Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection

Notification of the Explanatory Memorandum to the Lung Cancer Screening Ordinance

of 19 June 2024

The Explanatory Memorandum to the Lung Cancer Screening Ordinance of 15 May 2024 (Federal Law Gazette 2024 I, no. 162) is notified below (annex).

Bonn, 19 June 2024

Federal Ministry
for the Environment, Nature Conservation, Nuclear Safety
and Consumer Protection

By authority
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Annex

Explanatory Memorandum to the Lung Cancer Screening Ordinance

A. General remarks

I. Objective and necessity of the provisions

Lung cancer screening using low-dose computed tomography has been prohibited until now in Germany. Screening using ionising radiation to detect a non-communicable disease is only permitted if provided for in a statutory instrument of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection (BMUV) in accordance with section 84 (1) in conjunction with (2) of the Radiation Protection Act (*Strahlenschutzgesetz*) of 27 June 2017 (Federal Law Gazette I, p. 1966), as last amended by Article 2 of the Act of 20 May 2021 (Federal Law Gazette I, p. 1194; 2022 I, p. 15). The conditions as referred to in section 84 (2) sentence 2 of the Radiation Protection Act are now satisfied for the issue of such a statutory instrument to permit examinations using low-dose computed tomography for the purposes of the lung cancer screening of heavy smokers who have completed their 50th but not their 76th year of life. By way of this screening examination, a serious disease is detected at an early stage using a scientifically recognised examination procedure, thus facilitating the more effective treatment of diseased persons.

This follows from the scientific evaluation by the Federal Office for Radiation Protection (BfS) (Federal Gazette Official Section 6 December 2021 B4), as required by section 84 (3) of the Radiation Protection Act. In this scientific evaluation, in which it identified and evaluated, among other things, several randomised controlled studies as part of a systematic literature research, the Federal Office for Radiation Protection comes to the conclusion that for heavy smokers a positive risk-benefit balance exists for lung cancer screening examinations. The studies evaluated showed, in particular, that where lung cancer screening examinations are carried out tumours are diagnosed at an earlier tumour stage than is otherwise the case.

This draft must be seen in the following context: achievement on time of the goals set out in the United Nations General Assembly Resolution of 25 September 2015 “Transforming our world: the 2030 Agenda for Sustainable Development” is at risk. The draft contributes in particular to the achievement of Sustainable Development Goal 3 in the 2030 Agenda i.e. to “ensure healthy lives and promote well-being for all at all ages”.

II. Main elements of the draft

By way of the Ordinance lung cancer screening for heavy smokers using low-dose computed tomography is permitted.

To maximise the risk-benefit balance the Ordinance specifies further the persons who may be examined as part of the screening and establishes requirements in relation to the technical equipment, the performance of the examination, the further training and continuing professional development of the medical doctors involved and quality assurance.

The examination is permitted in the case of heavy smokers who have completed their 50th but not their 76th year of life. This is the group which, according to the state of scientific knowledge, profits from a screening examination when benefits and risks are weighed.

The additional radiation protection requirements are intended to ensure that the positive risk-benefit balance which has been demonstrated under clinical study conditions also exists under the conditions of the German healthcare system. For that reason, having due regard to the constraints of proportionality, risks are to be minimised and benefits maximised. This is achieved by way of requirements for high-quality technical equipment, a high level of training for the medical doctors involved and a high quality of diagnostic review involving more than one doctor.

III. Alternatives

The screening examination can only be permitted by way of issuing a statutory instrument.

Alternatives are only possible in terms of the detail both as regards the definition of the group for which the screening examination is permitted and as regards the requirements in relation to the technical equipment, the performance of the examination, the training of the medical doctors involved and the diagnostic review.

Were a narrower definition of the group to be adopted and stricter requirements imposed, this would risk impairing access to this screening examination because, for example, of a lack of qualified medical doctors or of the necessary technical equipment. The aim is to make it possible for every person for whom the benefits of the examination outweigh the risks to have access to the service.

A lowering of the requirements, on the other hand, was also considered, but ultimately rejected. The screening examination is performed on persons who do not exhibit any symptoms and where no concrete suspicion of disease exists. Whereas every person examined is exposed to a certain radiation risk and the general harm potential resulting from screening examinations (e.g. overdiagnosis, false-positive results), the individual benefit

of the examination arises only for those persons where a lung carcinoma is detected at an early stage and, as a result, treatment chances are improved. For that reason a high level of radiation protection is necessary.

IV. Regulatory competence

The power to issue the statutory instrument on the permissibility of using ionising radiation and radioactive substances on people to detect a non-communicable disease is set out in section 84 (2) of the Radiation Protection Act. The relevant instrument is a statutory instrument of the Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection not requiring the consent of the Bundesrat.

This statutory instrument regulates only the radiation protection aspects of the screening examination, establishing minimum requirements which ensure that the benefit of the screening examination outweighs the associated radiation risks.

V. Compatibility with European Union law and international treaties

The Ordinance implements the requirements of 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).

VI. Regulatory impact

1 Simplification of legal and administrative provisions

None.

2 Sustainability aspects

The Ordinance aligns with the German government's guiding principles on sustainable development in accordance with the German Sustainable Development Strategy, which implements the United Nations 2030 Agenda for Sustainable Development.

The draft ordinance contributes to the achievement of Sustainable Development Goal 3, that is to “ensure healthy lives and promote well-being for all at all ages” (good health and well-being), by taking advantage of innovative developments in the technology of computed tomography and in screening for lung carcinomas demonstrated in scientific evaluations to be of benefit. This Sustainable Development Goal requires under Target 3.4 by 2030 the reduction by one third of premature mortality from non-communicable diseases through prevention and treatment. Consequently, the German Sustainable Development Strategy measures under indicator field 3.1 "Health and nutrition: Living healthy longer” the national indicators of premature mortality of women (indicator 3.1.a) and of men (indicator 3.1.b). The target is to reduce the cases of death under the age of 70 by 2030 for women to 100 and for men to 190 per 100,000 inhabitants in each respective group. According to figures from the Federal Statistical Office (*Destatis*), malignant tumours were the main cause of premature deaths in 2020. As smokers are particularly at risk of developing a lung carcinoma, detection of a lung carcinoma at an early stage can reduce the risk of a premature death. The draft supports the achievement of these targets, establishing minimum requirements which ensure that the benefits of the screening examination outweigh the associated radiation risks. Detection of a carcinoma at an early stage can – in addition to preventing deaths – reduce the severity of the disease and likewise contribute to the health and well-being of the persons concerned.

Further, the principles of sustainable development include the use of scientific observations as a basis for all decision-making. Consequently, the draft follows the principles to “(1.) apply sustainable development as a guiding principle at all times and in all decisions” and “(6.) use education, science and innovation as drivers of sustainable development” as set out under the German Sustainable Development Strategy.

3 Budgetary expenditure not including compliance costs

The draft ordinance has no impact on public budgets; for the Federation, *Länder* and municipalities no budgetary expenditure not including compliance costs is involved.

4 Compliance costs

a) Overall outcome

For households no compliance costs arise.

For businesses the provisions may lead to annual compliance costs of an estimated 1,566,000 euros, which includes around 20,000 euros for information obligations. In addition, there are minimal one-off compliance costs amounting to less than 500 euros in total.

For the public administration of the *Länder* negligible annual compliance costs of under 100 euros are anticipated.

The draft ordinance implements directly without amendment requirements set out in 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). For that reason, the initiative does not fall within the one in, one out rule.

Directive 2013/59/Euratom establishes specific requirements for screening examinations, beyond the requirements applying to medical exposures in general, which must be observed under national law.

Under the Directive, a procedure using medical radiological installations for early diagnosis in population groups at risk is termed “health screening” (Article 4(40) of Directive 2013/59/Euratom). In accordance with Article 55(2)(f) of Directive 2013/59/Euratom, Member States must ensure that in the case of these procedures specific justification is carried out by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies. Further, in accordance with Article 55(2)(h) of Directive 2013/59/Euratom, screening examinations must be part of a health screening programme or require specific documented justification following guidelines from relevant medical scientific societies and the competent authority. Special attention shall be given to the provision of information to the individual subject to medical exposure, as required by point (d) of Article 57(1) of Directive 2013/59/Euratom. Further requirements for the health screening are set out in Article 61(1)(b), Article 61(1) second subparagraph and Article 61(2) of Directive 2013/59/Euratom, according to which Member States must ensure that appropriate medical radiological equipment, practical techniques and ancillary equipment are used, special attention is given to quality assurance programmes for these practices and the personnel obtain special training.

These requirements are ensured in Germany by means of issuing this Ordinance. The Ordinance is to be regarded as specific justification by the competent authority in conjunction with appropriate medical scientific societies or relevant bodies within the meaning of Article 55(2)(f) of Directive 2013/59/Euratom. It ensures that population groups at risk may be examined and therefore that the examinations constitute health screening within the meaning of the Directive (Article 4(40) and Article 55(2)(h) of Directive 2013/59/Euratom). By means of the provision on information in section 2 (1) sentence 1 no. 4, the requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection in section 4, the diagnostic review in section 5, the requirements concerning personnel in section 6 and quality assurance in section 7, the Ordinance establishes, as required by the Directive, requirements for the provision of information, the medical radiological equipment, practical techniques, the personnel and quality assurance (Article 55(2)(h) sentence 2 in conjunction with Article 57(1)(d), Article 61(1)(b) and Article 61(2) of Directive 2013/59/Euratom).

b) Specifications/Processes

Provision	Specification	Addressee (households, business, public administration)	Cost type (CC = Compliance costs, IO = Information obligation)	Amount in euros/hours
Section 1	Definitions	Business	No CC	
Section 2	Permissibility of lung cancer screening examinations	Business	CC for business	Business €713,000 p.a. Business €300 one-off
Section 3	Justifying indication	Business	CC for business	Business €154,000 p.a.
Section 4	Requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection	Business	CC for business	Business €190,000 p.a.
Section 5	Diagnostic review of the examination	Business	CC for business	Business €489,000 p.a.
Section 6	Requirements concerning personnel	Business	No CC	
Section 7	Quality assurance	Business	CC for business IO, CC for public administration	Business €20,000 p.a. IO, Public administration €100 p.a.

By means of the provisions, it is intended to permit the use of low-dose computed tomography, as a rule, for the purposes of lung cancer screening of smokers. For this group, examinations using ionising radiation have been permitted until now only where a suspicion of disease exists, for example abnormal coughing, not, however, screening examinations, that is, without any symptoms of disease and without a concrete suspicion of disease. The number of persons who could satisfy the conditions for participation in lung cancer screening is estimated to be around 5.5 million (see paragraph 3.3.2.3 of the Federal Office for Radiation Protection notification of 16 November 2021, Federal Gazette Official Section 6 December 2021 B4).

The Ordinance does not involve any decision on inclusion as an insurance benefit under statutory or private

health insurance. In the absence of a decision of the Joint Federal Committee (*Gemeinsamer Bundesausschuss*) which has entered into force, or a corresponding decision by private health insurers on the assumption of costs, the costs for screening examinations for lung cancer using low-dose computed tomography, as individual healthcare services, must be borne by participants themselves. The Statutory Scale of Fees for Doctors (*Gebührenordnung für Ärzte*) sets 241.31 euros as the permissible fee rate for the performance of computer-controlled tomography of the neck or thorax area; to this must be added the services of provision of information and the diagnostic reviews specified in this Ordinance such that in an individual case costs in the region of 280 to 300 euros for the examination must be expected. Especially given these circumstances it is questionable to what extent persons for whom the examination is permitted would make use of the offer. Further, even persons who regularly participate in the screening are likely, on the whole, to choose a greater screening interval than one examination every year.

The Federal Ministry for the Environment, Nature Conservation, Nuclear Safety and Consumer Protection assumes that a preventive examination for the purposes of lung cancer screening, in the absence of cause and not covered by health insurance, would be taken up by at most 5 percent of the persons who meet the criteria, on average every 5 years. That results in around 55,000 cases per year.

Reliable statements cannot be made on the compliance costs involved on the assumption that in future health insurers assume the costs of the examination. Even if the costs were to be assumed, conditions more restrictive than in the authorising ordinance could be imposed, for example a longer minimum period between examinations, a limitation on the number of repeat examinations, the establishment of additional requirements such as mandatory participation in a smoking cessation measure or only a partial assumption of costs. To that extent, the annual participation rate for this preventive examination cannot be reliably predicted in the event that health insurers assume the costs.

4.1 Compliance costs for households

For households no compliance costs arise, as they are not addressees of the provision.

4.2 Compliance costs for business

The labour costs for business have been determined on the basis of the table of business labour costs provided for in the Guideline for the determination and presentation of compliance costs in regulatory initiatives of the Federal Government (*Leitfaden zur Ermittlung und Darstellung des Erfüllungsaufwandes in Regelungsvorhaben der Bundesregierung*), January 2022 edition, Appendix VII, page 59, Economic sector Q, Human health and social care activities.

Compliance costs for business in connection with section 2 – Permissibility of lung cancer screening examinations

A consultation is held with the person who meets the personal requirements for a lung cancer screening examination for the provision of information in the context of general practitioner or specialist treatment provision; the person receives an information sheet. To this must be added a medical report containing the details that are relevant for the radiological assessment. On the assumption that for these purposes a questionnaire, compiled centrally, a report form for medical doctors and an information sheet for patients are to hand, the time required for the consultation and for the medical doctor to draft the report is estimated, in total, to be 12 minutes per case and the time required for auxiliary personnel to issue the report and ensure the availability of the information sheet to be 3 minutes. The compliance costs amount to 12.97 euros in an individual case, in total approximately 713,000 euros annually. For medical doctors the level of qualification “high” (59.10 euros/hour) and for the auxiliary personnel the level of qualification “basic” (22.90 euros/hour) is used. The material costs relating to the information are considered trivial as the information can be provided on paper or electronically.

To this must be added the one-off centralised drafting and distribution of the abovementioned documents. It is estimated that six hours of time involving a person with a medium level of qualification (30.00 euros/hour) and one hour of time involving a person with a high level of qualification (59.10 euros/hour) are required for this, resulting in one-off compliance costs of under 300 euros.

Compliance costs for business in connection with section 3 – Justifying indication

The time required for the medical doctor to provide and record the justifying indication is estimated at 3 minutes per case (59.10 euros/hour). On the assumption that a small proportion (5 percent) of the persons who were informed in accordance with section 2 do not undergo the radiological examination, the annual compliance costs arising amount to approximately 154,000 euros.

Compliance costs for business in connection with section 4 – Requirements for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection

The specifications for computed tomography scanners, diagnostic workstations, performance of examinations and software for computer-assisted detection are, as a rule, fulfilled by the existing technical equipment in radiological practices such that no additional purchases must be made. The time required for the practical execution of the examination is estimated to be 5 minutes (medium level of qualification, 30.00 euros/hour). To

this must be added the inquiry concerning the previous screening examinations (basic level of qualification, 22.90 euros/hour) estimated at 3 minutes. On the assumption that case numbers are as stated in the remarks on section 3, the compliance costs per case amount to 3.65 euros, in total approximately 190,000 euros.

Compliance costs for business in connection with section 5 – Diagnostic review of the examination

All diagnostic reviews are carried out by medical doctors (high level of qualification, 59.10 euros/hour).

The time required for the first diagnostic review by a medical doctor with and without software for computer-assisted detection amounts in an individual case to around 5 minutes; in total approximately 257,000 euros.

The Federal Office for Radiation Protection estimates that in around 30 percent of all scans (15,675 cases) the result is one in need of monitoring (see paragraph 3.8.2 of the Federal Office for Radiation Protection notification of 16 November 2021, Federal Gazette Official Section 6 December 2021 B4). The Ordinance provides in this case for a further diagnostic review subject to the same requirements carried out by a second reviewer who, in a further step, assesses the result jointly with the first reviewer. On the basis that the time required for the second diagnostic review is 5 minutes and for the joint assessment by two persons 5 minutes each are required, this results in 15 minutes per case and accordingly compliance costs are 232,000 euros.

The annual compliance costs resulting from the specifications provided for in section 5 therefore total 489,000 euros.

Compliance costs for business in connection with section 6 – Requirements concerning personnel

Medical doctors must fulfil the requirements of radiation protection law for the performance of computed tomography of the thorax. Completion of further training to become a specialist medical doctor is independent of any lung cancer screening. Consequently, additional compliance costs do not arise from this. The continuing professional development required in the area of lung cancer screening may result in additional compliance costs. These cannot be seriously quantified as neither the proportion of medical doctors who will participate can be predicted at this stage nor are the number of hours involved in the continuing professional development courses known.

Compliance costs for business in connection with section 7 – Quality assurance

The specifications concerning quality assurance correspond to the usual radiation protection requirements for comparable installations. Additional compliance costs arise by way of the documentation and safekeeping obligations under section 7 (2). The anonymised documentation of the number of persons examined and the number of results in need of monitoring and number of results in need of diagnosis requires very little time in an individual case and is estimated at one minute per case (basic level of qualification 22.90 euros/hour) such that the compliance costs amount to under 20,000 euros annually. There are currently some 1,000 radiological practices in Germany. If amongst these annually in 2 percent of the cases the documents must be provided on request to the public authority or to the medical body, based on a time requirement of 5 minutes per practice, this results in very minor additional compliance costs of less than 100 euros per year. In total the annual compliance costs in relation to the quality assurance obligations under section 7 amount to 20,000 euros per year.

4.3 Compliance costs for the public administration

The labour costs for the public administration have been determined on the basis of the table of public administration labour costs provided for in the Guideline for the determination and presentation of compliance costs in regulatory initiatives of the Federal Government, January 2022 edition, Appendix IX, page 63, Administrative level: *Land*, executive level (43.90 euros/hour).

Compliance costs for the public administration in connection with section 7 – Quality assurance

For the public administration of the *Länder*, alongside the inspections taking place in any event within the framework of the General Administrative Regulation Supervisory Programme (*Allgemeine Verwaltungsvorschrift Aufsichtsprogramm*), further compliance costs arise where the competent authority requires the production of the documents in accordance with section 7 (3) (see remarks on compliance costs for business in connection with section 7). This is likely to arise in a few individual cases. Assuming the time required in each case to be 5 minutes, the annual compliance costs are negligible, amounting to less than 100 euros per year.

5 **Further costs**

A licence must be obtained to use computed tomography scanners for lung cancer screening examinations in accordance with section 14 (3) of the Radiation Protection Act. On the assumption that only a certain proportion of radiological practices will offer the screening examination, minor adjustment costs will result. Subsequently, each year a small number of new licences or amended licences can be expected.

In addition, although radiological practices as small and medium-sized businesses are affected by the additional examinations in quantitative terms, at the same time, no qualitative requirements are imposed beyond the general specifications of radiation protection law. The costs involved in the additional examinations are offset by medical fee revenues for these examinations.

It is not anticipated that the Ordinance will have an influence on price levels, in particular consumer price levels.

6 Additional regulatory impact

No impacts on equal opportunities or demographics or consequences for the equivalence of living conditions are anticipated.

VII. Time limit; Evaluation

No time limit on the provisions is included. Pursuant to paragraph 7.1 of the General Administrative Regulation on the Scientific Evaluation of Screening Examinations to Detect Non-Communicable Diseases (*Allgemeine Verwaltungsvorschrift zur wissenschaftlichen Bewertung von Früherkennungsuntersuchungen zur Ermittlung nicht übertragbarer Krankheiten*), the Federal Office for Radiation Protection reviews the permitted screening examination every five years at least to determine whether the state of scientific knowledge has advanced. If this is the case, the Federal Office for Radiation Protection decides whether a comprehensive reassessment and a revision of the conditions and requirements in accordance with paragraph 3.2 of the Administrative Regulation is necessary. In this way the risk-benefit assessment of the examination is continuously evaluated in accordance with scientific criteria.

For other process and outcome evaluations, certain anonymised data are available, in addition, in accordance with section 7 (2).

B. Specific remarks

Section 1 – Definitions

Subsection (1)

In subsection (1) the term “low-dose computed tomography” is given a legally binding definition. In practice, no uniform understanding of the term has developed. As only low-dose computed tomography, not conventional computed tomography with a higher dose, is permitted, the term must be defined for reasons of legal certainty.

The decisive criterion for distinguishing a low-dose computed tomography from a conventional computed tomography is the comparatively low exposure to which the person examined is subjected. At the same time, as with every examination using computed tomography, also in the case of low-dose computed tomography, it is necessary to calibrate the dose amount individually for the person to be examined. To obtain the same diagnostic image quality, an increased dose is necessary as body weight increases. For that reason, no absolute values for the maximum dose to be used can be established.

Consequently the definition includes two forms of a low-dose computed tomography.

Under no. 1 a low-dose computed tomography is a computed tomography of the thorax in which, in order to achieve the image quality required for lung cancer screening, a volume computed tomography dose index of 1.3 milligrays is not exceeded. This corresponds to approximately half the dose of a conventional computed tomography of the thorax. For an individual of normal weight, it is possible to keep within – and, in fact, go well below – the value of 1.3 milligrays.

Pursuant to no. 2, however, it also constitutes a low-dose computed tomography if 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. For persons who considerably exceed normal weight, a volume computed tomography dose index of more than 1.3 milligrays may need to be selected to allow a proper diagnostic review of the scan. Exceedance of 1.3 milligrays requires a specific justification and is permitted in an individual case only in accordance with the conditions mentioned in the provision, that is, the exceedance is necessary, first, because of the physical build and, second, to achieve the image quality required. If these conditions are not met, then, in accordance with the definition, this no longer constitutes a low-dose computed tomography but a conventional computed tomography. It is not possible to set an absolute upper limit for a volume computed tomography dose index for the purposes of distinguishing conventional from low-dose computed tomography in this context because each person to be examined is different. However, in accordance with the principle of dose reduction in compliance with section 8 (2) sentence 1 of the Radiation Protection Act, the volume computed tomography dose index selected must always be as low as possible.

Sentence 2 clarifies that in the definition of the term the volume computed tomography dose index of an associated localiser radiograph is not included.

Subsection (2)

Subsection (2) defines the unit “packet year” in which cigarette consumption is stated in this Ordinance in accordance with sentence 1.

The term “cigarette consumption” covers only the consumption of cigarettes not, however, other tobacco products, such as pipes, e-cigarettes, chewing tobacco and snuff as well as nicotine patches. The consumption of e-cigarettes is also not covered even if the tobacco or tobacco substitute product is heated. This is because different tobacco products have different implications for the risk of lung cancer. Existing studies currently show a positive risk-benefit balance for lung cancer screening only in the case of cigarette consumption.

Pursuant to sentence 2, in order to determine cigarette consumption, for each year of cigarette consumption the average number of cigarettes smoked each day in that year is divided by 20. That is to say, based on the assumption that a packet contains 20 cigarettes, first, for each year of cigarette consumption the number of packets smoked per day is determined. If a person smokes 20 cigarettes a day, after a year, their cigarette consumption amounts to one packet year. If a person smokes only ten cigarettes, after a year, their cigarette consumption amounts to half a packet year. If consumption is 40 cigarettes a day, after a year, two packet years have been completed. The results for each year of cigarette consumption determined in this way are totalled in accordance with sentence 3.

Packet years relating to periods before a complete break from smoking are to be included, in accordance with sentence 4, only if the complete break amounts to less than ten years. This takes account of the fact that following a break of more than ten years the risk of lung cancer declines considerably and is once again similar to that of a non-smoker. For persons with a break from smoking of more than ten years, the benefit of a lung cancer screening examination is no longer given. Only when – subsequent to the break – consumption for at least 25 years involving at least 15 packet years is given, are the conditions for admission, in accordance with section 2 (1) sentence 1 no. 3 (a) (bb), once again fulfilled.

The Federal Office for Radiation Protection scientific report shows that smokers with a consumption of more than 15 cigarettes a day for at least 25 years or a consumption of more than ten cigarettes a day for at least 30 years benefit from a lung cancer screening examination (Federal Gazette Official Section 6 December 2021 B4)

This Ordinance uses, in place of such rigid requirements, a unit by which cigarette consumption can be expressed on a continuous scale. This has several advantages. First, persons whose cigarette consumption lies between 10 and 15 cigarettes are admitted to lung cancer screening earlier than would be the case if two thresholds of ten cigarettes a day for at least 30 years and 15 cigarettes a day for at least 25 years were established. For example, a person who consumes 12 cigarettes a day is admitted to a screening examination after only 25 years instead of after 30 years. Where consumption amounts to 11 cigarettes, the screening examination is permitted after 27 years. Second, cigarette consumption of less than ten cigarettes a day is also taken into account. If a person for a certain period smokes only five cigarettes a day, after a year, they reach 0.25 packet years. These periods of low consumption are also included. Third, variations in cigarette consumption can be better reflected as the resulting packet years are simply totalled in accordance with sentence 3. In this way, periods of very high consumption can balance periods of low consumption. In contrast, if a rigid threshold of 10 or 15 cigarettes a day were used, it would be uncertain whether and, if so, how periods of varying levels of consumption could be combined.

Subsection (3)

It is envisaged that a software for computer-assisted detection will be used as part of the diagnostic review. As these computer programs function very differently, the term must be defined.

The development of medical computer programs is advancing rapidly. There are many software solutions that can assist medical doctors in making a diagnosis. The term has been formulated in a sufficiently open fashion not to hinder this progress. Nonetheless, for lung cancer screening, only software for computer-assisted detection which analyses the digital image data of the computed tomography for the purposes of making a diagnosis should be used. For this reason, this criterion is included in the definition of the term. Specific requirements are set out additionally in section 4 (1) sentence 1 in conjunction with the Annex. The requirements of the law on medical devices remain unaffected.

Subsections (4) and (5)

In subsections (4) and (5) the terms “result in need of monitoring” and “result in need of diagnosis” are defined. The distinction between these two terms serves to draw a line between screening and an examination in the context of clinical diagnosis, which does not constitute a screening examination.

Pursuant to section 5 (16) of the Radiation Protection Act, “screening” means the use of X-radiation or radioactive substances in connection with medical exposure in order to examine persons who do not exhibit any symptoms of disease or any concrete suspicion of disease (asymptomatic individuals) in order to detect a specific disease.

In the case of a result in need of monitoring, as in the case of a normal result, the next examination using low-dose computed tomography remains a lung cancer screening examination. Therefore, this further examination is within the scope of this Ordinance. In the case of a result in need of diagnosis, further examinations, for example performance of an examination using positron emission tomography or also more invasive examinations such as a lung biopsy, are part of the clinical diagnosis. These do not constitute screening examinations.

Accordingly, a result in need of monitoring means, as set out in the definition, 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 examination for the purposes of lung cancer screening within 12 months is medically indicated without any concrete suspicion of disease existing. There are no focal alterations strongly suggesting the presence of a lung carcinoma. As a result, not only does the person not exhibit symptoms of disease but also no concrete suspicion of disease exists. To emphasise the fact that a result in need of monitoring does not trigger any concrete suspicion of disease, this criterion of an asymptomatic individual as defined in section 5 (16) of the Radiation Protection Act is repeated in the definition of a result in need of monitoring.

However, a result in need of monitoring differs from a result which is entirely normal in the sense that lung nodules are present which must be kept under close observation. The overwhelming majority of these nodules are benign. However, there are also nodules which are possibly malignant which cannot be characterised definitively at this stage in the low-dose computed tomography scan produced. Therefore, for persons with a result in need of monitoring a further screening examination is medically indicated before the expiry of the regular screening interval of at least 12 months as referred to in section 2 (1) sentence 1 no. 2 in order, for example, to detect lesion volume increase at an early stage. Consequently, this further examination is within the scope of this Ordinance. This ensures that for these persons a carcinoma can still be identified at an early stage and at the same time that persons with only benign nodules are not subjected unnecessarily to burdensome diagnostic examinations such as a biopsy.

A result in need of diagnosis suggests very strongly the presence of a lung carcinoma and must therefore be subject to a prompt clinical diagnosis. The subsequent diagnostic examinations do not constitute screening within the meaning of section 5 (16) of the Radiation Protection Act because in this case a concrete suspicion of disease exists. Thus, the result in need of diagnosis differs clearly from a result in need of monitoring.

Section 2 – Permissibility of lung cancer screening examinations

Subsection (1)

The conditions for the permissibility of examinations for the purposes of lung cancer screening are based on the scientific evaluation of the Federal Office for Radiation Protection. This shows that for persons who have completed their 50th but not their 76th year of life the expected benefit outweighs the risks from radiation exposure. Therefore, lung cancer screening examinations are deemed permissible in this age group if certain requirements are met.

No. 1

Active smokers and ex-smokers who have completed their 50th but not their 76th year of life are at the greatest risk of becoming diseased with and dying of lung cancer. For this reason the benefit of a lung cancer screening examination in comparison with the risks is the most pronounced in this age group. Outside of this age group, the risk-benefit balance of lung cancer screening examinations is lower, meaning that performance of screening examinations on a systematic basis is not justified.

No. 2

A positive risk-benefit balance exists where the interval following the last lung examination using computed tomography which is appropriate in qualitative terms for a diagnostic review in relation to a lung carcinoma amounts to at least 12 months. Shorter intervals would increase the radiation-related risk from screening examinations but not bring a decisive benefit for the person to be examined. This would constitute an unfavourable shift in the risk-benefit balance.

This applies both to the interval following previous screening examinations using low-dose computed tomography and to the interval following other lung examinations using conventional computed tomography or using low-dose computed tomography not performed in the context of a lung cancer screening examination. This is subject to the condition, however, that the examination is appropriate in qualitative terms for a diagnostic review in relation to a lung carcinoma. It is irrelevant in this connection for the diagnosis of which disease the examination was carried out. As a rule, lung cancer can be detected on computed tomography scans of the lung carried out for the purpose of diagnosing other diseases, provided that the computed tomography scan shows the whole lung in the necessary image quality. For that reason, also other lung examinations using computed tomography which were not performed in the framework of screening examinations must have been completed 12 months beforehand.

No. 3

A further condition is the production of a report drawn up by a specialist medical doctor or an experienced medical doctor undergoing further training in the field of internal medicine, general medicine or occupational medicine. The report contains the relevant details for the permissibility of a lung cancer screening examination with regard to cigarette consumption and the medical suitability profile of the person to be examined including the relevant anamnestic data.

On the basis of the report, the radiologist provides the justifying indication.

Letter (a)

Cigarette consumption is, by a long way, the most important risk factor for lung cancer and thus constitutes one of the essential conditions for admission to lung cancer screening.

Double letter (aa)

The benefit of the lung cancer screening examination has been shown for persons who have consumed cigarettes over a minimum period of 25 years. For these purposes, also the years before a complete break from smoking and the years of the break itself are included if the break amounts to less than 10 years. Thus, if, for example, a person after 10 years of cigarette consumption gives up smoking completely for five years but then smokes again for another 10 years, they fulfil the criterion. If, in the example, the break amounts, in contrast, to 10 years, the criterion is not fulfilled. After 10 years of giving up cigarettes completely, the risk of lung cancer declines so radically that a lung cancer screening examination no longer brings sufficient benefit.

Double letter (bb)

Further, a certain minimum quantity of cigarettes must have been smoked. The intensity of cigarette consumption is expressed in the unit “packet year”. The definition of the unit is set out in section 1 (2) of this Ordinance.

Letter (b)

In addition to the cigarette consumption, a medical suitability profile must be apparent from the medical report. While lung cancer screening examinations are shown to be expedient in statistical terms for heavy smokers who have completed their 50th but not their 76th year of life, the individual risk-benefit balance may be different in a specific case. The drawing up of a medical suitability profile is intended to permit an appropriate individualised balancing of risks and benefits and constitutes the basis on which the radiologist provides the justifying indication as referred to in section 3.

In particular, it should be stated whether – for health or other reasons – a person is suited for the lung cancer screening examination. Persons for whom treatment of a lung carcinoma is not possible or would not be expedient because of their state of health do not benefit from the screening examination. In addition, medical progress and new findings might allow consideration to be given in the future to further factors which may influence the risk of becoming diseased with lung cancer or the radiation-related risk and, as a result, have an influence on the individual risk-benefit balance.

No. 4

A further condition is that the person to be examined was informed in an oral consultation and through the provision of information in text form.

The condition applies in addition to other obligations to provide information in accordance with public or private law, in particular under section 630e of the Civil Code (*Bürgerliches Gesetzbuch*) and section 124 of the Radiation Protection Ordinance (*Strahlenschutzverordnung*) of 29 November 2018 (Federal Law Gazette I, p. 2034, at p. 2036; and 2021 I, p. 5261), as last amended by Article 2 of the Ordinance of 17 April 2024 (Federal Law Gazette I 2024, no. 132). These remain unaffected, as section 2 (1) sentence 3 clarifies. Thus, the provision of information which, in accordance with section 2 (1) sentence 1 no. 4 in conjunction with section 6 (3) of this Ordinance, must be effected by an internist, general practitioner or occupational physician is in addition to the information provided by the treating party within the meaning of section 630e of the Civil Code who performs the examination. In accordance with section 630e of the Civil Code, the treating party is obliged, as a party to the treatment contract for lung cancer screening using low-dose computed tomography, to provide information. The treatment contract for the performance of low-dose computed tomography for lung cancer screening exists only between the treating party, that is to say, as a rule, the radiologist or the radiological practice or clinic, and the person to be examined, meaning that the obligation to provide information under section 630e of the Civil Code also arises only within this relationship. The internist, general practitioner or occupational physician is not a party to the treatment contract concerning the performance of the lung cancer screening examination such that, in relation to this examination, they are also not subject to any obligations to provide information under section 630e of the Civil Code. Rather, their treatment contract with the patient concerns only the medical services that they perform, that is to say, in particular the drawing up of the medical report as referred to in section 2 (1) sentence 1 no. 3.

In other words, first, in accordance with the Ordinance, an oral consultation for the provision of information takes place with an internist, general practitioner or occupational physician concerning various specifically mentioned aspects of the lung cancer screening examination. Then, the treating party provides information, as referred to in section 630e of the Civil Code, concerning the screening examination. This reflects the fact that only through the prior provision of information by medical doctors from the various disciplines can it be ensured that the patient is properly informed of the benefits and risks of the examination. Only in this way can the patient reach an informed decision on whether to have the examination performed. In addition, the condition ensures that persons who are entitled to have the lung cancer screening examination can be provided with information about the procedure, benefits and certain risks at an early stage, that is, before referral to a radiologist.

By elevating the provision of information by an internist, general practitioner or occupational physician to a condition for the permissibility of the examination, this means that a lung cancer screening examination using low-dose computed tomography may only be performed after this provision of information has been effected. However, internists, general practitioners and occupational physicians are not obliged to offer this medical service. Likewise, the carrying out of an informational consultation does not result in liability on the part of the internist, general practitioner or occupational physician for defective services provided by other treating parties in the context of the lung cancer screening.

Radiologists performing the screening examination must verify that the condition is satisfied. They may discharge this obligation to verify by requiring the production of a certificate issued by the internist, general practitioner or occupational physician involved attesting to the provision of the information.

The information is to be provided by means of an oral consultation and the provision of information in text form. The purpose of the oral consultation is to provide the person to be examined with personal and individualised advice and to resolve questions. In contrast, the information in text form brings together all the matters on which information must be provided in the consultations with the internist, general practitioner or occupational physician and the radiologist. The intention is to provide the participant by way of a single document with an interdisciplinary overview. While the internist, general practitioner or occupational physician can provide detailed information on the individual benefit, treatability and further aspects concerning the person's general state of health, radiologists

can provide in-depth information on the radiation risk. It is therefore sensible to bring together this information in text form.

The Ordinance lists exhaustively the aspects on which the internist, general practitioner or occupational physician must provide information. The selection reflects the knowledge of these specialists. Hence, there is no requirement in the consultation to provide information on the radiation risk as internists, general practitioners and occupational physicians lack the detailed specialist knowledge for this. Consequently, in accordance with section 2 (1) sentence 2, it is mandatory to draw attention to the radiation risk only in the information in text form.

Letter (a)

The internist or general practitioner must provide information on the benefits of lung cancer screening. In the absence of in-depth knowledge on radiation-related risks they are not required to provide information on the radiation risk.

Letter (b)

In addition, information is to be provided on the possibility that the screening examination may produce false positive or false negative results and the possible consequences of this. False positive results may result in a considerable mental burden and, in the event of further diagnostic examinations, also a physical burden. False negative results may provide persons with a false sense of security. For that reason information on the possibility of false results constitutes an important aspect for the decision of the person to be examined.

Letter (c)

In the event of results in need of diagnosis, further diagnostic examinations are necessary which involve specific risks and physical and mental burdens. This applies in particular for a biopsy. If a participant in a lung cancer screening examination is not prepared to undergo the risks and burdens of diagnostic examinations in the event of a result in need of diagnosis, the screening examination itself may not be sensible from the participant's perspective. For this reason, information must be provided in this regard.

Letter (d)

The screening examination may result in the detection of lung carcinomas which would not have become clinically relevant. Thus, as a result of the screening examination, individuals may be unnecessarily confronted with a stressful diagnosis and possibly treatment. For this reason, information concerning this risk must be provided.

The information in text form must draw attention also to the radiation risk (section 2 (1) sentence 2).

Subsection (2)

This provision addresses the particular feature of a result in need of monitoring, which is defined in section 1 (4). For persons with a result in need of monitoring, a further screening examination is permissible on medical grounds before the expiry of the regular screening interval of at least 12 months.

Section 3 – Justifying indication

The justifying indication is of particular importance in the context of lung cancer screening because asymptomatic individuals are examined and the benefit for these persons, first, only exists if the conditions of section 2 are satisfied and, second, depends on the individual risk profile of the person to be examined.

For that reason, the radiation protection executive must ensure that a specialist medical doctor licensed to practise in the field of radiology verifies, first, that the conditions of section 2 are satisfied and, second, that the justifying indication as defined in section 83 (3) of the Radiation Protection Act exists. As regards the latter, due regard must be had to the report as referred to in section 2 (1) sentence 1 no. 3 in light of the complex balancing of benefits and risks in relation to the person to be examined.

No use is made of the authorisation provided for in section 84 (5) of the Radiation Protection Act as the conditions for its use are not satisfied. Under that provision, the statutory instrument authorising screening may permit exceptions from the obligation to obtain a justifying indication for screening which takes place as part of a screening programme insofar as the nature and scope of the inclusion criteria for the screening programme render unnecessary a decision on whether or by what means the procedure is to be performed. Because of the necessary individual balancing of benefits and risks with regard to a lung cancer screening examination, a decision in the individual case on whether or by what means the procedure is to be performed is necessary also in the framework of any screening programme within the meaning of section 84 (5) of the Radiation Protection Act.

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

Subsection (1)

The technical requirements for computed tomography scanners, diagnostic workstations, scanner settings applicable in the performance of examinations and for software necessary to ensure a positive risk-benefit balance for lung cancer screening are set out in the annex to this Ordinance. The radiation protection executive must ensure that the requirements are observed.

Subsection (2)

The provision ensures that in the technical execution of the lung cancer screening examination computed tomography scans, including the associated results, from the previous two most recent screening examinations are to hand or, if only one lung cancer screening examination has taken place, that this computed tomography scan is to hand. The previous scans contain important information for the diagnostic review of the low-dose computed tomography scan to be produced in the current examination. In particular the information on the volume doubling time of lung nodules is important for the reviewers.

If the previous scans are not to hand, lung cancer screening using low-dose computed tomography is nonetheless permissible if it is not possible to obtain the documents or if this results in a disproportionate effort. Reasons why it may be impossible to obtain one or both of the previous scans and their associated results include, in addition to the fact that no previous scan has been produced, for example, destruction of the previous scan because the deadline for retaining records has expired or legal obstacles, such as no release from confidentiality by the patient. A disproportionate effort for the radiation protection executive could arise, for example, if the last examination took place abroad or the medical practice has closed and it is unclear where the documents remain.

Section 5 – Diagnostic review of the examination

This Ordinance provides for different levels of diagnostic review. Depending on the degree of abnormality in the result, more than one reviewer must be involved. If the first reviewer, a radiologist, concludes that a result is normal, no additional medical doctors need to be involved (subsection (1)). If the first reviewer concludes that the result constitutes a result in need of monitoring or in need of diagnosis, an additional radiologist must be involved (subsection (2)). This achieves a high quality of results while, at the same time, safeguarding the resources of the healthcare system.

Subsection (1)

The radiation protection executive must ensure that a radiologist reviews the computed tomography scan first without and then using software for computer-assisted detection.

The provision ensures, first, that the medical doctor reviews the low-dose computed tomography scan without being influenced by the software. Second, the software then assists the medical doctor in the further diagnostic review, marking the abnormal areas. This kind of diagnostic review leads to a reduction in possible diagnostic review errors as the reviewer and software complement each other. Overall the software assists the reviewers and enhances the quality of results. If following this procedure the medical doctor concludes that the result is normal, no second reviewer must be involved. Where results are normal this is not necessary from a professional perspective, due to the high quality of results from the combination described. In this way, limited capacities in the healthcare sector can be preserved.

Subsection (2)

If the first reviewer concludes that the result constitutes a result in need of monitoring or a result in need of diagnosis, a second reviewer, who must also be a radiologist, must review the computed tomography scan independently. The second reviewer must review the computed tomography scan in the same way as the first reviewer, that is, first without and then using software for computer-assisted detection. By means of a second diagnostic review, sensitivity and specificity can be improved. This is shown, for example, by the German mammography screening programme in which for many years a second diagnostic review has been a tried and tested practice. The diagnostic review involving two reviewers each assisted by software significantly increases the quality of results.

Subsection (3)

For results requiring review by a first and second reviewer, a final joint assessment from the first and second reviewers is necessary. This ensures that the quality of the result is enhanced by way of communication between both reviewers. The involvement of additional persons, for example, from other medical specialisms, is not excluded. However, it is not mandatory to involve additional medical doctors.

Where results are in need of monitoring, a further screening examination is indicated before the expiry of the regular screening interval of at least 12 months as referred to in section 2 (1) sentence 1 no. 2. The date at which a further screening examination is medically expedient depends on the individual result of the person examined. For that reason, on the basis of their joint assessment, the two reviewers are to produce a joint recommendation on the timing of the next screening examination.

Section 6 – Requirements concerning personnel

Subsection (1) contains requirements for persons who use low-dose computed tomography, in particular who provide the justifying indication and perform the first diagnostic review. Subsection (2) establishes additional requirements for the second reviewer. Subsection (3) concerns the persons who exercise the tasks as referred to in section 2 (1) sentence 1 nos. 3 and 4.

Specific requirements are established with regard to the training and experience of the persons who use the screening examination as their competence and expertise is crucial to its overall effectiveness.

Subsection (1)

The radiation protection executive must ensure that every person who uses low-dose computed tomography in the context of lung cancer screening fulfils the requirements of subsection (1).

The requirements apply in addition to the requirements under section 145 (1) of the Radiation Protection Ordinance.

Sentence 1 no. 1

The requirement for completed further training to become a specialist medical doctor in the field of radiology ensures that the persons using low-dose computed tomography, in particular in the provision of the justifying indication and in the diagnostic reviews of the scan, have a high level of qualification. It goes beyond the requirements otherwise applicable for the use on humans as defined in section 145 (1) of the Radiation Protection Ordinance. Completed further training to become a specialist medical doctor in the field of radiology is required in addition to the necessary specialist knowledge in radiation protection.

The wording “specialist medical doctor in the field of radiology” is intentionally open-ended. The purpose is to clarify that the authority to perform lung cancer screening examinations does not depend on a particular designation as a specialist. This is intended to take account of possible future amendments or possible regional differences in the designation of specialists or the introduction of designations for areas of specific focus. Those differences of detail in the designation are unimportant as long as the further training took place in the field of radiology.

Further, the category is not limited to further training for medical doctors completed in Germany. If further training for medical doctors completed abroad entitles the holder to use the corresponding specialist designation in Germany, this also meets the requirements mentioned here.

Sentence 1 no. 2

The requirement that the person using low-dose computed tomography must have reviewed and documented at least 200 examinations of the lung using computed tomography of the thorax in the year before starting to practise lung cancer screening ensures that this person has already obtained sufficient competence and experience before starting to practise lung cancer screening. It is unimportant in this connection whether these examinations involved low-dose computed tomography or conventional computed tomography.

Sentence 1 no. 3

The provision requires knowledge to have been acquired by way of continuing professional development courses in the area of lung cancer screening examinations. The underlying intention is to improve the ability of radiologists to perform low-dose computed tomography and to review computed tomography scans.

Section 6 (1) sentences 2 to 4

In order to maintain and further develop experience and competence, the person using low-dose computed tomography must review and document 100 examinations in the first year of practising lung cancer screening, and from the second year of practising 200 examinations, using low-dose computed tomography for lung cancer screening. If this requirement is not fulfilled, the radiation protection executive must ensure that the person takes a continuing professional development course in which theoretical case study examples are to be reviewed and documented. Until the continuing professional development course has been completed, the practice of lung cancer screening must be suspended.

Lack of practical experience is thus compensated by way of continuing professional development courses and carrying out exercises using theoretical case study examples. This system has the advantage, in addition, that also persons whose practice has been interrupted, for example, because of parental leave or a period of prolonged sickness, who do not achieve the required number of cases may continue to perform lung cancer screening examinations. At the same time, the continuing professional development requirement ensures the high level of qualification.

Subsection (2)

Requirements for the second reviewer are established which go beyond those of subsection (1). This person must, in addition, work in an institution specialised in the examination and treatment of lung cancer and must fulfil higher case number requirements for each year of lung cancer screening.

The first reviewer must involve the second reviewer if the first reviewer concludes that the result constitutes a result in need of monitoring or in need of diagnosis. In these particularly sensitive and difficult cases, the first reviewer is thus provided with the assistance of a highly experienced radiologist. The additional requirement that the second reviewer works in an institution specialised in the examination and treatment of lung cancer fulfils the further function – in addition to the attendant high level of qualification of the radiologist in the area of lung cancer examinations – of establishing contact with an institution in which the disease could also be clinically diagnosed and treated. This ensures a seamless transition from screening to further examination and treatment.

For the remainder, the remarks concerning subsection (1) sentence 1 apply also in relation to the second reviewer as, in accordance with section 6 (2) sentence 1 no. 1, they must fulfil the requirements of section 6 (1) sentence 1.

Further, pursuant to subsection (2) sentence 3, section 6 (1) sentences 3 and 4 applies accordingly.

Subsection (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 provides information as referred to in section 2 (1) sentence 1 no. 4 fulfils the requirements of nos. 1 to 3.

These medical doctors play a central role in lung cancer screening. In particular, these are the persons who draw up a medical suitability profile of the person to be examined. For the fulfilment of these tasks, minimum requirements are established for the training and competence of the medical doctors.

A particular feature here is that the medical doctors concerned, as a rule, do not work in the area for which the radiation protection executive is responsible. Consequently, the radiation protection executive cannot ensure that the requirements are fulfilled, for example, by way of instruction, but can merely verify their fulfilment. If the radiation protection executive concludes that the requirements are not fulfilled, use of low-dose computed tomography is not permitted as in this case the conditions as referred to in section 2 (1) sentence 1 nos. 3 and 4 are not satisfied.

To satisfy the verification obligation, the radiation protection executive must establish through the presentation of appropriate evidence that the requirements are fulfilled. The requirements as referred to in nos. 1 and 2 are likely to be proven already through the use of the specialist designation and the signature of the medical doctor concerned under the report as referred to in section 2 (1) sentence 1 no. 3 of the Ordinance. The radiation protection executive may rely on a functioning supervisory body, which prevents persons who are not permitted to practise as a medical doctor or not entitled to use the specialist designation from offering medical services as a specialist medical doctor. In contrast, the radiation protection executive must require the presentation of specific proof in relation to the requirement as referred to in no. 3.

No. 1

Only licensed medical doctors and those medical doctors temporarily permitted to practise may carry out the activities set out in this Ordinance.

No. 2

The drawing up of the medical report as referred to in section 2 (1) sentence 1 no. 3 and the information as referred to in section 2 (1) sentence 1 no. 4 require specific specialist competence as an internist or general practitioner. This specialist competence is acquired through completion of further training to become a specialist medical doctor in the field of internal medicine, general medicine or occupational medicine. This includes further training to become a pulmonologist as further training in the field of internal medicine. In addition, persons are permitted to exercise the activity from the third year of further training to become a specialist medical doctor in the fields mentioned.

Thus, the group of persons entitled is expanded for reasons of securing the provision of medical care when compared with the scientific report of the Federal Office for Radiation Protection, in which a completed further training to become a specialist for pulmonology is called for (Federal Gazette Official Section 6 December 2021 B4, paragraph 3.5.1.1). To ensure the wide provision of medical care it is reasonable to authorise other internists and general practitioners and occupational physicians to exercise tasks in the context of lung cancer screening. Admittedly, specialist pulmonological knowledge is useful for the drawing up of the medical report, in particular the medical suitability profile and for the provision of information to participants. However, other internal medicine and general medicine knowledge also suffices.

The categories of specialists medical doctors mentioned have particular expertise with which to assess a person’s general state of health, in particular having due regard to pulmonological and also other internal medicine aspects. This ensures that for the lung cancer screening tasks mentioned both a high level of professional competence is assured and sufficient medical doctors are available for the likely number of participants.

The wording “specialist medical doctor in one of the following fields” is intentionally open-ended. The purpose is to clarify that the authority to perform activities in the context of lung cancer screening examinations does not depend on a specific designation as a specialist. This is intended to take account of possible future amendments or possible regional differences in the designation of specialists or the introduction of designations for areas of specific focus. Those differences of detail in the designation are unimportant as long as the further training took place in the field specified. In fact, especially in the field of internal medicine, there are numerous designations for areas of specific focus. Regardless of any designation for the area of specific focus, all specialist medical doctors in the field of internal medicine are covered.

Further, the category is not limited to further training for medical doctors completed in Germany. If further training for medical doctors completed abroad entitles the holder to use the corresponding specialist designation in Germany, this also meets the requirements mentioned here.

In light of the qualification acquired in the first two years of further training, persons are permitted to draw up the medical report and to inform participants also from the third year of further training onwards.

No. 3

The drawing up of the report as referred to in section 2 (1) sentence 1 no. 3 and the information as referred to in section 2 (1) sentence 1 no. 4 require, in addition to the specialist competence as referred to in no. 2, in-depth

knowledge of lung cancer screening. This in-depth knowledge is acquired as part of the further training to become a specialist medical doctor or by way of continuing professional development courses. This ensures that the medical doctor can appropriately examine and inform potential participants with regard to lung cancer screening as a whole, in particular with regard to benefits, risks and conditions under which the screening is permissible.

Section 7 – Quality assurance

This provision supplements the other quality assurance provisions of radiation protection law, in particular section 130 of the Radiation Protection Ordinance.

Subsection (1)

The purpose of the systematic screening examinations is to discover lung cancer at an early stage when it responds well to treatment. At the same time, the burden on participants should be kept to a minimum. Both can only be ensured through a comprehensive quality assurance system covering all organisational and technical measures involved in preparing, underpinning and verifying the development and maintenance of screening examination quality. The quality assurance system therefore goes beyond the physical and technical quality assurance as required by sections 115 and 116 of the Radiation Protection Ordinance, taking a systematic approach not simply to individual process steps but to the entire process throughout the screening chain and assures its quality. Individual elements of this quality assurance system may be taken from relevant guidelines or recommendations of professional bodies, for example, the Guideline of the German Medical Association on Quality Assurance in Diagnostic Radiology (*Leitlinie der Bundesärztekammer zur Qualitätssicherung in der Röntgendiagnostik*) (Version: 15 September 2022). Standards for process quality assurance in non-medical situations also provide an orientation.

The quality assurance system concerns in particular the aspects listed in nos. 1 to 4. These are aspects for which this Ordinance establishes fundamental rules. The aspects chosen correspond with minor amendments to the quality assurance rules in section 8 of the Breast Cancer Screening Ordinance of 17 December 2018 (Federal Law Gazette I, p. 2660), as amended by Article 1 of the Ordinance of 21 February 2024 (Federal Law Gazette 2024 I, no. 59) (*Brustkrebs-Früherkennungs-Verordnung*). In comparison with the Breast Cancer Screening Ordinance, no specific mention is given here to “technical quality” as this already follows from nos. 1 to 4.

Subsection (2)

Subsection (2) requires the radiation protection executive to collect and record on an anonymised basis the number of persons examined, the number of results in need of monitoring and the number of results in need of diagnosis. The data to be recorded are available on request to the competent authority and to the medical body for the purposes of carrying out, where necessary, a process and outcome evaluation of lung cancer screening and may be used in the assessment of whether the criteria for the renewal of a licence are fulfilled. It is intended, in particular, that insights on the quality of this screening examination may be obtained in this way. In order to minimise the efforts involved, only the collection and recording of key statistical parameters is required, which can easily be extracted from patient data.

Subsection (3)

This provision permits the competent authorities and medical bodies – beyond the powers as referred to in section 130 (6) of the Radiation Protection Ordinance and section 179 of the Radiation Protection Act – to obtain, on request, the information as referred to in subsection (2).

Section 8 – Entry into force

The period between promulgation and entry into force has been chosen such as to permit the necessary preparations to be made, for example drawing up the information in text form as referred to in section 2 (1) sentence 1 no. 4 or carrying out the necessary continuing professional development as referred to in section 6 (1) sentence 1 no. 3 without unnecessarily delaying the lifting of the preventive prohibition on screening examinations.

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

The requirements listed in the annex describe the technical parameters to limit the radiation exposure in low-dose computed tomography, as a rule, to a volume computed tomography dose index of under 1.3 milligrays and, at the same time, to achieve the necessary image quality. In doing so, consideration has been given to the technical possibilities with regard to radiation protection and image quality and regard had to the wide availability of computed tomography scanners. The starting point for these requirements is the scientific evaluation by the Federal Office for Radiation Protection on lung cancer screening using low-dose computed tomography in accordance with section 84 (3) of the Radiation Protection Act (Federal Gazette Official Section 6 December 2021 B4). In the course of the expert discussions which took place in the drafting of this Ordinance, adjustments were made to certain parameters in comparison with those requirements. For example, certain requirements were aligned with current German Medical Association guidelines and findings from relevant scientific studies appearing after the publication of the scientific evaluation were taken into account. Further, individual technical parameters have been aligned with the technical state-of-the-art.

Certain requirements have a particular influence on radiation exposure and image quality. For example, if the

preceding localiser radiograph is performed using the default settings of common computed tomography scanners, the associated radiation exposure can reach the magnitude of the subsequent low-dose computed tomography scan for the diagnostic imaging of the lung. For that reason, having regard to the total exposure of the person examined, additional requirements are set out here to reduce the chest dose of the localiser radiograph, for example, the posteroanterior projection. In total, the exposure resulting from the localiser radiograph must be limited to 20% of the dose from the subsequent computed tomography scan.

The requirements for scan mode, scan time, scan direction, rotation time and breathing instructions serve to reduce the motion artifacts in the image acquisition. Motion artifacts reduce image quality and, in this way, can significantly impair the quality of results.

The annex further includes requirements for the reconstruction process, the convolution kernel, the resolution, the slice thickness, the voxel size, the scan region and the reconstructed field of view. As a consequence, the use of modern, at least iterative, image reconstruction algorithms is required. In this connection, the parameters must be selected in such a way as to attain the necessary image quality with the lowest possible dose.

In addition to these specific requirements of the annex, the principle of reduction as referred to in section 83 (5) of the Radiation Protection Act and section 14 (3) sentence 1 no. 2 of the Radiation Protection Act applies. For this reason, further reduction measures are called for. This concerns, for example, the use of additional prefilters if the scanner is fitted with these.