

99006018001000

# X-ray equipment / interference emitters, report operation or apply for authorisation

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<https://fimportal.de/xzufi-services/6000994/L100009>

Modul	Sachverhalt
Leistungsschlüssel	99006018001000
Leistungsbezeichnung I	X-ray equipment / interference emitters, report operation or apply for authorisation
Leistungsbezeichnung II	X-ray equipment / interference emitters, report operation or apply for authorisation
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Sachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	

Modul	Sachverhalt
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	
Fachlich freigegeben am	
Fachlich freigegeben durch	
Handlungsgrundlage	<ul style="list-style-type: none"> <li>• § 12 Absatz 1 Nummer 4 und 5 [Strahlenschutzgesetz (StrlSchG)](<a href="https://www.gesetze-im-internet.de/strlschg/">https://www.gesetze-im-internet.de/strlschg/</a>) – Genehmigungsbedürftige Tätigkeiten</li> <li>• § 19 Absatz 1 und Absatz 2 StrlSchG – Genehmigungs- und anzeigebedürftiger Betrieb von Röntgeneinrichtungen</li> <li>• § 8 [Strahlenschutzverordnung (StrlSchV)](<a href="https://www.gesetze-im-internet.de/strlschv_2018/">https://www.gesetze-im-internet.de/strlschv_2018/</a>) – Genehmigungsfreier Betrieb von Störstrahlern</li> <li>• Anlage 3 Teil D StrlSchV – Genehmigungsfreie Tätigkeiten</li> <li>• [Sächsisches Kostenverzeichnis (KVZ)](<a href="https://revosax.sachsen.de/vorschrift/12126">https://revosax.sachsen.de/vorschrift/12126</a>) Lfd. Nr. 81</li> </ul>
Teaser	The following X-ray equipment must be reported in writing to the responsible supervisory/enforcement authority at least four weeks before commissioning:
Volltext	<p>#### Operation of X-ray equipment or interference emitters in accordance with the German Radiation Protection Act (StrlSchG)</p> <p>The following X-ray equipment must be reported in writing to the responsible supervisory/enforcement authority at least four weeks before commissioning:</p> <ul style="list-style-type: none"> <li>• with CE labelling in accordance with medical device law (MDR)</li> <li>• with type approval (BAZ) of the X-ray source</li> <li>• with BAZ as a full protection device (technical purposes)</li> <li>• with BAZ as a high protection device (technical purposes)</li> <li>• with BAZ as a basic protection device (technical</li> </ul>

## Modul

## Sachverhalt

purposes)

- with BAZ as a school X-ray unit

If an X-ray device has neither a type approval nor a CE marking in accordance with Article 20 (1) of Regulation (EU) 2017/745 or in accordance with the Medical Devices Act in the version valid up to and including 25 May 2021, you require a permit from the supervisory/enforcement authority (state directorate) to operate the X-ray device.

An operating licence is also required for an X-ray system for operation

- in technical radiography for coarse structure analysis in materials testing
- for the treatment of people
- for teleradiology
- in connection with the early detection of diseases
- outside an X-ray room,
- in an X-ray room that was not the subject of an expert examination for this X-ray equipment
- for operation in a mobile X-ray room

The operation of an interfering source is subject to authorisation, with the exception of an interfering source in the cases specified in the Radiation Protection Ordinance (StrlSchV).

### Contact point

When operating an X-ray device for use on humans, please also send a copy of the notification/application form to:

\*\*– > [die Ärztliche Stelle  
StrlSchV](<https://www.slaek.de/de/01/Qualitaetssicherung/20AerztlStelle/aerztlichestelle.php>)\*\*  
(Landesärztekammer)

Modul	Sachverhalt
	<p>or</p> <p>**– &gt; [die Zahnärztliche Stelle Röntgen](<a href="https://www.zahnaerzte-in-sachsen.de/praxis/praxisfuehrung/praxishandbuch/roentgen/informationen-anleitungen/">https://www.zahnaerzte-in-sachsen.de/praxis/praxisfuehrung/praxishandbuch/roentgen/informationen-anleitungen/</a>)** (Landeszahnärztekammer)</p>
<b>Erforderliche Unterlagen</b>	<ul style="list-style-type: none"> <li>• written notification or application (form)</li> <li>• Printout of the appointment of radiation protection officers</li> <li>• Proof of expertise</li> <li>• Type approval certificate and/or test report and, if applicable, certificate from the expert</li> <li>• Proof of sufficient personnel</li> <li>• for operations in medicine or dentistry: registration form and information sheet from the medical or dental centre (also a copy for the occupational health and safety administration)</li> </ul> <p>A list of all required documents can be found in the notification / application form.</p>
<b>Voraussetzungen</b>	<ul style="list-style-type: none"> <li>• Reliability of the applicant and the radiation protection officers</li> <li>• the required number of radiation protection officers appointed in writing</li> <li>• sufficient personnel with the necessary expertise in radiation protection or with the necessary knowledge of radiation protection</li> <li>• Guarantee of existing equipment and measures taken in accordance with the state of the art ,</li> <li>• Justification of the type of activity</li> <li>• other public law regulations do not prevent the operation</li> </ul> <p>There are further requirements for activities in connection with the use on humans (e.g. licence, involvement of a medical physics expert). It must also be ensured that the equipment is available and that the necessary measures are taken to ensure that the quality required for the application is achieved with the</p>

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	lowest possible exposure during examinations and with the dose distribution required for the intended purposes during treatments.
Kosten	<ul style="list-style-type: none"> <li>• for the display: none</li> <li>• for the operating licence: EUR 40.00 to EUR 1,600 (depending on costs)</li> </ul>
Verfahrensablauf	<p>The notification of the intended operation or the application for an operating licence must be submitted in writing on the form to the Occupational Health and Safety Administration of the Free State of Saxony ("competent authority").</p> <ul style="list-style-type: none"> <li>• You can obtain the required form online here via Amt24 or directly from the competent authority.</li> <li>• Complete the form and submit it with the required documents and evidence.</li> <li>• The competent authority will check your documents and you will receive a confirmation of notification or written notification of the result.</li> </ul> <p><b>**Note:**</b> If you are operating in medicine or dentistry, please also send the competent authority a copy of the "Registration form for X-ray systems" from the medical/dental authority (available via "Online application and forms" after regionalisation).</p> <p><b>#### Notifying changes</b></p> <p>Inform the regional directorate (occupational health and safety administration) and the medical/dental centre in writing of any changes in connection with the operation of an X-ray system or an interfering radiator, in particular in the event of</p> <ul style="list-style-type: none"> <li>• significant technical changes in accordance with the expert test guideline and</li> <li>• personal changes (address, name, change of persons responsible for radiation protection, co-users and similar).</li> </ul>

Modul	Sachverhalt
	<p><b>**Note:**</b> A new licence is required if the approved operation changes significantly.</p>
Bearbeitungsdauer	
Frist	Notification: no later than four weeks before commissioning
weiterführende Informationen	
Hinweise	Authorisations in accordance with the former X-ray Ordinance (RöV) continue to apply as long as the transitional provisions in accordance with Section 198 StrlSchG provide for this and provided that the requirements specified therein have been proven to the competent authority.
Rechtsbehelf	Appeal (more details on the procedure in the notification)
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	