examination or treatment until such time as they are not expected to cause an effective dose greater than 0.1 mSv to members of the public, including the owner of the animal.

Chapter 10

Supplementary requirements for use of sealed sources

Requirements for use of sealed sources and facilities, etc.

§ 45. Sealed sources shall be certified and tested, including tested for leaks in accordance with the prevailing standard in force for the type of radiation source.

§ 46. Containers for sealed sources shall be clearly and durably marked with:

1) the symbol for ionising radiation according to the prevailing standard supplemented by the legend in Danish: "Radioaktivitet" ("Radioactivity");
2) radionuclide and activity on a given date;
3) for high-activity sealed sources, if possible, the radiation source's engraved or embossed unique identifying code;
4) the container's type designation and serial number; and
5) manufacturer.

§ 47. Use or handling of sealed sources shall take place in such a way as to avoid direct touching of the radiation source.

§ 48. If the radiation beam is collimated, it shall be ensured that only individuals undergoing examination, treatment or non-medical imaging are exposed to the direct useful beam.

(2) Workers, carers and comforters shall be protected against scattered radiation.

§ 49. Sealed sources with activity greater than the value in Annex 3, which are outside of their storage location, must not be accessible to unauthorised persons.

§ 50. Use of sealed sources shall take place inside facilities.

(2) Exempt from (1) is the use of non-high-activity sealed sources which are designed with sufficient built-in shielding for the purposes of use outside of facilities.

(3) Use of sealed sources may likewise take place outside of facilities if the size or other attributes of the examined subjects do not permit use in a facility. In such cases, the use shall take place at specially-equipped locations and under conditions laid down by the Danish Health Authority.

§ 51. Special requirements for industrial radiography and brachytherapy and for facilities for industrial radiography and blood irradiation are set out in Annex 12.

Inspection of sealed sources, facilities and equipment

§ 52. Sealed sources, of which the activity is greater than 100 times the value in Annex 3 and, as applicable, associated facilities and equipment, shall undergo technical safety inspections at the intervals specified in (2)-(5).

(2) For sealed sources within security categories A and B, cf. Annex 6, the interval between inspections must not be longer than 13 months.

(3) For sealed sources within security category C, cf. Annex 6, the interval between inspections must not be longer than 25 months.

(4) For non-high-activity sealed sources used outside of facilities, the interval between inspections must not be longer than 25 months.

(5) For other non-high-activity sealed sources than those mentioned in (4), the interval between inspections must not be longer than 61 months.

(6) (1)-(5) are not applicable to sealed sources declared as radioactive waste. Facilities and equipment utilised for storage of radioactive waste shall undergo technical safety inspections if so determined by the Danish Health Authority.

§ 53. A technical safety inspection pursuant to Section 52 shall verify that sealed sources, facilities and equipment are in a sound condition and are technically satisfactory and compliant with all the radiation safety provisions of this Executive Order and the Executive Order on Ionising Radiation and Radiation Protection and any terms and conditions laid down by the Danish Health Authority.

(2) For high-activity sealed sources, the technical safety inspection shall comprise leak testing in accordance with international standards.

§ 54. If the technical safety inspection performed in accordance with Section 52 identifies severe defects in sealed sources, facilities or equipment, which might result in unintentional exposure of individuals, the technical safety inspection undertaking shall immediately notify the Danish Health Authority to that effect.

§ 55. The undertaking shall retain technical safety inspection reports for the last three inspections in accordance with Section 52. The name of the technical safety inspection enterprise and of the individual who conducted the inspection shall be stated in the inspection report.

(2) For high-activity sealed sources, a copy of the technical safety inspection report shall be submitted to the Danish Health Authority immediately after the inspection.

§ 56. Sealed sources shall be equipped with a marking showing the date of the last inspection and the latest date for the next one; cf. however (2). The marking shall be clearly visible and durable.

(2) If information on technical safety inspection dates by means of marking is not appropriate, the information on

the dates shall be provided by other means and in such a way that the information is easily accessible to anyone who uses and handles the radiation source.

§ 57. Facilities and equipment requiring periodic technical safety inspection shall be clearly and durably marked with information on the date of the last inspection and the latest date for the next one.

Special requirements for use of high-activity sealed sources

§ 58. The manufacturer or supplier shall ensure that high-activity sealed sources are identified and marked. Identification and marking shall be clearly visible and durable.

(2) The identification shall consist of a unique number engraved or embossed on the radiation source if practically achievable.

(3) The radiation source shall furthermore be marked with a radiation hazard warning if practically achievable.

§ 59. For high-activity sealed sources, the manufacturer shall ensure that documentation is available for the radiation source and the container. The documentation shall include photographs of the type of radiation source and container.

§ 60. Undertakings that use high-activity sealed sources shall ensure that each individual radiation source is accompanied by documentation comprising photographs of the radiation source, its container and other equipment, including transportation packaging.

§ 61. If the size or other attributes of the examined objects do not permit the use of high-activity sealed sources inside facilities, cf. Section 50(3), the work shall be carried out in the presence of at least two individuals, at least one of whom shall possess the knowledge, skills and competences set out in Annex 11.

§ 62. For use of high-activity sealed sources outside of their container, an acoustic dose rate alarm shall be used. The dose rate alarm shall be worn by the workers, when appropriate.

(2) For work in locations where an acoustic dose rate alarm would be difficult to hear, compensatory solutions shall be employed, such as a vibrating dose rate alarm.

§ 63. Following any use or handling of high-activity sealed sources, measuring equipment shall be employed for checking that the radiation source has been secured in the shielded position.

Chapter 11

Supplementary requirements for use of unsealed sources

Use inside and outside of facilities, etc.

§ 64. Use of unsealed sources subject to the licensing or notification requirements shall be confined to facilities or other premises meeting the facility fixtures and fittings requirements of Annex 13, and shall be in compliance with the maximum activity limits established by the Danish Health Authority.

(2) Exempt from (1), is use of unsealed sources authorised by the Danish Health Authority for practising in another type of facility or premises than those mentioned in Annex 13 or outside of facilities. In such cases, the Danish Health Authority lays down requirements for the use and for any facility fixtures and fittings.

(3) Special requirements for use of Br-82 for leak detection in piping are set out in Annex 14.

Instructions

§ 65. For use of unsealed sources, the following instructions shall be available:

1) instructions on the use, handling and storage etc. of unsealed sources;
2) instructions on transfer and discharge and disposal of radioactive waste;
3) instructions for cleaning staff, were relevant, and
4) instructions on precautions in the event of emergencies, accidents and incidents.

Marking

§ 66. Containers for unsealed sources shall be clearly and durably marked with:

1) the symbol for ionising radiation according to the prevailing standard, supplemented by the legend in Danish: "Radioaktivitet" ("Radioactivity");
2) radionuclide, activity and, as applicable, the activity concentration on a given date.
3) physical and chemical form; and
4) relevant contact name.

Minimisation of risk of contamination, etc.

§ 67. Use of unsealed sources shall take place in such a way that contamination of persons, objects, including equipment, surfaces, surroundings and the environment, and the risk of contamination, are kept as low as reasonably achievable.

(2) Workers shall wear suitable protective equipment for minimising the risk of contamination of the body.

(3) Where there is a risk of formation of airborne radioactive material, precautionary measures shall be implemented to minimise airborne radioactive material.

(4) Precautionary measures shall be implemented to limit the risk of dispersion of unsealed sources from human and animal patients administered radioactive material.

§ 68. Before and after any time spent in type A or type B isotope laboratories, laboratory coats and footwear shall be changed in the forelab or the transitional zone to the

facility.

§ 69. Suitable equipment for measurement for contamination from unsealed sources and, as applicable, dose rate measurement shall be available.

§ 70. Limit values for contamination of surfaces and objects, including equipment, are provided in Annex 5.

(2) The Danish Health Authority may establish other limit values for specific radionuclides than those specified in Annex 5.

§ 71. When using unsealed sources, continued monitoring for contamination with radioactive material must take place for people, surfaces, objects and equipment. Monitoring shall also be performed of people leaving a facility and of objects, including equipment, that are removed from the facility. The monitoring shall be commensurate with the nature and scale of the use.

(2) Contaminated people, surfaces and objects, including equipment, shall be cleaned as rapidly as possible. The cleaning shall continue for as long as it results in an effective reduction in activity.

(3) Residual contamination of surfaces and objects, including equipment, must not exceed the limit value in Annex 5 or a limit value established by the Danish Health Authority pursuant to Section 70(2).

(4) If contamination of a surface cannot be brought below the limit value, the contaminated surface shall be replaced, but in the case of contamination decaying to below the limit value within 12 months, it may be temporarily shielded. The Danish Health Authority may approve other approaches.

§ 72. The undertaking shall be able to document the completed monitoring, cf. Section 71. The documentation shall be commensurate with the nature and scale of the use and shall be retained for at least five years.

Activity determination, etc. for medical use

§ 73. Before any medical use of radioactive sources, the activity shall be determined.

(2) For sealed sources, the activity shall be determined as an element in acceptance testing in order to verify that the source activity is consistent with the source certificate.

(3) For unsealed sources, the activity shall be determined before every single administration of radioactive material to a patient.

(4) Prior to administration of radioactive material to a patient who is breast-feeding, a decision shall be made as to whether temporary or permanent suspension of breast-feeding is necessary.

Chapter 12

Security measures and emergency response

High-activity sealed sources

§ 74. High-activity sealed sources shall be categorised in a security category as specified in Annex 6.

(2) Based on its assessment of a high-activity sealed source and the type of use and practice, the Danish Health Authority may assign a radiation source to a different security category.

§ 75. A security officer shall be appointed for high-activity sealed sources

(2) The security officer shall monitor and assist in implementing the security measures established in the security plan; cf. Sections 77-79.

(3) The security officer shall possess knowledge, skills and competences concerning radiation protection and security measures commensurate with the nature and magnitude of the risk associated with the radiation source and the type of use and practice.

(4) The security officer's knowledge, skills and competences shall be updated as and when needed, although at intervals of no more than five years.

§ 76. For high-activity sealed sources within security categories A and B, a vulnerability assessment shall be prepared for approval by the Danish Health Authority.

§ 77. For high-activity sealed sources within security category A, a security plan shall be established on the basis of the Vulnerability Assessment.

(2) The security plan shall comprise the following topics:

1) Procedures for checking at least once daily that the radiation source is in the possession of the undertaking and has not been tampered with by unauthorised persons. Records shall be kept of these checks.
2) A system of access controls consisting of at least two identity checks to prevent unauthorised persons from gaining access to the area containing the radiation source.
3) A system for ensuring that intrusion by unauthorised persons into the area containing the radiation source or unauthorised removal of the radiation source are immediately detected and assessed, and, in the event of intrusion, the immediate deployment of resources sufficient to deter further intrusion or unauthorised removal of the radiation source.
4) A system of least two technical barriers to ensure that the radiation source cannot be removed before the response personnel reach the scene.
5) Procedure for selection and assessment of individuals authorised for independent access to the radiation source and sensitive information. This assessment

shall be repeated on a regular basis.
6) Measures to ensure that sensitive information concerning security aspects is identified and not disclosed to unauthorised persons.
7) Procedure for obtaining non-disclosure agreements from individuals with access to the information mentioned in No. 6.
8) A communication system for ensuring that relevant officers from the undertaking are contacted immediately in the event of theft, unintended access, misuse or the like. This system shall include at least two different means of communication.
9) Different security levels that can be activated based on the threat environment at any given time.

§ 78. For high-activity sealed sources within security category B, a security plan shall be established on the basis of the Vulnerability Assessment.

(2) The security plan shall comprise the following topics:
1) Procedures for checking at least once weekly that the radiation source is in the possession of the undertaking and has not been tampered with by unauthorised persons. Records shall be kept of these checks.
2) A system of access controls consisting of at least one identity check to prevent unauthorised persons from gaining access to the area containing the radiation source.
3) A system for ensuring that intrusion by unauthorised persons into the area containing the radiation source is immediately detected, and that in such an event resources are deployed immediately which will, with great probability, be sufficient to deter further intrusion or unauthorised removal of the radiation source.
4) Two technical barriers to minimise the likelihood of the radiation source being removed before the response personnel reach the scene.
5) Procedure for selection and assessment of individuals authorised for independent access to the radiation source and sensitive information. This assessment shall be repeated on a regular basis.
6) Measures to ensure that sensitive information concerning security aspects is identified and not disclosed to unauthorised persons.
7) Procedure for obtaining non-disclosure agreements from individuals with access to the information mentioned in No. 6.
8) Different security levels that can be activated based on the threat environment at any given time.

§ 79. For high-activity sealed sources within security category C, a security plan shall be established.

(2) The security plan shall comprise the following topics:
1) Procedures for checking at least once monthly that the radiation source is in the possession of the undertaking and has not been tampered with by unauthorised persons. Records shall be kept of these checks.
2) A system of access controls consisting of at least one identity check to prevent unauthorised persons from gaining access to the area containing the radiation source.
3) At least one technical barrier to reduce the likelihood of the radiation source being removed.
4) Procedure for selection and assessment of individuals authorised for independent access to the radiation source and sensitive information.
5) Measures to ensure that sensitive information concerning the radiation sources and security aspects is not disclosed to unauthorised persons.

§ 80. Security plans pursuant to Sections 77-79, which comprise high-activity sealed sources used or handled outside of facilities, shall contain compensatory measures which shall be implemented if it is not possible during use, handling or transport of the radiation source to meet the requirements for securing high-activity sealed sources which the security plan otherwise stipulates.

§ 81. The security plans pursuant to Section 77 and Section 78 and the related compensatory measures pursuant to Section 80 shall be approved by the Danish Health Authority.

(2) The security plans pursuant to Sections 77-79 and compensatory measures pursuant to Section 80 shall be established before high-activity sealed sources are acquired by an undertaking.

(3) The security plans pursuant to Sections 77-79 and compensatory measures pursuant to Section 80 must not be disclosed to the public domain, and it must be ensured that they do not come to the knowledge of unauthorised parties.

§ 82. Security measures must not compromise radiation protection and must not constitute a barrier to emergency response.

§ 83. An emergency response plan shall be established, which shall comprise an alerting plan and precautions in the event of:
1) emergencies, accidents and incidents involving high-activity sealed sources, including loss
2) fire, flooding, earthquake, power cut, etc. involving high-activity sealed sources, and
3) threatened or actual criminal acts involving high-activity sealed sources.

(2) Emergency response plans for high-activity sealed sources within security category A shall be approved by the Danish Health Authority before radiation sources are acquired.

§ 84. Vulnerability assessments, security and emergency response plans shall be kept up to date.

Unsealed sources

§ 85. Based on an assessment of radionuclide, activity, activity concentration, type of use and practice and other relevant factors, the Danish Health Authority may class unsealed sources within security categories equivalent to security categories A, B or C; cf. Annex 6. Where such categories have been established, security and emergency response measures shall be established to correspond with the requirements for high-activity sealed sources in the same security category.

Chapter 13

Appeals and Penalties

§ 86. 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.

§ 87. 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 3; Section 4; Section 14(1); Section 15(1); Section 16; Section 17; Section 18(1); Section 20; Section 21; Section 23(2); Section 24(2); Section 26; Section 27, first sentence; the provisions of Annexes 7, 8 and 9; cf. Section 29; the provisions of Annex 10; cf. Section 30; the provisions of Annex 11; cf. Section 31(1); Section 35(1), (2), first or third sentence; (3), 2nd sentence or (4)-(6); Sections 36-38, Section 40, Section 41(2), third sentence; Sections 42-50; Sections 53-63; the provisions of Annex 13; cf. Section 64(1); Sections 66-69; Sections 71-73, Section 74 (1); Section 81(3); Section 84; the provisions of Annex 12; cf. Section 54 or the provisions of Annex 14; cf. Section 64(3);
2) commencing use of radioactive material without a licence from, or without notification to, the Danish Health Authority; cf. Sections 5-7 with reference to Section 9; or failing to observe any terms and conditions laid down by the Danish Health Authority in a licence or subsequent to a notification;
3) granting clearance to materials, buildings, facilities or land without the Danish Health Authority's approval; cf. Section 10(2); Section 11(2) or (4) or Section 12(2); or failing to observe any terms and conditions laid down by the Danish Health Authority in an approval for clearance;
4) granting clearance to radioactive material, facilities that are not subject to the registration requirement or objects, including equipment, the clearance of which does not require the Danish Health Authority's approval, without the criteria for clearance of Section 10(1), first part, or Section 11(1) being met, or without being able to document this; cf. Section 13(1);
5) failing to observe any terms and conditions laid down by the Danish Health Authority concerning an approval pursuant to Section 14(2); Section 24(3); Section 27(2); Section 35(2), second sentence; Section 64(2) or Section 71(4), second sentence;
6) in the instances listed in Section 19(1), transferring, importing or exporting radioactive material without the Danish Health Authority's approval, or failing to observe any terms and conditions laid down by the Danish Health Authority in an approval pursuant to Section 19(1);
7) failing to transfer radioactive material no longer to be used by the undertaking within twelve months; cf. Section 22(1) and (2);
8) failing to ensure that an exposed worker, including an outside worker, employed in use of high-activity sealed sources has updated knowledge, skills and competences, as required by Section 31(2);
9) permitting radioactive material to be used for teaching at lower and upper secondary educational institutions without having appointed a teacher as required by Section 39(1), first sentence;
10) in implementing precautionary measures for radiation protection pursuant to Section 41, failing to apply the dose constraints mentioned in (1) of the provision or that have been determined by the medical physics expert; cf. Section 41(2);
11) failing to have sealed sources undergo technical safety inspection within the minimum intervals mentioned in Section 52 (2)-(5), or failing to have facilities and equipment used for storage of radioactive waste undergo technical safety inspection in accordance with the Danish Health Authority's requirements laid down to that effect pursuant to Section 52(6);
12) in relation to high-activity sealed sources or unsealed sources classed by the Danish Health Authority pursuant to Section 85 as corresponding to security category A, B or C, failing to appoint a security officer, cf. Section 75(1), or failing to ensure that the security officer has updated knowledge, skills or competences as required in Section 75(3) and (4);
13) in relation to high-activity sealed sources within security categories A or B or unsealed sources classed by the Danish Health Authority pursuant to Section 85 as corresponding to security categories A or B, failing to promptly establish a Vulnerability Assessment and a security plan approved by the Danish Health Authority; cf. Sections 76-78 and, where relevant, Section 80, with reference to Section 81(1) and (2);

14) in relation to high-activity sealed sources within security category C or unsealed sources classed by the Danish Health Authority pursuant to Section 85 as equivalent to security category C, failing to promptly establish a security plan; cf. Section 80, with reference to Section 81(2);
15) in relation to high-activity sealed sources or unsealed sources in the same security category, which the Danish Health Authority has classed in a security category pursuant to Section 85, and which shall be used or handled outside of facilities, failing to promptly establish compensatory measures approved by the Danish Health Authority; cf. Section 80, with reference to Section 81(1) and (2);
16) in relation to high-activity sealed sources or unsealed sources classed by the Danish Health Authority pursuant to Section 85 as equivalent to security categories A, B or C, failing to promptly implement all practical measures for putting in place the security plans pursuant to Sections 77-79 and, as applicable, Section 80; cf. Section 81(2);
17) in relation to high-activity sealed sources within security category A or unsealed sources classed by the Danish Health Authority pursuant to Section 85 as equivalent to security category A, failing to promptly establish an emergency response plan approved by the Danish Health Authority; cf. Section 83(2);

(2) In particularly aggravating circumstances, the penalty may be increased to imprisonment for up to two years.

(3) In sentencing pursuant to (2), the following shall be 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.

(4) Undertakings etc. (legal persons) may be held criminally liable pursuant to the rules of Chapter 5 of the Danish Criminal Code.

Chapter 14

Entry into force and transitional provisions

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

(2) The following executive orders are hereby repealed:

1) Executive Order No. 546 of 23 June 1993 on Transfer of Radioactive Substances.
2) Executive Order No. 85 of 2 February 2018 on Use of Radioactive Substances.

§ 89. A licence issued pursuant to the Act on Use, etc. of Radioactive Substances, cf. Act No. 94 of 31 March 1953, and rules laid down pursuant to that Act, for use of radioactive substances comprised by this Executive Order shall retain its validity until otherwise decided by the Danish Health Authority; cf. however (2) and (3). Any terms and conditions laid down by the Danish Health Authority in that licence shall remain in force until the Danish Health Authority decides otherwise.

(2) If a licence such as is mentioned in (1) is issued for a use of radioactive substances subject to the notification requirement of this Executive Order such a licence will be recognised as a notification as of 6 February 2018. Any terms and conditions laid down by the Danish Health Authority in that licence will remain in force until the Danish Health Authority decides otherwise.

(3) If a licence such as is mentioned in (1) is issued for a use of radioactive substances subject to neither the licensing nor the notification requirements of this Executive Order, that licence shall expire on 6 February 2018.

§ 90. The requirement of Section 16(3) for detailed specifications to be listed in records for a retroactive five-year period will not come into force until 6 February 2023. Until that date, the record shall contain information on items as they existed on 6 February 2018 since this information shall be updated and documented on an ongoing basis in the record. The first and second sentences apply equally to the requirement of Section 18(1) for further detailed matters to be documentable for a retroactive five-year period.

Danish Health Authority

SØREN BROSTRØM

/ Mette Øhlenschlæger

Annex 1

Regulatory control levels for use of radioactive material

1. Holding, application and storage, etc. of radioactive material

The total holdings, handling, application, including re-appliance, and storage of radioactive material at any given time shall be subject to a level of regulatory control which, for sealed sources, is dependent on the activity (*A*) and for unsealed sources depends on the activity concentration (*AC*) and the activity (*A*).

In the case of any holding, application and storage, etc. of one or more radionuclides, the sum of nuclide specific activity or the activity concentration divided by the corresponding exemption value, expressed as index values of activity (I_A) or activity concentration (I_{AC}) applies in determining the regulatory control level in accordance with the tables below. For further information on the calculation of index values, please consult Annexes 3 and 4.

The regulatory control level for sealed sources is shown in the table below:

Regulatory control level for sealed sources	Activity index (I_A)		
	$I_{A,Annex\ 3} \leq 1$	$1 < I_{A,Annex\ 3} \leq 100$	$100 < I_{A,Annex\ 3}$
	Exempt from the notification requirement	Notification	Licensing

The regulatory control level for unsealed sources is shown in the table below:

Regulatory control level for unsealed sources		Activity index (I_A)		
		$I_{A,Annex\ 3} \leq 1$	$1 < I_{A,Annex\ 3} \leq 10$	$10 < I_{A,Annex\ 3}$
Activity concentration index (I_{AC})	$1{,}000 < I_{AC,Annex\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,Annex\ 3} \leq 1{,}000$	Notification	Licensing	Licensing
	$I_{AC,Annex\ 3} \leq 1 < I_{AC,Annex\ 4}$	Exempt from the licensing and notification requirements*	Notification	Licensing

* However, if the total activity per month corresponds to an activity index greater than 10, notification is required.

2. Discharge of radioactive waste

Total discharge per month of radioactive material is subject to a regulatory control level contingent on the activity concentration (*AC*) and the activity (*A*).

In the case of discharge of one or more radionuclides, the sum of nuclide specific activity or the activity concentration divided by the corresponding exemption values, expressed as index values of activity (I_A) or activity concentration (I_{AC}) applies in determining the regulatory control level in accordance with the table below. For further information on the calculation of index values, please consult Annexes 3 and 4.

The regulatory control level for discharge of radioactive material is shown in the table below:

Regulatory control level for discharge of radioactive material		Activity index (I_A)		
		$I_{A,Annex\ 3} \leq 1$	$1 < I_{A,Annex\ 3} \leq 10$	$10 < I_{A,Annex\ 3}$
Activity concentration index (I_{AC})	$100 < I_{AC,Annex\ 3}$	Licensing	Licensing	Licensing
	$1 < I_{AC,Annex\ 3} \leq 100$	Notification	Licensing	Licensing
	$I_{AC,Annex\ 3} \leq 1 < I_{AC,Annex\ 4}$	Exempt from the licensing and notification requirements	Notification	Licensing

Annex 2

Criteria for exemption from the licensing or notification requirements and for clearance

The criteria for exemption for use of radioactive material from the licensing or notification requirements pursuant to Section 5(2) or Section 8(1), and for clearance of material pursuant to Section 10(1) are as follows:

1) The radiological risk associated with the use is sufficiently low for regulatory control to be unnecessary.
2) The use is justified.
3) The use is generally safe.
4) The use requires classification of exposed workers as no higher than category C.
5) The effective dose that could reasonably be expected to be incurred by any member of the public due to the cleared radioactive material is of the order of 10 µSv or less in a year for artificial radionuclides or of the order of 1 mSv or less in a year for naturally occurring radionuclides. Material containing naturally occurring radionuclides, where their processing for their radioactive, fissile or fertile properties is licensed, is subject to the dose criterion for artificial radionuclides.

Annex 3

Exemption values

Values of activity concentration and activity that may be applied as standard for exemption of limited quantities of any type of material.

Values of activity concentration ($AC_{E,c}$) and activity ($A_{E,c}$) for exemption from the licensing or notification requirements of limited quantities of any type of material are set out in the table below. The values are listed for individual radionuclides or for parent radionuclides and their progeny as applicable.

The criterion for exemption is met when the activity index ($I_{A,Annex\ 3}$) and the activity concentration index ($I_{AC,Annex\ 3}$) are less than or equal to 1. For radionuclide mixtures, this condition may be verified based on a best estimate of the composition of the mixture.

The index values are given by:

$$I_{A,Annex\ 3} = \sum_c \frac{A_c}{A_{E,c}} \qquad \text{and} \qquad I_{AC,Annex\ 3} = \sum_c \frac{AC_c}{AC_{E,c}}$$

were A_c and AC_c are, respectively the activity and the activity concentration of radionuclide *c*, and $A_{E,c}$ and $AC_{E,c}$ are the associated exemption values in the table below.

The Danish Health Authority may determine that the exemption value shall be applicable per gram of dry matter.

For radionuclides not included in the table below, the Danish Health Authority may approve values subject to application.

Radionuclide	Activity concentration ($AC_{E,c}$) [Bq/g]	Activity ($A_{E,c}$) [Bq]
H-3	1×10^6	1×10^9
Be-7	1×10^3	1×10^7
C-11	1×10^1	1×10^6
C-14	1×10^4	1×10^7
N-13	1×10^2	1×10^9
O-15	1×10^2	1×10^9
F-18	1×10^1	1×10^6
Na-22	1×10^1	1×10^6
Na-24	1×10^1	1×10^5
Si-31	1×10^3	1×10^6
P-32	1×10^3	1×10^5

P-33	1×10^5	1×10^8
S-35	1×10^5	1×10^8
Cl-36	1×10^4	1×10^6
Cl-38	1×10^1	1×10^5
Ar-37	1×10^6	1×10^8
Ar-41	1×10^2	1×10^9
K-40 (1)	1×10^2	1×10^6
K-42	1×10^2	1×10^6
K-43	1×10^1	1×10^6
Ca-45	1×10^4	1×10^7
Ca-47	1×10^1	1×10^6
Sc-46	1×10^1	1×10^6
Sc-47	1×10^2	1×10^6
Sc-48	1×10^1	1×10^5
V-48	1×10^1	1×10^5
Cr-51	1×10^3	1×10^7
Mn-51	1×10^1	1×10^5
Mn-52	1×10^1	1×10^5
Mn-52m	1×10^1	1×10^5
Mn-53	1×10^4	1×10^9
Mn-54	1×10^1	1×10^6
Mn-56	1×10^1	1×10^5
Fe-52	1×10^1	1×10^6
Fe-55	1×10^4	1×10^6
Fe-59	1×10^1	1×10^6
Co-55	1×10^1	1×10^6
Co-56	1×10^1	1×10^5
Co-57	1×10^2	1×10^6
Co-58	1×10^1	1×10^6
Co-58m	1×10^4	1×10^7
Co-60	1×10^1	1×10^5

Co-60m	1×10^3	1×10^6
Co-61	1×10^2	1×10^6
Co-62m	1×10^1	1×10^5
Ni-59	1×10^4	1×10^8
Ni-63	1×10^5	1×10^8
Ni-65	1×10^1	1×10^6
Cu-64	1×10^2	1×10^6
Cu-67	$1 \text{ x } 10^2$	$1 \text{ x } 10^6$
Zn-65	1×10^1	1×10^6
Zn-69	1×10^4	1×10^6
Zn-69m	1×10^2	1×10^6
Ga-68	1×10^1	1×10^5
Ga-72	1×10^1	1×10^5
Ge-68 (2)	1×10^1	1×10^5
Ge-71	1×10^4	1×10^8
As-73	1×10^3	1×10^7
As-74	1×10^1	1×10^6
As-76	1×10^2	1×10^5
As-77	1×10^3	1×10^6
Se-75	1×10^2	1×10^6
Br-82	1×10^1	1×10^6
Kr-74	1×10^2	1×10^9
Kr-76	1×10^2	1×10^9
Kr-77	1×10^2	1×10^9
Kr-79	1×10^3	1×10^5
Kr-81	1×10^4	1×10^7
Kr-81m	1×10^3	1×10^{10}
Kr-83m	1×10^5	1×10^{12}
Kr-85	1×10^5	1×10^4
Kr-85m	1×10^3	1×10^{10}
Kr-87	1×10^2	1×10^9

Kr-88	1×10^{2}	1×10^{9}
Rb-81	1×10^{1}	1×10^{6}
Rb-86	1×10^{2}	1×10^{5}
Sr-82 (2)	1×10^{1}	1×10^{5}
Sr-85	1×10^{2}	1×10^{6}
Sr-85m	1×10^{2}	1×10^{7}
Sr-87m	1×10^{2}	1×10^{6}
Sr-89	1×10^{3}	1×10^{6}
Sr-90 (2)	1×10^{2}	1×10^{4}
Sr-91	1×10^{1}	1×10^{5}
Sr-92	1×10^{1}	1×10^{6}
Y-90	1×10^{3}	1×10^{5}
Y-91	1×10^{3}	1×10^{6}
Y-91m	1×10^{2}	1×10^{6}
Y-92	1×10^{2}	1×10^{5}
Y-93	1×10^{2}	1×10^{5}
Zr-89	$1 \text{ x } 10^{1}$	$1 \text{ x } 10^{6}$
Zr-93 (2)	1×10^{3}	1×10^{7}
Zr-95	1×10^{1}	1×10^{6}
Zr-97 (2)	1×10^{1}	1×10^{5}
Nb-93m	1×10^{4}	1×10^{7}
Nb-94	1×10^{1}	1×10^{6}
Nb-95	1×10^{1}	1×10^{6}
Nb-97	1×10^{1}	1×10^{6}
Nb-98	1×10^{1}	1×10^{5}
Mo-90	1×10^{1}	1×10^{6}
Mo-93	1×10^{3}	1×10^{8}
Mo-99	1×10^{2}	1×10^{6}
Mo-101	1×10^{1}	1×10^{6}
Tc-96	1×10^{1}	1×10^{6}
Tc-96m	1×10^{3}	1×10^{7}

Tc-97	1×10^3	1×10^8
Tc-97m	1×10^3	1×10^7
Tc-99	1×10^4	1×10^7
Tc-99m	1×10^2	1×10^7
Ru-97	1×10^2	1×10^7
Ru-103	1×10^2	1×10^6
Ru-105	1×10^1	1×10^6
Ru-106 (2)	1×10^2	1×10^5
Rh-103m	1×10^4	1×10^8
Rh-105	1×10^2	1×10^7
Pd-103	1×10^3	1×10^8
Pd-109	1×10^3	1×10^6
Ag-105	1×10^2	1×10^6
Ag-108m (2)	1×10^1	1×10^6
Ag-110m	1×10^1	1×10^6
Ag-111	1×10^3	1×10^6
Cd-109	1×10^4	1×10^6
Cd-115	1×10^2	1×10^6
Cd-115m	1×10^3	1×10^6
In-111	1×10^2	1×10^6
In-113m	1×10^2	1×10^6
In-114m	1×10^2	1×10^6
In-115m	1×10^2	1×10^6
Sn-113	1×10^3	1×10^7
Sn-125	1×10^2	1×10^5
Sb-122	1×10^2	1×10^4
Sb-124	1×10^1	1×10^6
Sb-125	1×10^2	1×10^6
Te-123m	1×10^2	1×10^7
Te-125m	1×10^3	1×10^7
Te-127	1×10^3	1×10^6

Te-127m	1×10^3	1×10^7
Te-129	1×10^2	1×10^6
Te-129m	1×10^3	1×10^6
Te-131	1×10^2	1×10^5
Te-131m	1×10^1	1×10^6
Te-132	1×10^2	1×10^7
Te-133	1×10^1	1×10^5
Te-133m	1×10^1	1×10^5
Te-134	1×10^1	1×10^6
I-123	1×10^2	1×10^7
I-124	1×10^1	1×10^6
I-125	1×10^3	1×10^6
I-126	1×10^2	1×10^6
I-129	1×10^2	1×10^5
I-130	1×10^1	1×10^6
I-131	1×10^2	1×10^6
I-132	1×10^1	1×10^5
I-133	1×10^1	1×10^6
I-134	1×10^1	1×10^5
I-135	1×10^1	1×10^6
Xe-131m	1×10^4	1×10^4
Xe-133	1×10^3	1×10^4
Xe-135	1×10^3	1×10^{10}
Cs-129	1×10^2	1×10^5
Cs-131	1×10^3	1×10^6
Cs-132	1×10^1	1×10^5
Cs-134m	1×10^3	1×10^5
Cs-134	1×10^1	1×10^4
Cs-135	1×10^4	1×10^7
Cs-136	1×10^1	1×10^5
Cs-137 (2)	1×10^1	1×10^4

Cs-138	1×10^{1}	1×10^{4}
Ba-131	1×10^{2}	1×10^{6}
Ba-133	1 x 10^{2}	1 x 10^{6}
Ba-140 (2)	1×10^{1}	1×10^{5}
La-140	1×10^{1}	1×10^{5}
Ce-139	1×10^{2}	1×10^{6}
Ce-141	1×10^{2}	1×10^{7}
Ce-143	1×10^{2}	1×10^{6}
Ce-144 (2)	1×10^{2}	1×10^{5}
Pr-142	1×10^{2}	1×10^{5}
Pr-143	1×10^{4}	1×10^{6}
Nd-147	1×10^{2}	1×10^{6}
Nd-149	1×10^{2}	1×10^{6}
Pm-147	1×10^{4}	1×10^{7}
Pm-149	1×10^{3}	1×10^{6}
Sm-151	1×10^{4}	1×10^{8}
Sm-153	1×10^{2}	1×10^{6}
Eu-152	1×10^{1}	1×10^{6}
Eu-152m	1×10^{2}	1×10^{6}
Eu-154	1×10^{1}	1×10^{6}
Eu-155	1×10^{2}	1×10^{7}
Gd-153	1×10^{2}	1×10^{7}
Gd-159	1×10^{3}	1×10^{6}
Tb-160	1×10^{1}	1×10^{6}
Dy-165	1×10^{3}	1×10^{6}
Dy-166	1×10^{3}	1×10^{6}
Ho-166	1×10^{3}	1×10^{5}
Er-169	1×10^{4}	1×10^{7}
Er-171	1×10^{2}	1×10^{6}
Tm-170	1×10^{3}	1×10^{6}
Tm-171	1×10^{4}	1×10^{8}

Yb-175	1×10^3	1×10^7
Lu-176	1×10^2	1×10^6
Lu-177	1×10^3	1×10^7
Hf-181	1×10^1	1×10^6
Ta-182	1×10^1	1×10^4
W-181	1×10^3	1×10^7
W-185	1×10^4	1×10^7
W-187	1×10^2	1×10^6
Re-186	1×10^3	1×10^6
Re-188	1×10^2	1×10^5
Os-185	1×10^1	1×10^6
Os-191	1×10^2	1×10^7
Os-191m	1×10^3	1×10^7
Os-193	1×10^2	1×10^6
Ir-190	1×10^1	1×10^6
Ir-192	1×10^1	1×10^4
Ir-194	1×10^2	1×10^5
Pt-191	1×10^2	1×10^6
Pt-193m	1×10^3	1×10^7
Pt-197	1×10^3	1×10^6
Pt-197m	1×10^2	1×10^6
Au-198	1×10^2	1×10^6
Au-199	1×10^2	1×10^6
Hg-197	1×10^2	1×10^7
Hg-197m	1×10^2	1×10^6
Hg-203	1×10^2	1×10^5
Tl-200	1×10^1	1×10^6
Tl-201	1×10^2	1×10^6
Tl-202	1×10^2	1×10^6
Tl-204	1×10^4	1×10^4
Pb-203	1×10^2	1×10^6

Pb-210 (2)	1×10^1	1×10^4
Pb-212 (2)	1×10^1	1×10^5
Bi-206	1×10^1	1×10^5
Bi-207	1×10^1	1×10^6
Bi-210	1×10^3	1×10^6
Bi-212 (2)	1×10^1	1×10^5
Po-203	1×10^1	1×10^6
Po-205	1×10^1	1×10^6
Po-207	1×10^1	1×10^6
Po-209	$1 \text{ x } 10^1$	$1 \text{ x } 10^4$
Po-210	1×10^1	1×10^4
At-211	1×10^3	1×10^7
Rn-220 (2)	1×10^4	1×10^7
Rn-222 (2)	1×10^1	1×10^8
Ra-223 (2)	1×10^2	1×10^5
Ra-224 (2)	1×10^1	1×10^5
Ra-225	1×10^2	1×10^5
Ra-226 (2)	1×10^1	1×10^4
Ra-227	1×10^2	1×10^6
Ra-228 (2)	1×10^1	1×10^5
Ac-225 (2)	1×10^1	1×10^4
Ac-228	1×10^1	1×10^6
Th-226 (2)	1×10^3	1×10^7
Th-227	1×10^1	1×10^4
Th-228 (2)	1×10^0	1×10^4
Th-229 (2)	1×10^0	1×10^3
Th-230	1×10^0	1×10^4
Th-231	1×10^3	1×10^7
Th-232	$1 \text{ x } 10^1$	$1 \text{ x } 10^4$
Th-234 (2)	1×10^3	1×10^5
Pa-230	1×10^1	1×10^6

Pa-231	1×10^{0}	1×10^{3}
Pa-233	1×10^{2}	1×10^{7}
U-230 (2)	1×10^{1}	1×10^{5}
U-231	1×10^{2}	1×10^{7}
U-232 (2)	1×10^{0}	1×10^{3}
U-233	1×10^{1}	1×10^{4}
U-234	1×10^{1}	1×10^{4}
U-235 (2)	1×10^{1}	1×10^{4}
U-236	1×10^{1}	1×10^{4}
U-237	1×10^{2}	1×10^{6}
U-238 (2)	1×10^{1}	1×10^{4}
U-239	1×10^{2}	1×10^{6}
U-240	1×10^{3}	1×10^{7}
U-240 (2)	1×10^{1}	1×10^{6}
Np-237 (2)	1×10^{0}	1×10^{3}
Np-239	1×10^{2}	1×10^{7}
Np-240	1×10^{1}	1×10^{6}
Pu-234	1×10^{2}	1×10^{7}
Pu-235	1×10^{2}	1×10^{7}
Pu-236	1×10^{1}	1×10^{4}
Pu-237	1×10^{3}	1×10^{7}
Pu-238	1×10^{0}	1×10^{4}
Pu-239	1×10^{0}	1×10^{4}
Pu-240	1×10^{0}	1×10^{3}
Pu-241	1×10^{2}	1×10^{5}
Pu-242	1×10^{0}	1×10^{4}
Pu-243	1×10^{3}	1×10^{7}
Pu-244	1×10^{0}	1×10^{4}
Am-241	1×10^{0}	1×10^{4}
Am-242	1×10^{3}	1×10^{6}
Am-242m (2)	1×10^{0}	1×10^{4}

Am-243 (2)	1×10^{0}	1×10^{3}
Cm-242	1×10^{2}	1×10^{5}
Cm-243	1×10^{0}	1×10^{4}
Cm-244	1×10^{1}	1×10^{4}
Cm-245	1×10^{0}	1×10^{3}
Cm-246	1×10^{0}	1×10^{3}
Cm-247	1×10^{0}	1×10^{4}
Cm-248	1×10^{0}	1×10^{3}
Bk-249	1×10^{3}	1×10^{6}
Cf-246	1×10^{3}	1×10^{6}
Cf-248	1×10^{1}	1×10^{4}
Cf-249	1×10^{0}	1×10^{3}
Cf-250	1×10^{1}	1×10^{4}
Cf-251	1×10^{0}	1×10^{3}
Cf-252	1×10^{1}	1×10^{4}
Cf-253	1×10^{2}	1×10^{5}
Cf-254	1×10^{0}	1×10^{3}
Es-253	1×10^{2}	1×10^{5}
Es-254	1×10^{1}	1×10^{4}
Es-254m	1×10^{2}	1×10^{6}
Fm-254	1×10^{4}	1×10^{7}
Fm-255	1×10^{3}	1×10^{6}

(1) Potassium salts in quantities less than 1,000kg are exempt.

(2) Parent radionuclides and their progeny, if the dose contributions of those progeny are taken into account in the dose calculation thus requiring only the exemption level of the parent radionuclide to be considered, are listed in the table below.
m metastable.

Parent radionuclide	Progeny
Ge-68	Ga-68
Sr-82	Rb-82
Sr-90	Y-90
Zr-93	Nb-93m
Zr-97	Nb-97
Ru-106	Rh-106

Ag-108m	Ag-108
Cs-137	Ba-137m
Ba-140	La-140
Ce-144	Pr-144
Pb-210	Bi-210, Po-210
Pb-212	Bi-212, Tl-208 (0.36), Po-212 (0.64)
Bi-212	Tl-208 (0.36), Po-212 (0.64)
Rn-220	Po-216
Rn-222	Po-218, Pb-214, Bi-214, Po-214
Ra-223	Rn-219, Po-215, Pb-211, Bi-211, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Ra-226	Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
Ra-228	Ac-228
Ac-225	Fr-221, At-217, Bi-213, Po-213 (0.978), Tl-209 (0.0216), Pb-209 (0.978)
Th-226	Ra-222, Rn-218, Po-214
Th-228	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
Th-229	Ra-225, Ac-225, Fr-221, At-217, Bi-213, Po-213, Pb-209
Th-234	Pa-234m
U-230	Th-226, Ra-222, Rn-218, Po-214
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208 (0.36), Po-212 (0.64)
U-235	Th-231
U-238	Th-234, Pa-234m
U-240	Np-240m
Np-237	Pa-233
Am-242m	Am-242
Am-243	Np-239

m metastable.

Annex 4

Exemption and clearance values

Values of activity concentration that may be applied as standard for exemption or clearance of any quantity and type of material in solid form.

Values of activity concentration ($AC_{E,c}$) for exemption from the licensing or notification requirements and for clearance of material listed in the tables below for artificial radionuclides and for naturally occurring radionuclides. The values are listed for individual radionuclides or for parent radionuclides and their progeny as applicable.

The criterion for exemption or clearance is met when the activity concentration index ($I_{AC,Annex\ 4}$) is less than or equal to 1. For radionuclide mixtures, this condition may be verified based on a best estimate of the composition of the mixture.

The activity concentration index is given by:

$$I_{AC,Annex\ 4} = \sum_{c} \frac{AC_c}{AC_{E,c}}$$

where AC_c is the activity concentration for radionuclide c, and $AC_{E,c}$ is the associated exemption or clearance value in the relevant table below.

For naturally occurring radionuclides, the values may not be applied in order to exempt the incorporation into building materials of residues from industries processing naturally occurring radioactive material. In such contexts, compliance with the regulations regarding gamma radiation from building materials shall be verified; cf. Sections 102 and 103 of the Executive Order on Ionising Radiation and Radiation Protection.

The Danish Health Authority may determine that an activity concentration value shall be applicable per gram of dry matter.

For radionuclides not included in the tables below, the Danish Health Authority may approve values subject to application.

Artificial radionuclides – activity concentration values for exemption or clearance

Radionuclide	Activity concentration ($AC_{E,c}$) [Bq/g]
H-3	100
Be-7	10
C-14	1
F-18	10
Na-22	0.1
Na-24	1
Si-31	1,000
P-32	1,000
P-33	1,000

S-35	100
Cl-36	1
Cl-38	10
K-42	100
K-43	10
Ca-45	100
Ca-47	10
Sc-46	0.1
Sc-47	100
Sc-48	1
V-48	1
Cr-51	100
Mn-51	10
Mn-52	1
Mn-52m	10
Mn-53	100
Mn-54	0.1
Mn-56	10
Fe-52 (1)	10
Fe-55	1,000
Fe-59	1
Co-55	10
Co-56	0.1
Co-57	1
Co-58	1
Co-58m	10,000
Co-60	0.1
Co-60m	1,000
Co-61	100
Co-62m	10
Ni-59	100
Ni-63	100
Ni-65	10
Cu-64	100
Zn-65	0.1
Zn-69	1,000
Zn-69m (1)	10

Ga-72	10
Ge-71	10,000
As-73	1,000
As-74	10
As-76	10
As-77	1,000
Se-75	1
Br-82	1
Rb-86	100
Sr-85	1
Sr-85m	100
Sr-87m	100
Sr-89	1,000
Sr-90 (1)	1
Sr-91 (1)	10
Sr-92	10
Y-90	1,000
Y-91	100
Y-91m	100
Y-92	100
Y-93	100
Zr-93	10
Zr-95 (1)	1
Zr-97 (1)	10
Nb-93m	10
Nb-94	0.1
Nb-95	1
Nb-97 (1)	10
Nb-98	10
Mo-90	10
Mo-93	10
Mo-99 (1)	10
Mo-101 (1)	10
Tc-96	1
Tc-96m	1,000
Tc-97	10
Tc-97m	100

Tc-99	1
Tc-99m	100
Ru-97	10
Ru-103 (1)	1
Ru-105 (1)	10
Ru-106 (1)	0.1
Rh-103m	10,000
Rh-105	100
Pd-103 (1)	1,000
Pd-109 (1)	100
Ag-105	1
Ag-110m (1)	0.1
Ag-111	100
Cd-109 (1)	1
Cd-115 (1)	10
Cd-115m (1)	100
In-111	10
In-113m	100
In-114m (1)	10
In-115m	100
Sn-113 (1)	1
Sn-125	10
Sb-122	10
Sb-124	1
Sb-125 (1)	0.1
Te-123m	1
Te-125m	1,000
Te-127	1,000
Te-127m (1)	10
Te-129	100
Te-129m (1)	10
Te-131	100
Te-131m (1)	10
Te-132 (1)	1
Te-133	10
Te-133m	10

Te-134	10
I-123	100
I-125	100
I-126	10
I-129	0.01
I-130	10
I-131	10
I-132	10
I-133	10
I-134	10
I-135	10
Cs-129	10
Cs-131	1,000
Cs-132	10
Cs-134	0.1
Cs-134m	1,000
Cs-135	100
Cs-136	1
Cs-137 (1)	0.1
Cs-138	10
Ba-131	10
Ba-140	1
La-140	1
Ce-139	1
Ce-141	100
Ce-143	10
Ce-144 (1)	10
Pr-142	100
Pr-143	1,000
Nd-147	100
Nd-149	100
Pm-147	1,000
Pm-149	1,000
Sm-151	1,000
Sm-153	100
Eu-152	0.1
Eu-152m	100

Eu-154	0.1
Eu-155	1
Gd-153	10
Gd-159	100
Tb-160	1
Dy-165	1,000
Dy-166	100
Ho-166	100
Er-169	1,000
Er-171	100
Tm-170	100
Tm-171	1,000
Yb-175	100
Lu-177	100
Hf-181	1
Ta-182	0.1
W-181	10
W-185	1,000
W-187	10
Re-186	1,000
Re-188	100
Os-185	1
Os-191	100
Os-191m	1,000
Os-193	100
Ir-190	1
Ir-192	1
Ir-194	100
Pt-191	10
Pt-193m	1,000
Pt-197	1,000
Pt-197m	100
Au-198	10
Au-199	100
Hg-197	100
Hg-197m	100
Hg-203	10

Tl-200	10
Tl-201	100
Tl-202	10
Tl-204	1
Pb-203	10
Bi-206	1
Bi-207	0.1
Po-203	10
Po-205	10
Po-207	10
At-211	1,000
Ra-223	1
Ra-224	1
Ra-225	10
Ra-227	100
Th-226	1,000
Th-227	1
Th-229	0.1
Pa-230	10
Pa-233	10
U-230	10
U-231	100
U-232 (1)	0.1
U-233	1
U-236	10
U-237	100
U-239	100
U-240 (1)	100
Np-237 (1)	1
Np-239	100
Np-240	10
Pu-234	100
Pu-235	100
Pu-236	1
Pu-237	100
Pu-238	0.1
Pu-239	0.1

Pu-240	0.1
Pu-241	10
Pu-242	0.1
Pu-243	1,000
Pu-244 (1)	0.1
Am-241	0.1
Am-242	1,000
Am-242m (1)	0.1
Am-243 (1)	0.1
Cm-242	10
Cm-243	1
Cm-244	1
Cm-245	0.1
Cm-246	0.1
Cm-247 (1)	0.1
Cm-248	0.1
Bk-249	100
Cf-246	1,000
Cf-248	1
Cf-249	0.1
Cf-250	1
Cf-251	0.1
Cf-252	1
Cf-253	100
Cf-254	1
Es-253	100
Es-254 (1)	0.1
Es-254m (1)	10
Fm-254	10,000
Fm-255	100

(1) Parent radionuclides and their progeny, if the dose contributions of those progeny are taken into account in the dose calculation thus requiring only the activity concentration value of the parent radionuclide to be considered, are listed in the table below.
m metastable.

Parent radionuclide	Progeny
Fe-52	Mn-52m
Zn-69m	Zn-69
Sr-90	Y-90

Sr-91	Y-91m
Zr-95	Nb-95
Zr-97	Nb-97m, Nb-97
Nb-97	Nb-97m
Mo-99	Tc-99m
Mo-101	Tc-101
Ru-103	Rh-103m
Ru-105	Rh-105m
Ru-106	Rh-106
Pd-103	Rh-103m
Pd-109	Ag-109m
Ag-110m	Ag-110
Cd-109	Ag-109m
Cd-115	In-115m
Cd-115m	In-115m
In-114m	In-114
Sn-113	In-113m
Sb-125	Te-125m
Te-127m	Te-127
Te-129m	Te-129
Te-131m	Te-131
Te132	I-132
Cs-137	Ba-137m
Ce-144	Pr-144, Pr-144m
U-232	Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208
U-240	Np-240m, Np-240
Np237	Pa-233
Pu-244	U-240, Np-240m, Np-240
Am-242m	Np-238
Am-243	Np-239
Cm-247	Pu-243
Es-254	Bk-250
Es-254m	Fm-254

Naturally occurring radionuclides – activity concentration values for exemption or clearance

Radionuclide	Activity concentration ($AC_{E,c}$) [Bq/g]
U-238sec (1)	1
U-238+ (1)	5
U-234	5
Th-230	10
Ra-226+ (1)	1
Pb-210+ (1)	5
Po-210	5
U-235sec (1)	1
U-235+ (1)	5
Pa-231	5
Ac-227+ (1)	1
Th-232sec (1)	1
Th-232	5
Ra-228+ (1)	1
Th-228+ (1)	1
K-40	10

(1) Parent radionuclides and their progeny, if the dose contributions of those progeny are taken into account in the dose calculation thus requiring only the activity concentration value of the parent radionuclide to be considered, are listed in the table below.

Parent radionuclide	Progeny
U-238sec	Th-234, Pa-234m, U-234, Th-230, Ra-226, Rn-222, Po-218, Pb-214, Bi-214, Po-214, Pb-210, Bi-210, Po-210
U-238+	Th-234, Pa-234m
Ra-226+	Rn-222, Po-218, Pb-214, Bi-214
Pb-210+	Bi-210
U-235sec	Th-231, Pa-231, Ac-227, Th-227, Fr-223, Ra-223, Rn-219, Po-215, Pb-211, Bi-211, Tl-207, Po-211
U-235+	Th-231
Ac-227+	Th-227, Fr-223, Ra-223, Rn-219, Po-215, Pb-211, Bi-211, Tl-207, Po-211
Th-232sec	Ra-228, Ac-228, Th-228, Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Po-212, Tl-208
Ra-228+	Ac-228
Th-228+	Ra-224, Rn-220, Po-216, Pb-212, Bi-212, Tl-208, Po-212

Annex 5

Limit values for clearance and contamination

1. Limit values for clearance of buildings, facilities and objects, including equipment

Residual contamination on buildings, facilities and objects, including equipment, cf. Section 11(1), must not exceed the limit value for surface-specific activity concentration in the table in Subsection 3.

For a mixture of radionuclides, the criterion for clearance is met when the activity concentration index (I_{AC}) is less than or equal to 1. Where relevant, this condition may be verified based on a best estimate of the composition of the radionuclide mixture.

The activity concentration index is given by:

$$I_{AC} = \sum_{c} \frac{AC_c}{AC_{E,c}}$$

where AC_c is the activity concentration for radionuclide *c*, and $AC_{E,c}$ is the associated limit value in the table in Subsection 3.

2. Limit values for contamination of surfaces and objects, including equipment

Residual contamination inside and outside of controlled areas and on objects, including equipment brought out of facilities, cf. Section 71(3), must not exceed the limit value for surface specific activity concentration in the table in Subsection 3.

For a mixture of radionuclides, the criterion for residual contamination is met when the activity concentration index (I_{AC}), cf. Subsection 1, is less than or equal to 1. Where relevant, this condition may be verified based on a best estimate of the composition of the radionuclide mixture.

3. Limit values for surface-specific activity concentration

For radionuclides not included in the table below, the Danish Health Authority may approve values subject to application.

Radionuclide	Limit value for surface specific activity concentration for buildings, facilities and objects granted clearance for other purposes, cf. Subsection 1, and surfaces and objects outside of controlled areas, cf. Subsection 2. [Bq/cm²]	Limit value for surface-specific activity concentration for surfaces and objects inside controlled areas [Bq/cm²]
H-3	1,000	100,000
C-14	1,000	10,000
F-18	100	1,000
Na-22	0.1	10
Na-24	50	1,000

P-32	100	1,000
P-33	1,000	5,000
S-35	1,000	5,000
Cl-36	10	1,000
K-40	5	500
K-42	100	1,000
Ca-45	1,000	1,000
Sc-46	1	100
Cr-51	100	10,000
Mn-53	10,000	100,000
Mn-54	1	100
Fe-55	10,000	10,000
Fe-59	1	100
Co-56	0.5	50
Co-57	10	1,000
Co-58	1	100
Co-60	0.1	10
Ni-59	10,000	10,000
Ni-63	1,000	10,000
Zn-65	1	100
As-73	100	5,000
Se-75	5	500
Br-82	50	1,000
Rb-86	100	1,000
Sr-85	5	500
Sr-89	100	1,000
Sr-90	10	100
Y-90	100	1,000
Y-91	100	1,000
Zr-93	100	500
Zr-95	1	100
Nb-93m	100	10,000
Nb-94	0.5	50
Mo-93	10	5,000
Mo-99	100	1,000
Tc-97	50	10,000
Tc-97m	100	1,000

Tc-99	50	1,000
Tc-99m	1,000	10,000
Ru-106	5	500
Ag-108m	0.1	50
Ag-110m	0.1	50
In-111	100	10,000
Cd-109	10	1,000
Sn-113	5	1,000
Sb-124	1	100
Sb-125	1	100
Te-123m	10	1,000
Te-127m	100	1,000
I-123	1,000	10,000
I-125	50	500
I-129	5	100
I-131	50	500
Cs-134	0.5	50
Cs-135	1,000	5,000
Cs-137	1	1,000
Ce-139	10	1,000
Ce-144	10	500
Pm-147	1,000	1,000
Sm-151	1,000	5,000
Sm-153	100	1,000
Eu-152	0.5	50
Eu-154	0.5	50
Eu-155	10	1,000
Gd-153	10	1,000
Tb-160	1	100
Tm-170	100	1,000
Tm-171	1,000	10,000
Lu-177	500	1,000
Ta-182	1	100
W-181	10	5,000
W-185	500	5,000
Os-185	1	100
Ir-192	1	100

Tl-201	500	10,000
Tl-204	100	1,000
Pb-210	1	10
Bi-207	0.5	50
Po-210	1	10
Ra-223	1	1
Ra-224	1	10
Ra-226	0.1	10
Ra-228	0.1	10
Th-227	0.5	1
Th-228	0.1	0.5
Th-229	0.1	0.1
Th-230	0.1	0.5
Th-232	0.1	0.5
Pa-231	0.01	0.01
U-232	0.1	0.5
U-233	1	1
U-234	1	1
U-235	1	1
U-236	1	1
U-238	1	1
Np-237	0.5	1
Pu-236	0.5	1
Pu-238	0.1	0.5
Pu-239	0.1	0.5
Pu-240	0.1	0.5
Pu-241	5	10
Pu-242	0.1	0.5
Pu-244	0.1	0.5
Am-241	0.1	0.5
Am-242m	0.1	1
Am-243	0.1	0.5
Cm-242	1	5
Cm-243	0.1	1
Cm-244	0.5	1
Cm-245	0.1	0.5
Cm-246	0.1	0.5

Cm-247	0.1	0.5
Cm-248	0.05	0.1
Bk-249	10	100
Cf-248	1	1
Cf-249	0.1	0.5
Cf-250	0.1	1
Cf-251	0.1	0.5
Cf-252	0.5	1
Cf-254	0.1	1
Es-254	1	1

m metastable.

Annex 6

Security categories for high-activity sealed sources

Radionuclide	Lower activity limit for security categories		
	A [TBq]	B [TBq]	C [TBq]
Fe-55	800,000	8,000	800
Co-60	30	0.3	0.03
Se-75	200	2.0	0.2
Kr-85	30,000	300	30
Sr-90 (Y-90)	1,000	10	1.0
Pd-103	90,000	900	90
I-125	200	20	0.2
Cs-137	100	1.0	0.1
Pm-147	40,000	400	40
Gd-153	1,000	10	1.0
Y.-169	300	3.0	0.3
Tm-170	20,000	200	20
Ir-192	80	0.8	0.08
Tl-204	20,000	200	20
Ra-226	40	0.4	0.04
Pu-238	60	0.6	0.06
Pu-239/Be-9	60	0.6	0.06
Am-241	60	0.6	0.06
Am-241/Be-9	60	0.6	0.06
Cm-244	50	0.5	0.05
Cf-252	20	0.2	0.02

Sealed sources in which the activity is lower than the lower activity limit for security category C are not categorised into security categories.

The above limits for security categories are intended to serve as a guide only. Based on a specific assessment of a high-activity sealed source and the type of use and practice, the Danish Health Authority may assign a radiation source to a different security category; cf. Section 74(2).

For radionuclides not included in the table, the Danish Health Authority determines suitable values as and when required.

Annex 7

Requirements for the knowledge, skills and competences of radiation protection officers

The requirements listed under general and under each use or practice are cumulative unless otherwise indicated.

1. General – applicable to all the following uses or practices

– Familiarity with the fundamental principles of ionising radiation and radiation protection.
– Full familiarity with relevant legislation on radiation protection.

2. Medical use

– Training in and extensive practical experience with specific types of use of radioactive material within the radiation protection officer's remit.

3. Veterinary medical use

– Qualified as a veterinarian.
– Passed an examined course on isotopes which is approved by the Danish Health Authority.

4. Research, teaching and industrial applications

4.1. Manufacture of radionuclides and sealed sources

– Passed an examined course on isotopes which is approved by the Danish Health Authority.

4.2. Manufacture of devices incorporating sealed sources

– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.3. Applications for radiation sterilisation, etc. in industrial irradiation facilities

– Course for operators of industrial irradiation facilities which is approved by the Danish Health Authority.
– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.4. Applications for blood irradiation

– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.5. Applications for log-keeping

– Relevant long-cycle scientific education.
– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.6. Industrial radiography applications

– Course in radiation protection in connection with industrial radiography approved by the Danish Health Authority.
– Extensive practical experience with the use of sealed sources for industrial radiography inside and outside of facilities.

4.7. Applications for humidity and density measurement

– Course in the use of humidity and density meters approved by the Danish Health Authority.

4.8. Use of hand-held devices incorporating sealed sources

– Training in use of the specific types of radioactive sources and devices. The training shall be provided by the manufacturer or other competent person familiar with the specific types of radiation sources and devices.

4.9. Technical safety inspection, servicing and processing of sealed sources, facilities, devices and equipment

– Courses provided by the manufacturers of the specific types of radiation sources, devices and equipment, or alternatively, thorough peer-training.

– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.10. The use of unsealed sources for research, teaching at institutions of higher education, etc. which are subject to the licensing requirement

– Passed an examined course on isotopes which is approved by the Danish Health Authority.

4.11. The use of unsealed sources for research, teaching at institutions of higher education, etc. which are subject to the notification requirement

– No further requirements beyond the general requirements of Subsection 1.

4.12. Use for leak detection using Br-82 in piping

– Passed an examined course in the fundamentals of radiation protection approved by the Danish Health Authority.
– Extensive practical experience in performing leak detection using Br-82 and continuous maintenance thereof.
– An examined refresher course approved by the Danish Health Authority shall be passed at least every 5 years.

4.13. Use of unsealed and sealed sources for teaching purposes at lower and upper secondary educational institutions

– Education as a physics or chemistry teacher or the equivalent.

4.14. Handling and storage of NORM

– Course in the fundamentals of radiation protection approved by the Danish Health Authority.

Annex 8

Requirements for the knowledge, skills and competences of medical physics experts

Individuals who have completed one of the educations specified in the table below satisfy without further consideration the requirements for the education of a medical physics expert for the specific practice concerned. Other educations will be subject to individual assessment by the Danish Health Authority.

Where multiple sub-items are specified, the requirements are cumulative.

1. *Medical use of unsealed sources for examinations*
   – Medical physicist training within nuclear medicine.
   – Experience in use of unsealed sources and ancillary equipment for examinations.

2. *Medical use of sealed sources for examinations*
   – Medical physicist training within nuclear medicine or oncology.
   – Experience in use of sealed sources and ancillary equipment for examinations.

3. *Medical use of unsealed sources for treatment*
   – Medical physicist training within nuclear medicine.
   – Experience in use of unsealed sources and ancillary equipment for treatment.

4. *Medical use of sealed sources for treatment (brachytherapy)*
   – Medical physicist training within oncology.
   – Accreditation as an expert by the Danish Society for Medical Physics or equivalent knowledge, skills and competences.
   – Experience in use of sealed sources and ancillary equipment for treatment.

Annex 9

Requirements for the knowledge, skills and competences of radiation protection experts

Approval as a radiation protection expert requires documentation that the applicant possesses the education, knowledge, skills and competences listed below.

1) Completed academic master's degree or the equivalent in physics, technology, chemistry or biology or an equivalent scientific education.
2) In-depth expertise in ionising radiation.
3) In-depth knowledge of radiation protection legislation.
4) Mastery of methods for establishing and ensuring a high standard of radiation protection for humans, radiation sources, facilities and other installations, including the establishment of associated procedures.
5) Skills within:
   - Calculation methods regarding shielding and doses to individuals.
   - Specific matters pertaining to the discharge of radioactive material and environmental monitoring.
   - Selection and testing of measuring instruments.
   - Principles of quality management.
6) At least three years' practical experience following completion of their basic education and gaining the above-mentioned knowledge and skills concerning the specific practices and radiation sources for which approval as a radiation protection expert is being applied for.

Annex 10

Requirements for the knowledge, skills and competences of clinically-responsible practitioners

A clinically-responsible practitioner shall possess sufficient education and experience in irradiation of individuals for diagnostic or therapeutic purposes, including for assessment of the justification and the clinical results. Individuals who have completed one of the educations specified in the table below immediately satisfy the requirements for the education of a clinically-responsible practitioner for the specific application area concerned. Individuals who are in the process of completing any of the educations listed below may satisfy the requirements if the relevant part of the education has been completed; cf., for example, the descriptions of objectives for the study programme. Other educations will be subject to individual assessment by the Danish Health Authority.

The clinically-responsible practitioner shall moreover possess qualifications, either as part of their basic education or subsequent training, within the following areas:
– Generation and detection of radiation.
– Radioactivity and measurement of radioactivity.
– Dosimetry adapted to the area of application.
– Radiation biology.
– Radiation protection.

Area of application	Application	Education
Examination	Nuclear medical examinations	Medical specialist in clinical physiology and nuclear medicine
	Examinations using hybrid scanners	Medical specialist in diagnostic radiology or medical specialist in clinical physiology and nuclear medicine
	Medical exposure in connection with surgical procedures, etc.	Medical specialist within the relevant specialist field with supplementary education in radiation and radiation protection
Treatment	Treatment in a department of nuclear medicine	Medical specialist in clinical physiology and nuclear medicine
	Treatment in a department of oncology	Medical specialist in clinical oncology
	Treatment in any other department (e.g. department of endocrinology)	Medical specialist within the relevant specialist field with supplementary education in radiation and radiation protection

Annex 11

Requirements for the knowledge, skills and competences of exposed workers

Exposed workers employed in the types of uses and applications listed below and who possess the educations specified below will immediately be regarded as satisfying the requirement for special education stipulated in Section 31. Other educations will be assessed individually by the Danish Health Authority.

1. Medical use

1.1. Brachytherapy

1.1.1. Individuals who perform treatment shall be authorised practitioners with recognised competence in radiotherapy.

1.1.2. Trainees are permitted to perform treatment under the supervision of qualified staff.

1.2. Nuclear medicine

1.2.1. Individuals who handle radioactive material for purposes of examinations and treatment shall be qualified as bioanalysts, nurses or radiographers and have completed a supplementary course in radiation and radiation protection and handling of relevant radioactive material.

2. Research applications and teaching

2.1. Radiation sterilisation, etc. in industrial irradiation facilities

2.1.1. Operators are required to have passed a course for operators of industrial irradiation facilities which is approved by the Danish Health Authority.

2.1.2. Operators are required to have passed a course in the fundamentals of radiation protection approved by the Danish Health Authority.

2.2. Industrial radiography

2.2.1. Individuals performing industrial radiography shall have passed a course in radiation protection related to industrial radiography approved by the Danish Health Authority.

2.3. Log-keeping

2.3.1. Relevant long-cycle scientific education.

2.3.2. Course in the fundamentals of radiation protection approved by the Danish Health Authority.

2.4. Leak detection using Br-82 in piping

2.4.1. Passed an examined course in the fundamentals of radiation protection approved by the Danish Health Authority.

2.4.2. Extensive practical experience in performing leak detection using Br-82 and continuous maintenance thereof.

2.4.3. An examined refresher course approved by the Danish Health Authority shall be passed at least every 5 years.

2.5. Use of unsealed and sealed sources for teaching purposes at lower and upper secondary educational institutions

2.5.1. Education as a physics or chemistry teacher or the equivalent.

2.5.2. Familiarity with the fundamental principles of ionising radiation and radiation protection.

3. Technical safety inspection, servicing and processing of sealed sources, facilities, devices and equipment

3.1.1. Courses provided by the manufacturers of the specific types of radiation sources, devices and equipment, or alternatively, thorough peer-training.

3.1.2. Course in the fundamentals of radiation protection approved by the Danish Health Authority.

Annex 12

Special requirements for specific applications of sealed sources and for facilities

1. Industrial radiography

1.1. General requirements

1.1.1. For industrial radiography, Co-60, Se-75 and Ir-192 with a maximum activity of 400 GBq, 4,000 GBq and 1,500 GBq, respectively, may be used as the radiation source unless otherwise authorised by the Danish Health Authority.

1.1.2. A collimator shall be used unless otherwise authorised by the Danish Health Authority. The collimator shall as a minimum be capable of reducing the fraction of the beam of radiation that is not the useful beam by a factor of 100. Cylindrical beam limiting devices, where the radiation source is housed inside the tube, are exempt from the requirement for use of a collimator.

1.1.3. An instrument shall be available for dose rate measurement.

1.2. Use outside of facilities

1.2.1. Abundant shielding equipment shall be available in yellow and bearing the symbol for ionising radiation and easily comprehensible warning notices.

1.2.2. The operating cable shall be of sufficient length to ensure that the dose rate at the place of operation does not normally exceed 20 µSv/h, although at least eight metres.

1.2.3. The guide tube shall be as short as possible and no more than two metres in length.

1.2.4. Guide tubes must not be assembled from multiple lengths.

1.2.5. Around the assembly, an area shall be delimited within which any human presence is prohibited during exposure. Outside of this zone, the dose rate must not be greater than 60 µSv/h. However, at workplaces for individuals who are not involved in the radiography work, the dose rate must not be greater than 7.5 µSv/h. At the place of operation, the dose rate must not normally be greater than 20 µSv/h.

1.2.6. The area with dose rates exceeding 60 µSv/h shall be kept under continuous surveillance during exposure, and shall be cordoned off or otherwise access-controlled.

1.2.7. If it is not possible from the place of operation to survey the entire area mentioned in Subsection 1.2.6, special safety precautions shall be established to prevent access to the area during exposure.

1.2.8. After exposure, verification measurements shall be obtained to ensure that the radiation source is fully shielded before access is granted to the area specified in Subsection 1.2.6.

1.2.9. Every effort shall be made to prevent unauthorised persons occupying areas subject to dose rates greater than 7.5 µSv/h.

1.2.10. The undertaking shall notify the Danish Health Authority of any location where more than 200 exposures are performed per month outside of facilities. The Danish Health Authority shall be notified as soon as possible and, if possible, before work commences.

1.3. Fittings and fixtures for facilities for the purposes of industrial radiography

1.3.1. An acoustic alarm signal shall be activated in the event of intrusion into the facility during exposure.

1.3.2. The main entrance to the facility shall be installed with a red warning light which is lit constantly or flashes while exposure is in progress. A warning sign shall be mounted next to this light, bearing the symbol for ionising radiation and the legend in Danish: "STRÅLING NÅR LAMPEN LYSER" ("EXPOSURE WHEN LIGHT IS ON") or the like.

1.3.3. At the main entrance to the facility a notice shall state the restrictions that apply to use of the facility, the types of radiation sources and the direction of exposure. The name and contact details of the radiation protection officer shall also be stated.

1.3.4. Inside the facility, a red warning light shall be installed which is lit constantly or flashes while exposure is in progress. A warning sign shall be mounted next to this light, bearing the symbol for ionising radiation and the legend in Danish: "STRÅLING NÅR LAMPEN LYSER" ("EXPOSURE WHEN LIGHT IS ON") or the like. The warning light and the sign shall be visible from all entrances to the facility.

1.3.5. All shielding surfaces shall be clearly marked with specification of the shielding material and the thickness of the shielding.

1.3.6. If all shielding components of the facility do not provide adequate shielding as required in accordance with Section 21 and Section 22 of the Executive Order on Ionising Radiation and Radiation Protection, an approved beam direction shall be defined. The approved beam direction shall be specified clearly in the facility with marked zones and the legend in Danish: "TILLADT STRÅLEFELT" ("AUTHORISED RADIATION FIELD").

2. Brachytherapy

2.1. Requirements regarding personnel

2.1.1. During any treatment procedure, at least one individual qualified as a medical physicist within oncology shall be available.

2.1.2. Whenever a treatment is commenced, at least two individuals with the relevant education shall be present and assist in the treatment or supervise trainees in administering the treatment.

2.2. Test measurements

2.2.1. For brachytherapy using temporarily sited high-activity sealed sources, it must be ensured, upon completion of the treatment, that no sources of radiation remain inside the patient. For that purpose, a measuring instrument must be used to verify that all radiation sources that were used have been secured inside the shielding, and a test measurement shall be performed over the treatment site on the patient. The test measurement of the patient shall be documented in writing.

3. Facilities for blood irradiation

3.1. Fixtures and fittings, etc.

3.1.1. The facility shall be protected against fire and structural damage.

3.1.2. The facility shall be equipped with a device that emits an acoustic alarm in the event of dose rate elevation.

Annex 13

Requirements for facilities for use of unsealed sources

For use of unsealed sources subject to the licensing or notification requirements, and which is to take place in facilities in compliance with Section 64(1), the following requirements apply to facility fixtures and fittings.

1. Requirements for facilities consisting of isotope laboratories

1.1. Type C isotope laboratories

1.1.1. The facility shall be fitted out so as to minimise worker exposure and the risk and consequences of unintended exposure. The spatial dimensions shall be sufficient to ensure the safe use of radioactive material from a radiation protection point of view.

1.1.2. The facility shall be fitted out so as to prevent the dispersion of radioactive material to the surroundings as far as is reasonably achievable.

1.1.3. Any areas and objects inside the facility liable to become contaminated with radioactive material shall be kept to a minimum and shall be easy to access for cleaning.

1.1.4. All surfaces inside the facility shall be of such a material and of such a design as to make them easy to clean and to prevent them from retaining radioactive material.

1.1.5. Unauthorised persons must not be able to gain access to the facility.

1.1.6. There shall be at least one wash basin inside the facility. The wash basin shall be operable without the use of hands. If the practice does not permit a wash basin inside the facility, there shall be access to washing in an adjacent room, and access to this room shall, if possible, be hands-free.

1.1.7. If radioactive waste is discharged via drains in activity concentrations greater than the value in Annex 3, the facility shall, where reasonable from a radiation protection point of view, have a drain connected to a separate collector pipe or a technically equivalent solution to ensure that the waste is not dispersed to other rooms prior to its run-off to the point of discharge.

1.1.8. Collector pipes comprised by the requirement in Subsection 1.1.7 shall, at their access points, be labelled with the legend in Danish: "Isotopafløb" ("Isotope drain").

1.1.9. If radioactive material might become airborne to an extent that would be significant from a radiation protection point of view, the facility shall have a ventilation solution commensurate with the nature and scale of the use of radioactive material.

1.1.10. If radioactive material might become airborne to any extent of significance from a radiation protection point of view, the facility shall have a sufficient quantity of radiation safety cabinets.

1.1.11. The radiation safety cabinets shall meet the following requirements:

1.1.11.1. The radiation safety cabinet shall be equipped with a testing device to indicate whether the extraction unit is operating.

1.1.11.2. Prior to its acceptance into service, the safety cabinet shall be tested according to the relevant standard if such exists.

1.1.11.3. In the event of significant rearrangements, but at least once a year, the radiation safety cabinet shall undergo performance testing.

1.1.11.4. If filtration of the extract air from the radiation safety cabinet is necessary, the filter shall be sited so as to minimise any exposure.

1.1.12. Airborne radioactive material inside a radiation safety cabinet must not be dispersible to ambient laboratory air or to the air in other interiors.

1.1.13. Air exhaust from radiation safety cabinets shall ensure rapid and effective dilution with ambient air.

1.1.14. Incubators and other special cabinets shall be connected to the air extraction unit if there is a risk of generation of airborne radioactive material to an extent that is significant from a radiation protection point of view.

1.2. Type B isotope laboratories

1.2.1. The requirements of Subsections 1.1.1-1.1.14 shall be met.

1.2.2. Where the risk exists of significant contamination, the laboratory shall have a forelab or transitional zone with a wash basin, emergency shower, drain and space for changing and keeping protective clothing. The wash basin shall be operable hands-free. The flooring, walls, ceiling and fixtures in the forelab or transitional zone shall be of the same standard as those in the facility itself.

1.2.3. Transitions between the flooring and vertical surfaces, e.g. walls, plinths and piping lead-in, shall be rounded and extend at least 10 cm up the walls.

1.2.4. There shall be suitable negative pressure in relation to the surroundings. If a type B isotope laboratory is subject to a requirement in other legislation for positive pressure in relation to the surroundings, access to this shall be via a forelab or interlock ensuring suitable negative pressure in relation to the surroundings.

1.2.5. Testing devices shall be installed to indicate whether the ventilation system is operating.

1.2.6. In the event of significant rearrangements, though at least once a year, the ventilation system shall undergo performance testing.

1.3. Type A isotope laboratories

The Danish Health Authority lays down requirements for fixtures and fittings in type A isotope laboratories on a case-by-case basis.

1.4. Activity limits for use or handling at any one time in type C and B isotope laboratories

The maximum activity that can, as a rule, be authorised for use or handling at any one time in a type C and a type B isotope laboratory, respectively, is shown below:

Type C isotope laboratory	
Type of operation	Maximum activity that may be used or handled at any one time
Operation associated with low risk	10^2 · the value in Annex 3
Operation associated with moderate risk	10^1 · the value in Annex 3
Operation associated with significant risk	10^0 · the value in Annex 3

Type B isotope laboratory	
Type of operation	Maximum activity that may be used or handled at any one time
Operation associated with low risk	10^5 · the value in Annex 3
Operation associated with moderate risk	10^4 · the value in Annex 3
Operation associated with significant risk	10^3 · the value in Annex 3

Examples of operation associated with low risk: sampling from stock solution is not associated with the risk of inhalation of radioactive material or significant external exposure, dilution, administration in a patient.

Examples of operations associated with moderate risk: Chemical analysis, synthesis, labelling work, administration in animals.

Examples of operations associated with significant risk: Handling of radioactive material in gaseous, aerosol or powder form.

The Danish Health Authority may in specific cases authorise use or handling of higher activities in type B and C isotope laboratories than those shown in the charts above.

2. Requirements for facilities for medical use

2.1. Requirements for scanner rooms, injection rooms and wards

2.1.1. The requirements of Subsections 1.1.1-1.1.9 shall be met.

3. Requirements for facilities for veterinary medical use

3.1. Requirements for scanner rooms and injection rooms

3.1.1. The requirements of Subsections 1.1.1-1.1.9 shall be met.

3.2. Requirements for facilities for stabling

3.2.1. The requirements of Subsection 4.2 shall be met.

4. Requirements for facilities for storage or stabling

4.1. Requirements for facilities for storage of radioactive material, including radioactive waste

4.1.1. The requirements of Subsections 1.1.1-1.1.5 and Subsection 1.1.9 shall be met.

4.2. Requirements for facilities for stabling animals

4.2.1. The requirements of Subsections 1.1.1-1.1.5 and Subsections 1.1.7-1.1.13 shall be met.

4.2.2. Stables for large animals shall have floor drains and a means of hose-rinsing the floor.

4.2.3. Cages or pens for containment of animals administered with radioactive material with a total activity greater than the value in Annex 3 shall be marked with the symbol for ionising radiation, the legend in Danish: "Radioaktivet" ("Radioactive"), information about the radionuclide, activity, date, and a contact name.

5. Requirements for other interiors

The following are exempt from the requirement for use of unsealed sources to be confined to facilities:

a) practices associated with low risk in which the total activity of use or handling at any one time does not exceed 10 times the value in Annex 3;

b) practices associated with moderate risk in which the total activity of use or handling at any one time does not exceed the value in Annex 3;

c) practices associated with significant risk in which the total activity of use or handling at any one time does not exceed 0.1 times the value in Annex 3;

Interiors in which such practices take place shall, however, as a minimum be laboratory standard and meet the requirement in Subsection 1.1.4.

Annex 14

Special requirements for leak detection using Br-82 in piping

1. Special authorisation

Special authorisation shall be obtained from the Danish Health Authority for the following:

1.1. Use of more than 100 MBq Br-82 for any leak detection.

1.2. Leak detection to be unattended while in progress.

1.3. Leak detection for a pipeline that is not part of a central heating system or a service water system, which can be disconnected from the public water system.

1.4. Leak detection at large facilities such as swimming baths or facilities involving multiple households.

1.5. The use of more than 10 MBq Br-82 for leak detection at premises not connected to the public sewerage system and where the wastewater from the leak detection will be piped to a collection tank, septic drain field or the like.

2. Work instructions

A set of work instructions shall be available and shall be followed for the undertaking's performance of leak detection. The work instructions shall contain all the requirements for procedures, including radiation protection arrangements and measures in the event of accidents. The work instructions shall be approved by the Danish Health Authority.

3. Guidance for the client and the undertaking that will be repairing any leak detected

A guide shall be issued to the client for whom leak detection is performed, and a guide shall be issued to the undertaking that will be repairing the leak. The guides shall be approved by the Danish Health Authority.

4. Product testing and certification

The activity, activity concentration and radionuclide purity of Br-82 batches shall be verified by means of measurements obtained by the manufacturer. Any undertaking taking receipt of a Br-82 batch shall ensure that the batch is accompanied by a certificate stating all the measured values and the chemical state of the contents.

5. Maximum activity concentration

The activity concentration in a Br-82 solution must not exceed 10 MBq Br-82/ml.

6. Addition of Br-82 to the undertaking's container

The addition of Br-82 to the undertaking's container must only take place on the undertaking's own premises or those of the manufacturer/supplier.

7. Handling at the undertaking's premises

Any handling of Br-82 on the undertaking's premises shall take place indoors. The premises in which Br-82 is handled shall have easily cleanable surfaces that can be hosed down in case of contamination. The premises must have a drain and access to running water.

8. Storage

Any storage of Br-82 at the undertaking's premises or premises designated for the undertaking. The storage location shall be approved by the Danish Health Authority.

9. Performance of leak detection

For performance of leak detection procedure, the following shall be fulfilled:

9.1. The leak detection site shall be disconnected from the public water system.

9.2. The activity used for the leak detection shall be precisely determined.

9.3. During the leak detection procedure, residents and other unauthorised persons shall vacate any rooms where they might come into contact with the radioactive material.

9.4. The access route shall be cleared of unauthorised persons when Br-82 is moved from the vehicle to the leak detection site.

9.5. Waste water from the leak detection procedure shall be discharged to the public sewerage system. For leak detection procedures using a maximum of 10 MBq Br-82 it is, however, permitted to discharge the waste water to a collection tank, septic drain field or the like. Wastewater discharge to surrounding land is not permitted.

9.6. Upon completion of the leak detection procedure, the pipeline shall be flushed through thoroughly, and test measurements shall be conducted to ensure that no Br-82 residues are left in the system except for in the leak itself.

9.7. Test measurements shall verify that no Br-82 contamination is left at the client site. All contaminated equipment and waste from the leak detection procedure, e.g. gloves, pipette tips, wipes, etc. shall be returned to the undertaking.

10. Record-keeping

10.1. The undertaking shall keep a record of any leak detection procedures using Br-82 it carries out. For each leak detection procedure, the record shall provide the following data:

- Date of the leak detection procedure.
- Address at which the leak detection was carried out.
- Type of leak detection (heating or domestic water system)
- Precise activity of Br-82 that was used.
- Date of repair.

10.2. The record shall be retained for at least 5 years.

11. Annual list

11.1. Annually in January, the Danish Health Authority shall be sent a list of leak detection procedures performed using Br-82 in the preceding year.

11.2. For heating and domestic water systems, the list shall provide the following data:

- The number of leak detection procedures performed using Br-82.
- The number of leak detection procedures performed by other means.
- The highest activity Br-82 used for one leak detection.
- The average Br-82 activity used for each leak detection.