ACT No. 23 of 15/01/2018
Ministry of Health

Act on Ionising Radiation and Radiation Protection (The Radiation Protection Act)[1)]

WE MARGRETHE THE SECOND, by the Grace of God Queen of Denmark, do hereby make known that:

The Danish Parliament has passed and We have granted Our Royal Assent to the following Act:

Chapter 1

Introductory Provisions and Definitions

§ 1. The present Act is applicable to the use of radiation sources and exposure in any exposure situation; cf. however (2)-(5).

(2) Radioactive substances naturally occurring in the human body are exempt from the Act.

(3) Exposure to natural radiation is exempt from the Act.

(4) The Danish Health Authority may lay down rules for the provisions of the Act to be applicable, notwithstanding (3), to exposure to natural radiation in controllable situations which cannot be disregarded from a radiation protection point of view.

(5) The Danish Health Authority may lay down rules for the use of radiation sources and exposure to be exempted in whole or in part from the provisions of the Act when deemed appropriate from the point of view of radiation protection.

§ 2. Those bound by the rules of this Act, or rules pursuant thereto, are

1) the owner, lessee, leaser or borrower or whomsoever else holds right of use of a radioactive substance or is responsible for an area exposed to ionising radiation,
2) the person responsible for use of a radiation source, and
3) the undertaking that allows its workers to engage in the use of radiation sources or allows its workers to be exposed to ionising radiation.

(2) The Danish Health Authority may lay down rules for the allocation of responsibility between the parties designated in (1).

§ 3. In the present Act, the following definitions shall apply:

1) Worker: Any person who, regardless of any underlying contractual relationship, is engaged in a worker-like relation.
2) Use:
   a) Manufacture, processing, holding, import, export, transfer, handling, application, control, technical safety inspection, storage, disposal, recycling, reuse, discharge and transport of radioactive substances.
   b) The manufacture of radiation generators, in the process of which ionising radiation is generated, and the modification of radiation generators with implications from the point of view of radiation protection, and the installation, application, control and technical safety inspection of radiation generators.
3) Ionising radiation: Particles, including photons, capable of causing ionisation in substances directly or indirectly, but in the case of electromagnetic radiation only of a wavelength of 100 nm or less.
4) Quality assurance: All planned and systematic actions, including quality control, necessary to provide adequate assurance that a radiation source, an installation, equipment, a system or component or procedure will perform satisfactorily in compliance with agreed standards.
5) Medical exposure: Exposure incurred by patients or asymptomatic individuals as part of their own medical or dental diagnosis or treatment, and intended to benefit their health, as well as exposure incurred by carers and comforters and by volunteers in medical or biomedical research.

[1] This Act 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.

6) Natural radiation: Cosmic radiation and ionising radiation from naturally occurring radioactive materials unaffected by human activity.
7) Radioactive substance: A substance containing one or more radionuclides.
8) Radiation source: A radioactive substance or a radiation generator.
9) Exposure: Exposure to ionising radiation.
10) Radiation generator: A device capable of generating ionising radiation.
11) Unintended exposure: Exposure that significantly exceeds that incurred by persons and the environment through correct use of radiation sources, and medical exposure that is significantly different from the medical exposure intended for a given purpose.

Chapter 2

Justification, Optimisation and Dose Limitation

§ 4. The use of radiation sources and exposure shall take place solely if the health, financial, societal or other benefits of that use or exposure outweigh any detriment (justification).

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including that certain types of use or exposure are not justified, regarding assessment of the justification and regarding the considerations to include in the assessment.

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

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including as regards the compilation of safety assessments, regarding methods for ensuring optimisation in specific exposure situations and regarding the use of dose constraints and reference levels.

§ 6. The sum of doses to an individual shall not exceed the dose limits (dose limitation). Dose limits shall not apply to medical exposures.

(2) The Danish Health Authority lays down the dose limits and the rules regarding their applicability.

Chapter 3

Radiation Protection Measures, etc.

§ 7. The use of radiation sources and exposure shall be subject to the use of arrangements for protection against ionising radiation, including prevention of emergencies, accidents and incidents and remediation of the consequences hereof. Sufficient resources shall be assigned for radiation protection arrangements, for their implementation and ongoing evaluation to ensure that the radiation protection is effective and appropriate, and to ensure the identification and remediation of any defect or deficiency as well as the prevention of recurrence.

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including requirements regarding the use of radiation sources, including radiological monitoring, classification of workplaces, emergency procedures, quality assurance and categorisation of exposed workers.

§ 8. Radiation sources, facilities and equipment shall be constructed, organised, maintained, marked and kept secure in such a way that the likelihood and magnitude of exposure is as low as reasonably achievable.

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including requirements regarding radiation sources, facilities and equipment for protection, technical safety inspections and control.

§ 9. All relevant workers shall be informed of the risks associated with the use of radiation sources and exposure.

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including as regards which workers are comprised by the rules.

§ 10. All relevant workers shall be trained for, and instructed in, performing work in a manner appropriate from the point of view of radiation protection, and it shall be ensured that their competences are maintained and updated including relevant new knowledge, etc.

(2) The Danish Health Authority may lay down detailed rules regarding matters pursuant to (1), including the scope of worker instruction, knowledge, skills and competences.

Chapter 4

Radiation Protection Officers, Radiation Protection Experts and Medical Physics Experts

§ 11. The Danish Health Authority may lay down rules regarding the use, recognition and authorisation of radiation protection officers, radiation protection experts and medical physics experts.

(2) The Danish Health Authority may lay down rules regarding the remits and duties of radiation protection officers, radiation protection experts and medical physics experts.

(3) The Danish Health Authority may approve the education and training of radiation protection officers and radiation protection experts.

Chapter 5

Monitoring and Dosimetry Services

§ 12. The Danish Health Authority may lay down rules regarding dosimetric monitoring of workers, including the determination, evaluation and recording of doses and the approval of such dosimetry services.

(2) The Danish Health Authority keeps a register of doses to workers.

§ 13. The Danish Health Authority may lay down rules regarding the approval of dosimetry services rendered in relation to radiation protection.

Chapter 6

Emergencies, Accidents and Incidents

§ 14. The Danish Health Authority shall be notified immediately of emergencies, accidents or incidents that have resulted in, and of incidents that could have resulted in, unintended exposure to any type of radiation source or resulted in significant contamination with radioactive substances, and of any discovery, theft, loss, fire, flooding, etc. of significance from the point of view of radiation protection.

(2) The Danish Health Authority shall be notified concerning any circumstances that are systematic in nature, which might result in unintended exposure or significant contamination with radioactive substances.

(3) The Danish Health Authority may lay down detailed rules regarding notification pursuant to (1) and (2).

Chapter 7

Licensing, Notification, Clearance, Inspection, etc.

§ 15. The Danish Health Authority may lay down rules regarding licensing for, and notification of, the use of radiation sources or exposure.

§ 16. The Danish Health Authority may lay down rules regarding the clearance of radioactive substances, objects, sites and buildings.

§ 17. The Danish Health Authority may lay down conditions for approval, licensing or notification in accordance with the present Act or rules pursuant thereto.

§ 18. The Danish Health Authority conducts inspections of the use of radiation sources and exposure. The Danish Health Authority conducts its inspections commensurately with continuous assessment of the likelihood and impact of exposure.

(2) The Danish Health Authority may at any time, and without a court order, by presenting requisite proof of identity, demand from the party bound by Section 2 access to radiation sources, facilities, equipment, registers, protocols, security and emergency response plans, quality assurance systems and associated documentation, including documentation in the form of medical therapeutic data and the results of investigations, etc., and carry out photographic

or other documenting actions on site. The Danish Health Authority may as part of its inspection demand the disclosure of pertinent information and material of any nature; cf. the first sentence, by persons bound to do so by Section 2.

(3) The Police will provide requisite assistance in the exercise of the powers ensuing from (2), first sentence. Detailed rules for this assistance may be laid down by the Minister for Health following negotiations with the Minister for Justice.

§ 19. The Danish Health Authority may prohibit the use of radiation sources or exposure in contravention of the Act or rules or decisions pursuant thereto or order any such contraventions to be brought in order immediately or by a specified time limit.

§ 20. The Danish Health Authority may revoke a licence or amend the terms of a licence for the use of radiation sources or exposure if the use of radiation sources or the exposure are deemed not to be justified or optimised from the point of view of radiation protection on the basis of technological advances or new knowledge.

§ 21. The Danish Health Authority may require any party bound by Section 2 to carry out urgent actions, which the Danish Health Authority deems necessary to ensure radiation protection at that party's expense and risk.

§ 22. The Danish Health Authority compiles and publishes the main results of inspection programmes and inspection activities.

Chapter 8

The Danish Health Authority's independence

§ 23. The Danish Health Authority exercises its functions under this Act with full professional independence.

Chapter 9

Fees

§ 24. The Minister for Health may lay down rules regarding fees payable for the Danish Health Authority's inspection, advisory and assistance duties in accordance with the present Act or rules pursuant thereto.

Chapter 10

Appeals and Penalties

§ 25. Appeals against decisions made by the Danish Health Authority pursuant to the present Act or rules pursuant thereto may be lodged solely with the Minister for Health if the appeal pertains to legal matters.

§ 26. Except where other legislation carries a higher penalty, any contravention of Section 14, (1) or (2), or failure to respect a prohibition or order issued pursuant to Section 19 shall be punishable by a fine or by imprisonment for any term not exceeding one year. In particularly aggravating circumstances, the penalty may be increased to imprisonment for any term not exceeding two years.

(2) In sentencing pursuant to (1), the following shall be considered particularly aggravating circumstances:

1) that the offending party or others gained or intended to gain financial advantage by the contravention, or
2) that the contravention was committed out of wilful misconduct or gross negligence.

(3) Rules issued pursuant to this Act may stipulate liability for fine or imprisonment for contravention of the provisions or for contravention of terms, prohibitions or orders issued in accordance with the rules.

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

Chapter 11

Entry into Force, etc.

§ 27. The Act enters into force on 6 February 2018.

(2) The Act on the Use of X-rays, etc.; cf. Consolidation Act No. 1170 of 29 November 2011, and Act No. 94 of 31 March 1953 on Use, etc. of Radioactive Substances are hereby repealed.

(3) Rules laid down in pursuance of the acts cited in (2) shall remain in force until they are superseded or repealed by rules laid down pursuant to the present Act. Contravention of the regulations shall be punishable in accordance with the hitherto applicable rules.

§ 28. This Act does not extend to the Faroe Islands or Greenland except that the provisions hereof may be brought into force by an Order in Council for the Faroe Islands, subject to such amendments as are necessitated by the specific conditions prevailing in the Faroe Islands.

Given at Amalienborg Palace, 15 January 2018

Under Our Royal Hand and Seal

MARGRETHE R.

/ Minister for Health Ellen Trane Nørby