

Executive Order on Use of Radiation Generators¹

Pursuant to Section 2(1); Section 4(2); Section 5(2); Section 7(2); Section 8(2); Section 9(2); Section 10(2); Section 11(1); Section 15 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 radiation generators and associated facilities where such are required within the constraints set out in Sections 1-3, Section 8 and Section 9 of the Executive Order on Ionising Radiation and Radiation Protection.

(3) Any use of radiation generators resulting in induced radioactivity is additionally subject to the provisions of Executive Order No. 670 of 1 July 2019 on Use of Radioactive Substances.

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

- 1) General diagnostics: Medical application of radiation generators for imaging for the purpose of conventional radiological examinations, including their use for non-interventional fluoroscopy.
- 2) Dermatologic therapy: The treatment of skin disorders, excluding cancer, by means of radiation generators.
- 3) Industrial radiography: Radiography for industrial or research purposes, in which radiation generators are used inside or outside of facilities, e.g. for weld inspection. Industrial radiography does not comprise use of radiation generators in which the requisite shielding and safety features are built into the structure that houses the radiation source.
- 4) Interventional radiology: Medical application of radiation generators for imaging to facilitate the introduction and guidance of devices in the body.
- 5) X-ray radiation therapy: The treatment of cancer by means of radiation generators operating with a voltage less than or equal to 100 kV.
- 6) Self-shielded radiation generator: A radiation generator permanently integrated inside a shielding, which offers sufficient protection to permit the radiation generator to be operated outside of

facilities, with no restrictions on human proximity to the radiation generator.

- 7) Radiotherapy: The treatment of cancer by means of radiation generators operating with energies greater than or equal to 1 MeV.
- 8) Veterinary medical application: The use of radiation generators for veterinary medical examinations, treatment or research within this domain, and the exposure of animals for the purpose of research for advancing human examinations and treatment.

Chapter 2

Prohibition, licensing and notification

Prohibition

§ 3. The marketing of consumer products or the making of consumer products available to consumers is prohibited except in the case of radiation generators, as specified in Section 2(1), No. 2 in the Executive Order on Ionising Radiation and Radiation Protection, or if an assessment has been obtained from the Danish Health Authority that use of that consumer product is justified.

Licensing and notification

§ 4. A license from the Danish Health Authority is required for the following uses; cf. however Section 5 and Section 6:

- 1) Application of radiation generators.
- 2) Manufacture of radiation generators, including in the development phase insofar as the process generates radiation.
- 3) Alterations to radiation generators in any context, including during their cleaning, maintenance and repair, where the alterations might impact the radiation protection features, such as by disassembly of shielding, disconnection of interlock safety switches and manipulation of radiation generators, as well as the configuration of radiation generators for medical application to service mode.
- 4) Installation of radiation generators for medical and veterinary medical application and installation of radiation generators for other uses if the application in question requires a licence from the Danish Health Authority.
- 5) Acceptance and performance testing of radiation generators.
- 6) Technical safety inspection of radiation generators.

§ 5. Any use of radiation generators is, to the extent specified in Annex 1, exempt from the licensing requirement, but is subject to the requirement for

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.

notification to the Danish Health Authority.

§ 6. Technical safety inspection of radiation generators for medical examinations is exempt from the licensing and notification requirements if the undertaking performing the technical safety inspection is licensed to use the radiation generator or is subject to the requirement for notification for its use.

§ 7. A licence must be obtained or notification must be submitted before any use of radiation generators commences.

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

Chapter 3

Registration and inventories

§ 8. The following must be registered in the Danish Health Authority's Registry of Radiation Sources and Facilities:

- 1) Radiation generators the use of which is subject to the licensing or notification requirements; cf. Section 4 and Section 5.
- 2) All facilities for use of radiation generators where that use is subject to the licensing or notification requirements; cf. Section 4 and Section 5.

(2) For registration purposes, multiple radiation sources shielded inside the same cabinet and operated as an aggregate unit are regarded as constituting a single radiation generator.

(3) If a registered radiation generator or a registered facility is no longer in use, this must be notified to the Danish Health Authority.

§ 9. An undertaking licensed to use radiation generators or subject to the requirement for notification for using such generators must keep an inventory of all radiation generators used by the undertaking. The inventory must contain the following information for each radiation generator:

- 1) Manufacturer, model designation and serial number.
- 2) The specific use of the radiation generator.
- 3) Radiation type.
- 4) Maximum tube voltage and tube current, where relevant.
- 5) The installation location or place of use and, for mobile radiation generators, the storage location.
- 6) Date of the last technical safety inspection and the latest date of the next one.

§ 10. An undertaking responsible for a facility must keep an inventory containing the following information:

- 1) Information for unique identification of the facility.
- 2) A drawing of the installation with information on the design and the capacity of its features to provide

radiation protection.

- 3) Any classification as a controlled or supervised area.
- 4) For facilities subject to requirements for technical safety inspection, the date of the last inspection and the latest date for the next one.

Chapter 4

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

§ 11. Requirements for the knowledge, skills and competences of radiation protection officers, medical physics experts and radiation protection experts are set out in Annexes 2, 3 and 4, respectively.

§ 12. Requirements for the knowledge, skills and competences of clinically responsible practitioners are set out in Annex 5.

Chapter 5

Requirements for the knowledge, skills and competences of exposed workers

§ 13. Exposed workers employed for the specific types of use and practices specified in Annex 6 must be specially trained for this. Requirements for their knowledge, skills and competences are set out in the Annex.

Chapter 6

Requirements for use of radiation generators General requirements

§ 14. Radiation generators must be equipped with a marking containing unique identification of the radiation generator and information on the date of the last technical safety inspection and the latest date for the next one; cf. however (2). The marking must be clearly visible and durable.

(2) If information on technical safety inspection dates by means of marking is not appropriate, the information must be provided by other means and in such a way that the information is readily accessible to anyone who uses and handles the radiation generator.

§ 15. Mobile radiation generators that are not hand-held must be safely and stably secured to a stand.

§ 16. Radiation generators must as far as possible be operated from a control room or shielded operation station, unless otherwise specified by special requirements for specific applications.

§ 17. Exposure must be indicated by a clearly visible warning signal.

§ 18. Where radiation generators are to be used, it must be ensured that only individuals who are examined or treated or undergo non-medical imaging are exposed to the

direct, unshielded radiation. In the case of medical or veterinary medical examinations, the hands of the exposed worker may be permitted to be briefly present within the direct radiation field if this is required for performance of the examination.

(2) Workers, carers and comforters, and individuals assisting in supporting animals during veterinary medical exposures must be protected against scattered radiation.

§ 19. Radiation generators and ancillary equipment must be inspected at intervals commensurate with the specific practice. The interval between technical safety inspections must not be longer than 13 months.

(2) Facilities for use of radiation generators, where such use is subject to the licensing requirement, must undergo technical safety inspection at an interval commensurate with the specific use. The interval between technical safety inspections must not be longer than 13 months.

(3) The technical safety inspection must verify that radiation generators, 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.

(4) The undertaking must retain technical safety inspection reports for the last three inspections. The name of the technical safety inspection organisation and of the individual who conducted the inspection must be stated in the technical safety inspection report.

§ 20. If a radiation generator is left unattended in an unsound or technically unsatisfactory state or if it fails to comply with the radiation safety provisions set out in 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, it must be ensured that no one can be unintentionally exposed to radiation.

§ 21. Before any final disposal of a radiation generator it must be ensured that the radiation generator is not capable of generating radiation.

Signage

§ 22. Where use of radiation generators entails classification of an area as a supervised area; cf. Section 49 of the Executive Order on Ionising Radiation and Radiation Protection, the area must, commensurately with the nature and magnitude of the radiological risk, be installed with a warning sign for ionising radiation in accordance with the prevailing standard and supplemented with the following Danish text: "Strålingsgenerator. OVERVÅGET OMRÅDE. Risiko for ekstern bestråling" (Radiation Generator. SUPERVISED AREA. Risk of external exposure).

(2) Where use of radiation generators entails

classification of an area as a supervised area; cf. Section 50 of the Executive Order on Ionising Radiation and Radiation Protection, the area must be installed with a warning sign for ionising radiation in accordance with the prevailing standard and supplemented with the following Danish text: "Strålingsgenerator. KONTROLLERET OMRÅDE. Risiko for ekstern bestråling" (Radiation Generator. CONTROLLED AREA. Risk of external exposure).

(3) Warning signs in accordance with (1) and (2) must be clearly visible and durable.

Supplementary requirements for medical exposure

§ 23. The use of radiation generators outside of facilities must take place only if merited by the patient's condition.

§ 24. Where operation is performed from a control room or a shielded control station, it must be possible from that vantage point to observe the individual undergoing the medical exposure, and, if necessary, to stop the exposure.

(2) (1) is not applicable to intraoral radiography.

§ 25. Performance testing must be carried out at intervals of no longer than 13 months.

(2) For radiation generators for intraoral radiography, performance testing must be carried out at intervals of no longer than 10 years.

§ 26. The individual responsible for altering assemblies and, where relevant, examination protocols, as part of acceptance or performance testing procedure, technical safety inspection, other servicing, etc. must communicate alterations immediately to all relevant individuals in the undertaking.

§ 27. Radiation generators used for fluoroscopy must be equipped with a device to automatically control the dose rate, and an imaging system with built-in image intensification.

§ 28. Radiation generators used for interventional radiology or long-duration fluoroscopy procedures or long radiography series, e.g. cardiovascular examinations, must be equipped with a device for measuring the amount of radiation emitted by the radiation generator.

(2) Radiation generators, as mentioned in (1), must furthermore, insofar as it is feasible, be equipped with a device for measurement, by means of an indicator, of the skin dose to the examined person.

(3) The results of measurements mentioned in (1) and (2) must, during the procedure, be available to the operator of the radiation generator.

§ 29. Radiation generators used for interventional radiology, CT scans or planning, guiding and confirming procedures must be equipped with a device, which upon completion of the procedure, presents data on parameters of relevance for evaluation of patient dose.

(2) For radiation generators for interventional radiology or CT scanning, the data mentioned in (1) must be transferred automatically to the diagnostic report.

§ 30. Unless otherwise required pursuant to Section 28 or Section 29, radiation generators for screening or diagnostic purposes, except those in dental medicine settings, must be equipped with a device or similar means, which upon completion of the procedure presents data on parameters of relevance for evaluation of patient dose.

(2) The data mentioned in (1) must be transferred automatically to the diagnostic report where relevant.

§ 31. In examinations of individuals under 50 years of age, gonadal shielding must be employed, as detailed in (2) and (3), unless such protection would conceal areas of diagnostic interest or result in significantly impaired image quality or a significantly increased dose, or if the condition of the examined person makes shielding non-viable.

(2) Shielding of the testes must be performed if the radiation field comes closer to the testes than 5 cm. A capsule-type testicle shield with a lead equivalent of 0.5 mm must be employed for adults and 0.35 mm for children.

(3) The ovaries must be shielded if the ovaries are expected to be within the direct radiation field. Ovarian shields or lead rubber with a lead equivalent of at least 0.5 mm must be employed.

§ 32. Prior clarification of pregnancy status may be limited to such examinations in which the unborn child might be within the direct radiation field and where regard for timely performance of the examination permits clarification.

§ 33. Radiation generators used for treatment must have dose calibration performed after installation.

(2) Calibration of the dose must be carried out in accordance with a recognised dosimetric protocol.

(3) Dose calibration must be completed and approved prior to any therapeutic use.

(4) For radiation generators operating with a voltage less than or equal to 15 kV, the individual calculation of the dose to be delivered in accordance with the medical prescription, cf. Section 66, first sentence, of the Executive Order on Ionising Radiation and Radiation Protection, can be performed by consulting treatment tables. The treatment tables must be compiled by a medical physics expert based on dose calibration and must be updated at intervals of no more than 25 months.

§ 34. The independent dose verification to be conducted pursuant to Section 66 of the Executive Order on Ionising Radiation and Radiation Protection must be conducted at the start of the course of treatment to ascertain that there is sufficient overall certainty that each patient's radiotherapy treatment matches the planned one.

§ 35. Special requirements for use of radiation generators for dental purposes are set out in Annex 7.

§ 36. Special requirements for use of radiation generators for other examinations are set out in Annex 8.

§ 37. Special requirements for use of radiation generators for dermatologic therapy and X-ray radiation therapy are set out in Annex 9.

§ 38. Special requirements for use of radiation generators for radiotherapy are set out in Annex 10.

Supplementary requirements for veterinary medical application

§ 39. The animal must, as far as possible, be immobilised by anaesthesia or by means of ancillary appliances.

§ 40. Individuals other than exposed workers may, exceptionally, assist in supporting an animal during a veterinary medical examination provided that they are aged 18 years or over.

§ 41. Exposed workers or other individuals must not be present in the facility while veterinary medical treatment is in progress.

§ 42. In connection with the installation of a radiation generator and every technical safety inspection, compliance with operational limits and conditions must be tested; cf., however, (2).

(2) For radiation generators intended for intraoral radiography and operating with a voltage less than or equal to 70 kV, compliance with operational limits and conditions must be tested at the time of installation and from then on at intervals not exceeding 10 years.

§ 43. Special requirements for use of radiation generators for veterinary medical examinations are set out in Annex 11.

Supplementary requirements for industrial and research applications

§ 44. The use of radiation generators that are not self-shielded or that are not hand-held and meets the requirements of Section 45 with reference to Annex 12 or Section 46 with reference to Annex 13 must be confined to facilities.

(2) If the size or other attributes of the studied objects do not permit use in a facility, such use must take place at specially equipped sites and subject to terms laid down by the Danish Health Authority.

§ 45. Special requirements for the technical design of self-shielded radiation generators are set out in Annex 12.

§ 46. Special requirements for the technical design of hand-held radiation generators are set out in Annex 13.

§ 47. Special requirements for the technical design of radiation generators for industrial radiography are set out in Annex 14.

§ 48. Special requirements for use of radiation generators inside facilities, including supplementary requirements for industrial radiography, are set out in Annex 15.

§ 49. Special requirements for use of radiation generators for industrial radiography outside facilities are set out in Annex 16.

Supplementary requirements for use of radiation generators at lower and upper secondary educational institutions

§ 50. Use of radiation generators for teaching purposes must 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 6.

(2) Pupils must not operate hand-held radiation generators.

§ 51. The radiation generator must be equipped with a technical device to ensure that the radiation generator cannot deliver continuous exposure.

Supplementary requirements for manufacture, alteration and installation

§ 52. Throughout the process of manufacturing, altering and installing a radiation generator, all requirements applicable to use of the radiation generator in question must be complied with unless this is not feasible for process-related technical reasons.

§ 53. Upon completing the manufacture, alteration and installation of a radiation generator, the undertaking responsible for the respective process must ensure that the radiation generator is in a sound and technically satisfactory state and compliant with all the radiation safety provisions of this Executive Order and the Executive Order on Ionising Radiation and Radiation Protection and terms and conditions laid down by the Danish Health Authority before the radiation generator is put into use, whether by the undertaking or by others.

(2) Any undertaking responsible for any alteration must document the alteration carried out, and if the alteration was carried out on behalf of another undertaking, must issue that documentation to that undertaking.

§ 54. Category A exposed workers who perform tasks entailing the non-use of built-in safety devices or the removal of built-in shielding must wear a personal acoustic dose rate alarm unit.

(2) For work in locations where an acoustic dose rate

alarm would be difficult to hear, compensatory solutions must be employed, such as a vibrating dose rate alarm.

Chapter 7

Appeals and penalties

§ 55. 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.

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

- 1) contravening Section 3; Section 8(1); Section 9; Sections 14-18; Section 19(3) or (4); Section 21; Section 22(2); Section 24(1); Section 25; Sections 27-32; Section 34; Section 44, Sections 51-54; the provisions of Annex 7; cf. Section 35; the provisions of Annex 8; cf. Section 36; the provisions of Annex 9; cf. Section 37; the provisions of Annex 10; cf. Section 38; the provisions of Annex 11; cf. Section 43; the provisions of Annex 12; cf. Section 45; the provisions of Annex 13; cf. Section 46; the provisions of Annex 14; cf. Section 47; the provisions of Annex 15; cf. Section 48; or the provisions of Annex 16; cf. Section 49;
- 2) commencing use of radiation generators without a licence from, or without notification to, the Danish Health Authority; cf. Section 4 and Section 5 with reference to Section 7; or fails to observe any terms and conditions laid down by the Danish Health Authority in a licence or subsequent to a notification;
- 3) failing to ensure the inspection of any radiation generator, equipment or facility within the minimum intervals stipulated in Section 19(1), second sentence and (2), second sentence.
- 4) failing to ensure that no individual inadvertently incurs exposure from a radiation generator used by the undertaking, but which is left in an unsound or technically unsatisfactory state or fails to comply with the radiation safety provisions set out in Section 20 or meet any terms and conditions laid down by the Danish Health Authority.
- 5) permitting an individual who is not an exposed worker and who is not aged 18 years or over to assist in supporting an animal during a veterinary medical examination, cf. Section 40, or permits an individual to be present in a facility while veterinary medical treatment is taking place, cf. Section 41, or
- 6) permitting radiation generators to be used for teaching at lower and upper secondary educational institutions without having appointed a teacher as required by Section 50(1), first sentence.

(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) Companies and so on (legal persons) may be held criminally liable pursuant to the rules of Chapter 5 of the Danish Criminal Code.

Chapter 8

Entry into force and transitional provisions

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

(2) Executive Order No. 86 of 2 February 2018 on Use of Radiation Generators is hereby repealed.

§ 58. Any authorisation issued in accordance with rules laid down pursuant to the Act on Use of X-Rays, etc.; cf. Consolidation Act No. 1170 of 29 November 2011 shall retain its validity and, as of 6 February 2018, will be recognised as a licence. Any terms and conditions entailed by the authorisation will remain applicable until otherwise determined by the Danish Health Authority.

§ 59. An undertaking registered as the user of one or more radiological facilities or accelerators in accordance with rules laid down pursuant to the Act on Use of X-Rays, etc., cf. Consolidation Act No. 1170 of 29 November 2011, and which is subject to the licensing requirement of this Executive Order, will with effect from 6 February 2018 be registered by the Danish Health Authority as a licensee; cf., however (2) and (3). Any terms and conditions laid down by the Danish Health Authority for the registered use will remain applicable until otherwise determined by the Danish Health Authority.

(2) If such use pertains to a radiation generator subject to the notification requirement of this Executive Order, as of 6 February 2018 the registration will be recognised as

a notification. Any terms and conditions laid down by the Danish Health Authority for the registered use will remain applicable until otherwise determined by the Danish Health Authority.

(3) If such use pertains to a radiation generator subject to neither the licensing requirement nor the notification requirement of this Executive Order, the registration as a user will lapse as of 6 February 2018 and any terms and conditions attached to that registration, as laid down by the Danish Health Authority, will no longer be applicable.

§ 60. The requirement in Section 29(1) is applicable only to radiation generators mentioned in the provisions as being intended for use in planning, guiding and confirming procedures if those radiation generators were first marketed from 6 February 2018 onwards.

(2) The requirement in Section 29 (2) is applicable only to radiation generators installed from 6 February 2018 onwards.

§ 61. The requirements in Section 30 are applicable only to radiation generators first marketed 6 February 2018 onwards.

§ 62. Exposed workers authorised to perform examinations according to the provisions applicable to date in Executive Order No. 975 of 16 December 1998 by virtue of qualifications gained for operation of mammography equipment used in screening for breast cancer, cf. Guidance No. 71 of 4 October 2006, or nurse education followed by in-service training as a radiology nurse or other continuing education approved by the Danish Health Authority may continue to perform those examinations for which they were previously approved even though their education is not mentioned in Annex 6.

§ 63. For radiation generators installed before 6 February 2018, the requirements in Annex 7, Sections 1.2-1.4 shall not be applicable until 1 January 2023. In the period until that date, the image field diameter for these radiation generators must not exceed 60 mm instead of the image field size meeting the requirements of Annex 7, Section 1.5.2.

Danish Health Authority, 1 July 2019

SØREN BROSTRØM

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Annex 1

Use of radiation generators exempt from the licensing requirement but subject to the notification requirement

1. Radiation generators for medical application

- 1.1. Any use of radiation generators for intraoral radiography confined exclusively to the undertaking's own premises and operating with a voltage less than or equal to 70 kV. Any use of hand-held radiation generators is not, however, comprised by this exemption to the licensing requirement.
- 1.2. Any application of radiation generators for dental radiography by means of orthopantomographs and cephalostats confined exclusively to the undertaking's own premises.

2. Radiation generators for veterinary medical application

- 2.1. Any application of radiation generators for veterinary examinations confined exclusively to the undertaking's own premises. Any use of CT scanners, hand-held radiation generators and radiation generators for fluoroscopy is not, however, comprised by this exemption from the licensing requirement.
- 2.2. Technical safety inspections, except for control for compliance with operational limits and conditions, of radiation generators intended for intraoral radiography and operating with a voltage less than or equal to 70 kV.

3. Radiation generators for uses other than medical or veterinary medical application

- 3.1. Application and technical safety inspection of self-shielded radiation generators except for radiation generators for blood irradiation and sterilisation purposes.
- 3.2. Application and technical safety inspection of hand-held radiation generators.

Annex 2

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

The requirements listed for a specific use or application are cumulative.

1. Medical application

- Familiarity with the fundamental principles of ionising radiation and radiation protection.
- Education and extensive practical experience in the use of the specific types of radiation generators within the radiation protection officer's remit.

2. Veterinary medical application

2.1. Veterinary examinations

- Completion of a course in radiology as part of veterinary medical education or equivalent.
- Extensive practical experience of veterinary medical application of radiation generators.

3. Research and industrial applications

3.1. Cyclotrons for the production of radionuclides

- Training in radiation protection associated with operation of accelerators.
- Passed a course on unsealed radioactive sources which is approved by the Danish Health Authority.
- Extensive practical experience in operating cyclotrons.

3.2. Radiation sterilisation, etc. in industrial irradiation facilities

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

3.3. Industrial radiography

- Passed an examined course in radiation protection related to industrial radiography. This course must be approved by the Danish Health Authority.
- Extensive practical experience in industrial radiography using radiation generators inside and outside of facilities.

3.4. Hand-held radiation generators

- Training in the use of the specific types of radiation generators within the radiation protection officer's remit. The training must be provided by the manufacturer or other competent person familiar with the specific types of radiation generators.

3.5. Blood irradiation

- Course in the fundamentals of radiation protection which is approved by the Danish Health Authority.

4. Application in teaching

4.1. Teaching at lower and upper secondary educational institutions

- Education as a physics or chemistry teacher or the equivalent.
- Familiarity with the fundamental principles of ionising radiation and radiation protection.
- Full familiarity with relevant legislation on radiation protection.

5. Manufacture, installation, alteration and technical safety inspection, where the technical safety inspection is subject to requirements for special authorisation and acceptance and performance testing of radiation generators

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

- Training and extensive practical experience in the specific types of radiation generators within the radiation protection officer's remit. The training must be provided by the manufacturer or other competent person familiar with the specific types of radiation generators.
- Training or experience in measuring and assessing radiation fields and security measures for radiation protection for all individuals at the site.

Annex 3

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

Individuals who have completed one of the educations listed below immediately satisfy the requirements for the education of a medical physics expert for the specific application. Other educations will be subject to individual assessment by the Danish Health Authority. The requirements listed for a specific application or practice are cumulative.

- 1. Application of CBCT scanners in dental medical settings**
 - Medical physicist education within diagnostic radiology.
- 2. Application of radiographic devices in chiropractic settings and for general diagnostics at hospitals, etc.**
 - Medical physicist education within diagnostic radiology.
 - Extensive experience in operating radiographic devices.
- 3. Application of DXA scanners**
 - Medical physicist education.
- 4. Application of radiographic devices for CT scanning and interventional radiology**
 - Medical physicist education within diagnostic radiology.
 - Extensive experience in operating radiographic devices.
- 5. Application of radiographic devices for dermatologic therapy**
 - Medical physicist education.
 - Extensive experience in operating radiographic devices for dermatologic therapy.
- 6. Application of X-ray therapy apparatus**
 - Medical physicist education within oncology.
 - Extensive experience in operating X-ray therapy apparatus.
- 7. Application of electron and particle accelerators for radiotherapy**
 - Medical physicist education within oncology.
 - Expert approval from the Danish Society for Medical Physics.
 - Extensive experience of operating electron or particle accelerators.

Annex 4

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) Expertise in 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.
 - Selection and testing of measuring instruments.
 - Principles of quality management.
- 6) At least three years' practical experience following completion of their master's degree and gaining the above-mentioned knowledge and skills concerning the specific types of use and radiation sources for which approval as a radiation protection expert is being applied for.

Annex 5

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

A clinically responsible practitioner must possess sufficient education and experience in irradiation of individuals for diagnostic or therapeutic purposes, including 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 must moreover possess qualifications, either as part of their original education or subsequent education, within the following areas:

- Generation and detection of radiation.
- Dosimetry adapted to the area of application.
- Radiation biology.
- Radiation protection.

| Area of application | | Application | | Education |
|--|---------------------------|-------------|--|--|
| 1 | Dental | 1.1. | <i>Intraoral radiography</i> | • Dentist |
| | | | | • Dental hygienist |
| | | | | • Medical specialist in diagnostic radiology |
| | | 1.2. | <i>Radiography by means of orthopantomographs and cephalostats</i> | • Dentist |
| | | | | • Medical specialist in diagnostic radiology |
| | | 1.3. | <i>CBCT scanning</i> | • Dentist with recognised supplementary education |
| • Medical specialist in diagnostic radiology | | | | |
| 2 | Diagnostics and screening | 2.1. | <i>DXA scanning</i> | • Medical specialist in clinical physiology and nuclear medicine |
| | | | | • Medical specialist in diagnostic radiology |
| | | | | • Medical specialist within the relevant specialist field with supplementary education in radiation and radiation protection |
| | | 2.2. | <i>Chiropractic examinations</i> | • Chiropractor |
| | | 2.3. | <i>General diagnostics and CT scanning</i> | • Medical specialist in diagnostic radiology |

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|----|--------------------------------|------|---|--|
| | | 2.4. | <i>Examinations using hybrid scanners</i> | <ul style="list-style-type: none"> • Medical specialist in diagnostic radiology • Medical specialist in clinical physiology and nuclear medicine |
| 3. | Intervention | 3.1. | <i>All applications</i> | <ul style="list-style-type: none"> • Medical specialist in diagnostic radiology • Medical specialist within the relevant specialist field with supplementary education in radiation and radiation protection |
| 4. | Dosage planning | 4.1. | <i>Examinations in connection with radiotherapy and X-ray radiation therapy dosage planning</i> | <ul style="list-style-type: none"> • Medical specialist in diagnostic radiology • Medical specialist in clinical oncology |
| 5. | Dermatologic therapy | 5.1. | <i>All applications</i> | <ul style="list-style-type: none"> • Medical specialist in dermatology and venerology • Medical specialist in clinical oncology |
| 6. | X-ray radiation therapy | 6.1. | <i>All applications</i> | <ul style="list-style-type: none"> • Medical specialist in clinical oncology |
| 7. | Radiotherapy | 7.1. | <i>All applications</i> | <ul style="list-style-type: none"> • Medical specialist in clinical oncology |

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 13. Other educations will be assessed individually by the Danish Health Authority.

1. **Manufacture, alteration and installation and performance of acceptance and performance testing**

Individual workers must possess knowledge, skills and competences commensurate with the work to be performed as regards electrical installations and test measurement of exposure from radiation generators.

2. **Medical application**

2.1. *Intraoral radiography and radiography by means of orthopantomographs and cephalostats*

Individuals performing examinations must be educated as dentists, dental hygienists, radiology-trained dental nurses or as radiographers.

Trainees are permitted to perform examinations under the supervision of a qualified individual.

2.2. *Radiography by means of dental Cone Beam CT scanners*

An individual who performs examinations must be:

- qualified as a radiographer or
- qualified as a dentist, dental hygienist, radiology-trained dental nurse and must additionally have completed a practical course in CBCT dental radiology comprising the following elements:
 - Positioning of the examined person for various types of examinations.
 - Setting of exposure parameters.
 - Initial analysis of image quality.
 - Use of the associated software.

Trainees are permitted to perform examinations under the supervision of a qualified individual.

2.3. *DXA scanning*

An individual who performs examinations must:

- be qualified as a radiographer,
- be qualified as a medical laboratory technologist (Danish title: Bioanalytiker) and possess experience in performing nuclear medical examinations,
- be a qualified medical doctor with supplementary education in radiation and radiation protection or
- possess at least two years' relevant professional experience in the field of healthcare or through work with clients and have completed an approved DXA scanning education programme concluding with a proficiency test.

Trainees are permitted to perform examinations under the supervision of an individual with recognised education and experience.

2.4. *General diagnostics within chiropractic practice*

Individuals performing examinations must be qualified as a radiographer or chiropractor. Trainees are permitted to perform examinations under the supervision of a qualified individual.

2.5. *General diagnostics, CT scanning and interventional radiology at hospitals, etc.*

Individuals who perform examinations must either be qualified as radiographers or a medical specialists within the relevant specialist field with supplementary education in radiation and radiation protection and experience with relevant examinations or radiology-guided procedures. Trainees are permitted to perform examinations under the supervision of an individual with recognised education and experience.

2.6. *Hybrid scanners within nuclear medicine*

Individuals who perform examinations must either be qualified as a radiographer, a medical laboratory technologist at a department of nuclear medicine with supplementary education in CT scanning, or a medical specialist within the relevant specialist field, with supplementary education in radiation and radiation protection and experience with relevant examinations. Trainees are permitted to perform examinations under the supervision of an individual with recognised education and experience.

2.7. *Dermatologic therapy*

Individuals who perform treatment must possess experience in relevant therapies and be

- a radiographer
- a medical specialist in dermatology and venerology or
- a nurse trained in radiation and radiation protection.

Trainees are permitted to perform treatment under the supervision of an individual with recognised education and experience.

2.8. *X-ray radiation therapy*

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

Trainees are permitted to perform treatment under the supervision of a qualified individual.

2.9. *Treatment using electron and particle accelerators*

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

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

3. Veterinary medical application

Individuals performing veterinary medical examinations must be qualified as a veterinarian, veterinary nurse or possess equivalent radiographic competences.

4. Other applications

4.1. *Radiation sterilisation, etc. in industrial irradiation facilities*

Equipment operators must have completed a course for operators of industrial irradiation installations approved by the Danish Health Authority and a course in the fundamentals of radiation protection approved by the Danish Health Authority.

4.2. *Industrial radiography*

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

4.3. *Teaching at lower and upper secondary educational institutions*

Individuals who use radiation generators for teaching purposes at lower and upper secondary educational institutions must be qualified physics or chemistry teachers or the equivalent and possess fundamental knowledge of ionising radiation and radiation protection.

Special requirements for application of radiation generators for dental purposes

1. Radiographic devices for intraoral radiography

- 1.1. In rooms used for describing images, the lighting must be dimmable to a suitably low level for all details in the image to be clearly apparent.
- 1.2. The nominal tube voltage of radiographic devices must be minimum 60 kV and maximum 70 kV.
- 1.3. Radiographic devices must be equipped with a tube-head so that the distance from the X-ray tube focus to the end of the tube-head is at least 20 cm.
- 1.4. Radiographic devices must be equipped with collimation so that the radiation field's shape and size at the end of the tube-head matches the largest of the image receivers which are routinely in clinical use, but maximum 40 mm · 50 mm.
- 1.5. Operational limits and conditions:
 - 1.5.1. High voltage: The actual tube voltage must not deviate by more than 10% from the nominal tube voltage.
 - 1.5.2. Field size: The size of the image field must not exceed 40 mm · 50 mm.
 - 1.5.3. Dose reproducibility: The scattering must not exceed 20% of the average dose measured on the basis of a minimum of 3 measurements.
 - 1.5.4. Dose linearity: Must be better than 10% when measured across four mAs values distributed equally over the applied interval of exposure times.
The tolerance is compliant when the dose linearity conforms to the following expression:

$$\frac{X_{\max} - X_{\min}}{X_{\max} + X_{\min}} \leq 0.10$$

Where $X_{\max} = \left(\frac{D}{mAs}\right)_{\max}$ is the greatest ratio of all measurements between dose, D , and associated mAs value, mAs , and $X_{\min} = \left(\frac{D}{mAs}\right)_{\min}$ is the smallest ratio of all measurements between dose, D , and associated mAs value, mAs .

2. Orthopantomographs, cephalostats and Cone Beam CT scanners

- 2.1. When light field indication of the radiation field is employed, the light field indication must be visible on the examined person, if necessary, by dimming the ambient lighting.
- 2.2. In rooms used for describing images, the lighting must be dimmable to a suitably low level for all details in the image to be clearly apparent.
- 2.3. Operational limits and conditions:
 - 2.3.1. High voltage: The actual tube voltage must not deviate by more than 10% from the nominal tube voltage.
 - 2.3.2. Dose reproducibility: The standard deviation must not exceed 10% of the average dose measured on the basis of a minimum of 3 measurements.
 - 2.3.3. Dose linearity: Must be better than 10% when measured across four mAs values distributed equally over the applied interval of exposure times.
The tolerance is compliant when the dose linearity conforms to the following expression:

$$\frac{X_{\max} - X_{\min}}{X_{\max} + X_{\min}} \leq 0.10$$

Where $X_{\max} = \left(\frac{D}{mAs}\right)_{\max}$ is the greatest ratio of all measurements between dose, D , and associated mAs value, mAs , and $X_{\min} = \left(\frac{D}{mAs}\right)_{\min}$ is the smallest ratio of all measurements between dose, D , and associated mAs value, mAs .

Special requirements for application of radiation generators for other examinations

The requirements below apply to any application of radiation generators for examinations other than for dental purposes.

1. General requirements

- 1.1. The following must be accessible for each radiographic device:
 - 1.1.1. The requisite ancillary appliances for supporting the examined person during the examination.
 - 1.1.2. The requisite number of lead aprons and lead gloves for those workers, carers and comforters who might be expected to be present in the room during the examination.
 - 1.1.2.1. Lead aprons must have a primary lead equivalent of at least 0.35 mm, though at least 0.25 mm if the maximum tube voltage is less than or equal to 110 kV.
 - 1.1.2.2. Lead gloves must have a lead equivalent of at least 0.25 mm.
- 1.2. The lighting in the room must be dimmable to a suitably low level to ensure that:
 - 1.2.1. light field indication is visible on the examined person, and
 - 1.2.2. fluoroscopic images are clearly apparent.
- 1.3. In rooms used for describing images, the lighting must be dimmable to a suitably low level for all details in the image to be clearly apparent.

2. Supplementary requirements for applications outside of facilities

- 2.1. For radiography outside of facilities, workers, carers, comforters and members of the public must observe a distance of at least 5 metres from the examined person. If individuals who are necessary for the performance of the examination need to be in closer proximity, they must wear lead aprons.

Annex 9

Special requirements for application of radiation generators for dermatologic therapy and X-ray radiation therapy

1. For dermatologic therapy using energies less than or equal to 15 kV, the individual performing the treatment must perform extra verification of the positioning, ancillary appliances and treatment parameters prior to each treatment fraction.
2. For dermatologic therapy using energies greater than 15 kV and for X-ray radiation therapy, independent verification must be performed of the positioning, ancillary appliances and treatment parameters prior to each treatment fraction.
3. For dermatologic therapy and X-ray radiation therapy, the individual performing the treatment must remain in place at the control console and monitor the procedure for the duration of the treatment fraction.

Special requirements for application of radiation generators for radiotherapy

1. General requirements

- 1.1. Radiation generators for radiotherapy operating at nominal energies exceeding 1 MeV must be equipped with a verification system.
- 1.2. The transfer of treatment data must be performed electronically.
- 1.3. Each treatment is subject to the following requirements:
 - 1.3.1. Two individuals possessing recognised competence in radiotherapy must be present; cf. Annex 6, Section 2.9. These individuals shall approve the final positioning of the patient and treatment parameters or supervise trainees in performance of these tasks.
 - 1.3.2. A head of department in consultation with the medical physics expert may, on a case-by-case basis, grant approval for one of the two individuals who approves the final positioning of the patient and the treatment parameters to be a trainee if the competences yet to be attained are of no consequence for performance of the task.
 - 1.3.3. One of the above-mentioned individuals with recognised competence in radiotherapy shall remain at the control console and monitor the procedure. The other individual shall remain in immediate proximity during the treatment fraction.
 - 1.3.4. At least one individual qualified as a medical physicist within oncology must be immediately available to the department. A head of department in consultation with the medical physics expert may, on a case-by-case basis, grant approval for this individual to be a trainee medical physicist if the competences yet to be attained are of no consequence for performance of the task.

2. Requirements for facilities

- 2.1. Access to the facility must be secured in such a way that irradiation is suspended in the event of intrusion in the facility during the exposure. Recoupling must solely be possible from the place of operation.
- 2.2. Entrances to the facility must be installed with a red warning light which is lit constantly or flashes while exposure is in progress. A warning sign must be mounted next to this light, bearing the symbol for ionising radiation and the Danish text: "STRÅLING NÅR LAMPEN LYSER" (RADIATION WHEN LIGHT IS ON) or the like.
- 2.3. The facility must be effectively secured against unintended presence, for example by requiring the operator of the facility to activate a last-man-out switch located in the facility, so that it is easy to see that no one is unintentionally present.
- 2.4. Individuals accidentally present in the facility while it is in operation must have a means of exiting the room or of stopping the exposure by means of a clearly designated emergency stop switch.

Special requirements for application of radiation generators for veterinary medical examinations

1. Intraoral radiography

- 1.1. For above-table tube positioning, it must be ensured that the lower extremities of staff are prevented from entering the radiation field behind the image acquisition system. If this is ensured by mounting a shield behind the image acquisition system, the shield must have a lead equivalent of 0.5 mm.
- 1.2. Individuals must only be present in the area exposed solely to scattered radiation and not to the primary beam. The distance from the primary beam must be at least two metres unless closer proximity is required for performing the examination.
- 1.3. If proximity less than two metres from the animal is routinely required for performing the examination, lead aprons must be available.

2. Other veterinary medical examinations

- 2.1. The following must be accessible for each radiographic device:
 - 2.1.1. The requisite ancillary appliances for supporting the animal during the examination.
 - 2.1.2. The requisite number of lead aprons and lead gloves for those individuals who might be expected to be present in the room during the examination.
 - 2.1.2.1. Lead gloves must have a lead equivalent of at least 0.25 mm.
 - 2.1.2.2. Lead aprons must have a primary lead equivalent of at least 0.35 mm, though at least 0.25 mm if the maximum tube voltage is less than or equal to 110 kV.
- 2.2. If an individual who is not an exposed worker assists in supporting an animal during a veterinary medical exposure, that individual must receive detailed instructions.
- 2.3. For above-table tube positioning, it must be ensured that the lower extremities of staff are prevented from entering the radiation field behind the image acquisition system. This is ensured either by mounting a shield with a lead equivalent of at least 2 m behind the image acquisition system or by means of enclosed positioning of the animal which surrounds the entire field regardless of field size.

3. Supplementary requirements for applications for examinations outside of facilities

- 3.1. The application of radiographic devices outside of facilities must take place only if merited by the animal's size or other factors.
- 3.2. Individuals must not be present in the primary beam within a distance of 30 metres. The area where individuals are not permitted to be present must be sealed off.
- 3.3. Individuals must only be present in the area exposed solely to scattered radiation and not to the primary beam. The distance from the animal must be at least 5 metres. If individuals who are necessary for the performance of the examination need to be in closer proximity, they must wear lead aprons.
- 3.4. Cassettes may be held only by individuals if it is not feasible to use a fastened cassette holder. The cassette must then be equipped with a handle of sufficient length to prevent the individual from being exposed to the primary beam.

4. Operational limits and conditions

- 4.1. High voltage: The actual tube voltage must not deviate by more than 10% from the nominal tube voltage.
- 4.2. Exposure time: The actual exposure time must not deviate by more than 20% from the nominal exposure time.
- 4.3. Total filtration: The total filtration of the X-ray tube must be at least 2 mm aluminium for tube voltages of up to 100 kV and 3 mm aluminium for tube voltages exceeding 100 kV.

Special requirements for the technical design of self-shielded radiation generators for industrial and research applications

1. General requirements

- 1.1. A self-shielded radiation generator must be equipped with built-in shielding to ensure that the dose rate at all accessible external surfaces of the radiation generator does not exceed 5 $\mu\text{Sv/h}$.
- 1.2. The radiation generator must thus be designed so that exposure can only be delivered when all parts of the radiation shielding are correctly assembled and in the shielding position.
- 1.3. If exposure is stopped by opening the radiation generator's shielding, recoupling must not commence automatically upon the closure of this shielding, but only by means of reactivation from the location from which the radiation generator is operated.
- 1.4. The function of interlock switches, to secure the position of the shielding during exposure, must be secured against any fault in the switch and incorrect operation, for instance by means of applying two redundant interlock switches.
- 1.5. At least one exposure indicator must be present and visible from the location from which the radiation generator is operated.
- 1.6. If the radiation generator only has a single exposure indicator, this must be secured against faults so that the radiation generator is only able to deliver exposure when the exposure indicator is functioning correctly. Alternatively, the radiation generator must be equipped with at least two exposure indicators, and it must not be possible for these indicators to fail as a consequence of a single fault.
- 1.7. Exposure indicators must be accompanied by a sign stating the meaning of the signal.
- 1.8. Radiation generators must be of such design and size so as to ensure that no-one is present inside the shielding during exposure. Where this is not the case, the requirements for work inside installations, cf. Annex 15, shall apply.
- 1.9. Radiation generators must be accompanied by a concise user manual.

2. Supplementary requirements for self-shielded radiation generators with a permanent opening

- 2.1. If a self-shielded radiation generator has a permanent opening, which for example, constitutes a tunnel through which examined subjects pass, the radiation generator must have an emergency stop switch.
- 2.2. Radiation generators for baggage scanning must only deliver radiation while scanning is in progress, which may be ensured by, for example, activation by means of a photocell.
- 2.3. Radiation generators connected to production lines must disconnect automatically in the event of a prolonged production stoppage. Alternatively, it must be ensured that the primary beam is inaccessible to anyone.
- 2.4. At least one exposure indicator must be visible from each opening.

Annex 13

Special requirements for the technical design of hand-held radiation generators for industrial and research applications

1. Radiation generators must be designed so as to be straightforward to operate in a prudent manner from a safety point of view.
2. It must be possible to operate the radiation generator while limiting the effective dose to the operator to no more than 1 mSv/year or an equivalent dose to the skin or extremities not greater than 50 mSv/year.
3. Any leakage radiation from the radiation generator must not exceed 5 μ Sv/h at its surface.
4. The radiation generator must bear a symbol for ionising radiation.
5. The radiation generator must be fitted with a readily visible exposure indicator.
6. Application of a radiation generator must be enabled only by means of a key, code or equivalent security measures.
7. Exposure must be possible only when an object is present immediately in front of the radiation window.
8. Radiation generators must be equipped with a dead-man's switch.
9. The radiation generator must be accompanied by a user manual containing a warning about harmful effects of radiation, information about who is permitted to use the radiation generator and the name and contact details of the radiation protection officer. The user manual must be concise and must be available at the radiation generator.

Annex 14

Special requirements for the technical design of radiation generators for industrial radiography

1. The X-ray tube must either be connected to a timer which controls the exposure time or to a manually activated switch which permits exposure only while the switch is activated.
2. The X-ray tube must be shielded in such a way that the leakage radiation when the window is closed and during peak load is unable to exceed the following dose rates at a distance of 1 m from the focus:
 - 2.1. 1 mSv/h for pre-set voltages less than or equal to 150 kV.
 - 2.2. 2.5 mSv/h for pre-set voltages greater than 150 kV and less than or equal to 200 kV.
 - 2.3. 5 mSv/h for pre-set voltages greater than 200 kV.
3. The X-ray tube must be equipped with inherent filtration corresponding, as a minimum, to the following values:
 - 3.1. 2.0 mm aluminium for a maximum voltage greater than 50 kV and less than or equal to 100 kV.
 - 3.2. 3.0 mm aluminium for a maximum voltage greater than 100 kV and less than or equal to 200 kV.
 - 3.3. 4.0 mm aluminium for a maximum voltage greater than 200 kV and less than or equal to 300 kV.
 - 3.4. 0.5 mm copper for a maximum voltage greater than 300 kV.
4. X-ray tubes with less inherent filtration than specified above must at all times be accompanied by extra filtration, which must be used unless the radiographic testing technique requires lower filtration.
5. X-ray tubes with less inherent filtration than the equivalent of 1 mm aluminium must be mounted with a warning sign bearing the following Danish text: "ADVARSEL: FARLIG STRÅLING MED HØJ DOSISHASTIGHED. KAN FORÅRSAGE STRÅLEFORBRÆNDING PÅ FÅ SEKUNDER" (CAUTION: HAZARDOUS HIGH DOSE RATE RADIATION. CAPABLE OF CAUSING RADIATION BURNS WITHIN SECONDS).
6. The X-ray tube must be equipped with a red warning light which is lit constantly or flashes while exposure is in progress.
7. The control console must be equipped with a red light which is lit constantly or flashes while exposure is in progress and also a green light which lights when the exposure is interrupted.
8. The exposure function must be restricted by means of a locking device or the like to permit the exposure function to be blocked.
9. The control console must be furnished with a concise user manual.
10. The radiation generator must be marked with these specifications: Model, serial number, maximum tube voltage, maximum tube current, position of the focus, opening angle and inherent filtration.
11. On industrial panoramic X-ray apparatus, the belt-shaped area through which the direct beam is emitted must be clearly indicated.

Special requirements for industrial and research application of radiation generators inside facilities, including supplementary requirements for industrial radiography inside facilities

1. General requirements

- 1.1. Access to the facility must be secured in such a way that radiation is suspended automatically in the event of intrusion in the facility during the exposure. Recoupling must solely be possible from the place of operation.
- 1.2. Entrances to the facility must be installed with a red warning light, which is lit constantly or flashes while exposure is in progress. A warning sign must be mounted next to this light, bearing the symbol for ionising radiation and the Danish text "STRÅLING NÅR LAMPEN LYSER" (RADIATION WHEN LIGHT IS ON) or the like. If relevant, a warning light with an accompanying text must likewise be present inside the facility.
- 1.3. If relevant, the facility must be secured against unintended presence, for example by requiring the operator of the facility to activate a last man out switch located in the facility, so that prior to activating the switch, it is easy to see that no one is unintentionally present.
- 1.4. Individuals accidentally present in the facility during an exposure must have a means of exiting the room or of stopping the exposure by means of a clearly designated emergency stop switch.

2. Supplementary requirements for industrial radiography inside facilities

- 2.1. X-ray tubes and ancillary equipment for industrial radiography application inside facilities must meet the requirements of Annex 14.
- 2.2. For industrial radiography facilities it is generally sufficient to place a red warning light inside the facility, which is lit constantly or flashes while exposure is in progress. A warning sign must be mounted next to this light, bearing the symbol for ionising radiation and the Danish text "STRÅLING NÅR LAMPEN LYSER" (RADIATION WHEN LIGHT IS ON) or the like.
- 2.3. The requirement for the irradiation to be suspended automatically in the event of intrusion in the facility during the exposure may be replaced by the following requirements:
The facility must have a permanently mounted dose rate meter which activates an acoustic alarm in response to intrusion in the facility while exposure is in progress, and the main entrance to the facility must be equipped with a red warning light, which is lit constantly or flashes while exposure is in progress.
- 2.4. All shielding surfaces must be clearly marked with specification of the shielding material and the thickness of the shielding.
- 2.5. If not all shielding components of the facility provide adequate shielding as required in accordance with Section 21 and Section 22 in the Executive Order on Ionising Radiation and Radiation Protection, an approved beam direction must be defined. The approved beam direction must be specified clearly in the facility with marked zones and the text: "TILLADT STRÅLEFELT" (PERMISSIBLE RADIATION FIELD).
- 2.6. At the main entrance to the facility a notice must state the restrictions that apply to use of the facility concerning the types of radiation sources, energies, exposure direction and other relevant restrictions. The name and contact details of the radiation protection officer must also be stated.

Annex 16

Special requirements for application of radiation generators for industrial radiography outside facilities

1. X-ray tubes for industrial radiography application outside of facilities must meet the requirements of Annex 14.
2. A clearly visible red warning light must be available for setting up, and it must be connected to the control console and be lit while exposure is in progress.
3. The following equipment for use when appropriate must be available at all times:
 - 3.1. Measuring instrument for control of dose rates.
 - 3.2. Personal acoustic dose rate alarm to be worn by each individual participating in the work.
 - 3.3. Shutter with slit aperture for reducing the radiation field.
 - 3.4. Two shields with a lead equivalent of at least 2.0 mm for a maximum voltage less than or equal to 200 kV, and 3.0 mm for a maximum voltage greater than 200 kV and less than or equal to 300 kV. The thickness of the shielding must be clearly marked on the shield.
 - 3.5. Abundant barrier equipment in yellow bearing the symbol for ionising radiation and an easily comprehensible warning notice.
4. During testing and pre-heating, a shutter must be used for screening off the X-ray window attenuating the primary beam. For panoramic X-ray devices, a belt-shutter must be used. For requirements for the shielding effect, please refer to Annex 14, Section 2.
5. A tube-head and added filtration must be employed where relevant.
6. The cable connecting the X-ray tube and the control console must be of such a length (normally at least 20 m) to permit the console to be positioned where the dose rate is less than 20 $\mu\text{Sv/h}$.
7. Around the radiation source, an area must be delimited within which any human presence is prohibited during exposure, testing and pre-heating. Outside of this zone, the dose rate must not exceed 60 $\mu\text{Sv/h}$. At the place of the console, the dose rate should not exceed 20 $\mu\text{Sv/h}$. At workplaces for individuals who are not involved in radiography work, the dose rate must not exceed 7.5 $\mu\text{Sv/h}$. As far as possible it must be prevented that unauthorised persons occupy areas subject to dose rates greater than 7.5 $\mu\text{Sv/h}$.
8. The area with dose rates exceeding 60 $\mu\text{Sv/h}$ must be kept under continuous surveillance during exposure, testing and pre-heating and must be cordoned off or otherwise access-controlled.
9. If it is not possible from the place of operation to survey the entire area mentioned in Section 8, special safety precautions must be established to prevent access during exposure, testing and pre-heating.
10. After exposure, a verification measurement must be made to ensure that the exposure has stopped before access is granted to the area specified in Section 8.
11. The radiation field must be restricted to the size necessary for the procedure by means of a shutter with slit aperture or a tube-head. When a panoramic X-ray apparatus is used as a directional beam source, the x-ray window must be equipped with a mask to screen off the part of the window that is not to be used.
12. For work in locations where an acoustic dose rate alarm would be difficult to hear, compensatory solutions must be employed, such as a vibrating dose rate alarm.
13. The undertaking must notify the Danish Health Authority of any location where more than 200 exposures are performed per month outside of facilities. The Danish Health Authority must be notified as soon as possible and, if possible, before work commences.