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Operation of an X-ray facility or significant change in operation Issue

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/121297797/L100002>

Modul	Sachverhalt
Leistungsschlüssel	99006018001000, 99006018001000
Leistungsbezeichnung I	Operation of an X-ray facility or significant change in operation Issue
Leistungsbezeichnung II	Display operation of an X-ray device or significant change in operation
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)
Verrichtungskennung	Erteilung (001)

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SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	20.08.2024
Fachlich freigegeben durch	Ministry of Labor, Health and Social Affairs of the State of North Rhine-Westphalia
Handlungsgrundlage	<p>§ 12 Radiation Protection Act - StrlSchG</p> <p>§ 13 Radiation Protection Act - StrlSchG</p> <p>§ 15 Radiation Protection Act - StrlSchG</p> <p>§ 19 Radiation Protection Act - StrlSchG</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_13.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_15.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_19.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_13.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_15.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_19.html</p>
Teaser	If you wish to operate a mobile X-ray unit in connection with an application on animals in veterinary medicine, or if this approved activity changes significantly, you are obliged to notify the competent authority in order to obtain a permit for this.
Volltext	<p>With a permit for a mobile veterinary X-ray facility, you can put the facility into operation or make significant changes to it in accordance with the permit.</p> <p>Before you receive a permit, the competent authority will check whether you have submitted all the necessary documents and whether the legal requirements for granting the permit are met.</p> <p>Please note that the permit relates to the person named as responsible for radiation protection. If there</p>

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are any changes in this area, these must also be reported to the authority.

An example of other significant changes is the change of the image receiver of the approved X-ray equipment.

Erforderliche Unterlagen

§ 16 StrlSchG: Documents required for the application for licenses pursuant to § 12 paragraph 1 number 4

1\.. plans, drawings and descriptions which are necessary for the examination of the licensing requirements

2\.. information which makes it possible to check whether

a) the number of radiation protection officers necessary for the safe performance of the activity has been appointed and whether they have been granted the powers necessary for the performance of their duties.

b) it is ensured that the equipment is available and measures have been taken which are necessary according to the state of the art in order to comply with the protection regulations.

3\.. information that makes it possible to check whether the person responsible for radiation protection and the radiation protection officers are reliable and have the necessary expertise in radiation protection,

4\.. a copy of a radiation protection instruction in accordance with the legal ordinance pursuant to Section 73, if the issue of a radiation protection instruction is required, i.e. in particular

- Proof of expertise in radiation protection including proof of updating
- Certificate and test report on radiation protection testing of the device by an expert or an expert organization
- Type approval certificate with confirmation of routine testing or CE certificate of conformity
- Proof of knowledge of radiation protection for the personnel deployed, including updates of these

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certificates

In the case of approval of equipment for use on animals, a license or proof of temporary exercise of the medical profession must also be submitted in accordance with § 15 StrlSchG.

Voraussetzungen

The license is granted if the statutory licensing requirements pursuant to Sections 13 and 15 StrlSchG are met.

These are fulfilled if:

1. there are no facts that give rise to concerns about the reliability of the applicant, his legal representative or, in the case of legal entities or associations of persons without legal capacity, the persons authorized to represent or manage them by law, articles of association or partnership agreement and, if a radiation protection officer is not required, one of the aforementioned natural persons has the necessary expertise in radiation protection,
2. there are no facts that give rise to concerns about the reliability of the radiation protection officers and they have the necessary expertise in radiation protection,
3. the number of radiation protection officers necessary for the safe performance of the activity has been appointed and they have been granted the necessary powers to perform their duties,
4. it is ensured that the persons otherwise involved in the activity have the necessary knowledge and skills with regard to the possible radiation hazard and the protective measures to be applied,
5. there are no facts giving rise to doubts as to whether the personnel required to carry out the activity safely are available,
6. it is ensured that the equipment is available and that the measures have been taken which, in the case of an activity in accordance with § 12 paragraph 1 number 4, are necessary according to the state of the art so that the protective regulations are complied with,

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	<p>7. it is not an unjustified type of activity in accordance with an ordinance pursuant to Section 6 (3) or if, taking into account a report published in accordance with Section 7 (2), there are no significant doubts as to the justification of the type of activity, and</p> <p>8. there are no other public law provisions to the contrary and</p> <p>9. a license to practice medicine or a temporary authorization to practice medicine in accordance with § 15 StrlSchG is still available.</p>
Kosten	Cost amount (variable): from EUR 100 up to EUR 1,000
Verfahrensablauf	<p>As the operator of an X-ray machine, you must apply for a permit for operation or for a significant change.</p> <p>The authority will first check your application for completeness. The second step is to check whether all requirements are met.</p> <p>Documents may be requested at a later stage.</p> <p>The permit will be issued to you in writing.</p>
Bearbeitungsdauer	Up to 6 weeks
Frist	Approval must be obtained before commissioning or before making any significant changes.
weiterführende Informationen	
Hinweise	Approval must be obtained before the system is commissioned. The same applies to the planning of significant changes.
Rechtsbehelf	
Kurztext	<ul style="list-style-type: none"> • Operation of an X-ray facility or significant change to the operation Authorization <ul style="list-style-type: none"> • The operation of X-ray equipment in connection with an animal in veterinary medicine must be approved • Significant changes to an already approved facility must also be approved • This does not apply to X-ray equipment for the operation of which a notification in accordance with

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	<p>Section 19 (1) is sufficient, also taking into account the need for approval in accordance with Section 19 (2) (Radiation Protection Act - StrlSchG)</p> <ul style="list-style-type: none"> • Responsible: Department 55 of the respective district government
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	<p>Operation of an X-ray facility or significant change in operation Issue, Betrieb einer Röntgeneinrichtung oder wesentliche Änderung des Betriebs Erteilung</p>