

99006018001002

Heruntergeladen am 25.05.2025

<https://fimportal.de/xzufi-services/133832/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99006018001002
Leistungsbezeichnung I	
Leistungsbezeichnung II	X-ray facilities for teleradiology and screening; application for a license to operate
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	

Modul	Sachverhalt
Fachlich freigegeben am	28.08.2024
Fachlich freigegeben durch	Bayerisches Staatsministerium für Umwelt und Verbraucherschutz (Bavarian State Ministry of the Environment and Consumer Protection)
Handlungsgrundlage	https://www.gesetze-im-internet.de/strlSchg/_19.html https://www.gesetze-im-internet.de/strlSchg/_19.html
Teaser	If you wish to operate an X-ray facility for teleradiology or screening, you must apply for a permit from the competent authority.
Volltext	<p>**Teleradiology**</p> <p>If you operate an X-ray facility and the specialist doctor is not at the place where the examination is being carried out, it can only be operated within the scope of teleradiology. A permit is required for this.</p> <p>Authorization can only be granted if a doctor with specialist knowledge (teleradiologist) is available to provide the justifying indication and to carry out a prompt diagnosis based on the X-ray images transmitted to him.</p> <p>A doctor with knowledge/partial specialist knowledge in radiation protection must be available to support the teleradiologist and an MTRA at the location where the X-ray examination is carried out.</p> <p>These requirements must be contractually agreed between the operator of the X-ray facility and the teleradiologist.</p> <p>**Screening**</p> <p>Anyone operating an X-ray facility in connection with early detection must apply for a permit in accordance with Section 19 (2) of the Radiation Protection Act (StrlSchG) due to the special conditions for this operation (no justifiable indication required, higher requirements for image quality and the person making the findings).</p>

Modul

Sachverhalt

Approval can only be granted if evidence can be provided regarding the physicians responsible for the program, the other participating physicians, the X-ray facilities, any biopsy facilities and diagnostic facilities.

The relevant requirements must be contractually agreed between the physicians responsible for the program and the other participating physicians. Furthermore, approval from the Association of Statutory Health Insurance Physicians in Bavaria must be submitted for the doctors responsible for the program to take on the care mandate.

Erforderliche Unterlagen

• Required documents:

****Application for authorization for teleradiology****

- List of authorized persons for technical implementation (MTRA) with proof of permission according to the MTA Act and, if applicable, proof of updating
- List of teleradiologists with certificates of expertise in radiation protection and, if applicable, proof of updating
- List of physicians at the examination site with proof of knowledge of radiation protection or corresponding specialist knowledge and, if applicable, proof of updating.

Furthermore, the instruction of these persons to carry out the examinations within the scope of teleradiology must be confirmed by a teleradiologist.

- Proof of a medical physics expert who can be consulted when operating the X-ray equipment
- Cooperation agreement between the operator of the X-ray facility and the cooperation partner for teleradiology.
- Radiation protection instructions and work instructions for carrying out teleradiology
- Copy of the expert test report of the X-ray equipment used for teleradiology
- List and locations of the teleradiologists' imaging equipment
- Proof of testing of the teleradiologists' imaging equipment in accordance with DIN 6868-157
- Proof of testing of the data transmission links to

Modul

Sachverhalt

the locations of the teleradiologists' imaging equipment in accordance with DIN 6868-159

- Appointment of the responsible teleradiologist(s)
- Appointment of the radiation protection officer(s) (SSB) for the operation of the X-ray equipment intended for teleradiology.
- Justification for the extended teleradiology operation (see also separate form), if this is requested.

****Application for approval for screening****

- List of the X-ray equipment, the X-ray biopsy equipment, the independent diagnostic equipment and the doctors working in the screening unit.
- Printout of the approval of the Association of Statutory Health Insurance Physicians in Bavaria regarding the assumption of the care mandate.
- Proof of certification or current recertification of the screening unit by the Kooperationsgemeinschaft Mammographie.
- File number of the notification confirmations (or approvals) for the curative operation of all X-ray equipment/X-ray-assisted biopsy devices used in the screening unit.
- For the first application for approval: appointments of the necessary radiation protection officers for the screening operation with regard to the individual screening facilities
- Copies of the cooperation agreements (agreements) between the radiation protection officers of the mammography X-ray facilities used in the screening unit and the program manager (PVA) on the allocation of tasks and the exercise of all responsibilities and powers, including the necessary regulations on the authority to issue instructions within the scope of the screening operation by the PVA(s).
- In the event of changes for the new PVA(s): proof of the PVA(s)' specialist knowledge

Voraussetzungen

The application for approval and the required documents and evidence must be submitted to the competent authority.

Kosten

The costs for the permit depend on the administrative costs incurred. They amount to between EUR 250 and

Modul	Sachverhalt
	EUR 500 per application.
Verfahrensablauf	<p>You submit the permit application together with the required documents/evidence.</p> <p>The Trade Supervisory Office of the Government of Lower Franconia (X-ray Competence Center) checks the application and the documents for completeness and correctness. If the documents submitted are complete and plausible, the permit applied for will be issued by the competent authority.</p> <p>To ensure that your application is processed as quickly as possible, we recommend using the online procedure.</p>
Bearbeitungsdauer	
Frist	none
weiterführende Informationen	http://www.gewerbeaufsicht.bayern.de/ http://www.gewerbeaufsicht.bayern.de/
Hinweise	
Rechtsbehelf	
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal