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Applying for approval for the operation or significant modification of mobile X-ray equipment in veterinary medicine

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/406839195/L100008>

Modul	Sachverhalt
Leistungsschlüssel	99006018006001, 99006018006001
Leistungsbezeichnung I	Applying for approval for the operation or significant modification of mobile X-ray equipment in veterinary medicine
Leistungsbezeichnung II	
Typisierung	2 - Bundesauftragsverwaltung: Regelung
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Arbeitsschutz (006)

Modul	Sachverhalt
Verrichtungskennung	Genehmigung (006)
SDG-Informationsbereich	Vorschriften für und Anforderungen an Erzeugnisse
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	12.02.2024
Fachlich freigegeben durch	Ministry of Labor, Social Affairs, Health and Equality of the State of Saxony-Anhalt
Handlungsgrundlage	<p>§ 12 para. 1 no. 4 Radiation Protection Act - StrlSchG in conjunction with § 15 Radiation Protection Act - StrlSchG and</p> <p>§ 60 Radiation Protection Ordinance - StrlSchV</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_15.html</p> <p>https://www.gesetze-im-internet.de/strlschv_2018/_60.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_12.html</p> <p>https://www.gesetze-im-internet.de/strlschg/_15.html</p> <p>https://www.gesetze-im-internet.de/strlschv_2018/_60.html</p>
Teaser	Wf you wish to operate a technical X-ray device or make significant changes to it, you must first apply for a permit from the competent authority.
Volltext	You require a corresponding permit to operate or significantly change the operation of technical X-ray equipment that requires a permit. Before you receive the permit, the authorities will check the legal requirements and the documents submitted.
Erforderliche Unterlagen	<p>In addition to the main application for approval, the following documents must be submitted:</p> <p>1\. plans, drawings and descriptions required to check the conditions for approval,</p> <p>2\. information that makes it possible to check whether</p> <p>a) the number of radiation protection officers</p>

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necessary for the safe performance of the activity has been appointed and that they have been granted the necessary powers to perform 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 to ensure that the protection regulations are complied with,

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 if it is necessary to issue a radiation protection instruction,

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 to these certificates

Voraussetzungen

Approval will be granted if the relevant requirements are met. The requirements are met if

there are no facts that give rise to concerns about the reliability of the applicant, his legal representative or, in the case of legal persons or associations of persons without legal capacity, the persons authorized to represent or manage the company in accordance with the 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.

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1. 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 are 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,
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
8. other provisions of public law do not conflict with this.

Kosten

Gebühr: 125€ - 500€

Verfahrensablauf

- As the operator of an X-ray machine, you must apply for approval for operation or for a significant change.
 - If it is a construction procedure, it may be advisable to involve the radiation protection authority at an early stage.
 - The authority will first check your application for completeness. The second step is to check whether all requirements are met. Documents may be requested at a later stage. The permit will be issued to you in writing.

Bearbeitungsdauer

2 - 6 Woche(n)

Modul	Sachverhalt
Frist	Before commissioning the X-ray equipment
weiterführende Informationen	
Hinweise	https://verbraucherschutz.sachsen-anhalt.de/arbeitsschutz/strahlenschutz https://verbraucherschutz.sachsen-anhalt.de/arbeitsschutz/strahlenschutz
Rechtsbehelf	Wf the authority does not grant the permit or you wish to take legal action against the permit, you can file a complaint.
Kurztext	
Ansprechpunkt	State Office for Consumer Protection Saxony-Anhalt Department 51.4 Radiation protection
Zuständige Stelle	
Formulare	https://verbraucherschutz.sachsen-anhalt.de/fileadmin/Bibliothek/Politik_und_Verwaltung/MS/LAV_Verbraucherschutz/Arbeitsschutz/formulare/09-Roentgeneinrichtungen.pdf https://verbraucherschutz.sachsen-anhalt.de/fileadmin/Bibliothek/Politik_und_Verwaltung/MS/LAV_Verbraucherschutz/Arbeitsschutz/formulare/09-Roentgeneinrichtungen.pdf
Ursprungsportal	Genehmigung für den Betrieb oder die wesentliche Änderung einer mobilen Röntgeneinrichtung in der Tierheilkunde beantragen, Applying for approval for the operation or significant modification of mobile X-ray equipment in veterinary medicine