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Translation provided by Paul Skidmore and the Language Services of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection.  
Stand: Lungenkrebs-Früherkennungs-Verordnung vom 15. Mai 2024 (BGBl. 2024 I Nr. 162)  
Version information: Ordinance on the Permissibility of Using Low-Dose Computed Tomography for the Lung Cancer Screening of Smokers of 15 May 2024 (Federal Law Gazette 2024 I No. 162)

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## **Ordinance on the Permissibility of Using Low-Dose Computed Tomography for the Lung Cancer Screening of Smokers<sup>12</sup>**

### **(Lungenkrebs-Früherkennungs-Verordnung – LuKrFrühErkV)**

Ordinance on the Permissibility of Using Low-Dose Computed Tomography for the Lung Cancer Screening of Smokers in the version of 15 May 2024 (Federal Law Gazette 2024 I No. 162)

**Footnote 1:** This Ordinance transposes Article 55(2)(f) and (h) 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 (OJ L 13, 17.1.2014, p. 1).

**Footnote 2:** This is a translation of the Verordnung über die Zulässigkeit der Anwendung der Niedrigdosis-Computertomographie zur Früherkennung von Lungenkrebs bei rauchenden Personen (Lungenkrebs-Früherkennungs-Verordnung – LuKrFrühErkV) (BGBl. I 2024 Nr. 162). This is not an official translation. It is for informational purposes only.

On the basis of section 84 (2) of the Radiation Protection Act (*Strahlenschutzgesetz*), as last amended by Article 248 no. 1 of the Eleventh Competence Adjustment Ordinance (*Elfte Zuständigkeitsanpassungsverordnung*) of 19 June 2020 (Federal Law Gazette I, p. 1328), in conjunction with section 1 (2) of the Competence Adjustment Act (*Zuständigkeitsanpassungsgesetz*) of 16 August 2002 (Federal Law Gazette I, p. 3165) and the organisational decree of the Federal Chancellor of 8 December 2021 (Federal Law Gazette I, p. 5176), the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection orders as follows:

#### **Section 1 Definitions**

(1) 'Low-dose computed tomography' means a computed tomography of the thorax in which, in order to achieve the image quality required for lung cancer screening,

1. a volume computed tomography dose index of 1.3 milligrays is not exceeded or
2. a volume computed tomography dose index greater than 1.3 milligrays is necessary in the individual case due to the physical build of the person to be examined.

The volume computed tomography dose index of the associated localiser radiograph is not included in the volume computed tomography dose index of the low-dose computed tomography.

(2) 'Packet year' means the unit in which cigarette consumption is stated. To determine cigarette consumption in packet years, for each year of cigarette consumption the average number of cigarettes smoked per day in that year is divided by 20. The results for the individual years calculated in accordance with sentence 2 are totalled. Cigarette consumption before a complete break from smoking is to be included only if the complete break amounts to less than 10 years.

(3) 'Software for computer-assisted detection' means a computer program which assists medical doctors in the diagnostic review of computed tomography scans by analysing the digital image data.

(4) 'A result in need of monitoring' means a result in relation to an asymptomatic individual within the meaning of section 5 (16) of the Radiation Protection Act on the basis of which a further lung cancer screening examination within 12 months is medically indicated without any concrete suspicion of disease existing.

'(5) A result in need of diagnosis' means a result suggesting a lung carcinoma to such a strong degree that a concrete suspicion of disease exists and a prompt clinical diagnosis is called for.

## **Section 2**

### **Permissibility of lung cancer screening examinations**

(1) Lung cancer screening examinations using low-dose computed tomography are permitted in the case of persons

1. who have completed their 50<sup>th</sup> but not their 76<sup>th</sup> year of life,
2. whose last lung examination using computed tomography which was appropriate in qualitative terms for a diagnostic review in relation to a lung carcinoma took place at least 12 months ago,
3. who are in possession of a report from a person fulfilling the requirements of section 6 (3) from which the following is apparent:
  - a) cigarette consumption
    - aa) for a period of at least 25 years, calculated on the basis that the years before a complete break from smoking and the years of the complete break itself are only included if the break amounts to less than 10 years, and
    - bb) of at least 15 packet years and
  - b) a medical suitability profile of the person to be examined and the relevant anamnestic data and
4. who have been informed by a person fulfilling the requirements of section 6 (3) in an oral consultation and through the provision of information in text form of the following:
  - a) the benefits of the lung cancer screening examination,
  - b) the possibility that the lung cancer screening examination may produce false positive and false negative results and the possible consequences of this,
  - c) the subsequent diagnostic procedure in the event of a result in need of diagnosis, in particular of the risks and burdens of the diagnostic examinations and
  - d) the risk of overdiagnosis and overtreatment.

The information in text form must also draw attention to the radiation risk. Other obligations to provide information in accordance with public or private law remain unaffected.

(2) Following a result in need of monitoring, in derogation from subsection (1) sentence 1 no. 2, a lung cancer screening examination using low-dose computed tomography is permissible before the expiry of 12 months.

### **Section 3** **Justifying indication**

The radiation protection executive must ensure that a person who fulfils the requirements of section 6 (1)

1. verifies the conditions for permissibility as referred to in section 2 and
2. provides the justifying indication in accordance with section 83 (3) of the Radiation Protection Act for the lung cancer screening examination for the person to be examined having due regard to the report as referred to in section 2 (1) sentence 1 no. 3.

### **Section 4** **Requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection**

(1) The requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection follow from the annex to this Ordinance. The radiation protection executive must ensure that the requirements are observed.

(2) If the person to be examined has already undergone a lung cancer screening examination, the radiation protection executive must ensure that before a computed tomography scan is produced

1. the computed tomography scans, including the associated results acquired in the two most recent lung cancer screening examinations, are to hand or
2. if only one lung cancer screening examination has previously taken place, the computed tomography scan, including the associated results of the last lung cancer screening examination, is to hand.

If it is not possible to produce the documents or this would result in a disproportionate effort for the radiation protection executive, the requirement to have the documents to hand may be waived in an individual case.

### **Section 5** **Diagnostic review of the examination**

(1) The radiation protection executive must ensure that a person fulfilling the requirements of section 6 (1) reviews the computed tomography scan first without and then making use of software for computer-assisted detection (first reviewer).

(2) If the first reviewer concludes that the result constitutes a result in need of monitoring or in need of diagnosis, then the radiation protection executive must ensure that an additional person who fulfils the requirements of section 6 (2) reviews the computed tomography scan independently of the first reviewer first without and then making use of software for computer-assisted detection (second reviewer).

(3) The radiation protection executive must ensure that following the diagnostic review in accordance with subsection (2) a final joint assessment of the computed tomography scan is provided by the first and second reviewers. If the joint assessment concludes that the result constitutes a result in need of monitoring, a joint recommendation is to be made on the timing of the next lung cancer screening examination.

## **Section 6**

### **Requirements concerning personnel**

(1) The radiation protection executive must ensure that every person who uses low-dose computed tomography in the context of lung cancer screening examinations, in addition to satisfying the requirements of section 145 (1) of the Radiation Protection Ordinance (*Strahlenschutzverordnung*),

1. has completed further training to become a specialist medical doctor in the field of radiology,
2. has reviewed and documented at least 200 examinations using computed tomography of the thorax in the year before starting to practise lung cancer screening and
3. has acquired knowledge in the area of lung cancer screening examinations by way of continuing professional development courses.

Every person who uses low-dose computed tomography in the context of lung cancer screening examinations must review and document the following number of lung examinations using low-dose computed tomography for lung cancer screening:

1. 100 examinations in the first year of practising lung cancer screening and
2. 200 examinations per year from the second year of practising lung cancer screening.

If the requirement of sentence 2 is not fulfilled, the radiation protection executive must ensure that the person takes a continuing professional development course in which case study examples are to be reviewed and documented. The radiation protection executive must ensure that this person does not perform any lung cancer screening examinations until the continuing professional development course has been completed.

(2) The radiation protection executive must ensure that the second reviewer as defined in section 5 (2)

1. fulfils the requirements of subsection (1) sentence 1 and
2. works in an institution which is specialised in the examination and treatment of lung cancer.

The second reviewer must review and document the following number of lung examinations using low-dose computed tomography for lung cancer screening:

1. 200 examinations in the first year of practising lung cancer screening and
2. 400 examinations per year from the second year of practising lung cancer screening.

Subsection (1) sentences 3 and 4 applies accordingly.

(3) The radiation protection executive must verify whether the person who draws up a report as referred to in section 2 (1) sentence 1 no. 3 and informs the person to be examined as referred to in section 2 (1) sentence 1 no. 4

1. is entitled to practice the medical profession or is temporarily permitted to practice the medical profession,
2. has completed further training to become a specialist medical doctor in one of the following fields or is in at least the third year of further training to become a specialist medical doctor in one of the following fields:
  - a) internal medicine,
  - b) general medicine or

c) occupational medicine and

3. has acquired knowledge in the area of lung cancer screening as part of the further training to become a specialist medical doctor or by way of continuing professional development courses.

### **Section 7** **Quality assurance**

(1) The radiation protection executive must establish and operate a comprehensive quality assurance system. This must take account of organisational, medical and technical aspects, in particular

1. the nature and performance of the lung cancer screening examinations,
2. the diagnostic image quality of the computed tomography scan,
3. the physical-technical parameters for the acquisition of the computed tomography scan and
4. the diagnostic review of the computed tomography scan.

(2) The radiation protection executive must ensure that for the purposes of a process and outcome evaluation of lung cancer screening examinations, anonymised data on smokers are collected and recorded covering the following items:

1. the number of persons examined and
2. the number of results in need of monitoring and the number of results in need of diagnosis.

The radiation protection executive must retain the records for a period of 10 years.

(3) On request from the medical body or the competent authority, the radiation protection executive must provide the information as referred to in subsection (2).

### **Section 8** **Entry into force**

This Ordinance enters into force on 1 July 2024.

### **Annex** **(ad section 4 (1) sentence 1)**

#### **Requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection**

Parameter	Requirements
Volume computed tomography dose index of localiser radiograph	$\leq 0.2 \times$ target spiral computed tomogram volume computed tomography dose index
Localiser radiograph	In posteroanterior projection and in the same respiratory position as during the subsequent diagnostic computed tomography scan With supplementary lateral localiser radiograph if this is a technical requirement for automatic dose selection
Scan mode	Spiral for seamless capture within one breath-hold
Scan time	$\leq 15$ seconds
Rotation time	$\leq 0.5$ seconds
Single slice collimation	$\leq 0.7$ millimetre
Pitch	Between 0.9 and 1.2
Automatic voltage selection	Yes

Automatic dose selection/automatic tube current selection	Use of protocols with tube voltage adapted to body size (e.g. by means of automatic voltage selection) and adapted tube current (e.g. by means of sectoral tube current reduction)
Dynamic collimation	Hardware-based method for avoidance of overranging when detector coverage is greater than 4 centimetres
Convolution kernel	Lung: edge reconstruction filter Mediastinum: smooth reconstruction filter
Reconstruction process	Model-based iterative reconstruction or other methods with at least comparable dose reduction
Lateral resolution (xy)	Isotropic spatial resolution of 0.8 to 1 millimetre for contrasts upwards of 150 Hounsfield units Voxel size of 70–80% of the resolution
Positioning of the person to be examined	Supine with arms above head; centred on the isocentre
Gantry tilt	0°
Scan direction	Caudal–cranial
Spiral scan	Performed within one breath-hold following deep inhalation
Contrast medium	No
Scan region	Lung apex to dorsal recess
Field of view	Entire lung, otherwise as small as possible
Visualisation at the diagnostic workstation	Use of software for interactive visualisation of thicker slices and of thin-slice maximum intensity projection
Software for computer-assisted detection	Detection and volumetry of lung nodules, calculation of volume doubling time and storage of the adjudication as extended image documentation for structured diagnostic review